

ORIGINAL SUBMISSION



June 3, 2016

Dr. Antonia Mattia
Director, Division of Biotechnology and GRAS Notice Review
Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

Subject: GRAS Notification – Rice Bran Wax

Dear Dr. Mattia:

On behalf of The J.M. Smucker Co., ToxStrategies, Inc. (its agent) is submitting, for FDA review, Form 3667 and three copies of the GRAS notification as required. The enclosed document provides notice of a claim that the food ingredient, rice bran wax, described in the enclosed notification is exempt from the premarket approval requirement of the Federal Food, Drug, and Cosmetic Act because it has been determined to be generally recognized as safe (GRAS), based on scientific procedures, for addition to select foods as a texturizer.

If you have any questions or require additional information, please do not hesitate to contact me at 630-352-0303, or dschmitt@toxstrategies.com.

Sincerely,

(b) (6)

Donald F. Schmitt, M.P.H.
Senior Managing Scientist

655

<p>DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration</p> <p>GENERALLY RECOGNIZED AS SAFE (GRAS) NOTICE</p>	Form Approved: OMB No. 0910-0342; Expiration Date: 02/29/2016 (See last page for OMB Statement)	
	FDA USE ONLY	
	GRN NUMBER 000655	DATE OF RECEIPT
	ESTIMATED DAILY INTAKE	INTENDED USE FOR INTERNET
	NAME FOR INTERNET	
KEYWORDS		

Transmit completed form and attachments electronically via the Electronic Submission Gateway (*see Instructions*); OR Transmit completed form and attachments in paper format or on physical media to: Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835.

PART I – INTRODUCTORY INFORMATION ABOUT THE SUBMISSION

1. Type of Submission (*Check one*)

☒ New ☐ Amendment to GRN No. _____ ☐ Supplement to GRN No. _____

2. ☐ All electronic files included in this submission have been checked and found to be virus free. (*Check box to verify*)

3a. For New Submissions Only: Most recent presubmission meeting (*if any*) with FDA on the subject substance (yyyy/mm/dd): 2016-04-25

3b. For Amendments or Supplements: Is your amendment or supplement submitted in response to a communication from FDA? (*Check one*)

☐ Yes If yes, enter the date of communication (yyyy/mm/dd): _____

☐ No

PART II – INFORMATION ABOUT THE NOTIFIER

1a. Notifier	Name of Contact Person Dr. Brian Ellis		Position Manager, Industry & Government Affairs	
	Company (<i>if applicable</i>) The J.M. Smucker Company			
	Mailing Address (<i>number and street</i>) 1 Strawberry Lane			
City Orrville		State or Province Ohio	Zip Code/Postal Code 44667	Country United States of America
Telephone Number 330-684-6954		Fax Number	E-Mail Address brian.ellis@jmsmucker.com	
1b. Agent or Attorney (<i>if applicable</i>)	Name of Contact Person Donald F. Schmitt		Position Senior Managing Scientist	
	Company (<i>if applicable</i>) ToxStrategies, Inc.			
	Mailing Address (<i>number and street</i>) 739 Thornapple Drive			
City Naperville		State or Province Illinois	Zip Code/Postal Code 60540	Country United States of America
Telephone Number 630-352-0303		Fax Number	E-Mail Address dschmitt@toxstrategies.com	

PART III – GENERAL ADMINISTRATIVE INFORMATION

1. Name of Substance

Rice Bran Wax

2. Submission Format: (Check appropriate box(es))

☐ Electronic Submission Gateway

☒ Paper

If applicable give number and type of physical media _____

☐ Electronic files on physical media with paper signature page

3. For paper submissions only:

Number of volumes _____

Total number of pages _____

4. Does this submission incorporate any information in FDA's files by reference? (Check one)

☒ Yes (Proceed to Item 5) ☐ No (Proceed to Item 6)

5. The submission incorporates by reference information from a previous submission to FDA as indicated below (Check all that apply)

☒ a) GRAS Notice No. GRN 151

☐ b) GRAS Affirmation Petition No. GRP _____

☐ c) Food Additive Petition No. FAP _____

☐ d) Food Master File No. FMF _____

☐ e) Other or Additional (describe or enter information as above) _____

6. Statutory basis for determination of GRAS status (Check one)

☒ Scientific Procedures (21 CFR 170.30(b)) ☐ Experience based on common use in food (21 CFR 170.30(c))

7. Does the submission (including information that you are incorporating by reference) contain information that you view as trade secret or as confidential commercial or financial information?

☐ Yes (Proceed to Item 8)

☒ No (Proceed to Part IV)

8. Have you designated information in your submission that you view as trade secret or as confidential commercial or financial information (Check all that apply)

☐ Yes, see attached Designation of Confidential Information

☐ Yes, information is designated at the place where it occurs in the submission

☐ No

9. Have you attached a redacted copy of some or all of the submission? (Check one)

☐ Yes, a redacted copy of the complete submission

☐ Yes, a redacted copy of part(s) of the submission

☐ No

PART IV – INTENDED USE

1. Describe the intended use of the notified substance including the foods in which the substance will be used, the levels of use in such foods, the purpose for which the substance will be used, and any special population that will consume the substance (e.g., when a substance would be an ingredient in infant formula, identify infants as a special population).

Rice bran wax is proposed for use as a texturizing agent in peanut butter used in nutrition and granola-type bar products. The intended use will allow peanut butter to be the primary ingredient in nutritional/snack bars with a similar form and texture to granola bars and nutritional/energy bars. The proposed use of rice bran wax will be at levels from 3 – 4%.

2. Does the intended use of the notified substance include any use in meat, meat food product, poultry product, or egg product? (Check one)

☐ Yes

☒ No

PART V – IDENTITY

1. Information about the Identity of the Substance

	Name of Substance ¹	Registry Used (CAS, EC)	Registry No. ²	Biological Source (if applicable)	Substance Category (FOR FDA USE ONLY)
1	Rice bran wax	CAS No. 8016-60-2		Rice bran	
2					
3					

¹ Include chemical name or common name. Put synonyms (*whether chemical name, other scientific name, or common name*) for each respective item (1 - 3) in Item 3 of Part V (*synonyms*)

² Registry used e.g., CAS (*Chemical Abstracts Service*) and EC (*Refers to Enzyme Commission of the International Union of Biochemistry (IUB), now carried out by the Nomenclature Committee of the International Union of Biochemistry and Molecular Biology (IUBMB)*)

2. Description

Provide additional information to identify the notified substance(s), which may include chemical formula(s), empirical formula(s), structural formula(s), quantitative composition, characteristic properties (*such as molecular weight(s)*), and general composition of the substance. For substances from biological sources, you should include scientific information sufficient to identify the source (*e.g., genus, species, variety, strain, part of a plant source (such as roots or leaves), and organ or tissue of an animal source*), and include any known toxicants that could be in the source.

Rice bran wax is manufactured to meet the specifications on page 14 in Table 2.

3. Synonyms

Provide as available or relevant:

1	Oryza sativa (rice) bran wax or rice bran wax beads
2	
3	

PART VI – OTHER ELEMENTS IN YOUR GRAS NOTICE

(check list to help ensure your submission is complete – check all that apply)

- ☒ Any additional information about identity not covered in Part V of this form
- ☒ Method of Manufacture
- ☒ Specifications for food-grade material
- ☒ Information about dietary exposure
- ☒ Information about any self-limiting levels of use (which may include a statement that the intended use of the notified substance is not-self-limiting)
- ☐ Use in food before 1958 (which may include a statement that there is no information about use of the notified substance in food prior to 1958)
- ☒ Comprehensive discussion of the basis for the determination of GRAS status
- ☒ Bibliography

Other Information

Did you include any other information that you want FDA to consider in evaluating your GRAS notice?

☒ Yes ☐ No

Did you include this other information in the list of attachments?

☒ Yes ☐ No

PART VII – SIGNATURE

1. The undersigned is informing FDA that The J.M. Smucker Company

(name of notifier)

has concluded that the intended use(s) of Rice Bran Wax

(name of notified substance)

described on this form, as discussed in the attached notice, is (are) exempt from the premarket approval requirements of section 409 of the Federal Food, Drug, and Cosmetic Act because the intended use(s) is (are) generally recognized as safe.

2. ☒ The J.M. Smucker Company agrees to make the data and information that are the basis for the determination of GRAS status available to FDA if FDA asks to see them.

(name of notifier)

The J.M. Smucker Company

(name of notifier)

agrees to allow FDA to review and copy these data and information during customary business hours at the following location if FDA asks to do so.

1 Strawberry Lane, Orrville, Ohio 44667

(address of notifier or other location)

The J.M. Smucker Company

(name of notifier)

agrees to send these data and information to FDA if FDA asks to do so.

OR

☐ The complete record that supports the determination of GRAS status is available to FDA in the submitted notice and in GRP No.

(GRAS Affirmation Petition No.)

3. Signature of Responsible Official,
Agent or Attorney

Printed Name and Title

Donald F. Schmitt, Senior Managing Scientist

Date (mm/dd/yyyy)

06/03/2016

(b) (6)

PART VIII – LIST OF ATTACHMENTS

List your attached files or documents containing your submission, forms, amendments or supplements, and other pertinent information. Clearly identify the attachment with appropriate descriptive file names (or titles for paper documents), preferably as suggested in the guidance associated with this form. Number your attachments consecutively. When submitting paper documents, enter the inclusive page numbers of each portion of the document below.

Attachment Number	Attachment Name	Folder Location (select from menu) (Page Number(s) for paper Copy Only)
	Appendix A - Gas Chromatographs	pp. 40-50
	Appendix B - Analytical Results	pp. 51-113
	Appendix C - Stability Data	pp. 114
	Appendix D - Intake Assessment Report	pp. 115-128
	Exhibit 1- Report of the Expert Panel	pp. 129-143

OMB Statement: Public reporting burden for this collection of information is estimated to average 150 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, Room 400, Rockville, MD 20850. (Please do NOT return the form to this address.). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

GRAS

GRAS Determination of Rice Bran Wax for Use in Food

JUNE 3, 2016

ToxStrategies

Innovative solutions
Sound science

GRAS Determination of Rice Bran Wax for Use in Food

SUBMITTED BY:

The J.M. Smucker Co.
1 Strawberry Lane
Orrville, OH 44667

SUBMITTED TO:

U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Food Additive Safety
HFS-200
5100 Paint Branch Parkway
College Park MD 20740-3835

CONTACT FOR TECHNICAL OR OTHER INFORMATION

Donald F. Schmitt, MPH
ToxStrategies, Inc.
739 Thornapple Drive
Naperville, IL 60540

JUNE 3, 2016

Table of Contents

List of Acronyms	4
1.0. GRAS Exemption Claim	6
2.0 Introduction	11
3.0 Description of Substance	11
A. Identity	11
B. Common or Usual Name	11
C. CAS Registry Number	11
D. Trade Name	11
E. Manufacturing Process	12
F. Ingredient Specifications	14
G. Stability Data	16
4.0 Rice Bran Wax and Related Data Considered in Safety Assessment	17
5.0 History of Use/Regulatory Approval of Rice Bran Wax	20
6.0 Intended Use and Estimated Intake (EDI)	20
A. Purpose	20
B. Food Uses	20
C. Levels of Use	21
D. Estimated Exposure	21
7.0 Safety	23
A. Introduction	23
B. Safety Data	23
Absorption, Distribution, Metabolism, and Excretion (ADME)	23
Animal Toxicological Studies on Rice Bran and Carnauba Waxes	24
Allergy	28
Other Safety Concerns	29
C. Safety Data Summary	29
8.0 Basis for the GRAS Determination	31
A. Introduction	31
B. Safety Determination	31
C. General Recognition of the Safety of Rice Bran Wax	32
9.0 References	35
10.0 Appendices	39
Appendix A. Gas Chromatographs	40
Appendix B. Analytical Results	41
Appendix C. Stability Testing Results	42
Appendix D. Intake Assessment Report	43
Exhibit 1. Report of the Expert Panel	57

List of Acronyms

ANS	Scientific Panel on Food Additives and Nutrient Sources (EFSA)
AOAC	Association of Official Agricultural Chemists
bw	Body Weight
C	Celsius
CAS	Chemical Abstracts Service
CFR	Code of Federal Regulations
cfu	Colony Forming Units
cGMP	Current Good Manufacturing Practice
CIR	Cosmetic Ingredient Review
CONTAM	Panel on Contaminants in Food (EFSA)
EDI	Estimated Daily Intake
EFSA	European Food Safety Authority
EPA	Environmental Protection Agency
EC	European Commission
F	Fahrenheit
FAO	Food and Agriculture Organization of the United Nations
FCC	Food Chemicals Codex
FDA	Food and Drug Administration
FD&C	Federal Food, Drug, and Cosmetic Act
FDRL	Food and Drug Research Laboratory
g	Gram
GI	Gastrointestinal
GMP	Good Manufacturing Practice
GRAS	Generally Recognized as Safe
GRN	GRAS Notification
INS	International Number System
JAOCA	Journal of Association of Official Agricultural Chemists
JECFA	Joint FAO/WHO Expert Committee on Food Additives
kg	Kilogram
LD ₅₀	Median Lethal Dose
LOQ	Limit of Quantification
max	Maximum
meq	Millequivalent
mg	Milligram
ml	Milliliter
μM	Micromolar
ND	Not Detectable
NHANES	National Health and Examination Survey
NLM	National Library Medicine
NOAEL	No Observed Adverse Effect Level
°	Degrees
PCB	Polychlorinated Biphenyls
PCR	Polymerase Chain Reaction
ppm	Parts per Million

SCF	Scientific Committee on Food
TGA	Australian Therapeutic Goods Administration
US	United States
U.S.C	United States Code
USDA	United States Department of Agriculture
USP	United States Pharmacopeia
WHO	World Health Organization

1.0. GRAS Exemption Claim

A. Name and Address of Notifier

The J.M. Smucker Company (Smucker), through its agent ToxStrategies, Inc., hereby notifies the U.S. Food and Drug Administration (FDA) that the use of rice bran wax described below and which meets the specifications described herein is exempt from pre-market approval requirements of the Federal Food, Drug, and Cosmetic Act because Smucker has determined that such use is Generally Recognized as Safe (GRAS) through scientific procedures.

(b) (6)

Donald F. Schmitt, M.P.H.
Senior Managing Scientist
ToxStrategies, Inc.
Agent for Smucker

06/03/2016
Date

B. Name of GRAS Substance

The name of the substance that is the subject of this GRAS determination is rice bran wax. Rice bran wax is a hard, crystalline vegetable wax obtained from rice husks. The rice bran wax is processed from rice bran oil obtained from rice husks, and is not hydrogenated. It primarily consists of high molecular weight monoesters ranging from C48 to C64.

C. Intended Use in Food

Smucker proposes to use rice bran wax as a texturizing agent solely in peanut butter used in bar-form products. The intended use will allow peanut butter to be the primary ingredient in nutritional/snack bars with a similar form and texture to granola bars and nutritional/energy bars. The amount used will not exceed the amount reasonably required to accomplish its intended technical effect.

D. Basis for GRAS Determination

This assessment documents the evidence of the safety and the GRAS status of the proposed uses of Smucker's rice bran wax product. It consists of an evaluation of the safety and the GRAS status of the proposed uses of this ingredient, and the conclusion by a panel of experts (Expert Panel) qualified by scientific training and experience to evaluate the safety of substances added to food that the proposed uses of Smucker's rice bran wax ingredient are safe and GRAS as determined by scientific procedures.

Smucker's GRAS determination for the intended use of rice bran wax is based on scientific procedures as described under 21 CFR § 170.30(b). The intended use of the rice bran wax product has been determined to be safe and GRAS, and the safety of intake exposure under the proposed conditions of use is based on knowledge and information that is both publicly available

and widely accepted by experts qualified by scientific training and experience to evaluate the safety of substances in food. The publicly available safety data combined with the widely disseminated knowledge concerning the chemistry of rice bran wax and other wax sources such as carnauba wax and the long history of approval/use of such ingredients provide a sufficient basis for an assessment of the safety of rice bran wax for the uses proposed herein.

Brown rice and its derivatives have a long history of human consumption, with rice cultivation documented back to prehistoric times, starting in Asia and eventually spreading across Europe around the sixth century (Burlando and Cornara, 2014). Currently, rice is produced in most continents and serves as a dietary staple for a majority of populations across the world (Burlando and Cornara, 2014). Once harvested, the rice is hulled and the resulting brown rice can be further processed to generate derivatives such as rice bran oil, rice bran extract, and hydrolyzed rice protein. As referenced in the manufacturing process outlined above, rice bran wax comes from the bran, which is the part between the husk and endosperm of rice, and is a byproduct of bran oil (Burlando and Cornara, 2014; Andersen, 2006; Koster Keunen, 2016; Sabale et al., 2007). Rice bran wax is used in food as a release agent, brightener, coatings for confectioneries, chocolates, cakes, and tablets, treatment of vegetables and fruits and as a plasticizing material for chewing gum base. Non-food uses include cosmetics, polish for cars, floors, and shoes, office ink, textile oiling agent, and resin lubricant (Andersen, 2006).

Rice bran wax (CAS No. 8016-60-2) has been approved for use in various food applications in the US. It is permitted as a direct human food additive (21 CFR §172.890) when used in candy (maximum 50 ppm as a coating), fresh fruits and fresh vegetables (maximum 50 ppm as a coating), and chewing gum (maximum 2.5% in gum when used as a plasticizing material in chewing gum base, 21CFR §172.615). It is also permitted as an indirect food additive as Type VIII in table 1 of 176.170(c), at a maximum levels of 1.0 percent by weight of the polymer. After reviewing the available safety data, the Cosmetic Ingredient Review (CIR) Expert Panel concluded that rice-derived ingredients, including rice bran wax, are safe as cosmetic ingredients (e.g., 1% in lip stick) in the practices of use and concentrations as described in their safety assessment (Andersen, 2006). In addition, rice bran wax is eligible for use as active ingredients or excipients in listed medicines in Australia, with no restrictions (Australian Government, 2007).

The intended use of rice bran wax is solely in peanut butter used in bar products at levels from 3 – 4% and results in bar-form products with a similar form and texture to granola and nutritional energy bars. There are no proposed uses of rice bran wax in food products under US Department of Agriculture (USDA) jurisdiction.

Due to the limited amount of toxicological data available for rice bran wax, information on carnauba wax was also evaluated, as chain length and saturation have been shown to predict physio-chemical behavior of waxes and oils (EFSA, 2007; Maru et al., 2012). It is clear, based on the information discussed below, that the monoester fraction in carnauba wax can be considered to be nearly structurally identical to the monoester fraction of rice bran wax; i.e., the monoester fraction in carnauba wax is within a range of 54-84% of total constituents compared to up to 87-98% in rice bran wax. Therefore, published toxicity studies conducted on carnauba wax were deemed suitable for inclusion in the safety assessment of rice bran wax and considered

by the Expert Panel in its evaluation of the available data. In fact, in 2007, the European Food Safety Authority (EFSA, 2007) applied a similar approach bridging safety data from carnauba wax to beeswax. In this assessment, the EFSA Panel “noted that experimental biochemical and toxicological studies carried out specifically on beeswax were still lacking and considered that the data on beeswax itself were insufficient to establish an ADI. However, the Panel concluded that the safety of beeswax could be assessed, based on the available scientific literature on the main constituents of beeswax and plant waxes showing chemical structural similarities to beeswax, published since the last SCF evaluation”. The Panel concluded, “that the use of beeswax as an additive for the existing food uses and the proposed new food use is not of safety concern.” In the US, beeswax is also used in foods at levels not to exceed GMP (21 CFR § 184.1973).

The predominant monoester carbon chain lengths have been reported to be C48-64 and C56, for rice bran wax and carnauba wax, respectively (Koster Keunen, 2014; Maru et al., 2012; Puleo and Rit, 1992). Carnauba wax is considered to be the most chemically similar to rice bran wax, compared to other plant-based waxes (Koster Keunen, 2014; Puleo and Rit, 1992; Andersen, 2006). This similarity is based on the presence of specific monoesters, which comprise the majority (87-98%) of rice bran wax. In concurrent analyses performed for this GRAS dossier on the rice bran wax product and a carnauba wax product by the same manufacturer, the total monoester fraction was found to account for 87-98% and 54-84% of rice bran and carnauba wax, respectively. The relative percent of each monoester in these waxes demonstrates that the majority of the rice bran wax components are these monoesters and, as such, can be accounted for. The remaining ~2% of the rice bran wax product is made up of long chain fatty alcohols, long chain fatty acids, triglycerides, or rice bran oil. While the monoesters also comprise a major fraction of the carnauba wax samples, a large percentage is also made up of fatty alcohols (19-33%). In addition, carnauba wax has been shown to contain some fatty acids and complex esters that can only be analyzed with additional methods, e.g., via UV analysis; these can include resins and cinnamates (EFSA, 2007; Warth, 1956).

In addition, the history of use in foods of other vegetable-based waxes, in particular carnauba wax, provide sufficient safety study data for the proposed use of rice bran wax. As such, the available information suggests that rice bran wax should be considered safe for the intended uses proposed herein. Given the structural similarity of carnauba wax and rice bran wax, particularly the similar monoester chain length distribution and nearly identical physio-chemical properties, the available safety data for carnauba wax, primarily from studies on subchronic and reproductive/developmental toxicity, can be bridged to support the safety of the intended use of rice bran wax in this assessment.

The long-chain fatty acid esters present in rice bran wax and carnauba wax are generally thought to be poorly absorbed in the GI tract and as such, any absorption via the oral route of exposure is likely to be negligible (EFSA, 2012a,b). No published data were identified regarding the acute oral toxicity of rice bran wax; however, the CIR Panel reviewed three unpublished laboratory reports in its assessment all of which suggest rice bran wax is of low acute oral toxicity with an LD₅₀ of >5 g/kg in rats (Andersen, 2006). Similarly, EFSA (2012b) reviewed two unpublished studies and concluded that carnauba wax is of low acute oral toxicity. Neither rice bran nor carnauba wax showed mutagenic and/or genotoxic potential in studies (reviewed in Andersen

(2006) and EFSA (2012a,b)) and the EFSA CONTAM Panel determined there is no concern for genotoxicity for carnauba wax based on the available data and the lack of structural alerts (EFSA, 2012a).

While no repeated dose or reproductive/developmental toxicity studies were identified for rice bran wax, several studies evaluating the potential toxicity of carnauba wax via the oral route of exposure were reviewed. Subchronic toxicity studies in rats and beagle dogs reported no treatment-related adverse effects from carnauba wax given in the diet, and the EFSA ANS Panel derived NOAELs of 8800 mg/kg-bw/day (rat), 1500 mg/kg-bw/day (rat), and 250 mg/kg-bw/day (dog) from these studies (Rowland et al., 1982; Parent et al., 1983a; Edwards 1998 as cited by EFSA, 2012b). In a developmental toxicity study in rats given carnauba wax (0.1, 0.3, or 1% dietary, equivalent to 50, 150, and 500 mg/kg-bw/day) no significant treatment-related effects were reported (FDRL, 1977, as as cited in EFSA, 2012b). In a reproductive toxicity study, no treatment-related effects were reported following exposure to carnauba wax given in the diet of male and female rats (Parent et al., 1983b) and the EFSA ANS Panel determined the NOAEL to be 670 mg/kg-bw/day based on the highest dose given to female rats (EFSA, 2012b). In summary, all of the repeated dose and reproductive/developmental toxicity studies of carnauba wax resulted in NOAELs at the highest dose levels administered, the highest of which was a concentration of 10% (equivalent to 8,800 and 10,200 mg/kg-bw/day in males and females, respectively) administered in the diet of rats for 90 days.

While tests in guinea pigs and rabbits were negative for dermal sensitization, some isolated cases of allergy to rice or its derivatives have been reported (reviewed in Andersen, 2006; Burlando and Cornara, 2014). Given that rice bran wax contains little to no proteins, the component responsible for imparting allergic potential, rice bran wax is not likely to pose a significant allergenic risk.

Taken together, the available published and unpublished safety data for rice bran wax and the supportive toxicological data for carnauba wax, which is comprised of nearly identical chemical constituents, demonstrate that rice bran wax has little potential for toxicity. Brown rice and its derivatives have a long history of human consumption and importantly, the known history of use of rice bran wax in food such as candy, chewing gum, and fresh fruit and vegetables (21 CFR § 172.890 and 21 CFR § 172.615) is supportive of its safe use in food. Given the structural similarity of carnauba wax and rice bran wax, particularly the similar monoester chain length distribution and nearly identical physio-chemical properties, similar safety profiles can be predicted for these two waxes in toxicity studies. Although information on the potential carcinogenicity of both waxes is lacking, there is nothing in the chemical structure of rice bran wax, available genotoxicity data, or regulatory reviews of carnauba wax to suggest a carcinogenic potential. In addition, the history of use of other vegetable-based waxes, in particular carnauba wax, provide sufficient safety study data for the proposed use of rice bran wax. The FDA has listed carnauba wax (CAS No. 8015-86-9) as GRAS as a direct food substance for human consumption with no specific limitation other than good manufacturing practice (21 CFR § 184.1978). From the data reviewed herein, it is reasonable to conclude that the use of rice bran wax, which is a much structurally less complex wax compared to carnauba wax, could be similarly approved.

Given that rice bran wax meets the proposed specifications contained herein, the safe use of rice bran wax is justified by scientific procedures. In addition, the publicly available scientific literature is sufficient to support the safety and GRAS status of the proposed rice bran wax product. Therefore, since this safety evaluation was based on generally available and widely accepted data and information, it also satisfies the so-called "common knowledge" element of a GRAS determination.

Determination of the safety and GRAS status of rice bran wax that is the subject of this self-determination has been made through the deliberations of an Expert Panel convened by Smucker and comprised of Michael Carakostas, DVM, Ph.D., Stanley M. Tarka, Jr., Ph.D., and Thomas Vollmuth, Ph.D., who reviewed a dossier prepared by ToxStrategies as well as other information available to them. These individuals are qualified by scientific training and experience to evaluate the safety of food and food ingredients. They individually and collectively critically reviewed and evaluated published data and information pertinent to the safety of rice bran wax, and unanimously concluded that the intended use of rice bran wax in food, produced consistent with cGMP and meeting appropriate specifications as delineated herein, is "generally recognized as safe" ("GRAS") based on scientific procedures.

E. Availability of Information

The data and information that serve as the basis for this GRAS determination, as well any information that has become available since the GRAS determination, will be sent to the FDA upon request, or are available for the FDA's review and copying at reasonable times from ToxStrategies, Inc., Naperville, IL.

2.0 Introduction

This assessment documents the safety and the “Generally Recognized As Safe” status of rice bran wax used in food, when manufactured under current Good Manufacturing Practices (cGMP). In accordance with Section 201(s) of the United States (US) Federal Food, Drug, and Cosmetic Act (FD&C) § 409, a panel of independent scientific experts (Expert Panel), qualified by scientific training and relevant experience to evaluate the safety and GRAS status of the proposed uses and use levels of food ingredients, was convened to evaluate the proposed use of rice bran wax, as manufactured by Koster Keunen, Inc., in peanut butter used in bar products produced by The J.M. Smucker Co. (Smucker). This document summarizes information that may be used to determine whether there is reasonable certainty that no harm will result from the intended use of rice bran wax, and that such use would be GRAS. It includes data pertaining to the safety of rice bran wax obtained from comprehensive literature searches of databases including EMBASE, MEDLINE, TOXLINE, and PubMed, as well as other published sources, which were searched and identified by ToxStrategies, Inc. (ToxStrategies) through February 2016. Analytical data and other information that were deemed pertinent to the safety of Smucker’s products with rice bran wax, under the conditions of intended use, were also considered and are summarized herein. Finally, this report documents the conclusion by the Expert Panel that the proposed uses of rice bran wax in Smucker’s bar products are safe and suitable, and GRAS by scientific procedures.

3.0 Description of Substance

A. Identity

Rice bran wax is a hard, crystalline vegetable wax obtained from rice husks. It primarily consists of high molecular weight monoesters ranging from C48 to C64. See Appendix A for Gas Chromatographs identifying peaks for this ingredient. Rice bran wax is typically yellow to light brown in color with a melting point of 75 - 85.5°C. The rice bran wax under review is processed from rice bran oil obtained from rice husks, and is not hydrogenated.

B. Common or Usual Name

The ingredient under consideration is referred to as *Oryza sativa* (rice) bran wax, rice bran wax, or rice bran wax beads.

C. CAS Registry Number

The Chemical Abstracts Service (CAS) number for rice bran wax is 8016-60-2. The International Numbering System (INS) or E number is 908.

D. Trade Name

Rice Bran Wax (wax #224P).

E. Manufacturing Process

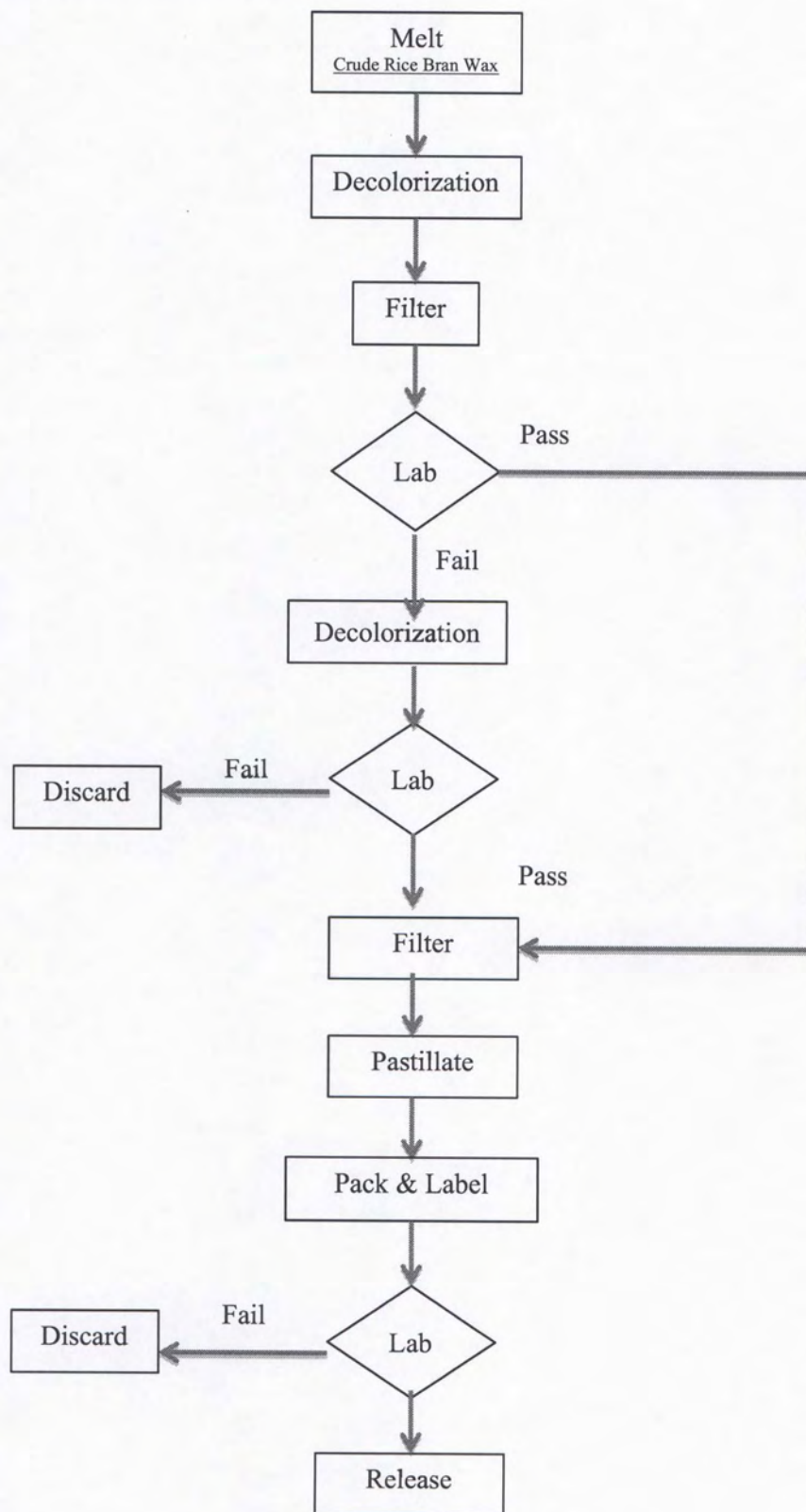
The rice bran wax that is the subject of this GRAS determination originates from rice husks. The rice bran wax is manufactured following current cGMP for food. The flow diagram of the manufacturing process presented in Figure 1 follows the narrative description below and results in an ingredient in compliance with the manufacturer's and Food Chemicals Codex (FCC) specifications.

The starting material, crude rice bran wax, is weighed and added to a clean melt tank and melted at a temperature of 220°F. During this process, settling separates out the non-rice bran wax solids. Next, the melted rice bran wax is transferred to a tank, containing one or more safe and suitable decoloring agents, which is maintained at 240°F and the wax is mixed and recirculated in the tank. Prior to continuing on to the filter process, a filter medium consisting of common and approved processing aids used in food manufacturing processes (See Table 1) is added. Once the filtering medium is adequately incorporated, the mixture is sent through the filter press and then back into the tank until the wax becomes clear. Once the wax is clear, a sample is collected and sent to the laboratory for aesthetics (color and odor) testing. If the wax does not meet aesthetics (color and odor) specifications, it is pumped into another tank and cooling water is turned on until the temperature reaches 180°F, a safe and suitable decoloring agent is added, and the temperature raised in a controlled method until it reaches 210°F. Once at 210°F, the temperature is raised 2°F every 5 minutes until the temperature reaches 240°F in order to remove the decoloring agent. A sample is again collected and tested for compliance with an aesthetic (color/odor) specification. If the wax meets the aesthetic specification (either with the first or second lab result), it is filtered through a 20-micron cartridge filter made from bleached cotton containing a polypropylene core and sent on to the pastillating (i.e., process of pelleting into uniform half spheres) step. If the wax is tested twice and fails, it is discarded. Once pastillated, the wax is sampled for quality testing, packaged, and labeled. The finished ingredient that passes all quality control measures is released for sale and placed into inventory. If a sample fails established quality parameters, the wax is discarded.

Table 1: Processing Aids

Processing Aid	CAS No.	CFR Reference
Activated Carbon	7440-44-0	21 CFR §173.25; 21 CFR §173.165
Silicon Dioxide	7631-86-9	21 CFR §172.480
Citric Acid	77-92-9	21 CFR §184.1033
Bentonite	1302-78-9	21 CFR §170.3
Diatomaceous Earth	68855-54-9, 91053-39-3, or 61790-53-2	21 CFR §172.820; 21 CFR §172.886

Figure 1. Process Flow Diagram



F. Ingredient Specifications

Food grade specifications and the assays/methods used for the analysis of rice bran wax (wax #224P) are presented in Table 2 below. A comparison of three non-consecutive lots of rice bran wax to the specifications below can be found in Table 3. The specification for total arsenic in Table 2 is 0.2 ppm and all analyzed lots were below the limit of quantitation for total arsenic of 10 ppb. Given a projected 90th percentile intake of rice bran wax of approximately 1.5 -2.0 grams per day (see Table 6) and applying the limit of quantification (LOQ) of 10 ppb (10 ug/kg) as being present in rice bran wax, the estimated daily total arsenic intake is approximately 0.015 – 0.020 ug/person/day and the inorganic arsenic intake a small percentage of that estimate. Therefore, the intake of total and inorganic arsenic from the intended use of rice bran wax is negligible, and would not be expected to contribute to the background dietary intake of arsenic. In addition, inorganic arsenic is water soluble, and thus the manufacturing process of rice bran wax will remove most of the inorganic arsenic. It should be noted that numerous other analyses of the final ingredient are conducted but are not included in the ingredient specifications (e.g., other physical/chemical properties, trace component analyses including additional pesticides, mycotoxins, polychlorinated dibenzo-p-dioxins, polychlorinated dibenzofurans, and dioxin-like polychlorinated biphenyls (PCBs)). Additional testing for other quality measures and contaminants are included in Table 4. Analytical results for the three non-consecutive lots of rice bran wax are provided in Appendix B.

Table 2: Ingredient Specification for Rice Bran Wax

Parameter	Specification	Assay/Analytical Method
Melting point	75.0 – 85.5 °C	USP 741, Class II
Acid value	≤ 13	USP 401
Saponification value	75 - 120	USP 401
Peroxide value	≤ 20 meq/kg	Koster Keunen 205
Gas chromatography	Conforms to Standard	Koster Keunen 208
Iodine value	≤ 20.0	USP 401
Color	Yellow to Light Brown	Visual
Total arsenic	0.2 ppm max	AOAC 984.27 Mod ¹ ., 2015.01 Mod ² , 993.14 Mod.
Cadmium	0.4 ppm max	AOAC 984.27 Mod ¹ ., 2015.01 Mod ² , 993.14 Mod.
Lead	0.2 ppm max	AOAC 984.27 Mod ¹ ., 2015.01 Mod ² , 993.14 Mod.
Mercury	0.1 ppm max	AOAC 984.27 Mod ¹ ., 2015.01 Mod ² , 993.14 Mod.
Hexane	1 ppm max	GC Headspace

¹Modified method

²Analysis performed with an open vessel microwave system with a hot plate digestion process, followed by analysis on ICP-MS. A specific spike is incorporated for the heavy metal being analyzed (e.g., arsenic). In addition, one internal standard (rhodium 203) is incorporated. An arsenic spike is incorporated for every batch of wax and justifies the digestion efficiency; also a blank sample is used to show there is no contamination, and an internal standard incorporated to monitor for analytical errors.

Table 3: Analytical Results of Three Lots of Rice Bran Wax Compared to Ingredient Specification

Parameter	Specification	Result 1	Result 2	Result 3
		Lot 18940	Lot 20033	Lot 20048
Melting point	75.0 – 85.5 °C	82.0	82.0	82.0
Acid value	≤ 13	1.8	0.6	0.6
Saponification value	75 - 120	78	81	77
Peroxide value	≤ 20 meq/kg	16	2	2
Gas chromatography	Conforms to Standard	Pass	Pass	Pass
Iodine value ^a	≤ 20.0	Pass	Pass	Pass
Color	Yellow to Light Brown	Pass	Pass	Pass
Total arsenic	0.2 ppm max	ND	ND	ND
Cadmium	0.4 ppm max	ND	ND	ND
Lead	0.2 ppm max	0.02	ND	0.01
Mercury	0.1 ppm max	ND	ND	ND
Hexane	1 ppm max	ND	ND	ND

ND=not detected

^aIodine value is measured prior to refining on incoming lots; refining will only lower the iodine value. The result is reported as passing since the final value may only be lower than the measured value and the specification for raw incoming wax is ≤20.

Table 4: Quality Control Parameters or Residual Contaminants for Non-Consecutive Lots of Rice Bran Wax

Parameter	Result 1	Result 2	Result 3
	Lot 18940	Lot 20033	Lot 20048
Microbiological			
Aerobic plate count	10 cfu/g	<10 cfu/g	<10 cfu/g
Coliform, plate count	<10 cfu/g	<10 cfu/g	<10 cfu/g
<i>E. Coli</i> , plate count	<10 cfu/g	<10 cfu/g	<10 cfu/g
Listeria genus (PCR)	Negative	Negative	Negative
Mold	<10 cfu/g	<10 cfu/g	<10 cfu/g
<i>Salmonella</i> (PCR)	Negative	Negative	Negative
Yeast	<10 cfu/g	<10 cfu/g	<10 cfu/g
Mycotoxins			
Aflatoxin B ₁	ND	ND	ND

Aflatoxin B ₂	ND	ND	ND
Aflatoxin G ₁	ND	ND	ND
Aflatoxin G ₂	ND	ND	ND

ND=not detected

The rice bran wax under consideration is yellow to light brown colored pastillates with a melting point of 75.0 – 85.5 °C. The USP Food Chemicals Codex (FCC) and 21 CFR § 172.890 contain a specification for rice bran wax and a comparison of the proposed rice bran wax ingredient (wax #224P) and the FCC specification is provided in Table 5. The rice bran wax product under consideration meets FCC specifications with the exception of melting point range. Rice Bran Wax is obtained by winterization/separation from rice bran oil and the melting point of the wax is typically determined by the degree of separation between the rice bran oil and the wax. Since the establishment of the FCC specification, methods for separating rice bran wax from rice bran oil have been improved, such that less rice bran oil is now present in the crude rice bran wax. As a result, these improvements can produce slightly increased melting points for rice bran wax.

Table 5: Ingredient Specifications Compared to FCC Specifications for Rice Bran Wax

Parameter	Rice Bran Wax (#224P) Specification	FCC Specification
Melting point	75.0 – 85.5 °C	75.0 – 80.0 °C
Free fatty acids content	<9.2% (equivalent to ≤ 13 acid value)	10% max
Saponification value	75 - 120	75 - 120
Iodine value	≤ 20	≤ 20.0
Lead	0.2 ppm max	3 ppm max

The specifications for rice bran wax also include a parameter for acid value as a substitute for the FCC measurement of percent free fatty acids. Acid value is a FCC-published method for fats and related substances and is appropriate for the indication of the free fatty acid content of rice bran wax. Specifically, acid value is reported to be the mg of potassium hydroxide (KOH) required to neutralize 1 gram of material (rice bran wax). Hence, an acid value of 13 (maximum) specifically means that it should require less than 13 mg of KOH to neutralize one gram of rice bran wax (see Appendix B for conversion formula).

The analytical (physical, chemical, and microbiological) results for rice bran wax summarized in the above tables and included in the certificate of analyses in Appendix B confirm that the ingredient meets the proposed analytical specifications and demonstrates the consistency of production. The analytical results also confirm the lack of impurities/contaminants (e.g., heavy metals, pesticides, mycotoxins, polychlorinated dibenzo-p-dioxins, polychlorinated dibenzofurans, and dioxin-like PCBs).

G. Stability Data

Rice bran wax is stable at normal storage and use temperatures. Stability tests, based on acid values, have shown that the rice bran wax ingredient has a shelf life of two years past the date of

manufacture, if stored under proper conditions. Stability test data can be found in Appendix C.

4.0 Rice Bran Wax and Related Data Considered in Safety Assessment

Due to the limited amount of toxicological data available for rice bran wax, information on carnauba wax was also evaluated, as chain length and saturation have been shown to predict physio-chemical behavior of waxes and oils (EFSA, 2007; Maru et al., 2012). It is clear, based on the information discussed below, that the monoester fraction in carnauba wax can be considered to be nearly structurally identical to the monoester fraction of rice bran wax; i.e., the monoester fraction in carnauba wax is within a range of 54-84% of total constituents compared to up to 87-98% in rice bran wax. Therefore, published toxicity studies conducted on carnauba wax were deemed suitable for inclusion in the safety assessment of rice bran wax and considered by the Expert Panel in its evaluation of the available data. In fact, in 2007, the European Food Safety Authority (EFSA, 2007) applied a similar approach bridging safety data from carnauba wax to beeswax. In this assessment, the EFSA Panel “noted that experimental biochemical and toxicological studies carried out specifically on beeswax were still lacking and considered that the data on beeswax itself were insufficient to establish an ADI. However, the Panel concluded that the safety of beeswax could be assessed, based on the available scientific literature on the main constituents of beeswax and plant waxes showing chemical structural similarities to beeswax, published since the last SCF evaluation”. The Panel concluded, “that the use of beeswax as an additive for the existing food uses and the proposed new food use is not of safety concern.” In the US, beeswax is also used in foods at levels not to exceed GMP (21 CFR § 184.1973).

The predominant monoester carbon chain lengths have been reported to be C48-64 and C56, for rice bran wax and carnauba wax, respectively (Koster Keunen, 2014; Maru et al., 2012; Puleo and Rit, 1992). Carnauba wax is considered to be the most chemically similar to rice bran wax, compared to other plant-based waxes (Koster Keunen, 2014; Puleo and Rit, 1992; Andersen, 2006). This similarity is based on the presence of specific monoesters, which comprise the majority (87-98%; Appendix A and Table 6) of rice bran wax. In concurrent analyses performed for this GRAS dossier on the rice bran wax product and a carnauba wax product by the same manufacturer, the total monoester fraction was found to account for 87-98% and 54-84% of rice bran and carnauba wax, respectively (Appendix A). The relative percent of each monoester in these waxes is shown in Table 6 and demonstrates that the majority of the rice bran wax components are these monoesters and, as such, can be accounted for. The remaining ~2% of the rice bran wax product is made up of long chain fatty alcohols, long chain fatty acids, triglycerides, or rice bran oil. While the monoesters also comprise a major fraction of the carnauba wax samples, a large percentage is also made up of fatty alcohols (19-33%). In addition, carnauba wax has been shown to contain some fatty acids and complex esters that can only be analyzed with additional methods, e.g., via UV analysis; these can include resins and cinnamates (EFSA, 2007; Warth, 1956).

Table 6. Chain Length Distribution of Rice Bran and Carnauba Wax Samples Using Gas Chromatograph Analysis^a

Carbon Chain Length	Rice Bran Wax^b (%)	Carnauba Wax^b (%)
<i>Approximate Total Fatty Alcohol Fraction (C-28 to C-34)</i>	--	18.95-32.67
C-28	--	0.24-1.70
C-30	--	2.27-3.97
C-32	--	12.57-19.80
C-34	--	3.87-7.20
<i>Approximate Total Monoester Fraction (C-48-C64)</i>	86.99-98.19	54.35-83.96
C-48	1.37-3.38	1.64-3.32
C-50	7.32-10.10	2.89-4.85
C-52	11.86-12.21	6.60-9.12
C-54	15.52-16.87	7.68-11.49
C-56	18.51-20.89	14.30-18.65
C-58	15.28-16.16	8.63-13.63
C-60	10.81-11.20	9.10-13.14
C-62	4.78-5.77	3.67-7.66
C-64	1.54-1.61	0.35-2.10

^aBased on analyses in Appendix 1 – note distributions are relative to the distribution that came off the column and are not necessarily a direct correlation to chemistry

^bRanges combined from three different samples

Given the structural similarity of carnauba wax and rice bran wax, particularly the similar monoester chain length distribution, nearly identical physico-chemical properties can be predicted for these two waxes. Rice bran wax and carnauba wax have similar hardness and melting points, and are often used interchangeably in consumer products. Maru et al. (2012) recently published a study comparing the physical-chemical properties of rice bran and carnauba waxes, providing support for the use of rice bran wax as a suitable substitute for carnauba wax in cosmetic and pharmaceutical products. Table 7 demonstrates the similar physical properties for both waxes as reported in the literature, as well the specifications for the rice bran wax product (see also Appendix B).

Table 7. Physical Properties of Rice Bran and Carnauba Waxes

Physical Properties	Rice Bran Wax Product Specifications	Rice Bran Wax ^b	Carnauba Wax ^b
Melting point, °C	75.0-85.5	75.3-82	78-88
Saponification value	75-120	56.9-120	78-95
Iodine value	≤20	4-19.4	5.0-14.0
Solubility	Insoluble in Water, Insoluble in ethanol, Soluble in heptane, and other solvents	Insoluble in water, soluble in ether, ethanol and isopropyl alcohol	Insoluble in water, soluble in ether, ethanol as well as other solvents
Specific gravity	0.90 - 0.99	0.912	0.990-0.999 at 25 °C
Acid value	≤13	2.848-13	2-10
Ester value	60 - 120	60-90	45-85
Hydroxyl value	10-55	19.62-54	50-54
Unsaponifiable matter (%w/w)	40 - 67	40-67	50-55
Hardness by durometer		100	100

^aSee also Appendix B

^bCompiled from Maru et al. (2012), Puleo and Rit (1992), and Warth (1956)

The FDA has listed carnauba wax (CAS No. 8015-86-9) as GRAS as a direct food substance for human consumption with no specific limitation other than good manufacturing practice (21 CFR § 184.1978). From the data presented above, it is reasonable to conclude that the use of rice bran wax, which is a much structurally less complex wax compared to carnauba wax, could be similarly approved.

In addition, the history of use in foods of other vegetable-based waxes, in particular carnauba wax, provide sufficient safety study data for the proposed use of rice bran wax. As such, the available information suggests that rice bran wax should be considered safe for the intended uses proposed herein. Given the structural similarity of carnauba wax and rice bran wax, particularly the similar monoester chain length distribution and nearly identical physio-chemical properties, the available safety data for carnauba wax, primarily from studies on subchronic and reproductive/developmental toxicity, can be bridged to support the safety of the intended use of rice bran wax in this assessment.

5.0 History of Use/Regulatory Approval of Rice Bran Wax

Rice, brown rice, and their derivatives have a long history of human consumption, with rice cultivation documented back to prehistoric times, starting in Asia and eventually spreading across Europe around the sixth century (Burlando and Cornara, 2014). Currently, rice is produced in most continents and serves as a dietary staple for a majority of populations across the world (Burlando and Cornara, 2014). Once harvested, the rice is hulled and the resulting brown rice can be further processed to generate derivatives such as rice bran oil, rice bran extract, and hydrolyzed rice protein. As referenced in the manufacturing process outlined above, rice bran wax comes from the bran, which is the part between the husk and endosperm of rice, and is a byproduct of bran oil (Burlando and Cornara, 2014; Andersen, 2006; Koster Keunen, 2016; Sabale et al., 2007). Rice bran wax is used in food as a release agent, brightener, coatings for confectioneries, chocolates, cakes, and tablets, treatment of vegetables and fruits and as a plasticizing material for chewing gum base. Non-food uses include cosmetics, polish for cars, floors, and shoes, office ink, textile oiling agent, and resin lubricant (Andersen, 2006).

Rice bran wax (CAS No. 8016-60-2) has been approved for use in various food applications in the US. It is permitted as a direct human food additive (21 CFR §172.890) when used in candy (maximum 50 ppm as a coating), fresh fruits and fresh vegetables (maximum 50 ppm as a coating), and chewing gum (maximum 2.5% in gum when used as a plasticizing material in chewing gum base, 21CFR §172.615). It is also permitted as an indirect food additive as Type VIII in table 1 of 176.170(c), at a maximum levels of 1.0 percent by weight of the polymer. After reviewing the available safety data, the Cosmetic Ingredient Review (CIR) Expert Panel concluded that rice-derived ingredients, including rice bran wax, are safe as cosmetic ingredients (e.g., 1% in lip stick) in the practices of use and concentrations as described in their safety assessment (Andersen, 2006). In addition, rice bran wax is eligible for use as active ingredients or excipients in listed medicines in Australia, with no restrictions (Australian Government, 2007).

6.0 Intended Use and Estimated Intake (EDI)

A. Purpose

Smucker's is proposing to use rice bran wax as a texturizing agent in peanut butter used in bar products. The intended use will allow peanut butter to be the primary ingredient in nutritional/snack bars with a similar form and texture to granola bars and nutritional/energy bars.

B. Food Uses

The intended use of rice bran wax is solely in peanut butter used in bar products and results in bar-form products with a similar form and texture to granola and nutritional energy bars. There are no proposed uses of rice bran wax in food products under USDA jurisdiction.

C. Levels of Use

The proposed rice bran wax will be used at levels from 3 – 4%.

D. Estimated Exposure

ToxStrategies, Inc. (ToxStrategies) conducted an intake assessment to estimate the mean and 90th percentile daily intake of the ingredient rice bran wax based on its new proposed use in foods. It was assumed for the purpose of this estimate that consumers of nutritional/snack bars would replace the consumption of all existing bars with the proposed peanut butter-based bars, in order to produce the highest (most conservative) estimate of potential rice bran wax consumption. Two-day average intake data were obtained from the National Health and Nutrition Examination Survey (NHANES) in 2009-2010 and 2011-2013.

Use levels of both 3% and 4% of rice bran wax in peanut butter used in bar products were estimated. Analyzing dietary survey data at 3% yielded a *per user* mean and 90th percentile estimated daily intake (EDI) of rice bran wax for the US population ages 2 and over of 0.76 and 1.29 g/day (0.013 and 0.028 g/kg BW/day, respectively). For the total US population ages 2 and over, the *per capita* mean and 90th percentile EDI were 0.08 and 0.32 g/day (0.001 and 0.004 g/kg BW/day), respectively.

Analyzing dietary survey data from NHANES at 4% yielded a *per user* mean and 90th percentile EDI of rice bran wax for the US population ages 2 and over of 1.02 and 1.72 g/day (0.018 and 0.037 g/kg BW/day, respectively). For the total US population ages 2 and over, the *per capita* mean and 90th percentile EDI were 0.11 and 0.42 g/day (0.002 and 0.005 g/kg BW/day, respectively). It should be noted that the intake estimates are extremely conservative and assume complete replacement of the intake of the selected bar products with the proposed peanut butter bar product containing rice bran wax. The intake estimates for use levels of 4% are summarized in Tables 6 - 7.

Table 6. Estimated Daily Intake for 4% Rice Bran Wax Use Level (g/day)

Food Category	Number of Users	Percent Users	EDI <i>per User</i> (g/day)		EDI <i>per Capita</i> (g/day)	
			Mean	90th Percentile	Mean	90th Percentile
US Population, Ages 2+						
Total bar replacement	1274	8.55	1.02	1.72	0.11	0.42
US Population, Ages 2-5						
Total bar replacement	142	9.90	0.79	1.50	0.11	0.48
US Population, Ages 6-18						
Total bar replacement	392	10.14	0.87	1.48	0.11	0.48
US Population, Ages 19+						
Total bar replacement	740	7.70	1.08	1.95	0.11	0.34

Table 7. Estimated Daily Intake for 4% Rice Bran Wax Use Level by Body Weight (mg/kg bw/day)

Food Category	Number of Users	EDI <i>per User</i> (mg/kg bw/day)		EDI <i>per Capita</i> (mg/kg bw/day)	
		Mean	90 th Percentile	Mean	90 th Percentile
US Population, Ages 2+					
Total bar replacement	1270	18	37	2	5
US Population, Ages 2-5					
Total bar replacement	142	49	105	7	29
US Population, Ages 6-18					
Total bar replacement	391	22	41	3	9
US Population, Ages 19+					
Total bar replacement	737	14	26	1	4

* Body weight was not reported for ~1% of survey participants. Users with incomplete body weight data were excluded from this analysis.

As stated previously, rice bran wax is permitted as a direct human food additive when used in candy (maximum 50 ppm as a coating), fresh fruits and fresh vegetables (maximum 50 ppm as a coating), and chewing gum (maximum 2.5% as a plasticizing material in gum base) (21 CFR § 172.890). Carnauba wax is similarly permitted as a GRAS direct human food ingredient, with no limitation other than cGMP, in baked goods and baking mixes, chewing gum, confections and frostings, fresh fruits and fruit juices, gravies and sauces, processed fruits and fruit juices, and soft candy (21 CFR § 184.1978).

The background exposure to rice bran wax from its approved uses in gum, candy, and fresh fruit and fresh vegetables is estimated to be approximately 100 mg/day, about half of which is estimated to come from fresh fruit/vegetables and the other half from chewing gum. The estimate is based on reported consumption levels for chewing gum (approximately 30 mg/kg/day for a 60 kg individual or 1.8 g gum/day), candy (mean intake of approximately 40 g candy/day), and fresh fruit and fresh vegetables (approximately 900 g fruits and vegetables/day) (Revolymmer Limited, 2011; Cook, 2011; Orlich et al., 2014; Shumow et al., 2012). Given the approved 2.5% maximum use level in chewing gum, the background exposure estimates for rice bran wax from its use in chewing gum would be higher for heavy users of chewing gum users (estimated to be on the order of 2-3x) as compared to mean intake estimates. Therefore, the background exposure to rice bran wax from current approved uses is estimated to be as high as 200 - 300 mg/day. The non-food use of rice bran wax in lipstick at a concentration of approximately 1% results in an extremely low level of oral consumption and does not add significantly to the background level of exposure to rice bran wax. Loretz et al. (2005) conducted a study of consumers and reported that the mean use of lipstick was 24 mg/day. Given a 1% concentration level and complete ingestion of the applied lipstick, the mean daily ingestion of rice bran wax from lipstick would

be approximately 0.24 mg/day or 240 µg/day, much lower than the daily intakes estimated for the current approved uses of rice bran wax.

We believe this background exposure estimate is extremely conservative given that other waxes are more commonly used as confectionery coatings (e.g., confectioners glaze (shellac) and carnauba wax) and as a coating for fruits and vegetables and alternative waxes and plasticizers are approved and used in chewing gum base in the U.S. In addition, it is generally acknowledged that waxes and plasticizers in gum base remain with the gum cud during chewing and are not released and subsequently ingested.

7.0 Safety

A. Introduction

As discussed in Section 4.0, the monoester fraction in carnauba wax can be considered to be nearly structurally identical to the monoester fraction of rice bran wax; i.e., the monoester fraction in carnauba wax (54-84%) is equivalent to up to 87-98% of the total rice bran wax composition. Therefore, toxicity studies conducted on carnauba wax were deemed suitable for inclusion in the safety assessment of rice bran wax and considered by the Expert Panel in its evaluation of the available data.

B. Safety Data

Absorption, Distribution, Metabolism, and Excretion (ADME)

The potential for absorption via the gastrointestinal (GI) tract is limited for rice bran wax. The long-chain fatty acid esters present in plant-based waxes such as rice bran wax and carnauba wax are generally thought to be poorly absorbed in the GI tract (EFSA, 2012a,b); uptake is thought to decrease as chain length and hydrophobicity increase (Hargrove et al., 2004). While some species have adapted to the use of wax esters as energy sources, humans are thought to be inefficient at this process (Hargrove et al., 2004). Supporting this conclusion, EFSA's Scientific Panel on Food Additives and Nutrient Sources (ANS) added to Food (EFSA, 2012b) reviewed one study evaluating the bioaccumulation of carnauba wax in rats as part of a 90-day toxicity feeding study; they note that the results of this study "indirectly suggested that lipid like components from the wax are not accumulated in tissues" (Edwards, 1998 as cited in EFSA, 2012b). EFSA's Panel on Contaminants in the Food Chain (CONTAM; EFSA, 2012a) considered that absorption of carnauba wax into the GI tract is likely to be low or will not occur, so that metabolism of wax by digestive enzymes or intestinal microbiota is unlikely. In situations where minor amounts of digestion occur, it has been shown that the resulting free fatty acid and alcohol can be absorbed by the epithelium and incorporated into normal cellular metabolic pathways (EFSA, 2012a,b; Hargrove et al., 2004). If a small amount of rice bran wax was absorbed and metabolized to some degree into ethyl alcohol (ethanol), exposure to ethanol would be low in contrast to exposure from the daily diet. Consumers are routinely exposed to incidental amounts of ethanol from consumption of food items such as orange juice, soft drinks, and breads.

GRN 151 (FDA, 2004) received a “no questions letter” for the use of ethyl alcohol as a preservative in the filling used in shelf-stable croissants at a concentration of 3,000 ppm. In addition, GRN 151 reported ethanol levels in ripening fruit and fruit juice ranging from 117 to 1,900 ppm and Logan and Distefano (1998) reported levels of ethanol in various baked goods ranging from 0 - 1.66 %. It is reasonable to conclude that any absorption of rice bran wax via the oral route of exposure would be negligible and does not present any safety concern.

Animal Toxicological Studies on Rice Bran and Carnauba Waxes

Acute Oral Toxicity

No published data were identified regarding the acute oral toxicity of rice bran wax. However, the CIR Panel reviewed three unpublished laboratory reports¹ in its assessment, all of which suggest rice bran wax is of low acute oral toxicity with an LD₅₀ of >5 g/kg in rats (Andersen, 2006). The study summaries provided in Andersen (2006) are described below.

An oral LD₅₀ of >24 g/kg was identified for rice bran wax (“RiceWax”; suspended in 25% gum arabic solution) in male mice (Nippon Bio-Test Laboratories, Inc. 1972 as cited in Andersen, 2006).

An oral LD₅₀ of >5 g/kg was identified for hydrogenated rice bran wax (“RiceWax”; administered 50% in corn oil) in white rats (Leberco Testing Inc. 1991a as cited in Andersen, 2006). One male rat had a dilated right kidney; no other effects were reported.

An oral LD₅₀ of >5 g/kg was identified for rice bran wax in albino rats (Consumer Product Testing Co. 1998f as cited in Andersen, 2006). Rice bran wax was administered in single oral dose of 5 mg/kg (12.5% suspension heated and cooled in corn oil) to male and female rats (n = 10). Following gross necropsy after 14 days post-exposure, one animal was found to have two red, firm nodules (3mm diameter) attached to fat adjacent to the bladder. No other adverse effects were reported.

Similarly, no published data were identified regarding the acute oral toxicity of carnauba wax. EFSA (2012a) reported that carnauba wax “is of low acute toxicity” and that “an oral LD₅₀ of greater than 1100 mg/kg-bw has been reported” (Liebert, 1984 as cited in EFSA, 2012a). In addition, EFSA (2012b) reviewed two unpublished laboratory reports¹ in its assessment. The study summaries provided in EFSA (2012b) are described below.

No deaths or adverse effects were reported after administering up to 20,000 mg/kg-bw of a lipstick product (5.6% carnauba wax) via gavage to 20 rats (Anonymous, 1984 as cited in EFSA, 2012b).

No deaths were reported after administering up to 500 mg/kg-bw of a blush product (10% carnauba wax diluted in 33.3% corn oil to make a wax concentration of 3.33%) via oral

¹A thorough search was performed, however, unpublished laboratory reports were not located or accessible for this review.

intubation in 5 rats (Anonymous, 1984 as cited in EFSA, 2012b).

Genotoxicity/Mutagenicity

No published data were identified regarding the genotoxicity/mutagenicity of rice bran wax. However, the CIR Panel reviewed one unpublished laboratory report² in its assessment, which concluded that rice bran wax was not mutagenic under the conditions of the assay (Andersen, 2006). The study summary provided in Andersen (2006) is described below.

Rice bran wax ("Rice Wax") did not show any mutagenic effect up to concentrations of 5,000 µg/ml in a histidine-dependent auxotroph of *Salmonella typhimurium* strain TA100 (Environmental Technical Laboratory, Ltd., 1998, as cited in Andersen, 2006). No increases in revertant colony numbers compared to control counts were observed with or without metabolic activation (S9 mixture).

Similarly, no published data were identified regarding the genotoxicity/mutagenicity of carnauba wax. EFSA (2012a,b)³; as well as SCF, 2001; JECFA, 1993; and Bassan et al., 2012) reviewed several unpublished laboratory reports² in its assessment. The EFSA CONTAM Panel determined there is no concern for genotoxicity for carnauba wax based on the available data and the lack of structural alerts (EFSA, 2012a). In addition, the ANS Panel concluded in its scientific opinion re-evaluating the safety of carnauba wax that "there is no concern for genotoxicity for carnauba wax", although they do note that there are limitations in testing insoluble compounds *in vitro* (EFSA, 2012b). The study summaries provided in EFSA (2012a,b) are described below.

Carnauba wax (0.031, 0.063, 0.125 0.25, or 0.5 mg/ml of 10% soybean oil) was evaluated in *in vitro* chromosomal aberration tests using human lymphocytes with and without S-9 metabolic activation (Edwards, 1996; 1997 as cited by EFSA, 2012b). No statistically significant increases in aberrant metaphases were reported in the first chromosomal aberration test (without metabolic activation for 3 hours) with or without gaps; however, there was a statistically significant linear trend for both the untreated control and treatment groups (without gaps). No statistically significant increases in aberrant metaphases or linear trend, were observed in the second test, with and without metabolic activation. However, due to a low response elicited by the positive control, cyclophosphamide, in this study (with metabolic activation), a third test was conducted using the same conditions. In this study, statistically significant increases in aberrant metaphases were measured for the positive control while no statistically significant effects were noted for the test article. The Panel concluded that, "carnauba wax is not regarded to cause structural chromosomal aberrations *in vitro* under the reported experimental conditions".

JECFA (1993) also reviewed studies evaluating the mutagenicity of carnauba wax; while complete study information was not available, the EFSA ANS Panel also considered these as part of its evaluation (EFSA, 2012b)⁴. This information is summarized in Table 8 below.

² A thorough search was performed, however, unpublished laboratory reports were not located or accessible for this review.

³ Note that some studies reviewed in EFSA (2012b) were not made available for review at that time; rather, the summaries provided are as reviewed by SCF (2001).

⁴ A thorough search was performed, however, these unpublished laboratory reports were not located or accessible for this review.

Table 8. JECFA (1993) Summary of the Results of Mutagenic Studies on Carnauba Wax; Adapted from EFSA (2012b)⁵

End-point	Test System	Concentration of Carnauba Wax	Results	References
Reverse mutation ^a	<i>S. typhimurium</i> TA1537, TA1538, TA98	3.3-1000 μ g in plate tests	Negative	(Mortelmans and Griffin, 1981)
Reverse mutation ^a	<i>S. typhimurium</i> TA1537, TA1538, TA98	0.01-0.5% in suspension tests	Negative	(Mortelmans and Griffin, 1981)
Reverse mutation ^a	<i>S. typhimurium</i> TA1537, TA1538, TA98	0.1-2.5% in suspension tests	Negative	(Mortelmans and Griffin, 1981)
Reverse Mutation ^b	<i>S. typhimurium</i> TA1535, TA1537, TA1538	0.01% in plate tests	Negative	(Litton Bionetics inc, 1975)
Reverse Mutation ^b	<i>S. typhimurium</i> TA1535, TA1537, TA1538	0.005 and 0.01% in suspension tests	Inconsistent changes ^c	(Litton Bionetics inc, 1975)
Gene Conversion ^b	<i>S. cerevisiae</i> D4	0.3 and 1.75% in suspension tests	Negative	(Litton Bionetics inc, 1975)

^a The Ames/Salmonella assays in the presence and absence of an Aroclor 1254-stimulated, rat-liver homogenate metabolic activation system, were used in this study.

^b A series of in vitro microbial assays with and without metabolic activation were used. In the activation assays, the tissue homogenate of liver, lung and testes were prepared from either mouse, rat or monkey.

^c The results from non-activation suspension tests were negative. The results from activation suspension tests showed scattered increased mutation responses in the presence of rat-liver or testes homogenate with strain TA1537, and in the presence of monkey-lung homogenate with TA1538.

Subchronic Oral Toxicity

No repeated dose studies were identified for rice bran wax. However, three longer-term studies evaluating the potential toxicity of carnauba wax via the oral route of exposure are summarized below.

Rowland et al. (1982) evaluated the subchronic oral toxicity of carnauba wax in rats in a 13-week study. Carnauba wax (0, 1, 5, or 10%, corresponding to 0, 800, 4200, or 8800 mg/kg-bw/day for males and 0, 900, 4600, 10200 mg/kg-bw/day for females, respectively) in the diet resulted in no treatment-related effects including changes in body weight, hematology, serum-enzyme levels, organ weights, or histology. In rats given carnauba wax, some significant but non-treatment-related changes were reported: increased mean food consumption, higher

⁵ Section 3.2.3 Genotoxicity, Table 5; Note that the studies were not made available for review at that time; rather, the summaries provided are as reviewed by JECFA (1993).

erythrocyte count at week 2 in male rats, changes in urine specific gravity, and changes in organ and relative organ weights. The authors concluded the no-effect level to be 10% in the diet, equivalent to 8,800 and 10,200 mg/kg-bw/day in males and females, respectively. Similarly, EFSA (2012a,b) identified a No Observed Adverse Effect Level (NOAEL) of 8,800 mg/kg-bw/day for carnauba wax based on the highest dose tested in males in this study.

No toxicity was observed in beagle dogs administered carnauba wax in the diet (0, 0.1, 0.3, or 1% carnauba wax, equivalent to 25, 75, and 250 mg/kg-bw/day, respectively) for 28 weeks (Parent et al., 1983a). The only significant finding was an increased free fatty acid level in male dogs in all treated groups compared to control animals at 26 weeks. The levels were determined to be within the normal historical range for beagle dogs in the breeding colony, and the authors noted the control dog values were comparatively lower than these historical levels which likely accounted for the observed difference, as opposed to abnormally increased levels in treated dogs. No other changes were noted in food consumption, body weight, behavior, blood and urine samples, organ weights, examined tissues (gross and microscopic), or biochemical analysis at the end of the study. The EFSA ANS Panel derived a NOAEL of 250 mg/kg-bw/day for carnauba wax based on the highest dose tested in this study.

In addition to the two studies summarized above, the EFSA ANS Panel (EFSA, 2012b; also in JECFA, 1993) also reviewed an unpublished report by Edwards (1998)⁶. In this study, rats were administered carnauba wax in the diet at levels of 0, 15, 150, or 1500 mg/kg-bw/day continuously for 90 days; 5 males and 5 females were also placed back on the control diet for another 90 days as a reversibility test. In some carnauba wax-treated animals, non-treatment-related changes included: significant increase in feed intake in the main study; lower chloride or protein concentration, higher albumin/globulin ratio, higher alanine aminotransferase and lactate dehydrogenase activities in 15 and 150 mg/kg-bw/day groups (few differences in reversibility groups); reduction in mean relative thymus weight of male rats (15 and 1500 mg/kg-bw/day groups); increase in mean absolute brain weight of the male rats fed 15 mg/kg-bw/day; higher incidence of liver necrosis in male rats (15 and 150 mg/kg-bw/day groups); and significantly higher incidence of liver vacuolization in the 150 mg/kg-bw/day group (not observed in the 1500 mg/kg-bw/day group). One female in the highest dose group died of a brain hemorrhage on day 52. The EFSA ANS Panel (EFSA, 2012b) determined the NOAEL to be 1500 mg/kg-bw/day for carnauba wax based on the highest dose tested in this study.

Reproductive and Developmental Toxicity

No reproductive or developmental toxicity studies were identified for rice bran wax. However, two studies evaluating the potential toxicity of carnauba wax are summarized below.

Parent et al. (1983b) evaluated the potential reproductive effects of carnauba wax (0, 0.1, 0.3, or 1%) given in the diet of male rats (equivalent to 0, 80, 250, and 810 mg/kg-bw/day) and female rats (equivalent to 0, 90, 270, and 670 mg/kg-bw/day). Following four weeks of the carnauba wax diet, rats were paired and diets continued through mating, gestation, and lactation. F₁

⁶ A thorough search was performed, however, unpublished laboratory reports were not located or accessible for this review.

generation rats were randomly selected and given the same diet for an additional 13 weeks and all animals were sacrificed after weaning. The number of pups born (dead or alive) was decreased, though not significantly, for treatment groups compared to controls (228-230 pups compared to 269 pups); no differences were noted in fertility, gestation, viability, or lactation indices. Some significant differences in food consumption were mentioned but concluded to be intermittent. In carnauba wax-treated animals, statistically-significant effects included: increased hematocrit (females in 0.1% and 1% groups); increased nitrogen urea levels (males in 1% group); increased chloride levels (males in 0.3% and 1% groups); decreased serum glutamatepyruvate transaminase and free fatty acid levels (males in all treatment groups); and decreased free fatty acids (females in 0.3% and 1% groups). The EFSA ANS Panel determined the NOAEL to be 670 mg/kg-bw/day based on the highest dose given to female rats (EFSA, 2012b).

In addition to the study summarized above, the EFSA ANS Panel (EFSA, 2012b⁷; originally reviewed by JECFA, 1993) also reviewed an unpublished report by FDRL (1977)⁸. In this study, the potential for developmental toxicity of carnauba wax was studied in rats. Carnauba wax (0, 0.1, 0.3, or 1%; equivalent to 0, 50, 150, and 500 mg/kg-bw/day) given in the diet of females for 2 weeks prior to mating and for the duration of gestation did not cause any treatment-related adverse developmental effects on maternal weight, reproductive parameters, or skeletal or soft tissue development of fetuses. Maternal body weight, gross pathology, number of corpora lutea, implantation sites, resorption sites, number of live and dead fetuses, weights of live fetuses, visceral pathology, and skeletal changes were evaluated.

Allergy

There are some reports in the literature of allergic responses to rice. However, rice bran wax and rice are two different foods given that rice bran wax contains little to no protein (<0.10g/100g as reported) and that waxes, oils, and other lipids are considered to have chemical structures that are nonallergenic. Therefore, rice bran wax is not likely to pose an allergenic risk due to its vanishingly small protein content. In its report, the CIR Panel provides a review of available animal and human data regarding the potential for sensitization and allergic reaction to rice (*Oryza sativa*) and its derived ingredients, including rice bran wax (Andersen, 2006). While tests in guinea pigs and rabbits were negative for dermal sensitization, the Expert Panel noted that some isolated cases of allergy to rice or its derivatives have been reported. Such reports include contact urticaria (raw rice), Quincke's edema (rice cereal), erythema of the hands, edema of the eyelids, and cough (raw rice); it is worth noting that in some cases, sensitivity to grains other than rice were also confirmed. Burlando and Cornara (2014) also reviewed cases including reactions such as rhinitis, asthma, pollinosis, rhinoconjunctivitis, and dermatitis (raw rice, boiled rice, rice pollen, rice flour). Following its review, the CIR Panel concluded that rice and its derivatives were not allergens of concern notwithstanding a few reported instances of hypersensitivity to rice (Andersen, 2006). Similarly, while Chowdury (2002) reports one case of contact dermatitis in reaction to carnauba wax, the EFSA CONTAM Panel (2012a) concluded it

⁷ Note that the study as reviewed in EFSA (2012b) was not made available to the Panel for review at that time.

⁸ A thorough search was performed, however, unpublished laboratory reports were not located or accessible for this review.

is not likely to be a “significant sensitizer”. In addition, the EFSA ANS Panel (2012b) reported that no information following exposure via the oral route was identified for carnauba wax.

Other Safety Concerns

Excessive Wax Intake

As with any wax product, excessive intake could result in intestinal obstruction (NLM, 2016). The intended use of rice bran wax is solely in peanut butter used in bar products and results in bar-form products similar to granola and nutritional energy bars and would be expected to result in consumption amounts that would not cause such an effect.

C. Safety Data Summary

Brown rice and its derivatives, such as rice bran wax, have a long history of human consumption, with rice cultivation documented back to prehistoric times (Burlando and Cornara, 2014). Rice bran wax has been approved for use in various food applications in the US and is permitted as a direct human food additive when used in candy, fruits and vegetables, and chewing gum (21CFR §172.890).

As discussed in Section 4.0, the monoester fraction in carnauba wax can be considered to be nearly structurally identical to the monoester fraction of rice bran wax; i.e., 54-84% monoester fraction in carnauba wax compared to up to 87-98% of the total rice bran wax composition. In fact, in 2007, the European Food Safety Authority (EFSA, 2007) applied a similar approach bridging safety data from carnauba wax to beeswax. In this assessment, the EFSA Panel “noted that experimental biochemical and toxicological studies carried out specifically on beeswax were still lacking and considered that the data on beeswax itself were insufficient to establish an ADI. However, the Panel concluded that the safety of beeswax could be assessed, based on the available scientific literature on the main constituents of beeswax and plant waxes showing chemical structural similarities to beeswax, published since the last SCF evaluation”. The Panel concluded, “that the use of beeswax as an additive for the existing food uses and the proposed new food use is not of safety concern.” In the US, beeswax is used in foods at levels not to exceed GMP (21 CFR § 184.1973).

The long-chain fatty acid esters present in rice bran wax and carnauba wax are generally thought to be poorly absorbed in the GI tract and as such, any absorption via the oral route of exposure is likely to be negligible (EFSA, 2012a,b). No published data were identified regarding the acute oral toxicity of rice bran wax; however, the CIR Panel reviewed three unpublished laboratory reports in its assessment all of which suggest rice bran wax is of low acute oral toxicity with an LD₅₀ of >5 g/kg in rats (Andersen, 2006). Similarly, EFSA (2012b) reviewed two unpublished studies and concluded that carnauba wax is of low acute oral toxicity. Neither rice bran nor carnauba wax showed mutagenic and/or genotoxic potential in studies (reviewed in Andersen (2006) and EFSA (2012a,b)) and the EFSA CONTAM Panel determined there is no concern for genotoxicity for carnauba wax based on the available data and the lack of structural alerts (EFSA, 2012a).

While no repeated dose or reproductive/developmental toxicity studies were identified for rice bran wax, several studies evaluating the potential toxicity of carnauba wax via the oral route of exposure were reviewed. Subchronic toxicity studies in rats and beagle dogs reported no treatment-related adverse effects from carnauba wax given in the diet, and the EFSA ANS Panel derived NOAELs of 8800 mg/kg-bw/day (rat), 1500 mg/kg-bw/day (rat), and 250 mg/kg-bw/day (dog) from these studies (Rowland et al., 1982; Parent et al., 1983a; Edwards 1998 as cited by EFSA, 2012b). In a developmental toxicity study in rats given carnauba wax (0.1, 0.3, or 1% dietary, equivalent to 50, 150, and 500 mg/kg-bw/day) no significant treatment-related effects were reported (FDRL, 1977, as cited in EFSA, 2012b). In a reproductive toxicity study, no treatment-related effects were reported following exposure to carnauba wax given in the diet of male and female rats (Parent et al., 1983b) and the EFSA ANS Panel determined the NOAEL to be 670 mg/kg-bw/day based on the highest dose given to female rats (EFSA, 2012b). In summary, all of the repeated dose and reproductive/developmental toxicity studies of carnauba wax resulted in NOAELs at the highest dose levels administered, the highest of which was a concentration of 10% (equivalent to 8,800 and 10,200 mg/kg-bw/day in males and females, respectively) administered in the diet of rats for 90 days.

While tests in guinea pigs and rabbits were negative for dermal sensitization, some isolated cases of allergy to rice or its derivatives have been reported (reviewed in Andersen, 2006; Burlando and Cornara, 2014). Given that rice bran wax contains little to no proteins, the component responsible for imparting allergic potential, rice bran wax is not likely to pose a significant allergenic risk.

Taken together, the available published and unpublished safety data for rice bran wax and the supportive toxicological data for carnauba wax, which is comprised of nearly identical chemical constituents, demonstrate that rice bran wax has little potential for toxicity. Brown rice and its derivatives have a long history of human consumption and importantly, the known history of use of rice bran wax in food such as candy, chewing gum, and fresh fruit and vegetables (21 CFR § 172.890 and 21 CFR § 172.615) is supportive of its safe use in food. While some key studies were not accessible for review, they have been reviewed in detail by authoritative experts or in the case of CIR, well-respected expert panels and deemed sufficient to demonstrate a lack of toxicological potential. The absence of a chronic toxicity study is not considered limiting, as data from the three subchronic toxicity studies on the structurally similar carnauba wax are considered to be sufficient for this purpose. Given the structural similarity of carnauba wax and rice bran wax, particularly the similar monoester chain length distribution and nearly identical physio-chemical properties, similar safety profiles can be predicted for these two waxes in toxicity studies. Although information on the potential carcinogenicity of both waxes is lacking, there is nothing in the chemical structure of rice bran wax, available genotoxicity data, or regulatory reviews of carnauba wax to suggest a carcinogenic potential. In addition, the history of use of other vegetable-based waxes, in particular carnauba wax, provide sufficient safety study data for the proposed use of rice bran wax. The FDA has listed carnauba wax (CAS No. 8015-86-9) as GRAS as a direct food substance for human consumption with no specific limitation other than good manufacturing practice (21 CFR § 184.1978), and as such, the available information suggests that rice bran wax could be considered safe for the intended uses proposed herein.

8.0 Basis for the GRAS Determination

A. Introduction

The regulatory framework for determining whether a substance can be considered GRAS in accordance with section 201(s) (21 U.S.C. § 321(s)) of FD&C Act (21 U.S.C. § 301 et. Seq.) ("the Act"), is set forth at 21 CFR 170.30, which states:

General recognition of safety may be based only on the view of experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food. The basis of such views may be either (1) scientific procedures or (2) in the case of a substance used in food prior to January 1, 1958, through experience based on common use in food. General recognition of safety requires common knowledge about the substance throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food.

General recognition of safety based upon scientific procedures shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation for the ingredient. General recognition of safety through scientific procedures shall ordinarily be based upon published studies, which may be corroborated by unpublished studies and other data and information.

These criteria are applied in the analysis below to determine whether the use of rice bran wax for use in food for human consumption is GRAS based upon scientific procedures. All data used in this GRAS determination are publicly available and generally known, and therefore meet the "general recognition" standard under the FD&C Act.

B. Safety Determination

The subject of this GRAS determination is the use of rice bran wax as a texturizer in peanut butter used in bar products and results in bar-form products similar in texture to that of granola and nutritional energy bars. There is common knowledge of a long history of human consumption of rice and rice bran wax.

The safety section describes preclinical safety studies of rice bran wax and other compositionally similar waxes and constituents of these waxes. Due to the limited amount of toxicological data available for rice bran wax, safety-related information was also obtained for carnauba wax because of its similar chemical composition. Carnauba wax is considered to be the most chemically similar to rice bran wax compared to other plant-based waxes, and the two are often used interchangeably in cosmetic and pharmaceutical products because of their nearly identical structure and physio-chemical properties. Monoester carbon chain lengths range from C48-64 for rice bran wax and carnauba wax; C56 is predominant in both rice bran wax and carnauba wax. In concurrent analyses performed for this GRAS dossier on the rice bran wax product and a carnauba wax product by the same manufacturer, the distribution of monoester peaks identified for rice bran wax and carnauba wax were similar.

All of the repeated dose and reproductive/developmental toxicity studies of carnauba wax resulted in NOAELs at the highest dose levels administered. NOAELs ranged from 250 to 10,800 mg/kg/day, the highest of which was a concentration of 10% (equivalent to 8,800 and 10,200 mg/kg-bw/day in males and females, respectively) administered in the diet of rats for 90 days. Estimated mean and 90th percentile intakes of rice bran wax of 18 mg/kg/day and 37 mg/kg/day, respectively were calculated (assuming a maximum 4% use level) for the US population ages 2 and over. This provides margins of exposure of approximately 14x and 7x, respectively for mean and 90th percentile intakes when compared to the lowest NOAEL reported from studies with carnauba wax. However, it should be noted that no adverse effects were reported in the highest dose level tested in these studies and the low margins of exposure of 7x and 14x are derived from the cited study in dogs with a NOAEL of only 250 mg/kg/day. Higher dose levels were not administered. When compared to other studies with NOAEL's of 10,800 mg/kg/day, margins of exposures increase to 560x to 292x for mean and 90th percentile intakes. In addition, since peanut butter bars with rice bran wax are not expected to totally replace all nutrition and granola products in bar form, margins of exposure can be expected to be even higher.

Taken together, the available published and unpublished safety data demonstrate that rice bran wax has little potential for toxicity when used in foods for human consumption. There is also nothing in the chemical structure of rice bran wax, available genotoxicity data, or regulatory reviews of rice bran wax or carnauba wax to suggest a carcinogenic potential.

Rice is not listed among the major food allergens by FDA as noted by its absence in the *Food Allergen Labeling and Consumer Protection Act of 2004*. Given that rice bran wax contains little to no proteins, the component responsible for imparting allergic potential, rice bran wax is not likely to pose an allergenic risk.

C. General Recognition of the Safety of Rice Bran Wax

The intended use of rice bran wax has been determined to be safe through scientific procedures as set forth in 21 CFR § 170.3(b), thus satisfying the so-called "technical" element of the GRAS determination and is based on the following:

- The rice bran wax that is the subject of this notification is a high melting point vegetable wax obtained from rice husks. The rice bran wax product is manufactured consistent with current cGMP for food (21 CFR Part 110). The raw materials and processing aids used in the manufacturing process are food grade and/or approved for use as in food.
- Brown rice, and their derivatives have a long history of human consumption with rice cultivation documented back to prehistoric times. Importantly, the known history of use of rice bran wax in food such as candy, chewing gum, and fresh fruit and vegetables (21 CFR § 172.890 and 21 CFR § 172.615) is supportive of its safe use in food.
- Safety studies of rice bran wax and carnauba wax have been conducted and are publicly available and/or have been previously reviewed and reported in summary form by an authoritative regulatory body. Based on the similar physical-chemical properties of rice

bran wax and carnauba wax, particularly the similar monoester chain length distribution, the available safety data for carnauba wax, primarily studies on subchronic and reproductive/developmental toxicity, are appropriately used as a bridge to rice bran wax in this safety assessment.

- All of the repeated dose and reproductive/developmental toxicity studies of carnauba wax resulted in NOAELs at the highest dose levels administered. NOAELs ranged from 250 to 10,800 mg/kg/day, the highest of which was a concentration of 10% (equivalent to 8,800 and 10,200 mg/kg-bw/day in males and females, respectively) administered in the diet of rats for 90 days. Estimated mean and 90th percentile intakes of rice bran wax of 18 mg/kg/day and 37 mg/kg/day, respectively were calculated (assuming a maximum 4% use level) for the US population ages 2 and over. This provides margins of exposure of approximately 14x and 7x, respectively for mean and 90th percentile intakes when compared to the lowest NOAEL reported from studies with carnauba wax. However, it should be noted that no adverse effects were reported in the highest dose level tested in these studies and the low margins of exposure of 7x and 14x are derived from the cited study in dogs with a NOAEL of only 250 mg/kg/day. Higher dose levels were not administered. When compared to other studies with NOAEL's of 10,800 mg/kg/day, margins of exposures increase to 560x to 292x for mean and 90th percentile intakes. In addition, since peanut butter bars with rice bran wax are not expected to totally replace all nutrition and granola products in bar form, margins of exposure can be expected to be even higher.
- Given that rice bran wax contains little to no proteins, the component responsible for imparting allergic potential, rice bran wax is not likely to pose an allergenic risk.
- The estimated mean and 90th percentile user only intakes of rice bran wax resulting from the proposed new use are below the NOAELs established in numerous toxicity studies, all of which were the highest dose levels administered.
- The publicly available scientific literature on the consumption and safety of rice bran wax and carnauba wax is sufficient to support the safety and GRAS status of the proposed rice bran wax product.

Since this safety evaluation was based on generally available and widely accepted data and information, it also satisfies the so-called "common knowledge" element of a GRAS determination.

Determination of the safety and GRAS status of rice bran wax that is the subject of this self-determination has been made through the deliberations of an Expert Panel convened by Smuckers and comprised of Michael Carakostas, DVM, Ph.D., Stanley M. Tarka, Jr., Ph.D., and Thomas Vollmuth, Ph.D. These individuals are qualified by scientific training and experience to evaluate the safety of substances intended to be added to foods. They have critically reviewed and evaluated the publicly available information summarized in this document and have individually and collectively concluded that rice bran wax, produced consistent with GMP and meeting the specifications described herein, is safe under its

intended conditions of use. The Panel further unanimously concludes that the use of rice bran wax is GRAS based on scientific procedures, and that other experts qualified to assess the safety of foods and food additives would concur with these conclusions. The Panel's GRAS opinion is included as Exhibit 1 to this document.

It is also Smuckers' opinion that other qualified scientists reviewing the same publicly available toxicological and safety information would reach the same conclusion. Smuckers has concluded that rice bran wax is GRAS under the intended conditions of use on the basis of scientific procedures; and therefore, it is excluded from the definition of a food additive and may be marketed and sold for its intended purpose in the U.S. without the promulgation of a food additive regulation under Title 21 of the CFR.

Smuckers is not aware of any information that would be inconsistent with a finding that the proposed use of rice bran wax in food for human consumption meeting appropriate specifications, and used according to GMP, is GRAS. Recent reviews of the scientific literature revealed no potential adverse health concerns.

9.0 References⁹

Andersen, FA. 2006. Amended final report on the safety assessment of oryza sativa (rice) bran oil, oryza sativa (rice) germ oil, rice bran acid, oryza sativa (rice) bran wax, hydrogenated rice bran wax, oryza sativa (rice) bran extract, oryza sativa (rice) extract, oryza sativa (rice) germ powder, oryza sativa (rice) starch, oryza sativa (rice) bran, hydrolyzed rice bran extract, hydrolyzed rice bran protein, hydrolyzed rice extract, and hydrolyzed rice protein. International Journal of Toxicology, 25(Suppl 2), 91-120.

Anonymous. 1984. Final report on the safety assessment of candelilla wax, carnauba wax, japan wax, and beeswax. Journal of the American College of Toxicology 3:1-41 Liebert MA. Inc. Publishers. **Report not available; as cited in EFSA, 2012b.**

Australian Government. 2007. Australian Therapeutic Goods Administration (TGA). Substances that may be used in Listed medicines in Australia.

Bassan, A, Fioravanzo, E, Pavan, M, Conto, A. 2012. European Food Safety Authority External Scientific Report: Reports on toxicokinetics, toxicity and allergenicity data on substances to be evaluated as acceptable previous cargoes for edible fats and oils (NP/EFSA/CONTAM/2011/01) – Batches n. 1, 2 and 3. EFSA Supporting Publications 2012:EN-274.

Burlando, B, Cornara, L. 2014. Therapeutic properties of rice constituents and derivatives (Oryza sativa L.): a review update. Trends in Food Science & Technology, 40(1), 82-98.

Chowdhury, MM. 2002. Allergic contact dermatitis from prime yellow carnauba wax and coathylene in mascara. Contact Dermatitis 46(4): 244. **Abstract only.**

Cook, R. 2011. Tracking demographics and US fruit and vegetable consumption patterns. Department of Agricultural and Resource Economics, University of California, Davis.

Consumer Product Testing Co. 1998f. Acute oral toxicity test in rats, rice bran wax S-100, Lot No. W90305. Unpublished data submitted by CTFA. 12 pages. **Report not available; as cited in Andersen, 2006.**

Edwards, AJ. 1996. A chromosome aberration study using human lymphocytes treated in vitro with carnauba wax. Study report from BIBRA International testing laboratory. Project No. 3066/1. Unpublished report. **Report not available; as cited in EFSA, 2012b.**

Edwards, AJ. 1997. Addendum to A chromosome aberration study using human lymphocytes treated *in vitro* with carnauba wax. Study report from BIBRA International testing laboratory. Addendum to Project No. 3066/1. Unpublished report. **Report not available; as cited in EFSA, 2012b.**

⁹ ToxStrategies attempted to locate all unpublished reports using all avenues available to us, but were unsuccessful. Even in their re-evaluation, EFSA (2012) noted that not all studies included in their original evaluation were available for re-review.

Edwards, AJ. 1998. A modified 90-day feeding study to investigate the potential for bioaccumulation of carnauba wax in the Fisher 344 rat, Study report from BIBRA International testing laboratory. Project No. 3180/1. Unpublished report. **Report not available; as cited in EFSA, 2012b.**

Environmental Technical Laboratory, LTD. 1998. Rice bran wax S-100: Bacterial mutation assay. Unpublished data submitted by CTFA. 5 pages). **Report not available; as cited in Andersen, 2006.**

European Commission Scientific Committee for Food (SCF). 2001. Opinion of the Scientific Committee on Food on carnauba wax. SCF/CS/ADD/MsAd/194.

European Food Safety Authority (EFSA). 2007. Beeswax (E 901) as a glazing agent and as carrier for flavours. Scientific Opinion of the Panel on Food additives, Flavourings, Processing aids and Materials in Contact with Food (AFC). The EFSA Journal (2007) 615, 1-28.

European Food Safety Authority (EFSA). 2012a. Scientific Opinion on the evaluation of the substances currently on the list in the Annex to Commission Directive 96/3/EC as acceptable previous cargoes for edible fats and oils – Part III of III. EFSA Journal 2012;10(12):2984.

European Food Safety Authority (EFSA). 2012b. Scientific Opinion on the re-evaluation of carnauba wax (E 903) as a food additive. EFSA Journal 2012;10(10):2880.

Food and Agriculture Organization of the United Nations (FAO). 2013. Carnuba Wax.

Food and Drug Administration (US FDA). 2004. GRN No. 151. GRAS Notification for Ethanol (Ethyl Alcohol). Prepared by Frito-Lay, Inc.

Food and Drug Research Laboratory (FDRL). 1977. Evaluation of the effects of carnauba wax in FDRL/Wistar derived rats after dietary exposure through one full generation. Unpublished report of July 8, 1977 submitted to Brazilian Embassy, Washington, D.C. **Report not available; as cited in EFSA, 2012b.**

Hargrove, JL, Greenspan, P, Hartle, DK. 2004. Nutritional significance and metabolism of very long chain fatty alcohols and acids from dietary waxes. Experimental Biology and Medicine, 229(3), 215-226.

Joint FAO/WHO Expert Committee on Food Additives (JEFCA).1993. Toxicological evaluation of certain food additives and naturally occurring toxicants. WHO Food Additive Series: 30 (758. Carnauba Wax).

Koster Keunen, 2014. Waxes for Personal Care Information Sheet.

Koster Keunen, 2016. Product Sheet. Retrieved from <http://www.koster-wax.com/eu/wax-products/organic-and-natural/rice-bran-wax>.

Leberco Testing Inc. 1991a. Acute oral toxicity in rats—Hydrogenated Rice Bran Wax. Unpublished data submitted by CTFA. 3 pages. **Report not available; as cited in Andersen, 2006.**

Liebert, MA. 1984. Final report on the safety assessment of candelilla wax, carnauba wax, Japan wax, and beeswax. Journal of the American College of Toxicology, 3, 1-41. **Report not available; as cited in EFSA, 2012a.**

Litton Bionetics inc. 1975. Mutagenic evaluation of compound MX8015869, carnauba wax (73-48). Unpublished report of April 15, 1975, submitted to Food and Drug Administration, Rockville, MD. **Report not available; quoted by JECFA (1993), as cited by EFSA (2012b).**

Logan BK, Distefano S. 1998. Ethanol content of various foods and soft drinks and their potential interference with a breath-alcohol test. Journal of Analytical Toxicology 32:181-183.

Loretz, LJ, Api, AM, Barraj, LM, Burdick, J, Dressler, WE, Gettings, SD, Han Hsu, H, Pan, YH, Re, TA, Renskers, KJ, Rothenstein A, Scrafford, CG, Sewall, C. 2005. Exposure data for cosmetic products: lipstick, body lotion, and face cream. Food and Chemical Toxicology 43(2):279-291.

Maps of the World. 2006. World Top 10 - Chewing Gum Consumer Countries. <http://www.mapsofworld.com/world-top-ten/world-top-ten-chewing-gum-consumer-countries.html>.

Maru, AD, Surawase, RK, Bodhe, PV. 2012. Studies on Physico-Chemical Properties of Rice Bran Wax and its Comparison with Carnauba Wax. International Journal of Pharmaceutical and Phytopharmacological Research. 1(4), 203-207.

Mortelmans, KE, Griffin, AF. 1981. Microbial mutagenesis testing of substances compound F73-048: carnauba wax, yellow. Unpublished SRI Report LSU-6909 from Frank B. Ross & Co. Submitted to Food and Drug Administration by Frank B. Ross & Co. Report (LSU-6909). **Report not available; quoted by JECFA (1993), as cited by EFSA (2012b).**

Nippon Bio-Test Laboratories Inc. 1972. Acute oral toxicity test of rice bran wax in mice. Submitted by FDA in response to an FOI request—1997. 4 pages. **Report not available; as cited in Andersen, 2006.**

National Library Medicine (NLM). 2016. Wax poisoning. www.nlm.nih.gov/medlineplus/ency/article/002815.htm

Orlich, MJ, Jaceldo-Siegl, K, Sabaté, J, Fan, J, Singh, PN, Fraser, GE. 2014. Patterns of food consumption among vegetarians and non-vegetarians. British Journal of Nutrition, 112(10), pp.1644-1653.

Parent, RA, Cox, GE, Babish, JG, Gallo, MA, Hess, FG, Becci, PJ. 1983a. Subchronic feeding

study of carnauba wax in beagle dogs. *Food and Chemical Toxicology* 21:85-87.

Parent, RA, Re, TA, Babish, JG, Cox, GE, Voss, KA, Becci PJ. 1983b. Reproduction and subchronic feeding study of carnauba wax in rats. *Food and Chemical Toxicology* 21:89-93.

Puleo, S, Rit, TP. 1992. Natural waxes: past, present and future. *Lipid Technology*, July/August 1992 Issue.

Revolymmer Limited. 2011. GRN No. 374; Maleated isoprenyl polymer with methoxy-polyethylene glycol (MIP-MPEG).
<http://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm269568.pdf>

Rowland, IR, Butterworth, KR, Gaunt, IF, Grasso, P, Gangolli, SD. 1982. Short-term toxicity study of carnauba wax in rats. *Food and Chemical Toxicology* 20, 467-471.

Sabale, V, Sabale, PM, Lakhotiya, CL. 2007. In vitro studies on rice bran wax as skin moisturizer. *Indian Journal of Pharmaceutical Sciences*, 69(2), 215.

Shumow L, Barraj LM, Murphy MM, Bi X, Bodor AR. 2012. Candy consumption in the United States. *FASEB Journal* 26:1005.3 (abstract).

ToxStrategies, Inc. 2016. Estimated Daily Intake of Rice Bran Wax.

United States Census Bureau. 2011. Facts for Features: Halloween. October 31.
http://www.census.gov/newsroom/releases/pdf/cb11ff-20_halloween.pdf.

United States Department of Agriculture (USDA). 2014. USDA Waxes Report: Carnauba Wax.

Warth AH. 1956. The chemistry and technology of waxes. New 2nd ed. Reinhold Publishing Co., New York.

10.0 Appendices

Appendix A. Gas Chromatographs

Chromatogram

Sample Name: C:\TC Data\Unknown001-20150830-095948.raw
 File Name: C:\TC Data\Unknown001-20150830-095948.raw
 Date: 8/30/2015 10:57:20 AM
 Method: unknown.mth
 Start Time: 0.00 min
 Offset: 0.00 mV

Sample #: 001-

Page 1 of 1

Time of Injection: 8/30/2015 9:58:39 AM

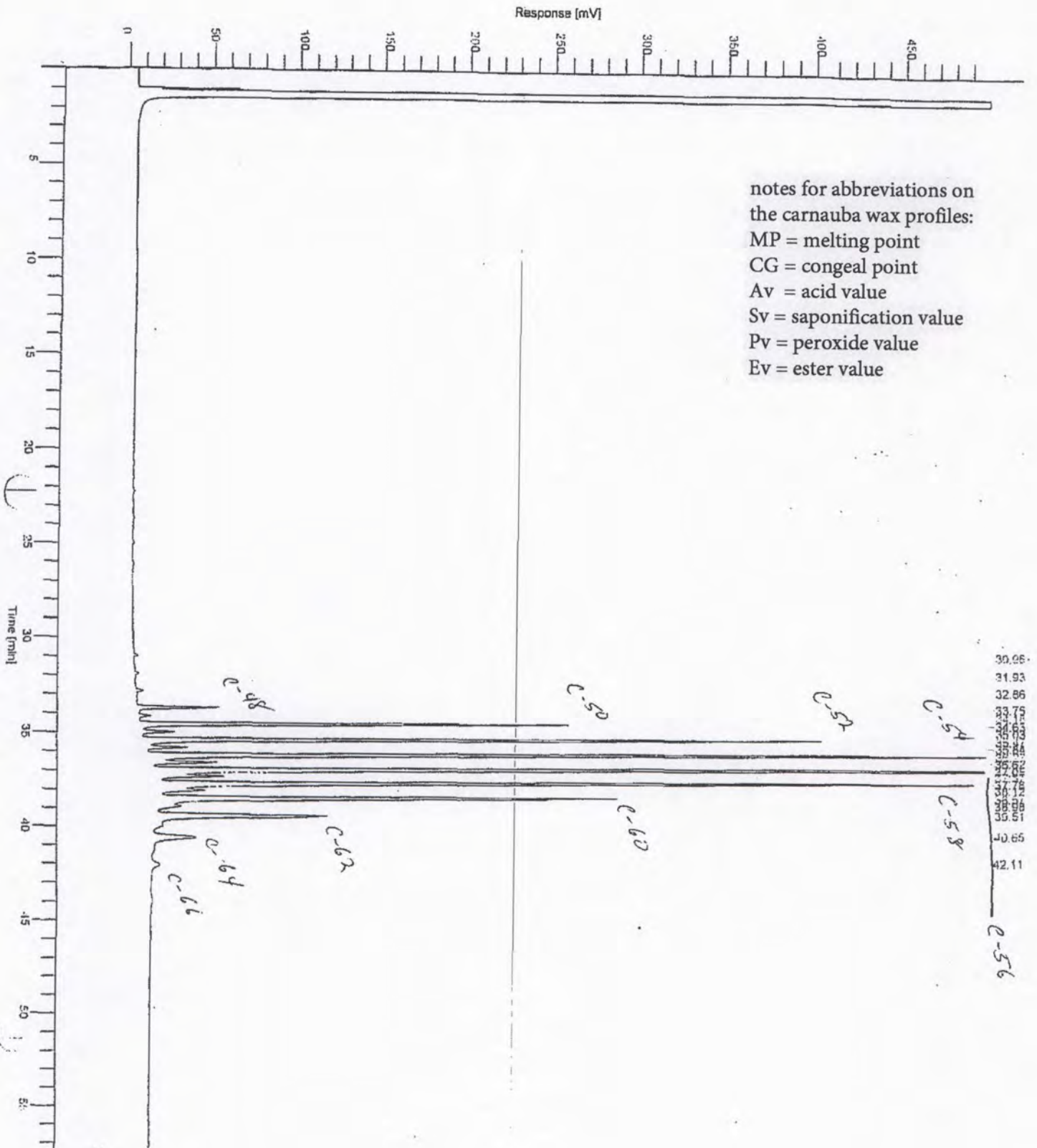
End Time: 57.58 min
 Plot Scale: 500.0 mV

Low Point: 0.00 mV

High Point: 500.00 mV

3906 :
 Rice Bran Wax
 B# 20033

notes for abbreviations on
 the carnauba wax profiles:
 MP = melting point
 CG = congeal point
 Av = acid value
 Sv = saponification value
 Pv = peroxide value
 Ev = ester value



Software Version : 6.3.2.0646
Reprocess Number : test-cb061b7723: 4626
Sample Name :
Instrument Name : Autosystem
Rack/Vial : 0/0
Sample Amount : 1.000000
Cycle : 1

Date : 6/30/2015 10:57:20 AM
Data Acquisition Time : 6/30/2015 9:59:39 AM
Channel : A
Operator : GC
Dilution Factor : 1.000000

Result File : C:\TC Data\Data\Unknown001-20150630-105720.rst
Sequence File : C:\TC Data\Sequence\Unknown.seq

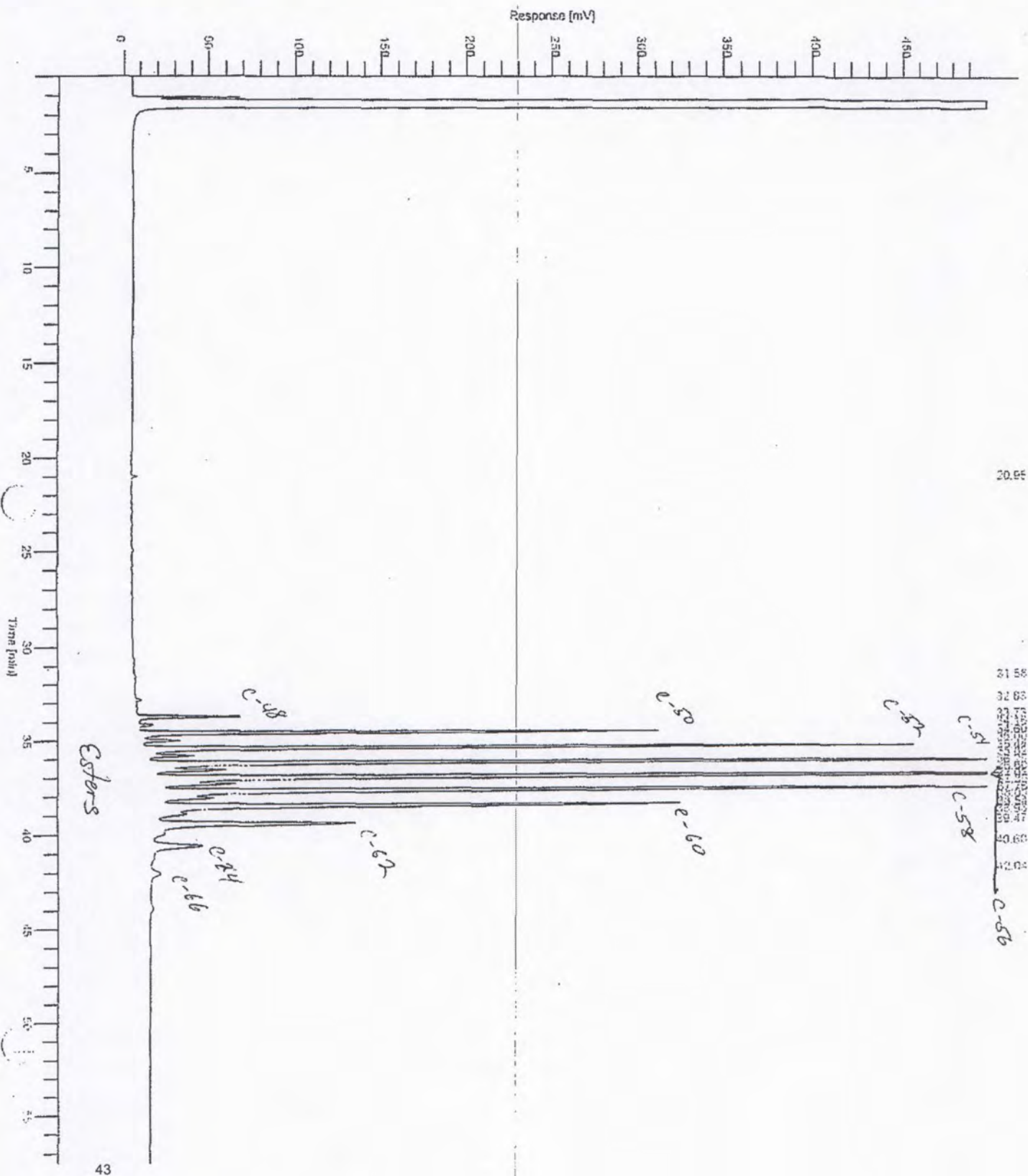
Rice Bran Wax (224P) B#20033

Peak #	Time [min]	Component Name	Area [uV*sec]	Norm. Area [%]
1	30.957		15661.13	0.06
2	31.933		13525.69	0.06
3	32.863		27870.63	0.11
4	33.753		333187.86	1.37
5	34.183		44937.57	0.19
6	34.627		1775411.71	7.32
7	35.028		137374.44	0.57
8	35.466		2876961.59	11.86
9	35.841		199670.29	0.82
10	36.274		4092070.98	16.87
11	36.624		344945.91	1.42
12	37.053		5069358.34	20.89
13	37.373		461433.74	1.90
14	37.780		3921734.22	16.16
15	38.119		381702.73	1.57
16	38.575		2717288.56	11.20
17	38.975		(b) (6)	

Chromatogram

Sample Name: C:\TC Data\Unknown\001-20150701-135314.raw
 File Name: C:\TC Data\Unknown\001-20150701-135314.raw
 Date: 7/1/2015 2:50:47 PM
 Method: unknown.mh
 Start Time: 0.00 min
 End Time: 57.56 min
 Plot Scale: 500.0 mV
 Time of Injection: 7/1/2015 1:53:08 PM
 Low Point: 0.00 mV
 High Point: 500.00 mV
 Offset: 0.00 mV

3912
 Rice Bran Wax
 B# 20048



Software Version : 6.3.2.0646
Reprocess Number : test-cb061b7723: 4634
Sample Name :
Instrument Name : Autosystem
Rack/Vial : 0/0
Sample Amount : 1.000000
Cycle : 1

Date : 7/1/2015 2:50:46 PM
Data Acquisition Time : 7/1/2015 1:53:06 PM
Channel : A
Operator : GC
Dilution Factor : 1.000000

Result File : C:\TC Data\Data\Unknown001-20150701-145046.rst
Sequence File : C:\TC Data\Sequence\Unknown.seq

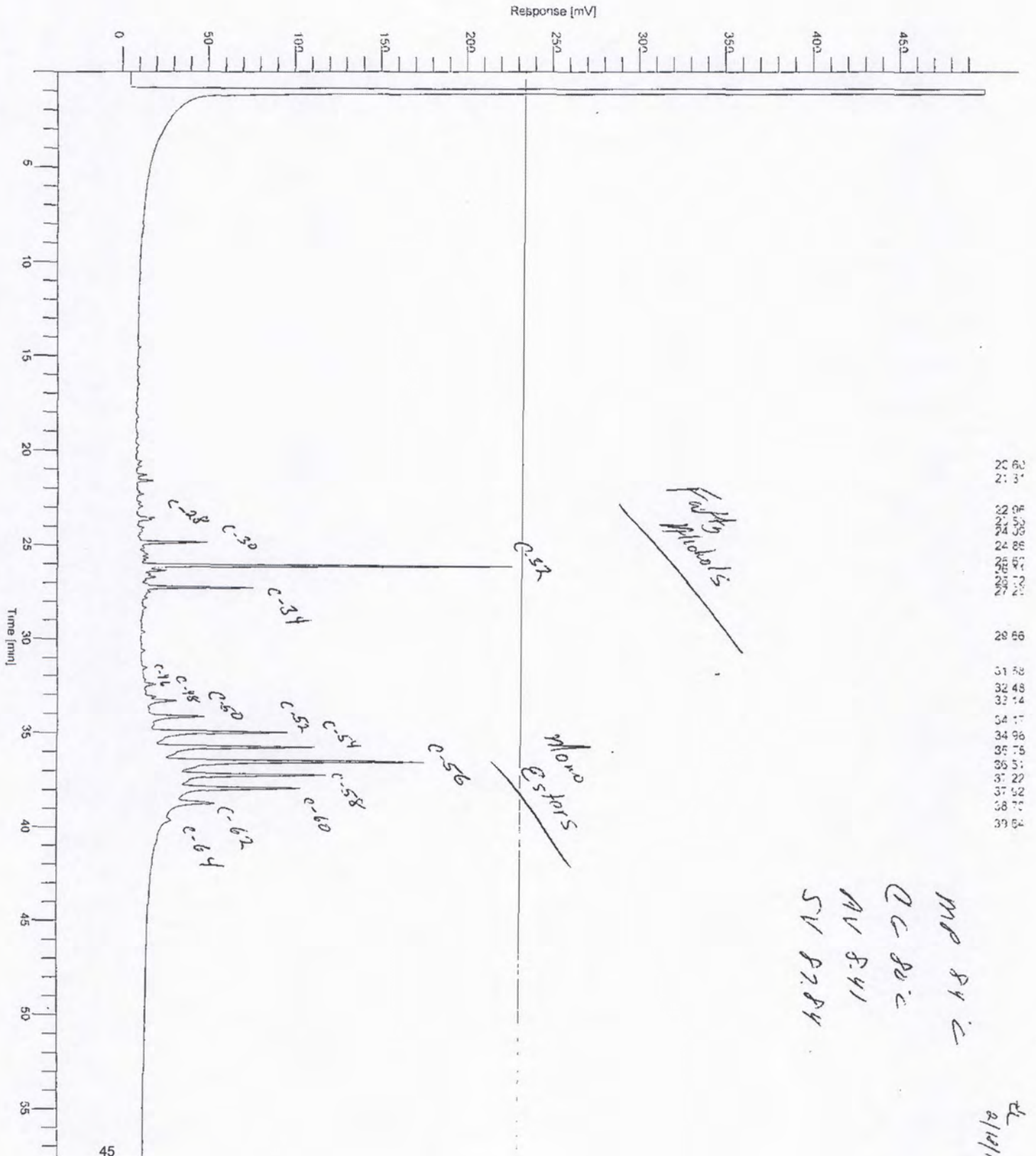
Rice Bran Wax (224P) B# 20048

Peak #	Time [min]	Component Name	Area [uV*sec]	Norm. Area [%]
1	20.983		20608.44	0.07
2	31.583		9702.14	0.03
3	32.832		24281.61	0.09
4	33.727		433007.48	1.52
5	34.157		57968.79	0.20
6	34.603		2231083.02	7.84
7	35.003		167512.56	0.59
8	35.444		3454763.34	12.15
9	35.819		238401.81	0.84
10	36.254		4755959.99	16.72
11	36.600		456174.59	1.60
12	37.033		5845335.81	20.55
13	37.347		558600.25	1.96
14	37.755		4507671.36	15.85
15	38.087		448114.81	1.58
16	38.543		3101139.67	10.90
17	38.932		232118.18	0.82
18	39.466		1358306.00	4.78
19	40.601		437570.71	1.54
20	42.040		106016.80	0.37
			28444337.37	100.00

Chromatogram

Sample Name : C:\TC Data\Data\Unknown001-20160217-140031.raw
 Sample #: 001-
 Page 1 of 1
 Date : 2/17/2016 2:58:04 PM
 Method : unknown.mth
 Time of Injection: 2/17/2016 2:00:23 PM
 Start Time : 0.00 min
 End Time : 57.56 min
 Low Point : 0.00 mV
 High Point : 500.00 mV
 Plot Offset: 0.00 mV
 Plot Scale: 500.0 mV

T-3 Carnauba
 # 5286-R



Software Version	: 6.3.2.0646	Date	: 2/17/2016 2:58:03 PM
Reprocess Number	: test-cb061b7723: 5386		
Sample Name	:	Data Acquisition Time	: 2/17/2016 2:00:23 PM
Instrument Name	: Autosystem	Channel	: A
Rack/Vial	: 0/0	Operator	: GC
Sample Amount	: 1.000000	Dilution Factor	: 1.000000
Cycle	: 1		

Result File : C:\TC Data\Data\Unknown001-20160217-145803.rst

Sequence File : C:\TC Data\Sequence\Unknown.seq

T-3 Carnauba Flakes # 5286-R

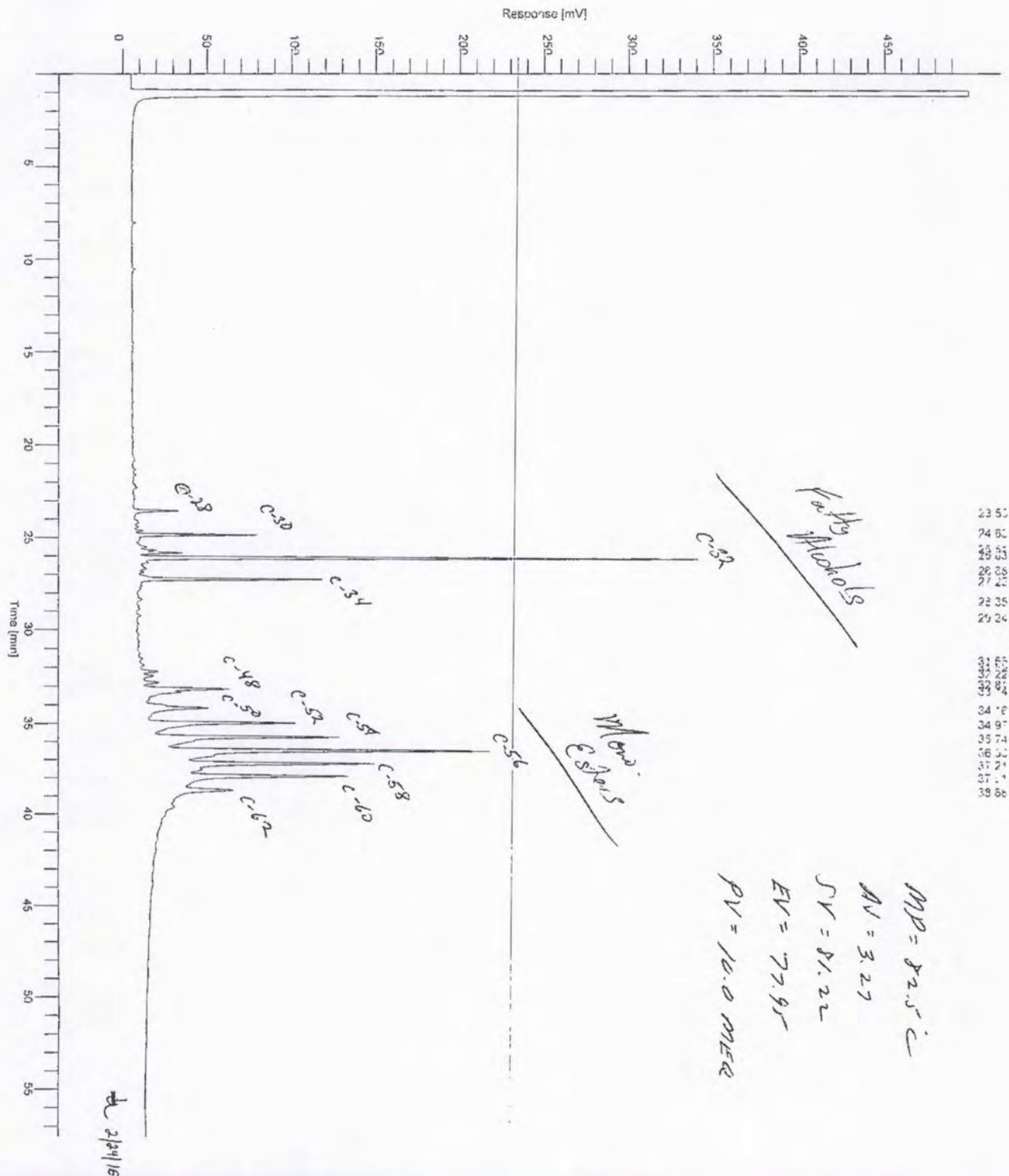
Peak #	Time [min]	Component Name	Area [uV*sec]	Norm. Area [%]
1	20.596		9111.38	0.09
2	21.311		40733.47	0.41
3	21.611		55455.17	0.55
4	22.958		19072.14	0.19
5	23.561		23596.74	0.24
6	24.085		12878.31	0.13
7	24.863		227363.72	2.27
8	25.693		14186.56	0.14
9	26.109		1257816.70	12.57
10	26.367		90345.62	0.90
11	26.722		69813.38	0.70
12	27.258		387583.64	3.87
13	29.656		14606.24	0.15
14	31.578		20858.26	0.21
15	32.480		50893.02	0.51
16	33.144		41603.89	0.42
17	33.345		164124.78	1.64
18	34.174		289167.89	2.89
19	34.981		660523.29	6.60
20	35.754		1035875.98	10.35
21	36.512		1866801.05	18.65
22	37.218		1364551.19	13.63
23	37.919		1315808.41	13.14
24	38.702		767197.97	7.66
25	39.643		210123.73	2.10
			10010092.53	100.00

Chromatogram

Sample Name : C:\TC Data\Unknown001-20160223-151800.raw
 File Name : C:\TC Data\Unknown001-20160223-151800.raw
 Date : 2/23/2016 4:15:33 PM
 Method : unknown.mth
 Start Time : 0.00 min
 End Time : 57.56 min
 Plot Scale : 500.0 mV
 Time of Injection : 2/23/2016 3:17:53 PM
 Low Point : 0.00 mV
 High Point : 500.00 mV
 Plot Offset : 0.00 mV

T-1 Carnauba Wax

#5287-R



Software Version : 6.3.2.0646
 Reprocess Number : test-cb061b7723: 5413
 Sample Name :
 Instrument Name : Autosystem
 Rack/Vial : 0/0
 Sample Amount : 1.000000
 Cycle : 1

Date : 2/23/2016 4:15:33 PM
 Data Acquisition Time : 2/23/2016 3:17:53 PM
 Channel : A
 Operator : GC
 Dilution Factor : 1.000000

Result File : C:\TC Data\Data\Unknown001-20160223-161533.rst
 Sequence File : C:\TC Data\Sequence\Unknown.seq

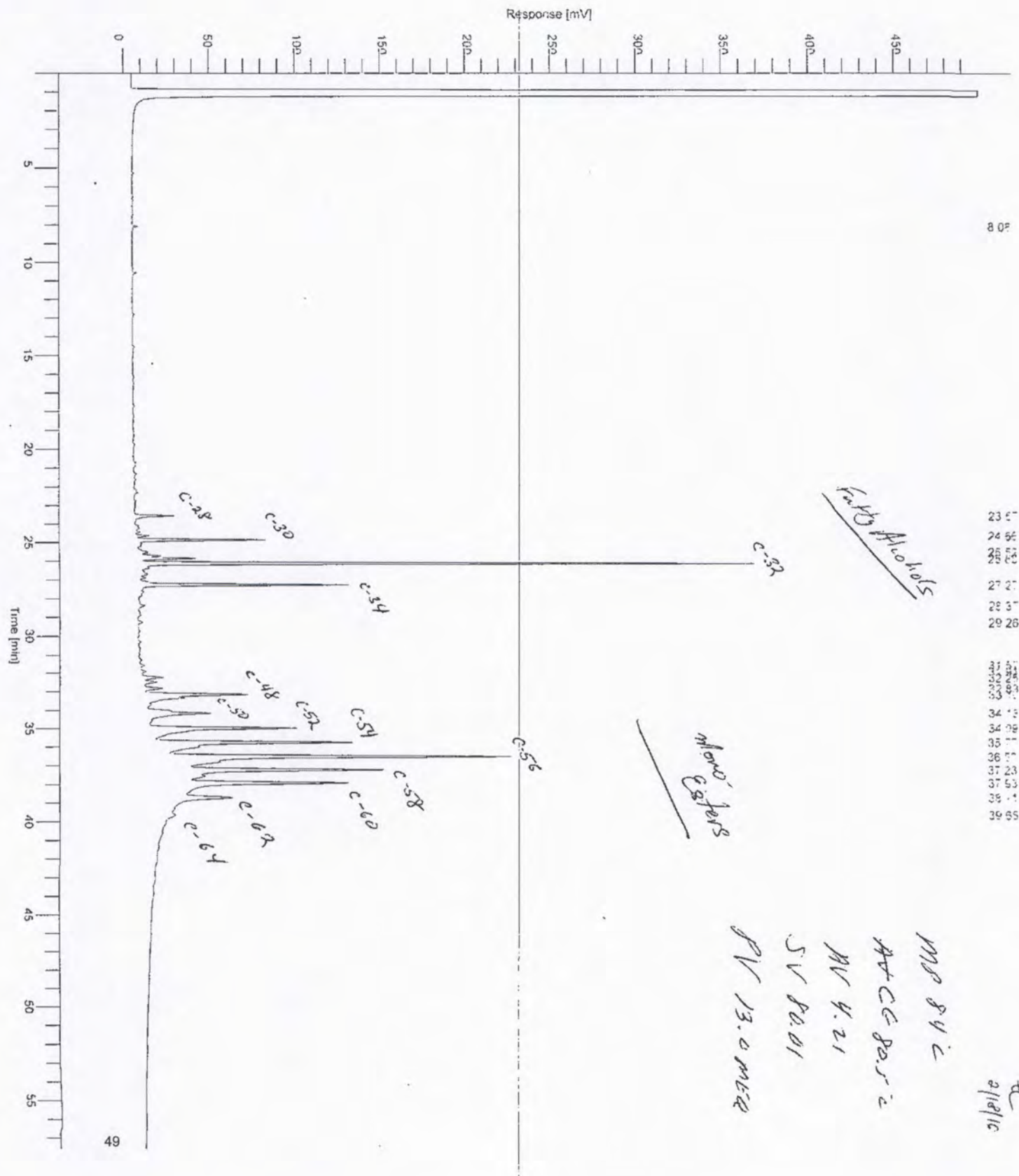
T-1 Carnauba #5287-R

Peak #	Time [min]	Component Name	Area [uV*sec]	Norm. Area [%]
1	23.548		177390.63	1.70
2	24.634		22601.86	0.22
3	24.853		404876.54	3.89
4	25.506		45627.92	0.44
5	25.682		57684.93	0.55
6	25.829		149399.25	1.44
7	26.107		1934391.08	18.59
8	26.676		32804.41	0.32
9	27.248		676701.50	6.50
10	28.348		21359.09	0.21
11	29.235		16992.61	0.16
12	31.555		16502.00	0.16
13	31.888		19306.12	0.19
14	32.224		82361.90	0.79
15	32.464		59563.31	0.57
16	32.808		74340.40	0.71
17	33.145		281851.16	2.71
18	34.160		427515.12	4.11
19	34.968		949204.51	9.12
20	35.743		1195038.81	11.49
21	36.505		1488333.51	14.30
22	37.209		899035.85	8.64
23	37.909		990264.09	9.52
24	38.684		381817.24	3.67
			10404963.86	100.00

Page 1 of 1

Time of Injection: 2/17/2016 3:12:31 PM
Low Point : 0.00 mV High Point : 500.00 mV

#5285-R



Software Version : 6.3.2.0646
 Reprocess Number : test-cb061b7723: 5387
 Sample Name :
 Instrument Name : Autosystem
 Rack/Vial : 0/0
 Sample Amount : 1.000000
 Cycle : 1

Date : 2/17/2016 4:10:11 PM
 Data Acquisition Time : 2/17/2016 3:12:31 PM
 Channel : A
 Operator : GC
 Dilution Factor : 1.000000

Result File : C:\TC Data\Data\Unknown001-20160217-161011.rst
 Sequence File : C:\TC Data\Sequence\Unknown.seq

T-1 Carnauba Flakes # 5285-R

Peak #	Time [min]	Component Name	Area [uV*sec]	Norm. Area [%]
1	8.080		12476.80	0.12
2	23.568		154879.42	1.48
3	24.656		38066.35	0.36
4	24.875		416705.13	3.97
5	25.524		44169.69	0.42
6	25.705		65590.92	0.63
7	25.852		190087.87	1.81
8	26.131		2076905.22	19.80
9	27.272		755469.45	7.20
10	28.371		24385.09	0.23
11	29.256		19658.70	0.19
12	31.573		17629.83	0.17
13	31.908		18699.34	0.18
14	32.245		97560.90	0.93
15	32.485		64133.40	0.61
16	32.827		80248.85	0.76
17	33.165		347921.38	3.32
18	34.181		508928.27	4.85
19	34.991		947752.46	9.03
20	35.767		805374.87	7.68
21	36.529		1539180.11	14.67
22	37.233		905818.55	8.63
23	37.933		954736.34	9.10
24	38.714		367844.62	3.51
25	39.649		36252.61	0.35
			10490476.17	100.00

Appendix B. Analytical Results

3344 NW Industrial Street
Portland, Oregon 97210 USA
Tel: (503) 223-1497
Fax: (503) 223-9436
e-mail: info@omicusa.com
www.omicusa.com

OMIC USA Inc.

A Member of OMIC Group of Companies
Independent Analytical Laboratory

Koster Keunen Inc.

1021 Echo Lake Road
Watertown, CT 06795

Report Date: April 01, 2015

ANALYTICAL REPORT

Sample ID : B#18940

Matrix: RICE BRAN WAX 224P

Date Received: February 20, 2015

Lab ID # : AB78145

PAH'S Screen

Analyte	Result	Units	MDL
1 *Acenaphthene	ND	ppb	120
2 *Acenaphthylene	ND	ppb	100
3 *Anthracene	ND	ppb	180
4 *Benz(a)anthracene	ND	ppb	130
5 *Benzo(a)pyrene	ND	ppb	90
6 *Benzo(b)fluoranthene	ND	ppb	100
7 *Benzo(g,h,i)perylene	ND	ppb	100
8 *Benzo(k)fluoranthene	ND	ppb	100
9 *Chrysene	ND	ppb	90
10 *Dibenzo(a,h)anthracene	ND	ppb	150
11 *Flouranthene	ND	ppb	120
12 *Fluorene	ND	ppb	190
13 *Indeno(1,2,3-cd)pyrene	ND	ppb	130
14 *Naphthalene	ND	ppb	120
15 *Phenanthrene	ND	ppb	100
16 *Pyrene	ND	ppb	90

Solvent Screen

Analyte	Result	Units	MDL
1 Hexane	ND	ppb	10

Negative = < 10 CFU/g; CFU=Colony Forming Unit; ppb=parts per billion (mcg/Kg or mcg/L); ppm=parts per million (mg/Kg or mg/L)
MDL=Minimum Detection Limit; ND=Not Detected; N/A=Not Applicable; Trace=Qualitative result < MDL; * = Analysis subcontracted

AB78145

Rev. 1

Koster Keunen Inc.

1021 Echo Lake Road
Watertown, CT 06795

Report Date: April 16, 2015

ANALYTICAL REPORT

Sample ID : B#18940

Matrix: RICE BRAN WAX 224P

Date Received: April 06, 2015

Lab ID # : AB79475

Arsenic Speciation

Analyte	Result	Units	MDL
1 Arsenate {As(V)}	N/A	ppb	5
2 Arsenite {As(III)}	N/A	ppb	5
3 Inorganic Arsenic	N/A	ppb	
4 Dimethylarsenic acid	N/A	ppb	5
5 Monomethylarsonic acid	N/A	ppb	5
6 Organic Arsenic	N/A	ppb	

Chemical Residue

Analyte	Result	Units	MDL
1 2,6-Diisopropylnaphthalene	ND	ppm	0.02
2 Abamectin	ND	ppm	0.05
3 Acephate	ND	ppm	0.25
4 Acetamiprid	ND	ppm	0.05
5 Acetochlor	ND	ppm	0.02
6 Acibenzolar-S-Methyl	ND	ppm	0.25
7 Acrinathrin	ND	ppm	0.02
8 Alachlor	ND	ppm	0.02
9 Aldicarb	ND	ppm	0.05
10 Aldicarb Sulfone	ND	ppm	0.1
11 Aldicarb Sulfoxide	ND	ppm	0.25
12 Aldrin	ND	ppm	0.01
13 Allethrin	ND	ppm	0.02
14 Amitryn	ND	ppm	0.05
15 Amitraz	ND	ppm	0.05
16 Anilofos	ND	ppm	0.02
17 Atrazine	ND	ppm	0.02

Negative = < 10 CFU/g; CFU=Colony Forming Unit; ppb=parts per billion (mcg/Kg or mcg/L); ppm=parts per million (mg/Kg or mg/L)
MDL=Minimum Detection Limit; ND=Not Detected; N/A=Not Applicable; Trace=Qualitative result < MDL; * = Analysis subcontracted

AB79475

ANALYTICAL REPORT

18	Azaconazole	ND	ppm	0.02
19	Azamethiphos	ND	ppm	0.05
20	Azinphos-Ethyl	ND	ppm	0.1
21	Azinphos-Methyl	ND	ppm	0.1
22	Azoxystrobin	ND	ppm	0.1
23	Benalaxyl	ND	ppm	0.02
24	Bendiocarb	ND	ppm	0.05
25	Benfluralin	ND	ppm	0.02
26	Benfuresate	ND	ppm	0.02
27	Benomyl (as Carbendazim)	ND	ppm	0.1
28	Benoxacor	ND	ppm	0.02
29	Bensulide	ND	ppm	0.1
30	Bentazone	ND	ppm	0.02
31	Benzobicyclon	ND	ppm	0.1
32	Benzo fenap	ND	ppm	0.05
33	Benzyladenine	ND	ppm	0.05
34	BHC's	ND	ppm	0.02
35	Bifenazate	ND	ppm	0.25
36	Bifenox	ND	ppm	0.02
37	Bifenthrin	ND	ppm	0.02
38	Bioresmethrin	ND	ppm	0.1
39	Bitertanol	ND	ppm	0.05
40	Boscalid	ND	ppm	0.02
41	Bromobutide	ND	ppm	0.02
42	Bromophos Methyl	ND	ppm	0.02
43	Bromophos-Ethyl	ND	ppm	0.02
44	Bromopropylate	ND	ppm	0.02
45	Bupirimate	ND	ppm	0.02
46	Buprofezin	ND	ppm	0.02
47	Butachlor	ND	ppm	0.02
48	Butafenacil	ND	ppm	0.02
49	Butamifos	ND	ppm	0.02
50	Butralin	ND	ppm	0.02
51	Butylate	ND	ppm	0.02
52	Cadusafos	ND	ppm	0.02
53	Cafenstrole	ND	ppm	0.05
54	Captan	ND	ppm	0.1
55	Carbaryl	ND	ppm	0.05
56	Carbendazim	ND	ppm	0.1
57	Carbofuran	ND	ppm	0.05
58	Carbophenothion	ND	ppm	0.02
59	Carboxin	N/A	ppm	0.02
60	Carfentrazone-Ethyl	ND	ppm	0.02
61	Carpropamid	ND	ppm	0.02
62	Chlorantraniliprole	ND	ppm	0.05
63	Chlorbenside	ND	ppm	0.02
64	Chlorbufam	ND	ppm	0.02
65	Chlordane	ND	ppm	0.02

Negative = < 10 CFU/g; CFU=Colony Forming Unit; ppb=parts per billion (mcg/Kg or mcg/L); ppm=parts per million (mg/Kg or mg/L)
MDL=Minimum Detection Limit; ND=Not Detected; N/A=Not Applicable; Trace=Qualitative result < MDL; * = Analysis subcontracted

AB79475

ANALYTICAL REPORT

66	Chlorethoxyfos	ND	ppm	0.02
67	Chlorfenapyr	ND	ppm	0.02
68	Chlorfenson	ND	ppm	0.02
69	Chlorfenvinphos	ND	ppm	0.02
70	Chloridazon	ND	ppm	0.5
71	Chlornitrofen	ND	ppm	0.1
72	Chlorobenzilate	ND	ppm	0.02
73	Chloroneb	ND	ppm	0.06
74	Chloroxuron	ND	ppm	0.25
75	Chlorpropham	ND	ppm	0.02
76	Chlorpyrifos	ND	ppm	0.02
77	Chlorpyrifos Methyl	ND	ppm	0.02
78	Chlorthal-Dimethyl	ND	ppm	0.08
79	Chlorthiofos	ND	ppm	0.1
80	Chlozolate	ND	ppm	0.1
81	Chromafenozide	ND	ppm	0.05
82	Cinidon-Ethyl	ND	ppm	0.05
83	Cinmethylin	ND	ppm	0.02
84	Clethodim	N/A	ppm	0.02
85	Clodinafop-Propargyl	ND	ppm	0.05
86	Clofentezine	ND	ppm	0.05
87	Clomazone	ND	ppm	0.04
88	Clomeprop	ND	ppm	0.1
89	Cloquintocet-Mexyl	ND	ppm	0.05
90	Clothianidin	ND	ppm	0.05
91	CPMC (Etofol)	ND	ppm	0.1
92	Cumyluron	ND	ppm	0.1
93	Cyanazine	ND	ppm	0.05
94	Cyanophenphos	ND	ppm	0.04
95	Cyanophos	ND	ppm	0.02
96	Cyazofamid	ND	ppm	0.05
97	Cycloate	ND	ppm	0.02
98	Cyflufenamid	ND	ppm	0.02
99	Cyfluthrin	ND	ppm	0.1
100	Cyhalofop-Butyl	ND	ppm	0.06
101	Cyhalothrin	ND	ppm	0.02
102	Cymoxanil	ND	ppm	0.1
103	Cypermethrin	ND	ppm	0.1
104	Cyproconazole	ND	ppm	0.02
105	Cyprodinil	ND	ppm	0.05
106	Daimuron	ND	ppm	0.05
107	DDD	ND	ppm	0.02
108	DDE	ND	ppm	0.02
109	DDT	ND	ppm	0.02
110	Deltamethrin	ND	ppm	0.04
111	Demeton O & S	N/A	ppm	0.04
112	Demeton-S-Methyl	N/A	ppm	0.02
113	Desmedipham	ND	ppm	1

Negative = < 10 CFU/g; CFU=Colony Forming Unit; ppb=parts per billion (mcg/Kg or mcg/L); ppm=parts per million (mg/Kg or mg/L)
MDL=Minimum Detection Limit; ND=Not Detected; N/A=Not Applicable; Trace=Qualitative result < MDL; * = Analysis subcontracted

AB79475

ANALYTICAL REPORT

114	Diapenthiuron	N/A	ppm	0.1
115	Dialifos	ND	ppm	0.1
116	Di-allate	ND	ppm	0.04
117	Diazinon	ND	ppm	0.02
118	Dichlobenil	ND	ppm	0.1
119	Dichlofenthion (ECP)	ND	ppm	0.02
120	Dichlofluanid	ND	ppm	0.1
121	Dichlormid	ND	ppm	0.02
122	Dichlorvos	ND	ppm	0.02
123	Diclobutrazol	ND	ppm	0.05
124	Diclocymet	ND	ppm	0.02
125	Diclofop-Methyl	ND	ppm	0.02
126	Diclomezine	ND	ppm	0.1
127	Dicloran	ND	ppm	0.04
128	Dicofol	ND	ppm	0.02
129	Dicrotophos	ND	ppm	0.02
130	Dieldrin	ND	ppm	0.01
131	Diethofencarb	ND	ppm	0.06
132	Difenoconazole	ND	ppm	0.06
133	Difenzoquat	ND	ppm	0.5
134	Diffubenzuron	ND	ppm	0.05
135	Diffufenican	ND	ppm	0.02
136	Dimepiperate	ND	ppm	0.02
137	Dimethametryn	ND	ppm	0.05
138	Dimethenamid	ND	ppm	0.02
139	Dimethoate	ND	ppm	0.02
140	Dimethylvinphos	ND	ppm	0.02
141	Diniconazole	ND	ppm	0.05
142	Dinotefuran	ND	ppm	0.05
143	Dioxathion	ND	ppm	0.1
144	Diphenamid	ND	ppm	0.02
145	Diphenylamine	ND	ppm	0.04
146	Disulfoton	N/A	ppm	0.02
147	Disulfoton Sulfone	ND	ppm	0.02
148	Dithiopyr	ND	ppm	0.02
149	Diuron	ND	ppm	0.05
150	Edifenphos	ND	ppm	0.02
151	Enamectin Benzoate	ND	ppm	0.05
152	Endosulfan	ND	ppm	0.02
153	Endosulfan Sulfate	ND	ppm	0.04
154	Endrin	ND	ppm	0.01
155	EPN	ND	ppm	0.02
156	Epoxiconazole	ND	ppm	0.02
157	EPTC	ND	ppm	0.02
158	Esfenvalerate	ND	ppm	0.04
159	Esprocarb	ND	ppm	0.02
160	Ethalfuralin	ND	ppm	0.02
161	Ethion	ND	ppm	0.02

Negative = < 10 CFU/g; CFU=Colony Forming Unit; ppb=parts per billion (mcg/Kg or mcg/L); ppm=parts per million (mg/Kg or mg/L)
MDL=Minimum Detection Limit; ND=Not Detected; N/A=Not Applicable; Trace=Qualitative result < MDL; * = Analysis subcontracted

AB79475

ANALYTICAL REPORT

162	Ethiprole	ND	ppm	0.05
163	Ethofumesate	ND	ppm	0.02
164	Ethoprophos	ND	ppm	0.025
165	Ethoxyquin	N/A	ppm	0.1
166	Ethychlozate	ND	ppm	0.05
167	Etobenzanid	ND	ppm	0.02
168	Etofenprox	ND	ppm	0.02
169	Etoxazole	ND	ppm	0.1
170	Etridiazole	ND	ppm	0.1
171	Etrimfos	ND	ppm	0.02
172	Famphur	ND	ppm	0.04
173	Fenamidone	ND	ppm	0.02
174	Fenamiphos	ND	ppm	0.1
175	Fenamiphos Sulfone	ND	ppm	0.02
176	Fenarimol	ND	ppm	0.02
177	Fenbuconazole	ND	ppm	0.05
178	Fenchlorphos	ND	ppm	0.02
179	Fenhexamid	ND	ppm	0.05
180	Fenitrothion	ND	ppm	0.02
181	Fenobucarb	ND	ppm	0.05
182	Fenothiocarb	ND	ppm	0.05
183	Fenoxanil	ND	ppm	0.05
184	Fenoxaprop-Ethyl	ND	ppm	0.02
185	Fenoxycarb	ND	ppm	0.1
186	Fenpropathrin	ND	ppm	0.02
187	Fenpropimorph	ND	ppm	0.02
188	Fenpyroximate	ND	ppm	0.1
189	Fensulfothion	ND	ppm	0.1
190	Fenthion	ND	ppm	0.02
191	Fentrazamide	ND	ppm	0.05
192	Fenvalerate	ND	ppm	0.04
193	Ferimzone	ND	ppm	0.05
194	Fipronil	ND	ppm	0.01
195	Flamprop-Methyl	ND	ppm	0.02
196	Fluacrypyrim	ND	ppm	0.1
197	Fluazifop-Butyl	ND	ppm	0.02
198	Fluazinam	ND	ppm	0.25
199	Flucythrinate	ND	ppm	0.04
200	Fludioxonil	ND	ppm	0.05
201	Flufenacet	ND	ppm	0.02
202	Fluometuron	ND	ppm	0.1
203	Fluquinconazole	ND	ppm	0.02
204	Fluridone	ND	ppm	0.05
205	Flusilazole	ND	ppm	0.02
206	Flusulfamide	ND	ppm	0.1
207	Fluthiacet Methyl	ND	ppm	0.15
208	Flutolanil	ND	ppm	0.02
209	Flutriafol	ND	ppm	0.1

Negative = < 10 CFU/g; CFU=Colony Forming Unit; ppb=parts per billion (mcg/Kg or mcg/L); ppm=parts per million (mg/Kg or mg/L)
MDL=Minimum Detection Limit; ND=Not Detected; N/A=Not Applicable; Trace=Qualitative result < MDL; * = Analysis subcontracted

AB79475

ANALYTICAL REPORT

210	Fluvalinate	ND	ppm	0.06
211	Fonofos	ND	ppm	0.02
212	Forchlorfenuron	ND	ppm	0.05
213	Fosthiazate	ND	ppm	0.1
214	Fthalide	ND	ppm	0.02
215	Furametpyr	ND	ppm	0.02
216	Furathiocarb	ND	ppm	0.05
217	Furilazole	ND	ppm	0.02
218	Halfenprox	ND	ppm	0.1
219	Haloxifop	ND	ppm	0.01
220	Haloxifop Methyl	ND	ppm	0.02
221	Heptachlor	ND	ppm	0.02
222	Heptachlor Epoxide	ND	ppm	0.02
223	Hexachlorobenzene	ND	ppm	0.02
224	Hexaconazole	ND	ppm	0.05
225	Hexazinone	ND	ppm	0.02
226	Hexythiazox	ND	ppm	0.1
227	Imazalil	ND	ppm	0.02
228	Imazamethabenz Methyl Ester	ND	ppm	0.2
229	Imibenconazole	ND	ppm	0.1
230	Imidacloprid	ND	ppm	0.1
231	Inabenfide	ND	ppm	0.05
232	Indoxacarb	ND	ppm	0.1
233	Iprobenfos	ND	ppm	0.02
234	Iprodione	ND	ppm	0.25
235	Iprovalicarb	ND	ppm	0.1
236	Isazophos	ND	ppm	0.02
237	Isocarbophos	ND	ppm	0.02
238	Isofenphos	ND	ppm	0.02
239	Isofenphos-Methyl	ND	ppm	0.02
240	Isoproc carb	ND	ppm	0.05
241	Isoprothiolane	ND	ppm	0.06
242	Isotianil	ND	ppm	0.02
243	Isouron	ND	ppm	0.1
244	Isoxadifen-Ethyl	ND	ppm	0.02
245	Isoxaflutole	ND	ppm	0.05
246	Isoxathion	ND	ppm	0.05
247	Kresoxim-Methyl	ND	ppm	0.02
248	Lenacil	ND	ppm	0.25
249	Lindane (gamma-BHC)	ND	ppm	0.02
250	Linuron	ND	ppm	0.1
251	Malathion	ND	ppm	0.02
252	Mandipropamid	ND	ppm	0.05
253	Mecarbam	ND	ppm	0.02
254	Mefenacet	ND	ppm	0.05
255	Mefenpyr-Diethyl	ND	ppm	0.05
256	Mepanipyrim	ND	ppm	0.02
257	Mephosfolan	ND	ppm	0.1

Negative = < 10 CFU/g; CFU=Colony Forming Unit; ppb=parts per billion (mcg/Kg or mcg/L); ppm=parts per million (mg/Kg or mg/L)
MDL=Minimum Detection Limit; ND=Not Detected; N/A=Not Applicable; Trace=Qualitative result < MDL; * = Analysis subcontracted

AB79475

ANALYTICAL REPORT

258	Mepronil	ND	ppm	0.02
259	Metaxyl / Mefenoxam	ND	ppm	0.02
260	Metconazole	ND	ppm	0.04
261	Methabenzthiazuron	N/A	ppm	0.02
262	Methacrifos	ND	ppm	0.02
263	Methamidophos	ND	ppm	0.05
264	Methidathion	ND	ppm	0.05
265	Methiocarb	ND	ppm	0.05
266	Methomyl	ND	ppm	0.05
267	Methoprene	ND	ppm	0.02
268	Methoxychlor	ND	ppm	0.02
269	Methoxyfenozide	ND	ppm	0.05
270	Metolachlor	ND	ppm	0.02
271	Metominostrobin	ND	ppm	0.02
272	Metribuzin	ND	ppm	0.02
273	Mevinphos	ND	ppm	0.02
274	Mirex	ND	ppm	0.2
275	Molinate	ND	ppm	0.02
276	Monocrotophos	ND	ppm	0.02
277	Monolinuron	ND	ppm	0.05
278	Myclobutanil	ND	ppm	0.02
279	Naled	ND	ppm	0.02
280	Naproanilide	ND	ppm	0.02
281	Napropamide	ND	ppm	0.02
282	Nitenpyram	ND	ppm	0.25
283	Nitrofen	ND	ppm	0.06
284	Nitrothal-Isopropyl	ND	ppm	0.02
285	Norflurazon	ND	ppm	0.06
286	Novaluron	ND	ppm	0.05
287	Ofurace	ND	ppm	0.05
288	Omethoate	ND	ppm	0.1
289	o-Phenyl Phenol	ND	ppm	0.1
290	Orysastrobin	ND	ppm	0.02
291	Oryzalin	ND	ppm	0.05
292	Oxadiazon	ND	ppm	0.02
293	Oxadixyl	ND	ppm	0.5
294	Oxamyl	ND	ppm	0.05
295	Oxaziclomefone	ND	ppm	0.05
296	Oxpoconazole-Fumarate	ND	ppm	0.15
297	Oxycarboxin	ND	ppm	0.25
298	Oxydemeton-Methyl	ND	ppm	0.05
299	Oxyfluorfen	ND	ppm	0.02
300	Paclobutrazol	ND	ppm	0.02
301	Parathion	ND	ppm	0.02
302	Parathion-Methyl	ND	ppm	0.02
303	Pebulate	ND	ppm	0.02
304	Penconazole	ND	ppm	0.02
305	Pencycuron	ND	ppm	0.05

Negative = < 10 CFU/g; CFU=Colony Forming Unit; ppb=parts per billion (mcg/Kg or mcg/L); ppm=parts per million (mg/Kg or mg/L)
MDL=Minimum Detection Limit; ND=Not Detected; N/A=Not Applicable; Trace=Qualitative result < MDL; * = Analysis subcontracted

AB79475

ANALYTICAL REPORT

306	Pendimethalin	ND	ppm	0.04
307	Pentoxazone	ND	ppm	0.02
308	Permethrin	ND	ppm	0.04
309	Perthane	ND	ppm	0.06
310	Phenmedipham	ND	ppm	0.25
311	Phenothiol	ND	ppm	0.1
312	Phenothrin	ND	ppm	0.04
313	Phenthoate	ND	ppm	0.02
314	Phorate	ND	ppm	0.02
315	Phorate Sulfone	ND	ppm	0.02
316	Phosalone	ND	ppm	0.02
317	Phosmet	ND	ppm	0.02
318	Phosphamidon	ND	ppm	0.02
319	Phoxim	ND	ppm	0.1
320	Picolinafen	ND	ppm	0.05
321	Piperonyl Butoxide	ND	ppm	0.04
322	Piperophos	ND	ppm	0.02
323	Pirimicarb	ND	ppm	0.02
324	Pirimioxyphos	ND	ppm	0.02
325	Pirimiphos Ethyl	ND	ppm	0.04
326	Pirimiphos-Methyl	ND	ppm	0.02
327	Pretilachlor	ND	ppm	0.02
328	Prochloraz	ND	ppm	0.02
329	Procymidone	ND	ppm	0.04
330	Profenofos	ND	ppm	0.02
331	Prohydrojasmon	ND	ppm	0.25
332	Prometryn	ND	ppm	0.04
333	Propachlor	ND	ppm	0.02
334	Propanil	ND	ppm	0.02
335	Propaphos	ND	ppm	0.02
336	Propargite	ND	ppm	0.02
337	Propazine	ND	ppm	0.02
338	Propetamphos	ND	ppm	0.02
339	Propiconazole	ND	ppm	0.06
340	Propoxur	ND	ppm	0.05
341	Propyzamide	ND	ppm	0.05
342	Prothiofos	ND	ppm	0.02
343	Pyraclofos	ND	ppm	0.04
344	Pyraclonil	ND	ppm	0.02
345	Pyraclostrobin	ND	ppm	0.05
346	Pyraflufen Ethyl	ND	ppm	0.02
347	Pyrazolynate	ND	ppm	0.05
348	Pyrazophos	ND	ppm	0.02
349	Pyrazoxyfen	ND	ppm	0.25
350	Pyrethrins	ND	ppm	0.2
351	Pyributicarb	ND	ppm	0.02
352	Pyridaben	ND	ppm	0.02
353	Pyridafenthion	ND	ppm	0.02

Negative = < 10 CFU/g; CFU=Colony Forming Unit; ppb=parts per billion (mcg/Kg or mcg/L); ppm=parts per million (mg/Kg or mg/L)
MDL=Minimum Detection Limit; ND=Not Detected; N/A=Not Applicable; Trace=Qualitative result < MDL; * = Analysis subcontracted

AB79475

ANALYTICAL REPORT

354	Pyrifenox	ND	ppm	0.02
355	Pyriftalid	ND	ppm	0.05
356	Pyrimethanil	ND	ppm	0.02
357	Pyrimidifen	ND	ppm	0.02
358	Pyriminobac-Methyl	ND	ppm	0.02
359	Pyriproxyfen	ND	ppm	0.02
360	Pyroquilon	ND	ppm	0.02
361	Quinalphos	ND	ppm	0.02
362	Quinoclamine	ND	ppm	0.05
363	Quinoxifen	ND	ppm	0.02
364	Quintozene	ND	ppm	0.02
365	Quizalofop-Ethyl	ND	ppm	0.02
366	Salithion (Dioxabenzofos)	ND	ppm	0.02
367	Sethoxydim	ND	ppm	0.25
368	Silafluofen	ND	ppm	0.02
369	Simazine	ND	ppm	0.1
370	Simeconazole	ND	ppm	0.05
371	Simetryn	ND	ppm	0.04
372	Spinosad	ND	ppm	0.05
373	Spiromesifen	ND	ppm	0.05
374	Sulfotep	ND	ppm	0.02
375	Sulprofos	ND	ppm	0.02
376	TCMTB (Benthiazole)	ND	ppm	0.04
377	Tebuconazole	ND	ppm	0.06
378	Tebufenozide	ND	ppm	0.25
379	Tebufenpyrad	ND	ppm	0.02
380	Tebupirimfos	ND	ppm	0.04
381	Tebuthiuron	ND	ppm	0.1
382	Tecnazene	ND	ppm	0.02
383	Tefluthrin	ND	ppm	0.04
384	Terbacil	ND	ppm	0.25
385	Terbufos	ND	ppm	0.01
386	Terbutryn	ND	ppm	0.04
387	Tetrachlorvinphos	ND	ppm	0.02
388	Tetraconazole	ND	ppm	0.02
389	Tetradifon	ND	ppm	0.02
390	Tetramethrin	ND	ppm	0.02
391	Thenylchlor	ND	ppm	0.02
392	Thiabendazole	ND	ppm	0.25
393	Thiacloprid	ND	ppm	0.1
394	Thiamethoxam	ND	ppm	0.05
395	Thiazopyr	ND	ppm	0.02
396	Thidiazuron	ND	ppm	0.15
397	Thifluzamide	ND	ppm	0.04
398	Thiobencarb	ND	ppm	0.02
399	Thiometon	ND	ppm	0.02
400	Tiadinil	ND	ppm	0.05
401	Tolclofos-Methyl	ND	ppm	0.02

Negative = < 10 CFU/g; CFU=Colony Forming Unit; ppb=parts per billion (mcg/Kg or mcg/L); ppm=parts per million (mg/Kg or mg/L)
MDL=Minimum Detection Limit; ND=Not Detected; N/A=Not Applicable; Trace=Qualitative result < MDL; * = Analysis subcontracted

AB79475

ANALYTICAL REPORT

402	Tralomethrin	ND	ppm	0.04
403	Triadimefon	ND	ppm	0.02
404	Triadimenol	ND	ppm	0.05
405	Tri-allate	ND	ppm	0.02
406	Triazophos	ND	ppm	0.02
407	Tribuphos	ND	ppm	0.02
408	Trichlamide	ND	ppm	0.1
409	Trichlorfon	ND	ppm	0.05
410	Tricyclazole	ND	ppm	0.1
411	Tridiphane	ND	ppm	0.04
412	Trifloxystrobin	ND	ppm	0.1
413	Triflumizole	ND	ppm	0.02
414	Triflumuron	ND	ppm	0.1
415	Trifluralin	ND	ppm	0.02
416	Triforine	ND	ppm	0.05
417	Triticonazole	ND	ppm	0.05
418	Uniconazole P	ND	ppm	0.1
419	Vinclozolin	ND	ppm	0.02
420	XMC	ND	ppm	0.05
421	Xyllycarb	ND	ppm	0.05
422	Zoxamide	ND	ppm	0.1

Minerals / Metals Screen

Analyte	Result	Units	MDL
1 Arsenic	ND	ppb	10
2 Cadmium	ND	ppb	10
3 Lead	21	ppb	10
4 Mercury	ND	ppb	5

Note:

1. The compounds reported as N/A did not recover from the matrix or had instrument interferences
2. The Lead analysis result is qualified as qualitative due the variation in quality control data
3. Unable to report the Arsenic Speciation results, however the total Arsenic determined by a different test method is not present.

Negative = < 10 CFU/g; CFU=Colony Forming Unit; ppb=parts per billion (mcg/Kg or mcg/L); ppm=parts per million (mg/Kg or mg/L)
MDL=Minimum Detection Limit; ND=Not Detected; N/A=Not Applicable; Trace=Qualitative result < MDL; * = Analysis subcontracted

AB79475

Koster Keunen Inc.

1021 Echo Lake Road
Watertown, CT 06795

Report Date: July 22, 2015

ANALYTICAL REPORT

Sample ID : B#18940
Date Received: May 06, 2015
Lab ID # : AB80320

Matrix: RICE BRAN WAX 224P

Persistent Organic Pollutants

Analyte	Result
1 *Dioxins/Furans/WHO-12 PCBs	Completed – see attached ALS Analysis Report

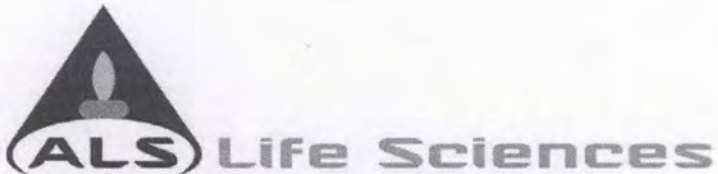
Microbiological Tests

Analyte	Result	Units
1 Aerobic Plate Count (APC)	10	CFU/g
2 Coliform, Plate Count	<10	CFU/g
3 E Coli, Plate Count	<10	CFU/g
4 Listeria Genus (by PCR)	Negative	
5 Mold	<10	CFU/g
6 Salmonella (by PCR)	Negative	
7 Yeast	<10	CFU/g

Mycotoxins Screen

Analyte	Result	Units	LOQ
1 Aflatoxin B1	ND	ppb	5
2 Aflatoxin B2	ND	ppb	5
3 Aflatoxin G1	ND	ppb	5
4 Aflatoxin G2	ND	ppb	5

*This analysis is outside the scope of OMIC USA operations and has been subcontracted to ALS laboratory. Their report analysis is attached in its entirety. OMIC USA assumes no responsibility for its interpretations or use.



1435 Norjohn Court, Unit 1, Burlington, ON, Canada L7L 0E6
Phone: 905-331-3111, FAX: 905-331-4567

Certificate of Analysis

ALS Project Contact: Ron McLeod
ALS Project ID: ALS800
ALS WO#: L1623923
Date of Report: 17-Jul-15
Date of Sample Receipt: 9-Jun-15

Client Name: ALS Environmental
Client Address: 10450 Stancliff Road, Suite 210
Houston, Texas 77099-4338

Client Contact: Nicole Brown
Client Project ID: E1500506

COMMENTS: PCDD/F by EPA 1613B

Percent recovery for 13C12 TCDD was below method acceptance criteria in Method blank. However, there was no native TCDD in the sample and therefore there is no compromise to the batch based upon this QC exceedance.

(b) (6)

Ron McLeod, PhD
Director, Air Toxics & Special Chemistries

Results in this certificate relate only to the samples as submitted to the laboratory.
This report shall not be reproduced, except in full, without the written permission of ALS Canada Ltd.

ALS Life Sciences	
Sample Analysis summary Report	
Sample Name	AB80320
ALS Sample ID	L1623923-1
Sample Size	1.00
Sample size units	g
Percent Moisture	n/a
Sample Matrix	Wax pellets
Sampling Date	6-May-15
Extraction Date	16-Jun-15
Target Analytes	pg/g
2,3,7,8-TCDD	<1.3
1,2,3,7,8-PeCDD	<1.0
1,2,3,4,7,8-HxCDD	<0.95
1,2,3,6,7,8-HxCDD	<1.0
1,2,3,7,8,9-HxCDD	<0.90
1,2,3,4,6,7,8-HpCDD	<0.91
OCDD	<0.87
2,3,7,8-TCDF	<0.79
1,2,3,7,8-PeCDF	<0.74
2,3,4,7,8-PeCDF	<0.62
1,2,3,4,7,8-HxCDF	<0.67
1,2,3,6,7,8-HxCDF	<0.65
2,3,4,6,7,8-HxCDF	<0.68
1,2,3,7,8,9-HxCDF	1.05
1,2,3,4,6,7,8-HpCDF	<0.55
1,2,3,4,7,8,9-HpCDF	<0.75
OCDF	1.24
Extraction Standards	% Rec
13C12-2,3,7,8-TCDD	54
13C12-1,2,3,7,8-PeCDD	84
13C12-1,2,3,4,7,8-HxCDD	85
13C12-1,2,3,6,7,8-HxCDD	107
13C12-1,2,3,4,6,7,8-HpCDD	68
13C12-OCDD	56
13C12-2,3,7,8-TCDF	83
13C12-1,2,3,7,8-PeCDF	89
13C12-2,3,4,7,8-PeCDF	95
13C12-1,2,3,4,7,8-HxCDF	93
13C12-1,2,3,6,7,8-HxCDF	108
13C12-2,3,4,6,7,8-HxCDF	97
13C12-1,2,3,7,8,9-HxCDF	92
13C12-1,2,3,4,6,7,8-HpCDF	85
13C12-1,2,3,4,7,8,9-HpCDF	73
Cleanup Standard	
37Cl4-2,3,7,8-TCDD (Cleanup)	52
Homologue Group Totals	pg/g
Total-TCDD	<1.3
Total-PeCDD	<0.59
Total-HxCDD	<0.95
Total-HpCDD	<0.68
Total-TCDF	<0.79
Total-PeCDF	<0.74
Total-HxCDF	1.97
Total-HpCDF	<0.75
Toxic Equivalency - (WHO 2005)	
Lower Bound PCDD/F TEQ (WHO 2005)	0.105
Mid Point PCDD/F TEQ (WHO 2005)	2.24
Upper Bound PCDD/F TEQ (WHO 2005)	3.20

ALS Life Sciences

Quality Control Summary Report

Sample Name	Method Blank	Laboratory Control Sample
ALS Sample ID	WG2108486-1	WG2108486-2
Sample Size	1.00	1.00
Sample size units	g	n/a
Percent Moisture	n/a	n/a
Sample Matrix	QC	QC
Sampling Date	n/a	n/a
Extraction Date	16-Jun-15	16-Jun-15
Target Analytes	pg/g	% Rec
2,3,7,8-TCDD	<8.6	93
1,2,3,7,8-PeCDD	<1.9	98
1,2,3,4,7,8-HxCDD	<2.2	101
1,2,3,6,7,8-HxCDD	<2.0	90
1,2,3,7,8,9-HxCDD	<2.1	97
1,2,3,4,6,7,8-HpCDD	<2.7	98
OCDD	<6.4	90
2,3,7,8-TCDF	<1.3	89
1,2,3,7,8-PeCDF	<1.7	96
2,3,4,7,8-PeCDF	<2.3	89
1,2,3,4,7,8-HxCDF	<0.88	97
1,2,3,6,7,8-HxCDF	<1.4	96
2,3,4,6,7,8-HxCDF	<1.9	100
1,2,3,7,8,9-HxCDF	2.73	97
1,2,3,4,6,7,8-HpCDF	<1.2	93
1,2,3,4,7,8,9-HpCDF	<1.7	94
OCDF	<4.1	98
Extraction Standards	% Rec	% Rec
13C12-2,3,7,8-TCDD	17	31
13C12-1,2,3,7,8-PeCDD	74	79
13C12-1,2,3,4,7,8-HxCDD	80	87
13C12-1,2,3,6,7,8-HxCDD	115	107
13C12-1,2,3,4,6,7,8-HpCDD	73	75
13C12-OCDD	76	65
13C12-2,3,7,8-TCDF	76	80
13C12-1,2,3,7,8-PeCDF	84	87
13C12-2,3,4,7,8-PeCDF	86	89
13C12-1,2,3,4,7,8-HxCDF	94	89
13C12-1,2,3,6,7,8-HxCDF	108	111
13C12-2,3,4,6,7,8-HxCDF	96	95
13C12-1,2,3,7,8,9-HxCDF	88	91
13C12-1,2,3,4,6,7,8-HpCDF	87	91
13C12-1,2,3,4,7,8,9-HpCDF	82	78
Cleanup Standard		
37Cl4-2,3,7,8-TCDD (Cleanup)	16	29
Homologue Group Totals	pg/g	
Total-TCDD	<8.6	
Total-PeCDD	<1.5	
Total-HxCDD	<2.2	
Total-HpCDD	<1.8	
Total-TCDF	1.31	
Total-PeCDF	2.26	
Total-HxCDF	2.73	
Total-HpCDF	<1.7	
Toxic Equivalency - (WHO 2005)		
Lower Bound PCDD/F TEQ (WHO 2005)	0.273	
Mid Point PCDD/F TEQ (WHO 2005)	8.01	
Upper Bound PCDD/F TEQ (WHO 2005)	12.8	

ALS Life Sciences

Sample Analysis Report

Sample Name **AB80320**
 ALS Sample ID **L1623923-1**
 Analysis Method **EPA 1613B**
 Analysis Type **Sample**
 Sample Matrix **Wax pellets**

Sampling Date **6-May-15**
 Extraction Date **16-Jun-15**
 Sample Size **1** g
 Percent Moisture **n/a**
 Split Ratio **1**

Approved:
A.All
 --e-signature--
 17-Jul-2015

Run Information

Run 1

Filename **1-150715A S:5**
 Run Date **15-Jul-15 15:39**
 Final Volume **25** uL
 Dilution Factor **1**
 Analysis Units **pg/g**
 Instrument - Column **HRMS-1 DB5MS60USE364727H**

Target Analytes	TEF (WHO 2005)	Ret. Time	Conc. pg/g	EDL pg/g	Flags	EMPC pg/g	LQL
2,3,7,8-TCDD	1	NotFnd	<1.3	1.3	U		13
1,2,3,7,8-PeCDD	1	31:29	<1.0	0.59	M,J,R	1.0	63
1,2,3,4,7,8-HxCDD	0.1	NotFnd	<0.95	0.95	M,U		63
1,2,3,6,7,8-HxCDD	0.1	33:40	<1.0	0.88	J,R	1.0	63
1,2,3,7,8,9-HxCDD	0.1	NotFnd	<0.90	0.90	U		63
1,2,3,4,6,7,8-HpCDD	0.01	35:12	<0.91	0.68	J,R	0.91	63
OCDD	0.0003	36:21	<0.87	0.87	U	0.62	130
2,3,7,8-TCDF	0.1	NotFnd	<0.79	0.79	U		13
1,2,3,7,8-PeCDF	0.03	NotFnd	<0.74	0.74	U		63
2,3,4,7,8-PeCDF	0.3	NotFnd	<0.62	0.62	U		63
1,2,3,4,7,8-HxCDF	0.1	33:07	<0.67	0.67	U		63
1,2,3,6,7,8-HxCDF	0.1	NotFnd	<0.65	0.65	U		63
2,3,4,6,7,8-HxCDF	0.1	33:31	<0.68	0.67	M,J,R	0.68	63
1,2,3,7,8,9-HxCDF	0.1	33:56	1.05	0.94	J,B		63
1,2,3,4,6,7,8-HpCDF	0.01	34:42	<0.55	0.49	J,R	0.55	63
1,2,3,4,7,8,9-HpCDF	0.01	NotFnd	<0.75	0.75	U		63
OCDF	0.0003	36:26	1.24	0.75	M,J		130

Extraction Standards	pg	% Rec	Limits
13C12-2,3,7,8-TCDD	2000	26:46	54 25-164
13C12-1,2,3,7,8-PeCDD	2000	31:28	84 25-181
13C12-1,2,3,4,7,8-HxCDD	2000	33:37	85 32-141 R
13C12-1,2,3,6,7,8-HxCDD	2000	33:40	107 28-130
13C12-1,2,3,4,6,7,8-HpCDD	2000	35:12	68 23-140
13C12-OCDD	4000	36:22	56 17-157
13C12-2,3,7,8-TCDF	2000	25:51	83 24-169
13C12-1,2,3,7,8-PeCDF	2000	30:27	89 24-185
13C12-2,3,4,7,8-PeCDF	2000	31:15	95 21-178
13C12-1,2,3,4,7,8-HxCDF	2000	33:06	93 26-152
13C12-1,2,3,6,7,8-HxCDF	2000	33:11	108 26-123
13C12-2,3,4,6,7,8-HxCDF	2000	33:31	97 29-147
13C12-1,2,3,7,8,9-HxCDF	2000	33:56	92 28-136
13C12-1,2,3,4,6,7,8-HpCDF	2000	34:42	85 28-143
13C12-1,2,3,4,7,8,9-HpCDF	2000	35:24	73 26-138

Cleanup Standard	pg	% Rec	Limits
37Cl4-2,3,7,8-TCDD (Cleanup)	40	26:48	52 35-197

Homologue Group Totals	# peaks	Conc. pg/g	EDL pg/g
Total-TCDD	0	<1.3	1.3 U
Total-PeCDD	0	<0.59	0.59 U
Total-HxCDD	0	<0.95	0.95 U
Total-HpCDD	0	<0.68	0.68 U
Total-TCDF	0	<0.79	0.79 U
Total-PeCDF	0	<0.74	0.74 U
Total-HxCDF	3	1.97	0.94
Total-HpCDF	0	<0.75	0.75 U

Toxic Equivalency - (WHO 2005)
 Lower Bound PCDD/F TEQ (WHO 2005)
 Mid Point PCDD/F TEQ (WHO 2005)
 Upper Bound PCDD/F TEQ (WHO 2005)

pg/g
 0.105
 2.24
 3.20

EDL Indicates the Estimated Detection Limit, based on the measured background noise for this target in this sample.
 TEF Indicates the Toxic Equivalency Factor
 M Indicates that a peak has been manually integrated.
 U Indicates that this compound was not detected above the MDL.
 J Indicates that a target analyte was detected below the calibrated range.
 R Indicates that the ion abundance ratio for this compound did not meet the acceptance criterion.
 B Indicates that this target was detected in the blank at greater than 10% of the sample concentration.

ALS Life Sciences

Laboratory Method Blank Analysis Report

Sample Name	Method Blank	Sampling Date	n/a	Approved:
ALS Sample ID	WG2108486-1	Extraction Date	16-Jun-15	A. Ali
Analysis Method	EPA 1613B	Sample Size	1 g	--e-signature--
Analysis Type	Blank	Percent Moisture	n/a	17-Jul-2015
Sample Matrix	QC	Split Ratio	1	

Run Information	Run 1
Filename	1-150715A S-4
Run Date	15-Jul-15 14:58
Final Volume	25 uL
Dilution Factor	1
Analysis Units	pg/g
Instrument - Column	HRMS-1 DB5MS60USE364727H

Target Analytes	TEF (WHO 2005)	Ret. Time	Conc. pg/g	EDL pg/g	Flags	EMPC pg/g	LQL
2,3,7,8-TCDD	1	NotFnd	<8.6	8.6	U		13
1,2,3,7,8-PeCDD	1	31:29	<1.9	1.5	M,J,R	1.9	63
1,2,3,4,7,8-HxCDD	0.1	NotFnd	<2.2	2.2	U		63
1,2,3,6,7,8-HxCDD	0.1	NotFnd	<2.0	2.0	U		63
1,2,3,7,8,9-HxCDD	0.1	NotFnd	<2.1	2.1	U		63
1,2,3,4,6,7,8-HpCDD	0.01	35:11	<2.7	1.8	M,J,R	2.7	63
OCDD	0.0003	36:22	<6.4	3.3	M,J,R	6.4	130
2,3,7,8-TCDF	0.1	25:52	<1.3	1.3	U	0.11	13
1,2,3,7,8-PeCDF	0.03	30:27	<1.7	1.1	M,J,R	1.7	63
2,3,4,7,8-PeCDF	0.3	31:15	<2.3	0.98	M,J,R	2.3	63
1,2,3,4,7,8-HxCDF	0.1	NotFnd	<0.88	0.88	U		63
1,2,3,6,7,8-HxCDF	0.1	33:10	<1.4	0.84	J,R	1.4	63
2,3,4,6,7,8-HxCDF	0.1	33:31	<1.9	0.88	M,J,R	1.9	63
1,2,3,7,8,9-HxCDF	0.1	33:56	2.73	1.2	M,J		63
1,2,3,4,6,7,8-HpCDF	0.01	NotFnd	<1.2	1.2	U		63
1,2,3,4,7,8,9-HpCDF	0.01	NotFnd	<1.7	1.7	U		63
OCDF	0.0003	36:27	<4.1	3.6	J,R	4.1	130

Extraction Standards	pg	% Rec	Limits
13C12-2,3,7,8-TCDD	2000	26:45	17 25-164
13C12-1,2,3,7,8-PeCDD	2000	31:27	74 25-181
13C12-1,2,3,4,7,8-HxCDD	2000	33:36	80 32-141
13C12-1,2,3,6,7,8-HxCDD	2000	33:39	115 28-130
13C12-1,2,3,4,6,7,8-HpCDD	2000	35:11	73 23-140
13C12-OCDD	4000	36:22	76 17-157
13C12-2,3,7,8-TCDF	2000	25:50	76 24-169
13C12-1,2,3,7,8-PeCDF	2000	30:26	84 24-185
13C12-2,3,4,7,8-PeCDF	2000	31:13	86 21-178
13C12-1,2,3,4,7,8-HxCDF	2000	33:05	94 26-152
13C12-1,2,3,6,7,8-HxCDF	2000	33:10	108 26-123
13C12-2,3,4,6,7,8-HxCDF	2000	33:30	96 29-147
13C12-1,2,3,7,8,9-HxCDF	2000	33:56	88 28-136
13C12-1,2,3,4,6,7,8-HpCDF	2000	34:41	87 28-143
13C12-1,2,3,4,7,8,9-HpCDF	2000	35:23	82 26-138

Cleanup Standard	pg	% Rec	Limits
37Cl4-2,3,7,8-TCDD (Cleanup)	40	26:46	16 35-197

Homologue Group Totals	# peaks	Conc. pg/g	EDL pg/g
Total-TCDD	0	<8.6	8.6 U
Total-PeCDD	0	<1.5	1.5 U
Total-HxCDD	0	<2.2	2.2 U
Total-HpCDD	0	<1.8	1.8 U
Total-TCDF	5	1.31	1.3
Total-PeCDF	2	2.26	1.1
Total-HxCDF	1	2.73	1.2
Total-HpCDF	0	<1.7	1.7 U

Toxic Equivalency - (WHO 2005)	pg/g
Lower Bound PCDD/F TEQ (WHO 2005)	0.273
Mid Point PCDD/F TEQ (WHO 2005)	8.01
Upper Bound PCDD/F TEQ (WHO 2005)	12.8

EDL	Indicates the Estimated Detection Limit, based on the measured background noise for this target in this sample.
TEF	Indicates the Toxic Equivalency Factor
M	Indicates that a peak has been manually integrated.
U	Indicates that this compound was not detected above the MDL.
J	Indicates that a target analyte was detected below the calibrated range.
R	Indicates that the ion abundance ratio for this compound did not meet the acceptance criterion.

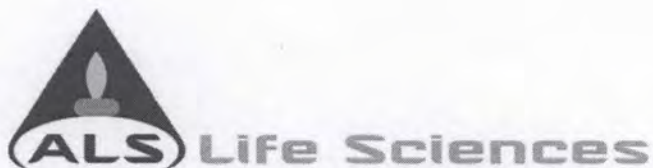
ALS Life Sciences

Laboratory Control Sample Analysis Report

Sample Name	Laboratory Control Sample	Sampling Date	n/a	Approved: A.Ali --e-signature-- 17-Jul-2015
ALS Sample ID	WG2108486-2	Extraction Date	16-Jun-15	
Analysis Method	EPA 1613B	Sample Size	1	
Analysis Type	LCS	Percent Moisture	n/a	
Sample Matrix	QC	Split Ratio	1	

Run Information	Run 1
Filename	1-150715A S:2
Run Date	15-Jul-15 13:34
Final Volume	25 uL
Dilution Factor	1
Analysis Units	%
Instrument - Column	HRMS-1 DB5MS60USE364727H

Target Analytes	pg	Ret. Time	% Rec	Limits	Flags
2,3,7,8-TCDD	200	26:48	93	67-158	
1,2,3,7,8-PeCDD	1000	31:29	98	70-142	
1,2,3,4,7,8-HxCDD	1000	33:38	101	70-164	
1,2,3,6,7,8-HxCDD	1000	33:40	90	76-134	
1,2,3,7,8,9-HxCDD	1000	33:48	97	64-162	
1,2,3,4,6,7,8-HpCDD	1000	35:12	98	70-140	
OCDD	2000	36:23	90	78-144	
2,3,7,8-TCDF	200	25:52	89	75-158	
1,2,3,7,8-PeCDF	1000	30:28	96	80-134	
2,3,4,7,8-PeCDF	1000	31:15	89	68-160	
1,2,3,4,7,8-HxCDF	1000	33:07	97	72-134	
1,2,3,6,7,8-HxCDF	1000	33:11	96	84-130	
2,3,4,6,7,8-HxCDF	1000	33:32	100	78-130	
1,2,3,7,8,9-HxCDF	1000	33:57	97	70-156	
1,2,3,4,6,7,8-HpCDF	1000	34:42	93	82-122	
1,2,3,4,7,8,9-HpCDF	1000	35:24	94	78-138	
OCDF	2000	36:26	98	63-170	
Extraction Standards	pg		% Rec	Limits	
13C12-2,3,7,8-TCDD	2000	26:47	31	20-175	
13C12-1,2,3,7,8-PeCDD	2000	31:28	79	21-227	
13C12-1,2,3,4,7,8-HxCDD	2000	33:37	87	21-193	
13C12-1,2,3,6,7,8-HxCDD	2000	33:40	107	25-163	
13C12-1,2,3,4,6,7,8-HpCDD	2000	35:12	75	26-166	
13C12-OCDD	4000	36:22	65	13-138	
13C12-2,3,7,8-TCDF	2000	25:51	80	22-152	
13C12-1,2,3,7,8-PeCDF	2000	30:27	87	21-192	
13C12-2,3,4,7,8-PeCDF	2000	31:15	89	13-328	
13C12-1,2,3,4,7,8-HxCDF	2000	33:07	89	19-202	
13C12-1,2,3,6,7,8-HxCDF	2000	33:11	111	21-159	
13C12-2,3,4,6,7,8-HxCDF	2000	33:31	95	17-205	
13C12-1,2,3,7,8,9-HxCDF	2000	33:57	91	22-176	
13C12-1,2,3,4,6,7,8-HpCDF	2000	34:42	91	21-158	
13C12-1,2,3,4,7,8,9-HpCDF	2000	35:24	78	20-186	
Cleanup Standard	pg				
37Cl4-2,3,7,8-TCDD (Cleanup)	40	26:48	29	31-191	



1435 Norjohn Court, Unit 1, Burlington, ON, Canada L7L 0E6
Phone: 905-331-3111, FAX: 905-331-4567

Certificate of Analysis

ALS Project Contact: Ron McLeod
ALS Project ID: ALS800
ALS WO#: L1623923
Date of Report: 17-Jul-15
Date of Sample Receipt: 9-Jun-15

Client Name: ALS Environmental
Client Address: 10450 Stancliff Road, Suite 210
Houston, Texas 77099-4338
Client Contact: Nicole Brown
Client Project ID: E1500506

COMMENTS: PCB Congeners by EPA 1668A

PCB Congener Group Totals and Total PCB are a sum of detected values, including EMPC values, consistent with USEPA CLP SOW CBC1.2

The 13C12-PCB-3 (in L1623923-1) and 13C12-PCB-1 (in the method blank) extraction standard recoveries were below the 1668A control limits but were well above the 1668C control limits. Due to isotope dilution technique there is no significant impact to data quality from these lower recoveries.

(b) (6)

Ron McLeod, PhD
Director Special Chemistries & Air Toxics, Eastern Canada

Results in this certificate relate only to the samples as submitted to the laboratory.

This report shall not be reproduced, except in full, without the written permission of ALS Canada Ltd.

ALS Life Sciences	
Sample Analysis summary Report	
Sample Name	AB80320
ALS Sample ID	L1623923-1
Sample Size	1.01
Sample size units	g
Percent Moisture	n/a
Sample Matrix	Wax pellets
Sampling Date	6-May-15
Extraction Date	n/a
Target Analytes	pg/g
PCB-001	7.49
PCB-002	7.48
PCB-003	<10
PCB-004	10.4
PCB-010	<0.44
PCB-009	<9.5
PCB-007	0.874
PCB-006	3.22
PCB-005	<0.45
PCB-008	19.0
PCB-014	<0.57
PCB-011	76.9
PCB-012/013	<0.67
PCB-015	<5.5
PCB-019	4.25
PCB-018/030	33.3
PCB-017	14.0
PCB-027	1.78
PCB-024	<0.22
PCB-016	14.8
PCB-032	9.92
PCB-034	<0.42
PCB-023	<0.38
PCB-026/029	6.01
PCB-025	1.89
PCB-031	41.0
PCB-020/028	42.0
PCB-021/033	22.6
PCB-022	13.8
PCB-036	<0.40
PCB-039	<0.45
PCB-038	<0.39
PCB-035	0.911
PCB-037	3.87
PCB-054	<0.39
PCB-050/053	7.46
PCB-045/051	10.4
PCB-046	3.30
PCB-052	50.7
PCB-073	<0.37
PCB-043	<1.8
PCB-049/069	23.1
PCB-048	10.6
PCB-044/047/065	43.2
PCB-059/062/075	3.26
PCB-042	10.1
PCB-040/041/071	23.1
PCB-064	16.5
PCB-072	<0.89
PCB-068	<0.74
PCB-057	<0.88
PCB-058	<0.91
PCB-067	<0.74
PCB-063	<0.85
PCB-061/070/074/076	45.2
PCB-066	24.9
PCB-055	<0.84
PCB-056	10.8
PCB-060	7.27
PCB-080	<0.83
PCB-079	<0.82
PCB-078	<0.88
PCB-081	<0.92
PCB-077	<0.98
PCB-104	0.240
PCB-096	<0.22
PCB-103	<0.17
PCB-094	<0.19
PCB-095	15.8
PCB-093/098/100/102	1.55

ALS Life Sciences	
Sample Analysis summary Report	
Sample Name	AB80320
ALS Sample ID	L1623923-1
PCB-088/091	<3.2
PCB-084	5.97
PCB-089	<0.71
PCB-121	<0.12
PCB-092	<2.1
PCB-090/101/113	13.9
PCB-083/099	9.21
PCB-112	<0.13
PCB-086/087/097/108/119/125	11.1
PCB-085/110/115/116/117	17.2
PCB-082	2.72
PCB-111	<0.13
PCB-120	<0.13
PCB-107/124	<4.3
PCB-109	<4.3
PCB-123	<4.3
PCB-106	<4.1
PCB-118	11.4
PCB-122	<4.3
PCB-114	<4.3
PCB-105	<4.9
PCB-127	<4.1
PCB-126	<6.2
PCB-155	<1.0
PCB-152	<0.19
PCB-150	<0.17
PCB-136	1.35
PCB-145	<0.19
PCB-148	<0.25
PCB-135/151	1.38
PCB-154	<0.22
PCB-144	0.471
PCB-147/149	5.77
PCB-134/143	<0.41
PCB-139/140	<0.36
PCB-131	<0.40
PCB-142	<0.42
PCB-132	2.82
PCB-133	<0.40
PCB-165	<0.30
PCB-146	0.831
PCB-161	<0.28
PCB-153/168	5.56
PCB-141	<1.3
PCB-130	<0.47
PCB-137/164	1.02
PCB-129/138/163	7.55
PCB-160	<0.27
PCB-158	<0.57
PCB-128/166	<0.49
PCB-159	<0.26
PCB-162	<0.24
PCB-167	0.517
PCB-156/157	1.01
PCB-169	<0.26
PCB-188	<3.0
PCB-179	<4.0
PCB-184	<3.4
PCB-176	<3.8
PCB-186	<3.9
PCB-178	<5.1
PCB-175	<4.8
PCB-187	<4.0
PCB-182	<4.5
PCB-183	<4.5
PCB-185	<4.6
PCB-174	<4.9
PCB-177	<5.0
PCB-181	<4.5
PCB-171/173	<5.0
PCB-172	<4.8
PCB-192	<3.6
PCB-180/193	<3.7
PCB-191	<3.3
PCB-170	<4.5
PCB-190	<2.8
PCB-189	<5.9
PCB-202	<0.21
PCB-201	<0.21

ALS Life Sciences	
Sample Analysis summary Report	
Sample Name	AB80320
ALS Sample ID	L1623923-1
PCB-204	<0.20
PCB-197	<0.19
PCB-200	<0.22
PCB-198/199	<0.50
PCB-196	<0.29
PCB-203	<0.28
PCB-195	<0.39
PCB-194	<0.37
PCB-205	<0.34
PCB-208	<0.82
PCB-207	<0.92
PCB-206	<1.7
PCB-209	<4.4
Extraction Standards	%
13C12-PCB-001	28
13C12-PCB-003	11
13C12-PCB-004	53
13C12-PCB-015	66
13C12-PCB-019	62
13C12-PCB-037	73
13C12-PCB-054	60
13C12-PCB-081	78
13C12-PCB-077	78
13C12-PCB-104	74
13C12-PCB-123	81
13C12-PCB-118	82
13C12-PCB-114	80
13C12-PCB-105	80
13C12-PCB-126	64
13C12-PCB-155	62
13C12-PCB-167	64
13C12-PCB-156/157	69
13C12-PCB-169	79
13C12-PCB-188	71
13C12-PCB-189	64
13C12-PCB-202	55
13C12-PCB-205	93
13C12-PCB-208	96
13C12-PCB-206	74
13C12-PCB-209	67
Cleanup Standards	%
13C12-PCB-028	71
13C12-PCB-111	81
13C12-PCB-178	73
Homologue Group Totals	pg/g
Total MonoCB	25.0
Total DiCB	125
Total TriCB	210
Total TetraCB	292
Total PentaCB	100
Total HexaCB	32.1
Total HeptaCB	0
Total OctaCB	0.780
Total NonaCB	0
DecaCB	0
Total PCB	785
Toxic Equivalency - (WHO 2005)	pg/g
Lower Bound PCB TEQ (WHO 2005)	0.000388
Mid Point PCB TEQ (WHO 2005)	0.315
Upper Bound PCB TEQ (WHO 2005)	0.629

ALS Life Sciences		
Quality Control Summary Report		
Sample Name	Method Blank	Laboratory Control Sample
ALS Sample ID	WG2108486-1	WG2108486-2
Sample Size	1	1
Sample size units	g	n/a
Percent Solids	n/a	n/a
Sample Matrix	QC	QC
Sampling Date	n/a	n/a
Extraction Date	n/a	n/a
Target Analytes	pg/g	%
PCB-001	<5.3	113
PCB-002	2.99	
PCB-003	<4.1	111
PCB-004	9.82	115
PCB-010	<0.45	
PCB-009	<8.4	
PCB-007	<1.4	
PCB-006	<0.39	
PCB-005	<0.44	
PCB-008	10.5	
PCB-014	<0.35	
PCB-011	<34	
PCB-012/013	0.973	
PCB-015	<2.3	113
PCB-019	<0.87	115
PCB-018/030	6.24	
PCB-017	2.92	
PCB-027	0.336	
PCB-024	<0.13	
PCB-016	<2.9	
PCB-032	<1.4	
PCB-034	<0.20	
PCB-023	<0.19	
PCB-026/029	<0.88	
PCB-025	<0.34	
PCB-031	3.99	
PCB-020/028	4.59	
PCB-021/033	2.76	
PCB-022	1.59	
PCB-036	<0.19	
PCB-039	<0.22	
PCB-038	<0.19	
PCB-035	<0.25	
PCB-037	1.12	99
PCB-054	<0.15	114
PCB-050/053	<0.36	
PCB-045/051	<1.3	
PCB-046	<0.27	
PCB-052	2.79	
PCB-073	<0.16	
PCB-043	<0.24	
PCB-049/069	1.07	
PCB-048	<0.31	
PCB-044/047/065	3.96	
PCB-059/062/075	<0.16	
PCB-042	<0.47	
PCB-040/041/071	<0.51	
PCB-064	<0.60	
PCB-072	<0.37	
PCB-068	<0.31	
PCB-057	<0.36	
PCB-058	<0.38	
PCB-067	<0.31	
PCB-063	<0.35	
PCB-061/070/074/076	<0.43	
PCB-066	<0.44	
PCB-055	<0.35	
PCB-056	<0.37	
PCB-060	<0.36	
PCB-080	<0.34	
PCB-079	<0.34	
PCB-078	<0.36	
PCB-081	<0.45	107
PCB-077	<0.35	106
PCB-104	<0.11	107
PCB-096	<0.11	
PCB-103	<0.11	
PCB-094	<0.12	
PCB-095	<0.75	
PCB-093/098/100/102	<0.11	

ALS Life Sciences		
Quality Control Summary Report		
Sample Name	Method Blank	Laboratory Control Sample
ALS Sample ID	WG2108486-1	WG2108486-2
PCB-088/091	0.189	
PCB-084	0.430	
PCB-089	<0.13	
PCB-121	<0.080	
PCB-092	<0.12	
PCB-090/101/113	0.970	
PCB-083/099	<0.13	
PCB-112	<0.081	
PCB-086/087/097/108/119/125	<0.43	
PCB-085/110/115/116/117	<0.67	
PCB-082	<0.14	
PCB-111	<0.082	
PCB-120	<0.082	
PCB-107/124	<0.13	
PCB-109	<0.12	
PCB-123	<0.12	113
PCB-106	<0.13	
PCB-118	0.711	110
PCB-122	<0.14	
PCB-114	<0.15	113
PCB-105	<0.11	110
PCB-127	<0.13	
PCB-126	0.278	112
PCB-155	<0.11	109
PCB-152	<0.075	
PCB-150	<0.068	
PCB-136	<0.077	
PCB-145	<0.077	
PCB-148	<0.099	
PCB-135/151	0.184	
PCB-154	<0.087	
PCB-144	<0.098	
PCB-147/149	0.490	
PCB-134/143	<0.13	
PCB-139/140	<0.11	
PCB-131	<0.12	
PCB-142	<0.13	
PCB-132	<0.18	
PCB-133	<0.12	
PCB-165	<0.093	
PCB-146	<0.10	
PCB-161	<0.087	
PCB-153/168	<0.25	
PCB-141	<0.12	
PCB-130	<0.14	
PCB-137/164	<0.10	
PCB-129/138/163	0.699	
PCB-160	<0.082	
PCB-158	<0.080	
PCB-128/166	<0.10	
PCB-159	<0.080	
PCB-162	<0.075	
PCB-167	<0.080	109
PCB-156/157	<0.26	109
PCB-169	0.288	108
PCB-188	<0.081	108
PCB-179	<0.10	
PCB-184	<0.086	
PCB-176	<0.097	
PCB-186	<0.10	
PCB-178	<0.13	
PCB-175	<0.13	
PCB-187	0.225	
PCB-182	<0.12	
PCB-183	<0.12	
PCB-185	<0.12	
PCB-174	<0.24	
PCB-177	<0.13	
PCB-181	<0.12	
PCB-171/173	<0.13	
PCB-172	<0.13	
PCB-192	<0.11	
PCB-180/193	<0.27	
PCB-191	<0.096	
PCB-170	<0.19	
PCB-190	0.0971	
PCB-189	<0.42	114
PCB-202	<0.078	111
PCB-201	<0.11	

ALS Life Sciences		
Quality Control Summary Report		
Sample Name	Method Blank	Laboratory Control Sample
ALS Sample ID	WG2108486-1	WG2108486-2
PCB-204	<0.10	
PCB-197	<0.10	
PCB-200	<0.12	
PCB-198/199	<0.15	
PCB-196	<0.16	
PCB-203	<0.14	
PCB-195	<0.32	
PCB-194	<0.30	
PCB-205	<0.44	108
PCB-208	<1.2	108
PCB-207	<1.2	
PCB-206	<1.9	118
PCB-209	1.18	115
Extraction Standards	%	%
13C12-PCB-001	15	30
13C12-PCB-003	42	30
13C12-PCB-004	46	35
13C12-PCB-015	49	45
13C12-PCB-019	49	42
13C12-PCB-037	58	55
13C12-PCB-054	50	38
13C12-PCB-081	64	64
13C12-PCB-077	67	68
13C12-PCB-104	58	47
13C12-PCB-123	66	67
13C12-PCB-118	39	69
13C12-PCB-114	67	68
13C12-PCB-105	70	73
13C12-PCB-126	84	78
13C12-PCB-155	60	50
13C12-PCB-167	93	82
13C12-PCB-156/157	88	81
13C12-PCB-169	79	89
13C12-PCB-188	67	65
13C12-PCB-189	50	81
13C12-PCB-202	86	73
13C12-PCB-205	84	91
13C12-PCB-208	109	82
13C12-PCB-206	110	90
13C12-PCB-209	116	78
Cleanup Standard	%	%
13C12-PCB-028	63	58
13C12-PCB-111	79	74
13C12-PCB-178	82	76
Homologue Group Totals	pg/g	
Total MonoCB	12.4	
Total DiCB	67.8	
Total TriCB	30.2	
Total TetraCB	12.2	
Total PentaCB	4.71	
Total HexaCB	2.54	
Total HeptaCB	1.02	
Total OctaCB	0	
Total NonaCB	0	
DecaCB	1.18	
Total PCB	132	
Toxic Equivalency - (WHO 2005)	pg/g	
Lower Bound PCB TEQ (WHO 2005)	0.0365	
Mid Point PCB TEQ (WHO 2005)	0.0366	
Upper Bound PCB TEQ (WHO 2005)	0.0367	

ALS Life Sciences

Sample Analysis Report

Sample Name AB80320
ALS Sample ID L1623923-1
Analysis Method EPA 1668C
Analysis Type Sample
Sample Matrix Wax pellets

Associated Method Blank WG2108486-1
Sampling Date 6-May-15
Extraction Date n/a
Sample Size 1.01 g
Percent Moisture n/a
Split Ratio 1

Approved:
E. Sabljic
 --e-signature--
 17-Jul-2015

Run Information

Run 1

Filename 5-150710A06
Run Date 10-Jul-15 16:27
Final Volume 45 ul
Dilution Factor 1
Analysis Units pg/g
Instrument - Column HRMS-5 SPBOCTYL55800-02B

Run 2

Filename 5-150713A09
Run Date 13-Jul-15 16:40
Final Volume 45 uL
Dilution Factor 10
Analysis Units pg/g
Instrument - Column HRMS-5 SPBOCTYL55800-02B

Target Analytes	Ret. Time	Conc. pg/g	EDL pg/g	EMPC pg/g	LQL	Ret. Time	Conc. pg/g	EDL pg/g	EMPC pg/g	LQL
PCB-001	8:50	7.49	0.51 J		45					
PCB-002	10:16	7.48	0.70 J,B		45					
PCB-003	10:22	<10	1.5 J,R	10	45					
PCB-004	10:32	10.4	0.68 J,B		45					
PCB-010	10:39	<0.44	0.44 U	0.32	45					
PCB-009	11:49	<9.5	0.44 J,R	9.5	45					
PCB-007	11:55	0.874	0.41 J		45					
PCB-006	12:04	3.22	0.39 J		45					
PCB-005	NotFnd	<0.45	0.45 U		45					
PCB-008	12:21	19.0	0.38 J,B		45					
PCB-014	NotFnd	<0.57	0.57 U		45					
PCB-011	13:52	76.9	0.68		45					
PCB-012/013	NotFnd	<0.67	0.67 U		45					
PCB-015	14:14	<5.5	0.90 J,R	5.5	45					
PCB-019	12:32	4.25	0.30 J		45					
PCB-018/030	13:39	33.3	0.25 J,B		45					
PCB-017	13:54	14.0	0.31 J,B		45					
PCB-027	14:01	1.78	0.22 J,B		45					
PCB-024	14:07	<0.22	0.22 U	0.092	45					
PCB-016	14:11	14.8	0.36 J		45					
PCB-032	14:29	9.92	0.20 J		45					
PCB-034	NotFnd	<0.42	0.42 U		45					
PCB-023	NotFnd	<0.38	0.38 U		45					
PCB-026/029	15:28	6.01	0.46 J		45					
PCB-025	15:36	1.89	0.36 J		45					
PCB-031	15:47	41.0	0.41 J		45					
PCB-020/028	15:57	42.0	0.42 J,B		45					
PCB-021/033	16:05	22.6	0.39 J,B		45					
PCB-022	16:19	13.8	0.43 J,B		45					
PCB-036	NotFnd	<0.40	0.40 U		45					
PCB-039	NotFnd	<0.45	0.45 U		45					
PCB-038	NotFnd	<0.39	0.39 U		45					
PCB-035	17:58	0.911	0.45 J		45					
PCB-037	18:11	3.87	0.59 J,B		45					
PCB-054	NotFnd	<0.39	0.39 U		45					
PCB-050/053	15:37	7.46	0.50 J		45					
PCB-045/051	16:01	10.4	0.52 J		45					
PCB-046	16:11	3.30	0.61 J		45					
PCB-052	16:56	50.7	0.53		45					
PCB-073	NotFnd	<0.37	0.37 U		45					
PCB-043	17:04	<1.8	0.56 J,R	1.8	45					
PCB-049/069	17:13	23.1	0.42 J		45					
PCB-048	17:22	10.6	0.51 J		45					
PCB-044/047/065	17:30	43.2	0.47 J		45					
PCB-059/062/075	17:40	3.26	0.37 J		45					
PCB-042	17:48	10.1	0.52 J		45					
PCB-040/041/071	18:03	23.1	0.51 J		45					
PCB-064	18:11	16.5	0.37 J		45					
PCB-072	NotFnd	<0.89	0.89 U		45					
PCB-068	NotFnd	<0.74	0.74 U		45					
PCB-057	NotFnd	<0.88	0.88 U		45					
PCB-058	NotFnd	<0.91	0.91 U		45					
PCB-067	19:14	<0.74	0.74 U	0.41	45					
PCB-063	19:22	<0.85	0.85 U	0.81	45					
PCB-061/070/074/076	19:34	45.2	0.86		45					
PCB-066	19:44	24.9	0.88 J		45					
PCB-055	19:53	<0.84	0.84 U	0.086	45					
PCB-056	20:06	10.8	0.89 J		45					
PCB-060	20:13	7.27	0.86 J		45					
PCB-080	NotFnd	<0.83	0.83 U		45					
PCB-079	NotFnd	<0.82	0.82 U		45					
PCB-078	NotFnd	<0.88	0.88 U		45					
PCB-081	NotFnd	<0.92	0.92 U		45					
PCB-077	NotFnd	<0.98	0.98 U		45					
PCB-104	17:28	0.240	0.077 J		45					
PCB-096	17:41	<0.22	0.068 J,R	0.22	45					

ALS Life Sciences

Sample Analysis Report

Sample Name **AB80320**
ALS Sample ID L1623923-1
Analysis Method EPA 1668C
Analysis Type Sample
Sample Matrix Wax pellets

Associated Method Blank WG2108486-1
Sampling Date 6-May-15
Extraction Date n/a
Sample Size 1.01 g
Percent Moisture n/a
Split Ratio 1

Approved:
E. Sabljic
--e-signature--
17-Jul-2015

Run Information

Run 1

Filename 5-150710A06
Run Date 10-Jul-15 16:27
Final Volume 45 uL
Dilution Factor 1
Analysis Units pg/g
Instrument - Column HRMS-5 SPBIOCTYL55800-02B

Run 2

5-150713A09
13-Jul-15 16:40
45 uL
10
pg/g
HRMS-5 SPBIOCTYL55800-02B

Target Analytes	Ret. Time	Conc. pg/g	EDL pg/g	Flags	EMPC pg/g	LQL	Ret. Time	Conc. pg/g	EDL pg/g	Flags	EMPC pg/g	LQL
PCB-103	18:41	<0.17	0.17 U		0.11	45						
PCB-094	NotFnd	<0.19	0.19 U			45						
PCB-095	19:04	15.8	0.20 J			45						
PCB-093/098/100/102	19:14	1.55	0.17 M,J			45						
PCB-088/091	19:32	<3.2	0.18 J,R		3.2	45						
PCB-084	19:40	5.97	0.21 J			45						
PCB-089	19:56	<0.71	0.20 J,R		0.71	45						
PCB-121	20:03	<0.12	0.12 U		0.036	45						
PCB-092	20:18	<2.1	0.19 J,R		2.1	45						
PCB-090/101/113	20:37	13.9	0.17 J			45						
PCB-083/099	20:55	9.21	0.19 J			45						
PCB-112	NotFnd	<0.13	0.13 U			45						
PCB-086/087/097/108/119/125	21:14	11.1	0.16 M,J			45						
PCB-085/110/115/116/117	21:39	17.2	0.14 M,J			45						
PCB-082	21:52	2.72	0.21 J			45						
PCB-111	NotFnd	<0.13	0.13 U			45						
PCB-120	NotFnd	<0.13	0.13 U			45						
PCB-107/124							NotFnd	<4.3	4.3 U			450
PCB-109							NotFnd	<4.3	4.3 U			450
PCB-123							NotFnd	<4.3	4.3 U			450
PCB-106							NotFnd	<4.1	4.1 U			450
PCB-118							23:17	11.4	4.2 J			450
PCB-122							NotFnd	<4.3	4.3 U			450
PCB-114							NotFnd	<4.3	4.3 U			450
PCB-105							23:55	<4.9	4.6 J,R	4.9		450
PCB-127							NotFnd	<4.1	4.1 U			450
PCB-126							NotFnd	<6.2	6.2 U			450
PCB-155	20:30	<1.0	0.19 J,R		1.0	45						
PCB-152	NotFnd	<0.19	0.19 U			45						
PCB-150	NotFnd	<0.17	0.17 U			45						
PCB-136	20:55	1.35	0.19 J			45						
PCB-145	NotFnd	<0.19	0.19 U			45						
PCB-148	21:46	<0.25	0.25 U		0.077	45						
PCB-135/151	22:10	1.38	0.25 J,B			45						
PCB-154	NotFnd	<0.22	0.22 U			45						
PCB-144	22:26	0.471	0.24 J			45						
PCB-147/149	22:37	5.77	0.36 M,J			45						
PCB-134/143	22:45	<0.41	0.41 U		0.35	45						
PCB-139/140	22:54	<0.36	0.36 U		0.21	45						
PCB-131	NotFnd	<0.40	0.40 U			45						
PCB-142	NotFnd	<0.42	0.42 U			45						
PCB-132	23:18	2.82	0.40 J			45						
PCB-133	23:32	<0.40	0.40 U		0.10	45						
PCB-165	NotFnd	<0.30	0.30 U			45						
PCB-146	23:51	0.831	0.33 J			45						
PCB-161	NotFnd	<0.28	0.28 U			45						
PCB-153/168	24:10	5.56	0.30 J			45						
PCB-141	24:17	<1.3	0.40 J,R		1.3	45						
PCB-130	24:31	<0.47	0.44 J,R		0.47	45						
PCB-137/164	24:39	1.02	0.33 J			45						
PCB-129/138/163	24:50	7.55	0.36 J			45						
PCB-160	NotFnd	<0.27	0.27 U			45						
PCB-158	25:02	<0.57	0.26 J,R		0.57	45						
PCB-128/166	25:31	<0.49	0.33 J,R		0.49	45						
PCB-159	NotFnd	<0.26	0.26 U			45						
PCB-162	NotFnd	<0.24	0.24 U			45						
PCB-167	26:23	0.517	0.30 J			45						
PCB-156/157	26:59	1.01	0.32 J			45						
PCB-169	NotFnd	<0.26	0.26 U			45						
PCB-188							NotFnd	<3.0	3.0 U			450
PCB-179							NotFnd	<4.0	4.0 U			450
PCB-184							NotFnd	<3.4	3.4 U			450
PCB-176							NotFnd	<3.8	3.8 U			450
PCB-186							NotFnd	<3.9	3.9 U			450
PCB-178							NotFnd	<5.1	5.1 U			450
PCB-175							NotFnd	<4.8	4.8 U			450
PCB-187							25:32	<4.0	4.0 U			450

ALS Life Sciences

Sample Analysis Report

Sample Name **AB80320**
ALS Sample ID L1623923-1
Analysis Method EPA 1668C
Analysis Type Sample
Sample Matrix Wax pellets

Associated Method Blank WG2108486-1
Sampling Date 6-May-15
Extraction Date n/a
Sample Size 1.01 g
Percent Moisture n/a
Split Ratio 1

Approved:
E. Sabljic
--e-signature--
17-Jul-2015

Run Information

Run 1

Filename 5-150710A06
Run Date 10-Jul-15 16:27
Final Volume 45 ul
Dilution Factor 1
Analysis Units pg/g
Instrument - Column HRMS-5 SPBOCTYL55800-02B

Run 2

5-150713A09
13-Jul-15 16:40
45 uL
10
pg/g
HRMS-5 SPBOCTYL55800-02B

Target Analytes	Ret. Time	Conc. pg/g	EDL pg/g	EMPC pg/g	LQL	Ret. Time	Conc. pg/g	EDL pg/g	EMPC pg/g	LQL
PCB-182						25:37	<4.5	4.5 U	2.3	450
PCB-183						NotFnd	<4.5	4.5 U		450
PCB-185						NotFnd	<4.6	4.6 U		450
PCB-174						NotFnd	<4.9	4.9 U		450
PCB-177						NotFnd	<5.0	5.0 U		450
PCB-181						26:27	<4.5	4.5 U	0.45	450
PCB-171/173						NotFnd	<5.0	5.0 U		450
PCB-172						27:20	<4.8	4.8 U	2.2	450
PCB-192						NotFnd	<3.6	3.6 U		450
PCB-180/193						NotFnd	<3.7	3.7 U		450
PCB-191						NotFnd	<3.3	3.3 U		450
PCB-170						NotFnd	<4.5	4.5 U		450
PCB-190						NotFnd	<2.8	2.8 U		450
PCB-189						NotFnd	<5.9	5.9 U		450
PCB-202	NotFnd	<0.21	0.21 U		45					
PCB-201	NotFnd	<0.21	0.21 U		45					
PCB-204	NotFnd	<0.20	0.20 U		45					
PCB-197	NotFnd	<0.19	0.19 U		45					
PCB-200	NotFnd	<0.22	0.22 U		45					
PCB-198/199	28:39	<0.50	0.29 J,R	0.50	45					
PCB-196	29:00	<0.29	0.29 U	0.21	45					
PCB-203	29:06	<0.28	0.27 J,R	0.28	45					
PCB-195	NotFnd	<0.39	0.39 U		45					
PCB-194	31:02	<0.37	0.37 U	0.25	45					
PCB-205	NotFnd	<0.34	0.34 U		45					
PCB-208	NotFnd	<0.82	0.82 U		45					
PCB-207	NotFnd	<0.92	0.92 U		45					
PCB-206	NotFnd	<1.7	1.7 U		45					
PCB-209						NotFnd	<4.4	4.4 U		450

Extraction Standards	pg	%	Limits	%
13C12-PCB-001 2000	8:50	28	25-150	
13C12-PCB-003 2000	10:23	11	25-150	
13C12-PCB-004 2000	10:31	53	25-150	
13C12-PCB-015 2000	14:14	66	25-150	
13C12-PCB-019 2000	12:31	62	25-150	
13C12-PCB-037 2000	18:11	73	25-150	
13C12-PCB-054 2000	14:22	60	25-150	
13C12-PCB-081 2000	21:46	78	25-150	
13C12-PCB-077 2000	22:04	78	25-150	
13C12-PCB-104 2000	17:27	74	25-150	
13C12-PCB-123 2000	23:03	81	25-150	
13C12-PCB-118 2000	23:14	82	25-150	
13C12-PCB-114 2000	23:31	80	25-150	
13C12-PCB-105 2000	23:52	80	25-150	
13C12-PCB-126 2000			25-150	25:31 64
13C12-PCB-155 2000	20:28	62	25-150	
13C12-PCB-167 2000	26:22	64	25-150	
13C12-PCB-156/157 4000	26:59	69	25-150	
13C12-PCB-169 2000	28:39	79	25-150	
13C12-PCB-188 2000	23:28	71	25-150	
13C12-PCB-189 2000			25-150	29:57 64
13C12-PCB-202 2000	26:14	55	25-150	
13C12-PCB-205 2000	31:18	93	25-150	
13C12-PCB-208 2000	29:39	96	25-150	
13C12-PCB-206 2000	32:22	74	25-150	
13C12-PCB-209 2000			25-150	33:32 67

Cleanup Standards	pg	%	
13C12-PCB-028 2000	15:56	71	30-135
13C12-PCB-111 2000	22:00	81	30-135
13C12-PCB-178 2000	25:02	73	30-135

ALS Life Sciences

Sample Analysis Report

Sample Name AB80320
ALS Sample ID L1623923-1
Analysis Method EPA 1668C
Analysis Type Sample
Sample Matrix Wax pellets

Associated Method Blank WG2108486-1
Sampling Date 6-May-15
Extraction Date n/a
Sample Size 1.01 g
Percent Moisture n/a
Split Ratio 1

Approved:
E. Sabljic
 --e-signature--
 17-Jul-2015

Run Information

Run 1

Filename 5-150710A06
Run Date 10-Jul-15 16:27
Final Volume 45 ul
Dilution Factor 1
Analysis Units pg/g
Instrument - Column HRMS-5 SPBOCTYL55800-02B

Run 2

Filename 5-150713A09
Run Date 13-Jul-15 16:40
Final Volume 45 uL
Dilution Factor 10
Analysis Units pg/g
Instrument - Column HRMS-5 SPBOCTYL55800-02B

Target Analytes	Ret. Time	Conc. pg/g	EDL pg/g	Flags	EMPC pg/g	LQL	Ret. Time	Conc. pg/g	EDL pg/g	Flags	EMPC pg/g	LQL
Homologue Group Totals												
Total MonoCB		25.0	0.51	J		45						
Total DiCB		125	0.38	J		45						
Total TriCB		210	0.2	J		45						
Total TetraCB		292	0.37	J		45						
Total PentaCB		100	0.068	J		45						
Total HexaCB		32.1	0.17	J		45						
Total HeptaCB		0	2.8	U		45						
Total OctaCB		0.780	0.19	J		45						
Total NonaCB		0	0.82	U		45						
DecaCB		0	4.4	U		45						
Total PCB		785		J								

Toxic Equivalency - (WHO 2005)

pg/g

Lower Bound PCB TEQ (WHO 2005)

0.000388

Mid Point PCB TEQ (WHO 2005)

0.315

Upper Bound PCB TEQ (WHO 2005)

0.629

EDL	Indicates the Estimated Detection Limit, based on the measured background noise for this target in this sample.
TEF	Indicates the Toxic Equivalency Factor
M	Indicates that a peak has been manually integrated.
U	Indicates that the analyte was not detected at or above the reported estimated detection limit.
J	Indicates that the analyte was positively identified. The associated numerical result is an estimate.
R	Indicates that the ion abundance ratio for this analyte did not meet the control limit. The reported value represents an estimated concentration.
B	Indicates that this target was detected in the blank at greater than 10% of the sample concentration.

ALS Life Sciences

Laboratory Method Blank Analysis Report

Sample Name
ALS Sample ID

Method Blank
WG2108486-1

Analysis Method
EPA 1668C

Analysis Type
Blank

Sample Matrix
QC

Sampling Date
n/a

Extraction Date
n/a

Sample Size
1 g

Percent Moisture
n/a

Split Ratio
1

Approved:
E. Sabljic
--e-signature--
17-Jul-2015

Run Information

Run 1

Filename
5-150710A05

Run Date
10-Jul-15 15:48

Final Volume
45 ul

Dilution Factor
1

Analysis Units
pg/g

Instrument - Column
HRMS-5 SPB0CTYL55800-02B

Target Analytes	Ret. Time	Conc. pg/g	EDL pg/g	Flags	EMPC pg/g	LQL
PCB-001	9:12	<5.3	1.0 J,R		5.3	45
PCB-002	10:19	2.99	0.54 J			45
PCB-003	10:26	<4.1	0.43 J,R		4.1	45
PCB-004	10:36	9.82	0.61 J			45
PCB-010	10:43	<0.45	0.43 J,R		0.45	45
PCB-009	11:51	<8.4	0.43 J,R		8.4	45
PCB-007	11:57	<1.4	0.40 J,R		1.4	45
PCB-006	NotFnd	<0.39	0.39 U			45
PCB-005	12:18	<0.44	0.44 U			45
PCB-008	12:23	10.5	0.37 J			45
PCB-014	NotFnd	<0.35	0.35 U			45
PCB-011	13:53	<34	0.42 J,R		34	45
PCB-012/013	14:05	0.973	0.41 J			45
PCB-015	14:15	<2.3	0.57 J,R		2.3	45
PCB-019	12:34	<0.87	0.25 J,R		0.87	45
PCB-018/030	13:41	6.24	0.15 J			45
PCB-017	13:56	2.92	0.18 J			45
PCB-027	14:03	0.336	0.13 J			45
PCB-024	14:08	<0.13	0.13 U		0.024	45
PCB-016	14:12	<2.9	0.21 J,R		2.9	45
PCB-032	14:30	<1.4	0.12 J,R		1.4	45
PCB-034	NotFnd	<0.20	0.20 U			45
PCB-023	NotFnd	<0.19	0.19 U			45
PCB-026/029	15:28	<0.88	0.22 J,R		0.88	45
PCB-025	15:36	<0.34	0.17 J,R		0.34	45
PCB-031	15:47	3.99	0.20 J			45
PCB-020/028	15:57	4.59	0.20 J			45
PCB-021/033	16:06	2.76	0.19 J			45
PCB-022	16:19	1.59	0.21 J			45
PCB-036	NotFnd	<0.19	0.19 U			45
PCB-039	NotFnd	<0.22	0.22 U			45
PCB-038	NotFnd	<0.19	0.19 U			45
PCB-035	17:58	<0.25	0.22 J,R		0.25	45
PCB-037	18:12	1.12	0.28 J			45
PCB-054	14:25	<0.15	0.15 U		0.077	45
PCB-050/053	15:38	<0.36	0.22 J,R		0.36	45
PCB-045/051	16:02	<1.3	0.23 J,R		1.3	45
PCB-046	NotFnd	<0.27	0.27 U			45
PCB-052	16:57	2.79	0.23 J			45
PCB-073	NotFnd	<0.16	0.16 U			45
PCB-043	NotFnd	<0.24	0.24 U			45
PCB-049/069	17:13	1.07	0.18 J			45
PCB-048	17:22	<0.31	0.22 J,R		0.31	45
PCB-044/047/065	17:31	3.96	0.20 J			45
PCB-059/062/075	17:41	<0.16	0.16 U		0.074	45
PCB-042	17:48	<0.47	0.23 J,R		0.47	45
PCB-040/041/071	18:03	<0.51	0.23 J,R		0.51	45
PCB-064	18:11	<0.60	0.16 J,R		0.60	45
PCB-072	NotFnd	<0.37	0.37 U			45
PCB-068	18:46	<0.31	0.31 U		0.29	45
PCB-057	NotFnd	<0.36	0.36 U			45
PCB-058	NotFnd	<0.38	0.38 U			45
PCB-067	NotFnd	<0.31	0.31 U			45
PCB-063	NotFnd	<0.35	0.35 U			45
PCB-061/070/074/076	19:34	<0.43	0.36 J,R		0.43	45
PCB-066	19:44	<0.44	0.36 J,R		0.44	45
PCB-055	19:48	<0.35	0.35 U		0.11	45
PCB-056	20:06	<0.37	0.37 U		0.14	45
PCB-060	NotFnd	<0.36	0.36 U			45
PCB-080	NotFnd	<0.34	0.34 U			45
PCB-079	NotFnd	<0.34	0.34 U			45
PCB-078	NotFnd	<0.36	0.36 U			45
PCB-081	NotFnd	<0.45	0.45 U			45
PCB-077	NotFnd	<0.35	0.35 U			45
PCB-104	NotFnd	<0.11	0.11 U			45
PCB-096	NotFnd	<0.11	0.11 U			45

ALS Life Sciences

Laboratory Method Blank Analysis Report

Sample Name ALS Sample ID	Method Blank WG2108486-1	Sampling Date n/a			
Analysis Method EPA 1668C		Extraction Date n/a			
Analysis Type Blank		Sample Size 1	g		Approved: E. Sabljic
Sample Matrix QC		Percent Moisture n/a			--e-signature--
		Split Ratio 1			17-Jul-2015

Run Information	Run 1
Filename	5-150710A05
Run Date	10-Jul-15 15:48
Final Volume	45 ul
Dilution Factor	1
Analysis Units	pg/g
Instrument - Column	HRMS-5 SPBIOCTYL55800-02B

Target Analytes	Ret. Time	Conc. pg/g	EDL pg/g	Flags	EMPC pg/g	LQL
PCB-103	18:43	<0.11	0.11 U			45
PCB-094	NotFnd	<0.12	0.12 U			45
PCB-095	19:05	<0.75	0.12 J,R		0.75	45
PCB-093/098/100/102	NotFnd	<0.11	0.11 U			45
PCB-088/091	19:32	0.189	0.12 J			45
PCB-084	19:40	0.430	0.13 J			45
PCB-089	NotFnd	<0.13	0.13 U			45
PCB-121	20:07	<0.080	0.080 U			45
PCB-092	20:18	<0.12	0.12 U		0.063	45
PCB-090/101/113	20:37	0.970	0.11 J			45
PCB-083/099	20:57	<0.13	0.12 J,R		0.13	45
PCB-112	NotFnd	<0.081	0.081 U			45
PCB-086/087/097/108/119/125	21:17	<0.43	0.10 J,R		0.43	45
PCB-085/110/115/116/117	21:41	<0.67	0.092 J,R		0.67	45
PCB-082	NotFnd	<0.14	0.14 U			45
PCB-111	21:58	<0.082	0.082 U		0.0025	45
PCB-120	22:16	<0.082	0.082 U		0.043	45
PCB-107/124	NotFnd	<0.13	0.13 U			45
PCB-109	NotFnd	<0.12	0.12 U			45
PCB-123	23:04	<0.12	0.12 J,R		0.12	45
PCB-106	NotFnd	<0.13	0.13 U			45
PCB-118	23:16	0.711	0.21 J			45
PCB-122	NotFnd	<0.14	0.14 U			45
PCB-114	23:33	<0.15	0.11 J,R		0.15	45
PCB-105	23:55	<0.11	0.11 U		0.093	45
PCB-127	NotFnd	<0.13	0.13 U			45
PCB-126	25:28	0.278	0.11 J			45
PCB-155	20:29	<0.11	0.099 J,R		0.11	45
PCB-152	NotFnd	<0.075	0.075 U			45
PCB-150	20:43	<0.068	0.068 U		0.016	45
PCB-136	NotFnd	<0.077	0.077 U			45
PCB-145	21:01	<0.077	0.077 U		0.011	45
PCB-148	21:47	<0.099	0.099 U			45
PCB-135/151	22:11	0.184	0.099 J			45
PCB-154	NotFnd	<0.087	0.087 U			45
PCB-144	NotFnd	<0.098	0.098 U			45
PCB-147/149	22:39	0.490	0.11 J			45
PCB-134/143	22:49	<0.13	0.13 U		0.033	45
PCB-139/140	NotFnd	<0.11	0.11 U			45
PCB-131	NotFnd	<0.12	0.12 U			45
PCB-142	NotFnd	<0.13	0.13 U			45
PCB-132	23:20	<0.18	0.12 J,R		0.18	45
PCB-133	NotFnd	<0.12	0.12 U			45
PCB-165	23:46	<0.093	0.093 U		0.015	45
PCB-146	23:52	<0.10	0.10 J,R		0.10	45
PCB-161	NotFnd	<0.087	0.087 U			45
PCB-153/168	24:12	<0.25	0.092 J,R		0.25	45
PCB-141	24:18	<0.12	0.12 U		0.073	45
PCB-130	NotFnd	<0.14	0.14 U			45
PCB-137/164	NotFnd	<0.10	0.10 U			45
PCB-129/138/163	24:52	0.699	0.11 J			45
PCB-160	24:58	<0.082	0.082 U		0.017	45
PCB-158	25:03	<0.080	0.080 U		0.050	45
PCB-128/166	25:31	<0.10	0.10 U		0.019	45
PCB-159	26:00	<0.080	0.080 U		0.040	45
PCB-162	26:11	<0.075	0.075 U		0.047	45
PCB-167	26:24	<0.080	0.071 J,R		0.080	45
PCB-156/157	27:00	<0.26	0.090 J,R		0.26	45
PCB-169	28:41	0.288	0.093 J			45
PCB-188	23:31	<0.081	0.081 U		0.050	45
PCB-179	23:42	<0.10	0.10 U		0.054	45
PCB-184	NotFnd	<0.086	0.086 U			45
PCB-176	NotFnd	<0.097	0.097 U			45
PCB-186	NotFnd	<0.10	0.10 U			45
PCB-178	25:06	<0.13	0.13 U		0.054	45
PCB-175	25:24	<0.13	0.13 U		0.046	45
PCB-187	25:32	0.225	0.11 J			45

ALS Life Sciences

Laboratory Method Blank Analysis Report

Sample Name ALS Sample ID	Method Blank WG2108486-1	Sampling Date Extraction Date Sample Size Percent Moisture Split Ratio	n/a n/a 1 n/a 1	g	Approved: E. Sabljic ---signature--- 17-Jul-2015
Analysis Method Analysis Type Sample Matrix	EPA 1668C Blank QC				

Run Information

Run 1

Filename 5-150710A05
 Run Date 10-Jul-15 15:48
 Final Volume 45 ul
 Dilution Factor 1
 Analysis Units pg/g
 Instrument - Column HRMS-5 SPBOCTYL55800-02B

Target Analytes	Ret. Time	Conc. pg/g	EDL pg/g	Flags	EMPC pg/g	LQL
PCB-182	25:37	<0.12	0.12 U		0.069	45
PCB-183	25:53	<0.12	0.12 U		0.099	45
PCB-185	25:56	<0.12	0.12 U		0.064	45
PCB-174	26:00	<0.24	0.12 J,R		0.24	45
PCB-177	26:13	<0.13	0.13 U		0.071	45
PCB-181	26:23	<0.12	0.12 U		0.040	45
PCB-171/173	NotFnd	<0.13	0.13 U			45
PCB-172	27:19	<0.13	0.13 U		0.087	45
PCB-192	NotFnd	<0.11	0.11 U			45
PCB-180/193	27:42	<0.27	0.11 J,R		0.27	45
PCB-191	NotFnd	<0.096	0.096 U			45
PCB-170	28:22	<0.19	0.14 J,R		0.19	45
PCB-190	28:39	0.0971	0.091 J			45
PCB-189	NotFnd	<0.42	0.42 U			45
PCB-202	26:16	<0.078	0.078 U		0.036	45
PCB-201	26:44	<0.11	0.11 U		0.10	45
PCB-204	NotFnd	<0.10	0.10 U			45
PCB-197	NotFnd	<0.10	0.10 U			45
PCB-200	NotFnd	<0.12	0.12 U			45
PCB-198/199	28:39	<0.15	0.15 U		0.072	45
PCB-196	29:03	<0.16	0.16 U		0.041	45
PCB-203	29:07	<0.14	0.14 U		0.035	45
PCB-195	NotFnd	<0.32	0.32 U			45
PCB-194	NotFnd	<0.30	0.30 U			45
PCB-205	NotFnd	<0.44	0.44 U			45
PCB-208	NotFnd	<1.2	1.2 U			45
PCB-207	NotFnd	<1.2	1.2 U			45
PCB-206	NotFnd	<1.9	1.9 U			45
PCB-209	33:31	1.18	0.35 J			45

Extraction Standards	ng		%	Limits
13C12-PCB-001	2000	9:11	15	25-150 R
13C12-PCB-003	2000	10:26	42	25-150
13C12-PCB-004	2000	10:35	46	25-150
13C12-PCB-015	2000	14:15	49	25-150
13C12-PCB-019	2000	12:33	49	25-150
13C12-PCB-037	2000	18:11	58	25-150
13C12-PCB-054	2000	14:24	50	25-150
13C12-PCB-081	2000	21:47	64	25-150
13C12-PCB-077	2000	22:05	67	25-150
13C12-PCB-104	2000	17:28	58	25-150
13C12-PCB-123	2000	23:05	66	25-150
13C12-PCB-118	2000	23:15	39	25-150
13C12-PCB-114	2000	23:33	67	25-150
13C12-PCB-105	2000	23:53	70	25-150
13C12-PCB-126	2000	25:29	84	25-150
13C12-PCB-155	2000	20:29	60	25-150
13C12-PCB-167	2000	26:23	93	25-150
13C12-PCB-156/157	4000	27:00	88	25-150
13C12-PCB-169	2000	28:39	79	25-150
13C12-PCB-188	2000	23:29	67	25-150
13C12-PCB-189	2000	29:55	50	25-150
13C12-PCB-202	2000	26:14	86	25-150
13C12-PCB-205	2000	31:21	84	25-150
13C12-PCB-208	2000	29:39	109	25-150
13C12-PCB-206	2000	32:23	110	25-150
13C12-PCB-209	2000	33:31	116	25-150

Cleanup Standards	ng		%	
13C12-PCB-028	2000	15:57	63	30-135
13C12-PCB-111	2000	22:02	79	30-135
13C12-PCB-178	2000	25:03	82	30-135

ALS Life Sciences

Laboratory Method Blank Analysis Report

[illegible]

Run Information

Run 1

Filename	5-150710A05
Run Date	10-Jul-15 15:48
Final Volume	45 ul
Dilution Factor	1
Analysis Units	pg/g
Instrument - Column	HRMS-5 SPB0CTYLS5800-028

Target Analytes	Ret. Time	Conc. pg/g	EDL pg/g	Flags	EMPC pg/g	LQL
Homologue Group Totals						
Total MonoCB		12.4	0.43	J		45
Total DiCB		67.8	0.35	J		45
Total TriCB		30.2	0.12	J		45
Total TetraCB		12.2	0.15	J		45
Total PentaCB		4.71	0.08	J		45
Total HexaCB		2.54	0.068	J		45
Total HeptaCB		1.02	0.081	J		45
Total OctaCB		0	0.078	U		45
Total NonaCB		0	1.2	U		45
DecaCB		1.18	0.35	J		45
Total PCB		132		J		

Toxic Equivalency - (WHO 2005)	pg/g
Lower Bound PCB TEQ (WHO 2005)	0.0365
Mid Point PCB TEQ (WHO 2005)	0.0366
Upper Bound PCB TEQ (WHO 2005)	0.0367

EDL	Indicates the Estimated Detection Limit, based on the measured background noise for this target in this sample.		
TEF	Indicates the Toxic Equivalency Factor	TEQ	Indicates the Toxic Equivalency
U	Indicates that the analyte was not detected at or above the reported estimated detection limit.		
J	Indicates that the analyte was positively identified. The associated numerical result is an estimate.		
R	Indicates that the ion abundance ratio for this analyte did not meet the control limit. The reported value represents an estimated concentration.		

ALS Life Sciences

Laboratory Control Sample Analysis Report

Sample Name ALS Sample ID	Laboratory Control Sample WG2108486-2	Sampling Date	n/a		
		Extraction Date	n/a		
Analysis Method Analysis Type	EPA 1668C LCS	Sample Size	1	n/a	
Sample Matrix	QC	Percent Moisture	n/a		
		Split Ratio	1		
					Approved: E. Sabljic --e-signature-- 17-Jul-2015

Run Information	Run 1
Filename	5-150710A03
Run Date	10-Jul-15 14:29
Final Volume	45 ul
Dilution Factor	1
Analysis Units	%
Instrument - Column	0 0

Target Analytes	ng	Ret. Time	%	Limits	Flags
PCB-001 1000		8:51	113	50-150	
PCB-002 1000					
PCB-003 1000		10:23	111	50-150	
PCB-004 1000		10:32	115	50-150	
PCB-010 1000					
PCB-009 1000					
PCB-007 1000					
PCB-006 1000					
PCB-005 1000					
PCB-008 1000					
PCB-014 1000					
PCB-011 1000					
PCB-012/013 1000					
PCB-015 1000		14:14	113	50-150	
PCB-019 1000		12:32	115	50-150	
PCB-018/030 1000					
PCB-017 1000					
PCB-027 1000					
PCB-024 1000					
PCB-016 1000					
PCB-032 1000					
PCB-034 1000					
PCB-023 1000					
PCB-026/029 1000					
PCB-025 1000					
PCB-031 1000					
PCB-020/028 1000					
PCB-021/033 1000					
PCB-022 1000					
PCB-036 1000					
PCB-039 1000					
PCB-038 1000					
PCB-035 1000					
PCB-037 1000		18:11	99	50-150	
PCB-054 1000		14:23	114	50-150	
PCB-050/053 1000					
PCB-045/051 1000					
PCB-046 1000					
PCB-052 1000					
PCB-073 1000					
PCB-043 1000					
PCB-049/069 1000					
PCB-048 1000					
PCB-044/047/065 1000					
PCB-059/062/075 1000					
PCB-042 1000					
PCB-040/041/071 1000					
PCB-064 1000					
PCB-072 1000					
PCB-068 1000					
PCB-057 1000					
PCB-058 1000					
PCB-067 1000					
PCB-063 1000					
PCB-061/070/074/076 1000					
PCB-066 1000					
PCB-055 1000					
PCB-056 1000					
PCB-060 1000					
PCB-080 1000					
PCB-079 1000					
PCB-078 1000					
PCB-081 1000		21:46	107	50-150	
PCB-077 1000		22:04	106	50-150	
PCB-104 1000		17:28	107	50-150	
PCB-096 1000					

ALS Life Sciences

Laboratory Control Sample Analysis Report

Sample Name ALS Sample ID	Laboratory Control Sample WG2108486-2	Sampling Date n/a		
Analysis Method EPA 1668C		Extraction Date n/a		
Analysis Type LCS		Sample Size 1	n/a	Approved: E. Sabljic
Sample Matrix QC		Percent Moisture n/a		--e-signature--
		Split Ratio 1		17-Jul-2015

Run Information	Run 1
Filename	5-150710A03
Run Date	10-Jul-15 14:29
Final Volume	45 ul
Dilution Factor	1
Analysis Units	%
Instrument - Column	0 0

Target Analytes	ng	Ret. Time	%	Limits	Flags
PCB-103 1000					
PCB-094 1000					
PCB-095 1000					
PCB-093/098/100/102 1000					
PCB-088/091 1000					
PCB-084 1000					
PCB-089 1000					
PCB-121 1000					
PCB-092 1000					
PCB-090/101/113 1000					
PCB-083/099 1000					
PCB-112 1000					
PCB-086/087/097/108/119/125 1000					
PCB-085/110/115/116/117 1000					
PCB-082 1000					
PCB-111 1000					
PCB-120 1000					
PCB-107/124 1000					
PCB-109 1000					
PCB-123 1000		23:03	113	50-150	
PCB-106 1000					
PCB-118 1000		23:14	110	50-150	
PCB-122 1000					
PCB-114 1000		23:31	113	50-150	
PCB-105 1000		23:52	110	50-150	
PCB-127 1000					
PCB-126 1000		25:28	112	50-150	
PCB-155 1000		20:29	109	50-150	
PCB-152 1000					
PCB-150 1000					
PCB-136 1000					
PCB-145 1000					
PCB-148 1000					
PCB-135/151 1000					
PCB-154 1000					
PCB-144 1000					
PCB-147/149 1000					
PCB-134/143 1000					
PCB-139/140 1000					
PCB-131 1000					
PCB-142 1000					
PCB-132 1000					
PCB-133 1000					
PCB-165 1000					
PCB-146 1000					
PCB-161 1000					
PCB-153/168 1000					
PCB-141 1000					
PCB-130 1000					
PCB-137/164 1000					
PCB-129/138/163 1000					
PCB-160 1000					
PCB-158 1000					
PCB-128/166 1000					
PCB-159 1000					
PCB-162 1000					
PCB-167 1000		26:22	109	50-150	
PCB-156/157 2000		26:59	109	50-150	
PCB-169 1000		28:39	108	50-150	
PCB-188 1000		23:28	108	50-150	
PCB-179 1000					
PCB-184 1000					
PCB-176 1000					
PCB-186 1000					
PCB-178 1000					
PCB-175 1000					
PCB-187 1000					

ALS Life Sciences

Laboratory Control Sample Analysis Report

Sample Name
ALS Sample ID
Laboratory Control Sample
WG2108486-2
Analysis Method
EPA 1668C
Analysis Type
LCS
Sample Matrix
QC

Sampling Date n/a
Extraction Date n/a
Sample Size 1 n/a
Percent Moisture n/a
Split Ratio 1

Approved:
E. Sabljic
--e-signature--
17-Jul-2015

Run Information

Run 1

Filename 5-150710A03
Run Date 10-Jul-15 14:29
Final Volume 45 ul
Dilution Factor 1
Analysis Units %
Instrument - Column 0 0

Target Analytes	ng	Ret. Time	%	Limits	Flags
PCB-182 1000					
PCB-183 1000					
PCB-185 1000					
PCB-174 1000					
PCB-177 1000					
PCB-181 1000					
PCB-171/173 1000					
PCB-172 1000					
PCB-192 1000					
PCB-180/193 1000					
PCB-191 1000					
PCB-170 1000					
PCB-190 1000					
PCB-189 1000		29:55	114	50-150	
PCB-202 1000		26:14	111	50-150	
PCB-201 1000					
PCB-204 1000					
PCB-197 1000					
PCB-200 1000					
PCB-198/199 1000					
PCB-196 1000					
PCB-203 1000					
PCB-195 1000					
PCB-194 1000					
PCB-205 1000		31:18	108	50-150	
PCB-208 1000		29:39	108	50-150	
PCB-207 1000					
PCB-206 1000		32:22	118	50-150	
PCB-209 1000		33:30	115	50-150	

Extraction Standards	ng		%	Limits
13C12-PCB-001 2000		8:50	30	30-140
13C12-PCB-003 2000		10:23	30	30-140
13C12-PCB-004 2000		10:31	35	30-140
13C12-PCB-015 2000		14:13	45	30-140
13C12-PCB-019 2000		12:31	42	30-140
13C12-PCB-037 2000		18:10	55	30-140
13C12-PCB-054 2000		14:22	38	30-140
13C12-PCB-081 2000		21:45	64	30-140
13C12-PCB-077 2000		22:03	68	30-140
13C12-PCB-104 2000		17:27	47	30-140
13C12-PCB-123 2000		23:03	67	30-140
13C12-PCB-118 2000		23:13	69	30-140
13C12-PCB-114 2000		23:30	68	30-140
13C12-PCB-105 2000		23:51	73	30-140
13C12-PCB-126 2000		25:27	78	30-140
13C12-PCB-155 2000		20:28	50	30-140
13C12-PCB-167 2000		26:21	82	30-140
13C12-PCB-156/157 4000		26:58	81	30-140
13C12-PCB-169 2000		28:38	89	30-140
13C12-PCB-188 2000		23:27	65	30-140
13C12-PCB-189 2000		29:54	81	30-140
13C12-PCB-202 2000		26:13	73	30-140
13C12-PCB-205 2000		31:17	91	30-140
13C12-PCB-208 2000		29:38	82	30-140
13C12-PCB-206 2000		32:22	90	30-140
13C12-PCB-209 2000		33:29	78	30-140

Cleanup Standards	ng		%	Limits
13C12-PCB-028 2000		15:56	58	40-125
13C12-PCB-111 2000		21:59	74	40-125
13C12-PCB-178 2000		25:01	76	40-125

Koster Keunen Inc.

Report Date: July 30, 2015

1021 Echo Lake Road
Watertown, CT 06795

ANALYTICAL REPORT

Sample ID : B#20033

Matrix: RICE BRAN WAX 224P

Date Received: July 15, 2015

Lab ID #: AB82050

Chemical Residue

Analyte	Result	Units	LOQ
1 2,4-Dichlorobenzophenone	ND	ppm	0.02
2 2,6-Diisopropyl naphthalene	ND	ppm	0.04
3 4,4-Dichlorobenzophenone	ND	ppm	0.02
4 Abamectin	ND	ppm	0.05
5 Acephate	ND	ppm	0.1
6 Acetamiprid	ND	ppm	0.05
7 Acetochlor	ND	ppm	0.02
8 Acibenzolar-S-methyl	ND	ppm	0.05
9 Acrinathrin	ND	ppm	0.02
10 Alachlor	ND	ppm	0.02
11 Aldicarb	ND	ppm	0.05
12 Aldicarb-sulfone	ND	ppm	0.05
13 Aldicarb-sulfoxide	ND	ppm	0.1
14 Aldrin	ND	ppm	0.02
15 Allethrin	ND	ppm	0.2
16 Ametryn	ND	ppm	0.05
17 Amitraz	ND	ppm	0.05
18 Anilofos	ND	ppm	0.05
19 Atrazine	ND	ppm	0.02
20 Azaconazole	ND	ppm	0.02
21 Azamethiphos	ND	ppm	0.05
22 Azinphos-ethyl	ND	ppm	0.05
23 Azinphos-methyl	ND	ppm	0.05
24 Azoxystrobin	ND	ppm	0.05
25 Benalaxyl	ND	ppm	0.02
26 Bendiocarb	ND	ppm	0.05
27 Benfluralin	ND	ppm	0.02
28 Benfuresate	ND	ppm	0.02
29 Benomyl (as Carbendazim)	ND	ppm	0.05
30 Benoxacor	ND	ppm	0.02
31 Bensulide	ND	ppm	0.05
32 Bentazone	ND	ppm	0.02

Negative = < 10 CFU/g; CFU=Colony Forming Unit; ppb=parts per billion (mcg/Kg or mcg/L); ppm=parts per million (mg/Kg or mg/L)
LOQ= Limit of Quantification; ND=Not Detected; N/A=Not Applicable; Trace=Qualitative result < LOQ; * = Analysis subcontracted

ANALYTICAL REPORT

33	Benzobicyclon	ND	ppm	0.05
34	Benzofenap	ND	ppm	0.05
35	Benzyladenine	ND	ppm	0.05
36	BHC (alpha)	ND	ppm	0.02
37	BHC (beta)	ND	ppm	0.02
38	BHC (delta)	ND	ppm	0.02
39	Bifenazate	ND	ppm	0.05
40	Bifenox	ND	ppm	0.02
41	Bifenthrin	ND	ppm	0.02
42	Bioresmethrin (as Resmethrin)	ND	ppm	0.1
43	Bitertanol	ND	ppm	0.05
44	Boscalid	ND	ppm	0.02
45	Bromobutide	ND	ppm	0.02
46	Bromophos-ethyl	ND	ppm	0.05
47	Bromophos-methyl	ND	ppm	0.05
48	Bromopropylate	ND	ppm	0.02
49	Bupirimate	ND	ppm	0.02
50	Buprofezin	ND	ppm	0.02
51	Butachlor	ND	ppm	0.02
52	Butafenacil	ND	ppm	0.02
53	Butamifos	ND	ppm	0.05
54	Butralin	ND	ppm	0.02
55	Butylate	ND	ppm	0.02
56	Cadusafos	ND	ppm	0.05
57	Cafenstrole	ND	ppm	0.05
58	Captan	ND	ppm	0.1
59	Carbaryl	ND	ppm	0.05
60	Carbendazim	ND	ppm	0.05
61	Carbofuran	ND	ppm	0.05
62	Carbophenothion	ND	ppm	0.05
63	Carboxin	ND	ppm	0.02
64	Carfentrazone-ethyl	ND	ppm	0.02
65	Carpopamid	ND	ppm	0.02
66	Chlorantraniliprole	ND	ppm	0.05
67	Chlorbenside	ND	ppm	0.02
68	Chlorbufam	ND	ppm	0.02
69	Chlordane (cis)	ND	ppm	0.02
70	Chlordane (trans)	ND	ppm	0.02
71	Chlorethoxyfos	ND	ppm	0.02
72	Chlorfenapyr	ND	ppm	0.02
73	Chlorfenson	ND	ppm	0.02
74	Chlorfenvinphos	ND	ppm	0.05
75	Chloridazon	ND	ppm	0.05
76	Chlornitrofen	ND	ppm	0.02
77	Chlorobenzilate	ND	ppm	0.02
78	Chloroneb	ND	ppm	0.02
79	Chloroxuron	ND	ppm	0.05
80	Chlorpropham	ND	ppm	0.02
81	Chlorpyrifos	ND	ppm	0.05
82	Chlorpyrifos-methyl	ND	ppm	0.05
83	Chlorthal-dimethyl	ND	ppm	0.02
84	Chlorthiofos	ND	ppm	0.05
85	Chlozolinate	ND	ppm	0.02
86	Chromafenozide	ND	ppm	0.05

Negative = < 10 CFU/g; CFU=Colony Forming Unit; ppb=parts per billion (mcg/Kg or mcg/L); ppm=parts per million (mg/Kg or mg/L)
 LOQ= Limit of Quantification; ND=Not Detected; N/A=Not Applicable; Trace=Qualitative result < LOQ; * = Analysis subcontracted

ANALYTICAL REPORT

87	Cinidon-ethyl	ND	ppm	0.05
88	Cinmethylin	ND	ppm	0.02
89	Clethodim	ND	ppm	0.02
90	Clodinafop-propargyl	ND	ppm	0.05
91	Clofentezine	ND	ppm	0.05
92	Clomazone	ND	ppm	0.02
93	Clomeprop	ND	ppm	0.05
94	Cloquintocet-mexyl	ND	ppm	0.05
95	Clothianidin	ND	ppm	0.05
96	CPMC (Etofol)	ND	ppm	0.05
97	Cumyluron	ND	ppm	0.05
98	Cyanazine	ND	ppm	0.05
99	Cyanophenphos	ND	ppm	0.05
100	Cyanophos	ND	ppm	0.05
101	Cyazofamid	ND	ppm	0.05
102	Cycloate	ND	ppm	0.02
103	Cyflufenamid	ND	ppm	0.02
104	Cyfluthrin	ND	ppm	0.02
105	Cyhalofop-butyl	ND	ppm	0.02
106	Cyhalothrin (gamma)	ND	ppm	0.02
107	Cyhalothrin (lambda)	ND	ppm	0.02
108	Cymoxanil	ND	ppm	0.05
109	Cypermethrin	ND	ppm	0.02
110	Cyproconazole	ND	ppm	0.02
111	Cyprodinil	ND	ppm	0.05
112	Daimuron	ND	ppm	0.05
113	DDD	ND	ppm	0.02
114	DDE	ND	ppm	0.02
115	DDT	ND	ppm	0.02
116	Deltamethrin	ND	ppm	0.02
117	Demeton O & S	ND	ppm	0.05
118	Demeton-S-methyl	ND	ppm	0.05
119	Desmedipham	ND	ppm	0.1
120	Diafenthiuron	N/A	ppm	0.1
121	Dialifos	ND	ppm	0.05
122	Di-allate	ND	ppm	0.02
123	Diazinon	ND	ppm	0.05
124	Dichlobenil	ND	ppm	0.02
125	Dichlofenthion (ECP)	ND	ppm	0.05
126	Dichlofluanid	ND	ppm	0.02
127	Dichlormid	ND	ppm	0.02
128	Dichlorvos	ND	ppm	0.05
129	Diclobutrazol	ND	ppm	0.05
130	Diclocymet	ND	ppm	0.02
131	Diclofop-methyl	ND	ppm	0.02
132	Diclomezine	ND	ppm	0.05
133	Dicloran	ND	ppm	0.02
134	Dicrotophos	ND	ppm	0.05
135	Dieldrin	ND	ppm	0.02
136	Diethofencarb	ND	ppm	0.02
137	Difenoconazole	ND	ppm	0.02
138	Difenzoquat	ND	ppm	0.05
139	Diffubenzuron	ND	ppm	0.05
140	Diffufenican	ND	ppm	0.02

Negative = < 10 CFU/g; CFU=Colony Forming Unit; ppb=parts per billion (mcg/Kg or mcg/L); ppm=parts per million (mg/Kg or mg/L)
 LOQ= Limit of Quantification; ND=Not Detected; N/A=Not Applicable; Trace=Qualitative result < LOQ; * = Analysis subcontracted

ANALYTICAL REPORT

141	Dimepiperate	ND	ppm	0.02
142	Dimethametryn	ND	ppm	0.05
143	Dimethenamid	ND	ppm	0.02
144	Dimethoate	ND	ppm	0.05
145	Dimethylvinphos	ND	ppm	0.05
146	Diniconazole	ND	ppm	0.05
147	Dinotefuran	ND	ppm	0.05
148	Dioxathion	ND	ppm	0.05
149	Diphenamid	ND	ppm	0.02
150	Diphenylamine	ND	ppm	0.02
151	Disulfoton	ND	ppm	0.02
152	Disulfoton-sulfone	ND	ppm	0.02
153	Dithiopyr	ND	ppm	0.02
154	Diuron	ND	ppm	0.05
155	Edifenphos	ND	ppm	0.05
156	Emamectin-benzoate	ND	ppm	0.05
157	Endosulfan (alpha)	ND	ppm	0.02
158	Endosulfan (beta)	ND	ppm	0.02
159	Endosulfan-sulfate	ND	ppm	0.04
160	Endrin	ND	ppm	0.02
161	EPN	ND	ppm	0.05
162	Epoxiconazole	ND	ppm	0.02
163	EPTC	ND	ppm	0.02
164	Esfenvalerate	ND	ppm	0.04
165	Esprocarb	ND	ppm	0.02
166	Ethalfuralin	ND	ppm	0.02
167	Ethion	ND	ppm	0.05
168	Ethiprole	ND	ppm	0.05
169	Ethofumesate	ND	ppm	0.02
170	Ethoprophos	ND	ppm	0.025
171	Ethoxyquin	N/A	ppm	0.1
172	Ethychlozate	ND	ppm	0.05
173	Etobenzanid	ND	ppm	0.02
174	Etofenprox	ND	ppm	0.02
175	Etoxazole	ND	ppm	0.02
176	Etridiazole	ND	ppm	0.02
177	Etrimfos	ND	ppm	0.05
178	Famphur	ND	ppm	0.02
179	Fenamidone	ND	ppm	0.02
180	Fenamiphos	ND	ppm	0.05
181	Fenamiphos-sulfone	ND	ppm	0.05
182	Fenarimol	ND	ppm	0.02
183	Fenbuconazole	ND	ppm	0.05
184	Fenchlorphos	ND	ppm	0.05
185	Fenhexamid	ND	ppm	0.05
186	Fenitrothion	ND	ppm	0.05
187	Fenobucarb	ND	ppm	0.05
188	Fenothiocarb	ND	ppm	0.05
189	Fenoxanil	ND	ppm	0.05
190	Fenoxaprop-ethyl	ND	ppm	0.02
191	Fenoxycarb	ND	ppm	0.05
192	Fenpropathrin	ND	ppm	0.02
193	Fenpropimorph	ND	ppm	0.02
194	Fenpyroximate	ND	ppm	0.05

Negative = < 10 CFU/g; CFU=Colony Forming Unit; ppb=parts per billion (mcg/Kg or mcg/L); ppm=parts per million (mg/Kg or mg/L)
 LOQ= Limit of Quantification; ND=Not Detected; N/A=Not Applicable; Trace=Qualitative result < LOQ; * = Analysis subcontracted

ANALYTICAL REPORT

195	Fensulfothion	ND	ppm	0.05
196	Fenthion	ND	ppm	0.05
197	Fentrazamide	ND	ppm	0.05
198	Fenvalerate	ND	ppm	0.04
199	Ferimzone E	ND	ppm	0.05
200	Ferimzone Z	ND	ppm	0.05
201	Fipronil	ND	ppm	0.01
202	Flamprop-methyl	ND	ppm	0.02
203	Fluacrypyrim	ND	ppm	0.05
204	Fluazifop-butyl	ND	ppm	0.02
205	Fluazinam	ND	ppm	0.05
206	Flucythrinate	ND	ppm	0.02
207	Fludioxonil	ND	ppm	0.05
208	Flufenacet	ND	ppm	0.02
209	Fluometuron	ND	ppm	0.05
210	Fluquinconazole	ND	ppm	0.02
211	Fluridone	ND	ppm	0.05
212	Flusilazole	ND	ppm	0.02
213	Flusulfamide	ND	ppm	0.05
214	Fluthiacet-methyl	ND	ppm	0.05
215	Flutolanil	ND	ppm	0.02
216	Flutriafol	ND	ppm	0.05
217	Fluvalinate	0.03	ppm	0.02
218	Fonofos	ND	ppm	0.05
219	Forchlorfenuron	ND	ppm	0.05
220	Fosthiazate	ND	ppm	0.05
221	Fthalide	ND	ppm	0.02
222	Furametpyr	ND	ppm	0.02
223	Furathiocarb	ND	ppm	0.05
224	Furilazole	ND	ppm	0.02
225	Halfenprox	ND	ppm	0.02
226	Haloxyfop	ND	ppm	0.01
227	Haloxyfop-methyl	ND	ppm	0.02
228	Heptachlor	ND	ppm	0.02
229	Heptachlor-epoxide	ND	ppm	0.02
230	Hexachlorobenzene	ND	ppm	0.02
231	Hexaconazole	ND	ppm	0.05
232	Hexazinone	ND	ppm	0.02
233	Hexythiazox	ND	ppm	0.05
234	Imazalil	ND	ppm	0.05
235	Imazamethabenz-methyl-ester	ND	ppm	0.05
236	Imibenconazole	ND	ppm	0.05
237	Imidacloprid	ND	ppm	0.05
238	Inabenfide	ND	ppm	0.05
239	Indoxacarb	ND	ppm	0.05
240	Iprobenfos	ND	ppm	0.05
241	Iprodione	ND	ppm	0.05
242	Iprovalicarb	ND	ppm	0.05
243	Isazophos	ND	ppm	0.05
244	Isocarbophos	ND	ppm	0.05
245	Isofenphos	ND	ppm	0.05
246	Isofenphos-methyl	ND	ppm	0.05
247	Isoproc carb	ND	ppm	0.05
248	Isoprothiolane	ND	ppm	0.02

Negative = < 10 CFU/g; CFU=Colony Forming Unit; ppb=parts per billion (mcg/Kg or mcg/L); ppm=parts per million (mg/Kg or mg/L)
 LOQ= Limit of Quantification; ND=Not Detected; N/A=Not Applicable; Trace=Qualitative result < LOQ; * = Analysis subcontracted

ANALYTICAL REPORT

249	Isotianil	ND	ppm	0.02
250	Isouron	ND	ppm	0.05
251	Isoxadifen-ethyl	ND	ppm	0.02
252	Isoxaflutole	ND	ppm	0.05
253	Isoxathion	ND	ppm	0.05
254	Kresoxim-methyl	ND	ppm	0.02
255	Lenacil	ND	ppm	0.05
256	Lindane	ND	ppm	0.02
257	Linuron	ND	ppm	0.05
258	Malathion	ND	ppm	0.05
259	Mandipropamid	ND	ppm	0.05
260	Mecarbam	ND	ppm	0.05
261	Mefenacet	ND	ppm	0.05
262	Mefenpyr-Diethyl	ND	ppm	0.05
263	Mepanipyrim	ND	ppm	0.02
264	Mephosfolan	ND	ppm	0.05
265	Mepronil	ND	ppm	0.02
266	Metaxyl	ND	ppm	0.02
267	Metconazole	ND	ppm	0.02
268	Methabenzthiazuron	ND	ppm	0.05
269	Methacrifos	ND	ppm	0.05
270	Methamidophos	ND	ppm	0.05
271	Methidathion	ND	ppm	0.05
272	Methiocarb	ND	ppm	0.05
273	Methomyl	ND	ppm	0.05
274	Methoprene	ND	ppm	0.02
275	Methoxychlor	ND	ppm	0.02
276	Methoxyfenozide	ND	ppm	0.05
277	Metolachlor	ND	ppm	0.02
278	Metominostrobin	ND	ppm	0.02
279	Metribuzin	ND	ppm	0.02
280	Mevinphos	ND	ppm	0.05
281	Mirex	ND	ppm	0.02
282	Molinate	ND	ppm	0.02
283	Monocrotophos	ND	ppm	0.05
284	Monolinuron	ND	ppm	0.05
285	Myclobutanil	ND	ppm	0.02
286	Naled (screened as Dichlorvos)	ND	ppm	0.05
287	Naproanilide	ND	ppm	0.02
288	Napropamide	ND	ppm	0.02
289	Nitenpyram	ND	ppm	0.05
290	Nitrofen	ND	ppm	0.02
291	Nitrothal-isopropyl	ND	ppm	0.02
292	Norflurazon	ND	ppm	0.02
293	Novaluron	ND	ppm	0.05
294	Ofurace	ND	ppm	0.05
295	Omethoate	ND	ppm	0.05
296	o-Phenylphenol	ND	ppm	0.1
297	Orysastrobin	ND	ppm	0.02
298	Oryzalin	ND	ppm	0.05
299	Oxadiazon	ND	ppm	0.02
300	Oxadixyl	ND	ppm	0.1
301	Oxamyl	ND	ppm	0.05
302	Oxaziclomefone	ND	ppm	0.05

Negative = < 10 CFU/g; CFU=Colony Forming Unit; ppb=parts per billion (mcg/Kg or mcg/L); ppm=parts per million (mg/Kg or mg/L)
 LOQ= Limit of Quantification; ND=Not Detected; N/A=Not Applicable; Trace=Qualitative result < LOQ; * = Analysis subcontracted

ANALYTICAL REPORT

303	Oxpoconazole-fumarate	ND	ppm	0.1
304	Oxycarboxin	ND	ppm	0.05
305	Oxydemeton-methyl	ND	ppm	0.05
306	Oxyfluorfen	ND	ppm	0.02
307	Paclobutrazol	ND	ppm	0.02
308	Parathion	ND	ppm	0.05
309	Parathion-methyl	ND	ppm	0.05
310	Pebulate	ND	ppm	0.02
311	Penconazole	ND	ppm	0.02
312	Pencycuron	ND	ppm	0.05
313	Pendimethalin	ND	ppm	0.02
314	Pentoxazone	ND	ppm	0.02
315	Permethrin	ND	ppm	0.02
316	Perthane	ND	ppm	0.02
317	Phenmedipham	ND	ppm	0.05
318	Phenothiol	ND	ppm	0.02
319	Phenothrin	ND	ppm	0.02
320	Phenthoate	ND	ppm	0.05
321	Phorate	ND	ppm	0.05
322	Phorate-sulfone	ND	ppm	0.05
323	Phosalone	ND	ppm	0.05
324	Phosmet	ND	ppm	0.05
325	Phosphamidon	ND	ppm	0.05
326	Phoxim	ND	ppm	0.05
327	Picolinafen	ND	ppm	0.05
328	Piperonyl-butoxide	ND	ppm	0.02
329	Piperophos	ND	ppm	0.05
330	Pirimicarb	ND	ppm	0.02
331	Pirimioxyphos	ND	ppm	0.05
332	Pirimiphos-ethyl	ND	ppm	0.05
333	Pirimiphos-methyl	ND	ppm	0.05
334	Pretilachlor	ND	ppm	0.02
335	Prochloraz	ND	ppm	0.02
336	Procymidone	ND	ppm	0.02
337	Profenofos	ND	ppm	0.05
338	Prohydrojasmon	ND	ppm	0.1
339	Prometryn	ND	ppm	0.02
340	Propachlor	ND	ppm	0.02
341	Propanil	ND	ppm	0.02
342	Propaphos	ND	ppm	0.05
343	Propargite	ND	ppm	0.05
344	Propazine	ND	ppm	0.02
345	Propetamphos	ND	ppm	0.05
346	Propiconazole	ND	ppm	0.02
347	Propoxur	ND	ppm	0.05
348	Propyzamide	ND	ppm	0.05
349	Prothiofos	ND	ppm	0.05
350	Pyraclufos	ND	ppm	0.05
351	Pyraclonil	ND	ppm	0.02
352	Pyraclostrobin	ND	ppm	0.05
353	Pyraflufen-ethyl	ND	ppm	0.02
354	Pyrazolynate	ND	ppm	0.05
355	Pyrazophos	ND	ppm	0.05
356	Pyrazoxyfen	ND	ppm	0.05

Negative = < 10 CFU/g; CFU=Colony Forming Unit; ppb=parts per billion (mcg/Kg or mcg/L); ppm=parts per million (mg/Kg or mg/L)
 LOQ= Limit of Quantification; ND=Not Detected; N/A=Not Applicable; Trace=Qualitative result < LOQ; * = Analysis subcontracted

ANALYTICAL REPORT

357	Pyrethrins	ND	ppm	0.25
358	Pyributicarb	ND	ppm	0.02
359	Pyridaben	ND	ppm	0.02
360	Pyridafenthion	ND	ppm	0.05
361	Pyrifenox	ND	ppm	0.02
362	Pyriftalid	ND	ppm	0.05
363	Pyrimethanil	ND	ppm	0.02
364	Pyrimidifen	ND	ppm	0.02
365	Pyriminobac-methyl	ND	ppm	0.02
366	Pyriproxyfen	ND	ppm	0.02
367	Pyroquilon	ND	ppm	0.02
368	Quinalphos	ND	ppm	0.05
369	Quinoclamine	ND	ppm	0.05
370	Quinoxifen	ND	ppm	0.05
371	Quintozene	ND	ppm	0.02
372	Quizalofop-ethyl	ND	ppm	0.02
373	Salithion	ND	ppm	0.05
374	Sethoxydim	ND	ppm	0.05
375	Silafluofen	ND	ppm	0.02
376	Simazine	ND	ppm	0.02
377	Simeconazole	ND	ppm	0.05
378	Simetryn	ND	ppm	0.02
379	Spinosad	ND	ppm	0.05
380	Spiromesifen	ND	ppm	0.1
381	Sulfotep	ND	ppm	0.05
382	Sulprofos	ND	ppm	0.05
383	TCMTB	ND	ppm	0.05
384	Tebuconazole	ND	ppm	0.02
385	Tebufenozide	ND	ppm	0.1
386	Tebufenpyrad	ND	ppm	0.02
387	Tebupirimfos	ND	ppm	0.05
388	Tebuthiuron	ND	ppm	0.05
389	Tecnazene	ND	ppm	0.02
390	Tefluthrin	ND	ppm	0.02
391	Terbacil	ND	ppm	0.05
392	Terbufos	ND	ppm	0.05
393	Terbutryn	ND	ppm	0.02
394	Tetraclorvinphos	ND	ppm	0.05
395	Tetraconazole	ND	ppm	0.02
396	Tetradifon	ND	ppm	0.02
397	Tetrahydrophthalimide	ND	ppm	0.1
398	Tetramethrin	ND	ppm	0.02
399	Thenylchlor	ND	ppm	0.02
400	Thiabendazole	ND	ppm	0.05
401	Thiacloprid	ND	ppm	0.05
402	Thiamethoxam	ND	ppm	0.05
403	Thiazopyr	ND	ppm	0.02
404	Thidiazuron	ND	ppm	0.05
405	Thifluzamide	ND	ppm	0.02
406	Thiobencarb	ND	ppm	0.02
407	Thiometon	ND	ppm	0.02
408	Tiadinil	ND	ppm	0.05
409	Tolclofos-methyl	ND	ppm	0.05
410	Tralomethrin	ND	ppm	0.02

Negative = < 10 CFU/g; CFU=Colony Forming Unit; ppb=parts per billion (mcg/Kg or mcg/L); ppm=parts per million (mg/Kg or mg/L)
 LOQ= Limit of Quantification; ND=Not Detected; N/A=Not Applicable; Trace=Qualitative result < LOQ; * = Analysis subcontracted

ANALYTICAL REPORT

411	Triadimefon	ND	ppm	0.02
412	Triadimenol	ND	ppm	0.05
413	Tri-allate	ND	ppm	0.02
414	Triazophos	ND	ppm	0.05
415	Tribuphos	ND	ppm	0.05
416	Trichlamide	ND	ppm	0.02
417	Trichlorfon	ND	ppm	0.05
418	Tricyclazole	ND	ppm	0.05
419	Tridiphane	ND	ppm	0.02
420	Trifloxystrobin	ND	ppm	0.05
421	Triflumizole	ND	ppm	0.02
422	Triflumuron	ND	ppm	0.05
423	Trifluralin	ND	ppm	0.02
424	Triforine	ND	ppm	0.05
425	Triticonazole	ND	ppm	0.05
426	Uniconazole-P	ND	ppm	0.05
427	Vinclozolin	ND	ppm	0.02
428	XMC	ND	ppm	0.05
429	Xylylcarb	ND	ppm	0.05
430	Zoxamide	ND	ppm	0.05

Persistent Organic Pollutants

Analyte	Result
1 **Dioxins / Furans / WHO-12 PCBs	Complete - see attached eurofins Analysis Report

Microbiological Tests

Analyte	Result	Units
1 Aerobic Plate Count (APC)	< 10	CFU/g
2 Coliform, Plate Count	<10	CFU/g
3 E Coli, Plate Count	<10	CFU/g
4 Listeria Genus (by PCR)	Negative	
5 Mold	<10	CFU/g
6 Salmonella (by PCR)	Negative	
7 Yeast	<10	CFU/g

Minerals / Metals Screen

Analyte	Result	Units	LOQ
1 Arsenic	ND	ppb	10
2 Cadmium	ND	ppb	10
3 Lead	ND	ppb	10
4 Mercury	ND	ppb	5

Mycotoxins Screen

Analyte	Result	Units	LOQ
1 Aflatoxin B1	ND	ppb	5
2 Aflatoxin B2	ND	ppb	5
3 Aflatoxin G1	ND	ppb	5
4 Aflatoxin G2	ND	ppb	5

**This analysis is outside the scope of OMIC USA operations and has been subcontracted to eurofins laboratory. Their report analysis is attached in its entirety. OMIC USA assumes no responsibility for its interpretations or use.

Negative = < 10 CFU/g; CFU=Colony Forming Unit; ppb=parts per billion (mcg/Kg or mcg/L); ppm=parts per million (mg/Kg or mg/L)
LOQ= Limit of Quantification; ND=Not Detected; N/A=Not Applicable; Trace=Qualitative result < LOQ; * = Analysis subcontracted

ANALYTICAL REPORT

PAH'S Screen

Analyte	Result	Units	LOQ
1 *Acenaphthene	ND	ppm	43
2 *Acenaphthylene	ND	ppm	38
3 *Anthracene	ND	ppm	65
4 *Benz(a)anthracene	ND	ppm	49
5 *Benzo(a)pyrene	ND	ppm	32
6 *Benzo(b)fluoranthene	ND	ppm	38
7 *Benzo(g,h,i)perylene	ND	ppm	38
8 *Benzo(k)fluoranthene	ND	ppm	38
9 *Chrysene	ND	ppm	32
10 *Dibenzo(a,h)anthracene	ND	ppm	54
11 *Flouranthene	ND	ppm	43
12 *Fluorene	ND	ppm	70
13 *Indeno((1,2,3-cd)pyrene	ND	ppm	49
14 *Napthalene	ND	ppm	43
15 *Phenanthrene	ND	ppm	38
16 *Pyrene	ND	ppm	32

Solvent Screen

Analyte	Result	Units	LOQ
1 Hexane	ND	ppb	10

Negative = < 10 CFU/g; CFU=Colony Forming Unit; ppb=parts per billion (mcg/Kg or mcg/L); ppm=parts per million (mg/Kg or mg/L)
LOQ= Limit of Quantification; ND=Not Detected; N/A=Not Applicable; Trace=Qualitative result < LOQ; * = Analysis subcontracted

Sample Description: AB82050 RICE BRAN WAX Composite Solid
Rice Bran Wax

LL Sample # G5 7968745
LL Group # 1577323
Account # 30091

Project Name: Rice Bran Wax

Collected: 07/15/2015 13:45 by DF

OMIC USA Inc.

3344 NW Industrial St
Portland OR

Submitted: 07/16/2015 09:45

Reported: 07/28/2015 15:28

CAT No.	Analysis Name	CAS Number	As Received Result	As Received EDL	Dilution Factor
Dioxins/Furans EPA 1613B modified					
12963	2378-TCDD	1746-01-6	< 0.155	0.155	1
12963	2378-TCDF	51207-31-9	< 0.102	0.102	1
12963	12378-PeCDD	40321-76-4	< 0.117	0.117	1
12963	12378-PeCDF	57117-41-6	< 0.0701	0.0701	1
12963	23478-PeCDF	57117-31-4	< 0.0638	0.0638	1
12963	123478-HxCDD	39227-28-6	< 0.0605	0.0605	1
12963	123678-HxCDD	57653-85-7	< 0.0652	0.0652	1
12963	123789-HxCDD	19408-74-3	< 0.0729	0.0729	1
12963	123478-HxCDF	70648-26-9	< 0.0547	0.0547	1
12963	123678-HxCDF	57117-44-9	< 0.0565	0.0565	1
12963	123789-HxCDF	72918-21-9	< 0.0653	0.0653	1
12963	234678-HxCDF	60851-34-5	< 0.0554	0.0554	1
12963	1234678-HpCDD	35822-46-9	< 0.0776	0.0776	1
12963	1234678-HpCDF	67562-39-4	< 0.0368	0.0368	1
12963	1234789-HpCDF	55673-89-7	< 0.0494	0.0494	1
12963	OCDD	3268-87-9	0.377	0.108	1
12963	OCDF	39001-02-0	< 0.172	0.172	1
D/F Toxic Equivalents EPA 1613B modified					
12963	WHO2005 PCDD/F TEQ Lower Bound	n.a.	0.000113		1
12963	WHO2005 PCDD/F TEQ Upper Bound	n.a.	0.349		1
WHO 12 PCBs EPA 1668 modified					
12942	PCB77	32598-13-3	< 0.165	0.165	1
12942	PCB81	70362-50-4	0.395	0.179	1
12942	PCB105	32598-14-4	3.28	0.169	1
12942	PCB114	74472-37-0	0.449	0.204	1
12942	PCB118	31508-00-6	10.3	0.167	1
12942	PCB123	65510-44-3	< 0.167	0.167	1
12942	PCB126	57465-28-8	< 0.171	0.171	1
12942	PCB156	38380-08-4	< 0.144	0.144	1
12942	PCB157	69782-90-7	< 0.126	0.126	1
12942	PCB167	52663-72-6	< 0.170	0.170	1
12942	PCB169	32774-16-6	< 0.120	0.120	1
12942	PCB189	39635-31-9	< 0.0855	0.0855	1
PCB Toxic Equivalents EPA 1668 modified					
12942	TEQ PCB WHO 2005 -EDLx0.0	n.a.	0.000538		1
12942	TEQ PCB WHO 2005 -EDLx1.0	n.a.	0.0212		1

General Sample Comments

WHO(2005)-PCDD/F + DLPCB TEQ (lower-bound) = 0.000654 pg/g
WHO(2005)-PCDD/F + DLPCB TEQ (upper-bound) = 0.370 pg/g

Sample Description: AB82050 RICE BRAN WAX Composite Solid
Rice Bran Wax

LL Sample # G5 7968745
LL Group # 1577323
Account # 30091

Project Name: Rice Bran Wax

Collected: 07/15/2015 13:45 by DF

OMIC USA Inc.

Submitted: 07/16/2015 09:45

3344 NW Industrial St
Portland OR

Reported: 07/28/2015 15:28

Laboratory Sample Analysis Record

CAT No.	Analysis Name	Method	Trial#	Batch#	Analysis Date and Time	Analyst	Dilution Factor
12963	Solid Dioxins and Furans	EPA 1613B modified	1	15204005	07/23/2015 21:56	Michael A Ziegler	1
12942	Solid WHO12 + 6 Indicators	EPA 1668 modified	1	15204005	07/23/2015 20:32	Michael A Ziegler	1
12961	Dioxins/Furans/PCBs in Oil	EPA 1613B modified	2	15204005	07/23/2015 08:10	Deborah M Zimmerman	1

The following defines common symbols and abbreviations used in reporting technical data:

RL	Reporting Limit	BMQL	Below Minimum Quantitation Level
N.D.	none detected	MPN	Most Probable Number
TNTC	Too Numerous To Count	CP Units	cobalt-chloroplatinate units
IU	International Units	NTU	nephelometric turbidity units
umhos/cm	micromhos/cm	ng	nanogram(s)
C	degrees Celsius	F	degrees Fahrenheit
meq	milliequivalents	lb.	pound(s)
g	gram(s)	kg	kilogram(s)
µg	microgram(s)	mg	milligram(s)
mL	milliliter(s)	L	liter(s)
m3	cubic meter(s)	µL	microliter(s)
		pg/L	picogram/liter
<	less than		
>	greater than		
ppm	parts per million - One ppm is equivalent to one milligram per kilogram (mg/kg) or one gram per million grams. For aqueous liquids, ppm is usually taken to be equivalent to milligrams per liter (mg/l), because one liter of water has a weight very close to a kilogram. For gases or vapors, one ppm is equivalent to one microliter per liter of gas.		
ppb	parts per billion		
Dry weight basis	Results printed under this heading have been adjusted for moisture content. This increases the analyte weight concentration to approximate the value present in a similar sample without moisture. All other results are reported on an as-received basis.		

Laboratory Data Qualifiers:

- B - Analyte detected in the blank
- C - Result confirmed by reanalysis
- E - Concentration exceeds the calibration range
- J (or G, I, X) - estimated value \geq the Method Detection Limit (MDL or DL) and the $<$ Limit of Quantitation (LOQ or RL)
- P - Concentration difference between the primary and confirmation column $>40\%$. The lower result is reported.
- U - Analyte was not detected at the value indicated
- V - Concentration difference between the primary and confirmation column $>100\%$. The reporting limit is raised due to this disparity and evident interference...

Additional Organic and Inorganic CLP qualifiers may be used with Form 1 reports as defined by the CLP methods. Qualifiers specific to Dioxin/Furans and PCB Congeners are detailed on the individual Analysis Report.

Analytical test results meet all requirements of the associated regulatory program (i.e., NELAC (TNI), DoD, ISO17025) unless otherwise noted under the individual analysis.

Measurement uncertainty values, as applicable, are available upon request.

Tests results relate only to the sample tested. Clients should be aware that a critical step in a chemical or microbiological analysis is the collection of the sample. Unless the sample analyzed is truly representative of the bulk of material involved, the test results will be meaningless. If you have questions regarding the proper techniques of collecting samples, please contact us. We cannot be held responsible for sample integrity, however, unless sampling has been performed by a member of our staff.

This report shall not be reproduced except in full, without the written approval of the laboratory.

Times are local to the area of activity. Parameters listed in the 40 CFR Part 136 Table II as "analyze immediately" are not performed within 15 minutes.

WARRANTY AND LIMITS OF LIABILITY - In accepting analytical work, we warrant the accuracy of test results for the sample as submitted. THE FOREGOING EXPRESS WARRANTY IS EXCLUSIVE AND IS GIVEN IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED. WE DISCLAIM ANY OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING A WARRANTY OF FITNESS FOR PARTICULAR PURPOSE AND WARRANTY OF MERCHANTABILITY. IN NO EVENT SHALL EUROFINS LANCASTER LABORATORIES ENVIRONMENTAL, LLC BE LIABLE FOR INDIRECT, SPECIAL, CONSEQUENTIAL, OR INCIDENTAL DAMAGES INCLUDING, BUT NOT LIMITED TO, DAMAGES FOR LOSS OF PROFIT OR GOODWILL REGARDLESS OF (A) THE NEGLIGENCE (EITHER SOLE OR CONCURRENT) OF EUROFINS LANCASTER LABORATORIES ENVIRONMENTAL AND (B) WHETHER EUROFINS LANCASTER LABORATORIES ENVIRONMENTAL HAS BEEN INFORMED OF THE POSSIBILITY OF SUCH DAMAGES. We accept no legal responsibility for the purposes for which the client uses the test results. No purchase order or other order for work shall be accepted by Eurofins Lancaster Laboratories Environmental which includes any conditions that vary from the Standard Terms and Conditions, and Eurofins Lancaster Laboratories Environmental hereby objects to any conflicting terms contained in any acceptance or order submitted by client.

Koster Keunen Inc.

Report Date: July 28, 2015

1021 Echo Lake Road
Watertown, CT 06795

ANALYTICAL REPORT

Sample ID : B#20048

Matrix: RICE BRAN WAX 224P

Date Received: July 06, 2015

Lab ID #: AB81761

Chemical Residue

Analyte	Result	Units	LOQ
1 2,4-Dichlorobenzophenone	ND	ppm	0.02
2 2,6-Diisopropylnaphthalene	ND	ppm	0.04
3 4,4-Dichlorobenzophenone	ND	ppm	0.02
4 Abamectin	ND	ppm	0.05
5 Acephate	ND	ppm	0.1
6 Acetamiprid	ND	ppm	0.05
7 Acetochlor	ND	ppm	0.02
8 Acibenzolar-S-methyl	ND	ppm	0.05
9 Acrinathrin	ND	ppm	0.02
10 Alachlor	ND	ppm	0.02
11 Aldicarb	ND	ppm	0.05
12 Aldicarb-sulfone	ND	ppm	0.05
13 Aldicarb-sulfoxide	ND	ppm	0.1
14 Aldrin	ND	ppm	0.02
15 Allethrin	ND	ppm	0.2
16 Ametryn	ND	ppm	0.05
17 Amitraz	ND	ppm	0.05
18 Anilofos	ND	ppm	0.05
19 Atrazine	ND	ppm	0.02
20 Azaconazole	ND	ppm	0.02
21 Azamethiphos	ND	ppm	0.05
22 Azinphos-ethyl	ND	ppm	0.05
23 Azinphos-methyl	ND	ppm	0.05
24 Azoxystrobin	ND	ppm	0.05
25 Benalaxyl	ND	ppm	0.02
26 Bendiocarb	ND	ppm	0.05
27 Benfluralin	ND	ppm	0.02
28 Benfuresate	ND	ppm	0.02
29 Benomyl (as Carbendazim)	ND	ppm	0.05
30 Benoxacor	ND	ppm	0.02
31 Bensulide	ND	ppm	0.05
32 Bentazone	ND	ppm	0.02

Negative = < 10 CFU/g; CFU=Colony Forming Unit; ppb=parts per billion (mcg/Kg or mcg/L); ppm=parts per million (mg/Kg or mg/L)
LOQ= Limit of Quantification; ND=Not Detected; N/A=Not Applicable; Trace=Qualitative result < LOQ; * = Analysis subcontracted

ANALYTICAL REPORT

33	Benzobicyclon	ND	ppm	0.05
34	Benzofenap	ND	ppm	0.05
35	Benzyladenine	ND	ppm	0.05
36	BHC (alpha)	ND	ppm	0.02
37	BHC (beta)	ND	ppm	0.02
38	BHC (delta)	ND	ppm	0.02
39	Bifenazate	ND	ppm	0.05
40	BifenoX	ND	ppm	0.02
41	Bifenthrin	ND	ppm	0.02
42	Bioresmethrin (as Resmethrin)	ND	ppm	0.1
43	Bitertanol	ND	ppm	0.05
44	Boscalid	ND	ppm	0.02
45	Bromobutide	ND	ppm	0.02
46	Bromophos-ethyl	ND	ppm	0.05
47	Bromophos-methyl	ND	ppm	0.05
48	Bromopropylate	ND	ppm	0.02
49	Bupirimate	ND	ppm	0.02
50	Buprofezin	ND	ppm	0.02
51	Butachlor	ND	ppm	0.02
52	Butafenacil	ND	ppm	0.02
53	Butamifos	ND	ppm	0.05
54	Butralin	ND	ppm	0.02
55	Butylate	ND	ppm	0.02
56	Cadusafos	ND	ppm	0.05
57	Cafenstrole	ND	ppm	0.05
58	Captan	ND	ppm	0.1
59	Carbaryl	ND	ppm	0.05
60	Carbendazim	ND	ppm	0.05
61	Carbofuran	ND	ppm	0.05
62	Carbophenothion	ND	ppm	0.05
63	Carboxin	ND	ppm	0.02
64	Carfentrazone-ethyl	ND	ppm	0.02
65	Carpropamid	ND	ppm	0.02
66	Chlorantraniliprole	ND	ppm	0.05
67	Chlorbenside	ND	ppm	0.02
68	Chlorbufam	ND	ppm	0.02
69	Chlordane (cis)	ND	ppm	0.02
70	Chlordane (trans)	ND	ppm	0.02
71	Chlorethoxyfos	ND	ppm	0.02
72	Chlorfenapyr	ND	ppm	0.02
73	Chlorfenson	ND	ppm	0.02
74	Chlorfenvinphos	ND	ppm	0.05
75	Chloridazon	ND	ppm	0.05
76	Chlornitrofen	ND	ppm	0.02
77	Chlorobenzilate	ND	ppm	0.02
78	Chloroneb	ND	ppm	0.02
79	Chloroxuron	ND	ppm	0.05
80	Chlorpropham	ND	ppm	0.02
81	Chlorpyrifos	ND	ppm	0.05
82	Chlorpyrifos-methyl	ND	ppm	0.05
83	Chlorthal-dimethyl	ND	ppm	0.02
84	Chlorthiofos	ND	ppm	0.05
85	Chlozoline	ND	ppm	0.02

Negative = < 10 CFU/g; CFU=Colony Forming Unit; ppb=parts per billion (mcg/Kg or mcg/L); ppm=parts per million (mg/Kg or mg/L)
 LOQ= Limit of Quantification; ND=Not Detected; N/A=Not Applicable; Trace=Qualitative result < LOQ; * = Analysis subcontracted

ANALYTICAL REPORT

86	Chromafenozide	ND	ppm	0.05
87	Cinidon-ethyl	ND	ppm	0.05
88	Cinmethylin	ND	ppm	0.02
89	Clethodim	ND	ppm	0.02
90	Clodinafop-propargyl	ND	ppm	0.05
91	Clofentezine	ND	ppm	0.05
92	Clomazone	ND	ppm	0.02
93	Clomeprop	ND	ppm	0.05
94	Cloquintocet-mexyl	ND	ppm	0.05
95	Clothianidin	ND	ppm	0.05
96	CPMC (Etofol)	ND	ppm	0.05
97	Cumyluron	ND	ppm	0.05
98	Cyanazine	ND	ppm	0.05
99	Cyanophenphos	ND	ppm	0.05
100	Cyanophos	ND	ppm	0.05
101	Cyazofamid	ND	ppm	0.05
102	Cycloate	ND	ppm	0.02
103	Cyflufenamid	ND	ppm	0.02
104	Cyfluthrin	ND	ppm	0.02
105	Cyhalofop-butyl	ND	ppm	0.02
106	Cyhalothrin (gamma)	ND	ppm	0.02
107	Cyhalothrin (lambda)	ND	ppm	0.02
108	Cymoxanil	ND	ppm	0.05
109	Cypermethrin	ND	ppm	0.02
110	Cyproconazole	ND	ppm	0.02
111	Cyprodinil	ND	ppm	0.05
112	Daimuron	ND	ppm	0.05
113	DDD	ND	ppm	0.02
114	DDE	ND	ppm	0.02
115	DDT	ND	ppm	0.02
116	Deltamethrin	ND	ppm	0.02
117	Demeton O & S	ND	ppm	0.05
118	Demeton-S-methyl	ND	ppm	0.05
119	Desmedipham	ND	ppm	0.1
120	Diafenthiuron	ND	ppm	0.1
121	Dialifos	ND	ppm	0.05
122	Di-allate	ND	ppm	0.02
123	Diazinon	ND	ppm	0.05
124	Dichlobenil	ND	ppm	0.02
125	Dichlofenthion (ECP)	ND	ppm	0.05
126	Dichlofluanid	ND	ppm	0.02
127	Dichlormid	ND	ppm	0.02
128	Dichlorvos	ND	ppm	0.05
129	Diclobutrazol	ND	ppm	0.05
130	Diclocymet	ND	ppm	0.02
131	Diclofop-methyl	ND	ppm	0.02
132	Diomezine	ND	ppm	0.05
133	Dicloran	ND	ppm	0.02
134	Dicrotophos	ND	ppm	0.05
135	Dieldrin	ND	ppm	0.02
136	Diethofencarb	ND	ppm	0.02
137	Difenoconazole	ND	ppm	0.02
138	Difenzoquat	ND	ppm	0.05

Negative = < 10 CFU/g; CFU=Colony Forming Unit; ppb=parts per billion (mcg/Kg or mcg/L); ppm=parts per million (mg/Kg or mg/L)
 LOQ= Limit of Quantification; ND=Not Detected; N/A=Not Applicable; Trace=Qualitative result < LOQ; * = Analysis subcontracted

ANALYTICAL REPORT

139	Diffubenzuron	ND	ppm	0.05
140	Diffufenican	ND	ppm	0.02
141	Dimepiperate	ND	ppm	0.02
142	Dimethametryn	ND	ppm	0.05
143	Dimethenamid	ND	ppm	0.02
144	Dimethoate	ND	ppm	0.05
145	Dimethylvinphos	ND	ppm	0.05
146	Diniconazole	ND	ppm	0.05
147	Dinotefuran	ND	ppm	0.05
148	Dioxathion	ND	ppm	0.05
149	Diphenamid	ND	ppm	0.02
150	Diphenylamine	ND	ppm	0.02
151	Disulfoton	ND	ppm	0.02
152	Disulfoton-sulfone	ND	ppm	0.02
153	Dithiopyr	ND	ppm	0.02
154	Diuron	ND	ppm	0.05
155	Edifenphos	ND	ppm	0.05
156	Emamectin-benzoate	ND	ppm	0.05
157	Endosulfan (alpha)	ND	ppm	0.02
158	Endosulfan (beta)	ND	ppm	0.02
159	Endosulfan-sulfate	ND	ppm	0.04
160	Endrin	ND	ppm	0.02
161	EPN	ND	ppm	0.05
162	Epoxiconazole	ND	ppm	0.02
163	EPTC	ND	ppm	0.02
164	Esfenvalerate	ND	ppm	0.04
165	Esprocarb	ND	ppm	0.02
166	Ethalfuralin	ND	ppm	0.02
167	Ethion	ND	ppm	0.05
168	Ethiprole	ND	ppm	0.05
169	Ethofumesate	ND	ppm	0.02
170	Ethoprophos	ND	ppm	0.025
171	Ethoxyquin	N/A	ppm	0.1
172	Ethychlozate	ND	ppm	0.05
173	Etobenzanid	ND	ppm	0.02
174	Etofenprox	ND	ppm	0.02
175	Etoxazole	ND	ppm	0.02
176	Etridiazole	ND	ppm	0.02
177	Etrimfos	ND	ppm	0.05
178	Famphur	ND	ppm	0.02
179	Fenamidone	ND	ppm	0.02
180	Fenamiphos	ND	ppm	0.05
181	Fenamiphos-sulfone	ND	ppm	0.05
182	Fenarimol	ND	ppm	0.02
183	Fenbuconazole	ND	ppm	0.05
184	Fenchlorphos	ND	ppm	0.05
185	Fenhexamid	ND	ppm	0.05
186	Fenitrothion	ND	ppm	0.05
187	Fenobucarb	ND	ppm	0.05
188	Fenothiocarb	ND	ppm	0.05
189	Fenoxanil	ND	ppm	0.05
190	Fenoxaprop-ethyl	ND	ppm	0.02
191	Fenoxycarb	ND	ppm	0.05

Negative = < 10 CFU/g; CFU=Colony Forming Unit; ppb=parts per billion (mcg/Kg or mcg/L); ppm=parts per million (mg/Kg or mg/L)
 LOQ= Limit of Quantification; ND=Not Detected; N/A=Not Applicable; Trace=Qualitative result < LOQ; * = Analysis subcontracted

ANALYTICAL REPORT

192	Fenpropathrin	ND	ppm	0.02
193	Fenpropimorph	ND	ppm	0.02
194	Fenpyroximate	ND	ppm	0.05
195	Fensulfothion	ND	ppm	0.05
196	Fenthion	ND	ppm	0.05
197	Fentrazamide	ND	ppm	0.05
198	Fenvalerate	ND	ppm	0.04
199	Ferimzone E	ND	ppm	0.05
200	Ferimzone Z	ND	ppm	0.05
201	Fipronil	ND	ppm	0.01
202	Flamprop-methyl	ND	ppm	0.02
203	Fluacrypyrim	ND	ppm	0.05
204	Fluazifop-butyl	ND	ppm	0.02
205	Fluazinam	ND	ppm	0.05
206	Flucythrinate	ND	ppm	0.02
207	Fludioxonil	ND	ppm	0.05
208	Flufenacet	ND	ppm	0.02
209	Fluometuron	ND	ppm	0.05
210	Fluquinconazole	ND	ppm	0.02
211	Fluridone	ND	ppm	0.05
212	Flusilazole	ND	ppm	0.02
213	Flusulfamide	ND	ppm	0.05
214	Fluthiacet-methyl	ND	ppm	0.05
215	Flutolanil	ND	ppm	0.02
216	Flutriafol	ND	ppm	0.05
217	Fluvalinate	ND	ppm	0.02
218	Fonofos	ND	ppm	0.05
219	Forchlorfenuron	ND	ppm	0.05
220	Fosthiazate	ND	ppm	0.05
221	Fthalide	ND	ppm	0.02
222	Furametpyr	ND	ppm	0.02
223	Furathiocarb	ND	ppm	0.05
224	Furilazole	ND	ppm	0.02
225	Halfenprox	ND	ppm	0.02
226	Haloxfop	ND	ppm	0.01
227	Haloxfop-methyl	ND	ppm	0.02
228	Heptachlor	ND	ppm	0.02
229	Heptachlor-epoxide	ND	ppm	0.02
230	Hexachlorobenzene	ND	ppm	0.02
231	Hexaconazole	ND	ppm	0.05
232	Hexazinone	ND	ppm	0.02
233	Hexythiazox	ND	ppm	0.05
234	Imazalil	ND	ppm	0.05
235	Imazamethabenz-methyl-ester	ND	ppm	0.05
236	Imibenconazole	ND	ppm	0.05
237	Imidacloprid	ND	ppm	0.05
238	Inabenfide	ND	ppm	0.05
239	Indoxacarb	ND	ppm	0.05
240	Iprobenfos	ND	ppm	0.05
241	Iprodione	ND	ppm	0.05
242	Iprovalicarb	ND	ppm	0.05
243	Isazophos	ND	ppm	0.05
244	Isocarbophos	ND	ppm	0.05

Negative = < 10 CFU/g; CFU=Colony Forming Unit; ppb=parts per billion (mcg/Kg or mcg/L); ppm=parts per million (mg/Kg or mg/L)
 LOQ= Limit of Quantification; ND=Not Detected; N/A=Not Applicable; Trace=Qualitative result < LOQ; * = Analysis subcontracted

ANALYTICAL REPORT

245	Isofenphos	ND	ppm	0.05
246	Isofenphos-methyl	ND	ppm	0.05
247	Isoprocarb	ND	ppm	0.05
248	Isoprothiolane	ND	ppm	0.02
249	Isotianil	ND	ppm	0.02
250	Isouron	ND	ppm	0.05
251	Isoxadifen-ethyl	ND	ppm	0.02
252	Isoxaflutole	ND	ppm	0.05
253	Isoxathion	ND	ppm	0.05
254	Kresoxim-methyl	ND	ppm	0.02
255	Lenacil	ND	ppm	0.05
256	Lindane	ND	ppm	0.02
257	Linuron	ND	ppm	0.05
258	Malathion	ND	ppm	0.05
259	Mandipropamid	ND	ppm	0.05
260	Mecarbam	ND	ppm	0.05
261	Mefenacet	ND	ppm	0.05
262	Mefenpyr-Diethyl	ND	ppm	0.05
263	Mepanipirim	ND	ppm	0.02
264	Mephosfolan	ND	ppm	0.05
265	Mepronil	ND	ppm	0.02
266	Metalaxyl	ND	ppm	0.02
267	Metconazole	ND	ppm	0.02
268	Methabenzthiazuron	ND	ppm	0.05
269	Methacrifos	ND	ppm	0.05
270	Methamidophos	ND	ppm	0.05
271	Methidathion	ND	ppm	0.05
272	Methiocarb	ND	ppm	0.05
273	Methomyl	ND	ppm	0.05
274	Methoprene	ND	ppm	0.02
275	Methoxychlor	ND	ppm	0.02
276	Methoxyfenozide	ND	ppm	0.05
277	Metolachlor	ND	ppm	0.02
278	Metominostrobin	ND	ppm	0.02
279	Metribuzin	ND	ppm	0.02
280	Mevinphos	ND	ppm	0.05
281	Mirex	ND	ppm	0.02
282	Molinate	ND	ppm	0.02
283	Monocrotophos	ND	ppm	0.05
284	Monolinuron	ND	ppm	0.05
285	Myclobutanil	ND	ppm	0.02
286	Naled (screened as Dichlorvos)	ND	ppm	0.05
287	Naproanilide	ND	ppm	0.02
288	Napropamide	ND	ppm	0.02
289	Nitenpyram	ND	ppm	0.05
290	Nitrofen	ND	ppm	0.02
291	Nitrothal-isopropyl	ND	ppm	0.02
292	Norflurazon	ND	ppm	0.02
293	Novaluron	ND	ppm	0.05
294	Ofurace	ND	ppm	0.05
295	Omethoate	ND	ppm	0.05
296	o-Phenylphenol	ND	ppm	0.1
297	Orysastrobin	ND	ppm	0.02

Negative = < 10 CFU/g; CFU=Colony Forming Unit; ppb=parts per billion (mcg/Kg or mcg/L); ppm=parts per million (mg/Kg or mg/L)
 LOQ= Limit of Quantification; ND=Not Detected; N/A=Not Applicable; Trace=Qualitative result < LOQ; * = Analysis subcontracted

ANALYTICAL REPORT

298	Oryzalin	ND	ppm	0.05
299	Oxadiazon	ND	ppm	0.02
300	Oxadixyl	ND	ppm	0.1
301	Oxamyl	ND	ppm	0.05
302	Oxaziclomefone	ND	ppm	0.05
303	Oxpoconazole-fumarate	ND	ppm	0.1
304	Oxycarboxin	ND	ppm	0.05
305	Oxydemeton-methyl	ND	ppm	0.05
306	Oxyfluorfen	ND	ppm	0.02
307	Paclobutrazol	ND	ppm	0.02
308	Parathion	ND	ppm	0.05
309	Parathion-methyl	ND	ppm	0.05
310	Pebulate	ND	ppm	0.02
311	Penconazole	ND	ppm	0.02
312	Pencycuron	ND	ppm	0.05
313	Pendimethalin	ND	ppm	0.02
314	Pentoxazone	ND	ppm	0.02
315	Permethrin	ND	ppm	0.02
316	Perthane	ND	ppm	0.02
317	Phenmedipham	ND	ppm	0.05
318	Phenothiol	ND	ppm	0.02
319	Phenothrin	ND	ppm	0.02
320	Phenthoate	ND	ppm	0.05
321	Phorate	ND	ppm	0.05
322	Phorate-sulfone	ND	ppm	0.05
323	Phosalone	ND	ppm	0.05
324	Phosmet	ND	ppm	0.05
325	Phosphamidon	ND	ppm	0.05
326	Phoxim	ND	ppm	0.05
327	Picolinafen	ND	ppm	0.05
328	Piperonyl-butoxide	ND	ppm	0.02
329	Piperophos	ND	ppm	0.05
330	Pirimicarb	ND	ppm	0.02
331	Pirimioxyphos	ND	ppm	0.05
332	Pirimiphos-ethyl	ND	ppm	0.05
333	Pirimiphos-methyl	ND	ppm	0.05
334	Pretilachlor	ND	ppm	0.02
335	Prochloraz	ND	ppm	0.02
336	Procymidone	ND	ppm	0.02
337	Profenofos	ND	ppm	0.05
338	Prohydrojasmon	ND	ppm	0.1
339	Prometryn	ND	ppm	0.02
340	Propachlor	ND	ppm	0.02
341	Propanil	ND	ppm	0.02
342	Propaphos	ND	ppm	0.05
343	Propargite	ND	ppm	0.05
344	Propazine	ND	ppm	0.02
345	Propetamphos	ND	ppm	0.05
346	Propiconazole	ND	ppm	0.02
347	Propoxur	ND	ppm	0.05
348	Propyzamide	ND	ppm	0.05
349	Prothiofos	ND	ppm	0.05
350	Pyraclofos	ND	ppm	0.05

Negative = < 10 CFU/g; CFU=Colony Forming Unit; ppb=parts per billion (mcg/Kg or mcg/L); ppm=parts per million (mg/Kg or mg/L)
 LOQ= Limit of Quantification; ND=Not Detected; N/A=Not Applicable; Trace=Qualitative result < LOQ; * = Analysis subcontracted

ANALYTICAL REPORT

351	Pyraclonil	ND	ppm	0.02
352	Pyraclostrobin	ND	ppm	0.05
353	Pyraflufen-ethyl	ND	ppm	0.02
354	Pyrazolynate	ND	ppm	0.05
355	Pyrazophos	ND	ppm	0.05
356	Pyrazoxyfen	ND	ppm	0.05
357	Pyrethrins	ND	ppm	0.25
358	Pyributicarb	ND	ppm	0.02
359	Pyridaben	ND	ppm	0.02
360	Pyridafenthion	ND	ppm	0.05
361	Pyrifenox	ND	ppm	0.02
362	Pyriftalid	ND	ppm	0.05
363	Pyrimethanil	ND	ppm	0.02
364	Pyrimidifen	ND	ppm	0.02
365	Pyriminobac-methyl	ND	ppm	0.02
366	Pyriproxyfen	ND	ppm	0.02
367	Pyroquilon	ND	ppm	0.02
368	Quinalphos	ND	ppm	0.05
369	Quinoclamine	ND	ppm	0.05
370	Quinoxifen	ND	ppm	0.05
371	Quintozene	ND	ppm	0.02
372	Quizalofop-ethyl	ND	ppm	0.02
373	Salithion	ND	ppm	0.05
374	Sethoxydim	ND	ppm	0.05
375	Silafluofen	ND	ppm	0.02
376	Simazine	ND	ppm	0.02
377	Simeconazole	ND	ppm	0.05
378	Simetryn	ND	ppm	0.02
379	Spinosad	ND	ppm	0.05
380	Spiromesifen	ND	ppm	0.1
381	Sulfotep	ND	ppm	0.05
382	Sulprofos	ND	ppm	0.05
383	TCMTB	ND	ppm	0.05
384	Tebuconazole	ND	ppm	0.02
385	Tebufenozide	ND	ppm	0.1
386	Tebufenpyrad	ND	ppm	0.02
387	Tebupirimfos	ND	ppm	0.05
388	Tebuthiuron	ND	ppm	0.05
389	Tecnazene	ND	ppm	0.02
390	Tefluthrin	ND	ppm	0.02
391	Terbacil	ND	ppm	0.05
392	Terbufos	ND	ppm	0.05
393	Terbutryn	ND	ppm	0.02
394	Tetrachlorvinphos	ND	ppm	0.05
395	Tetraconazole	ND	ppm	0.02
396	Tetradifon	ND	ppm	0.02
397	Tetrahydrophthalimide	ND	ppm	0.1
398	Tetramethrin	ND	ppm	0.02
399	Thenylchlor	ND	ppm	0.02
400	Thiabendazole	ND	ppm	0.05
401	Thiacloprid	ND	ppm	0.05
402	Thiamethoxam	ND	ppm	0.05
403	Thiazopyr	ND	ppm	0.02

Negative = < 10 CFU/g; CFU=Colony Forming Unit; ppb=parts per billion (mcg/Kg or mcg/L); ppm=parts per million (mg/Kg or mg/L)
 LOQ= Limit of Quantification; ND=Not Detected; N/A=Not Applicable; Trace=Qualitative result < LOQ; * = Analysis subcontracted

ANALYTICAL REPORT

404	Thidiazuron	ND	ppm	0.05
405	Thiifluzamide	ND	ppm	0.02
406	Thiobencarb	ND	ppm	0.02
407	Thiometon	ND	ppm	0.02
408	Tiadinil	ND	ppm	0.05
409	Tolclofos-methyl	ND	ppm	0.05
410	Tralomethrin	ND	ppm	0.02
411	Triadimefon	ND	ppm	0.02
412	Triadimenol	ND	ppm	0.05
413	Tri-allate	ND	ppm	0.02
414	Triazophos	ND	ppm	0.05
415	Tribuphos	ND	ppm	0.05
416	Trichlamide	ND	ppm	0.02
417	Trichlorfon	ND	ppm	0.05
418	Tricyclazole	ND	ppm	0.05
419	Tridiphane	ND	ppm	0.02
420	Trifloxystrobin	ND	ppm	0.05
421	Triflumizole	ND	ppm	0.02
422	Triflumuron	ND	ppm	0.05
423	Trifluralin	ND	ppm	0.02
424	Triforine	ND	ppm	0.05
425	Triticonazole	ND	ppm	0.05
426	Uniconazole-P	ND	ppm	0.05
427	Vinclozolin	ND	ppm	0.02
428	XMC	ND	ppm	0.05
429	Xylylcarb	ND	ppm	0.05
430	Zoxamide	ND	ppm	0.05

Persistent Organic Pollutants

Analyte	Result
1 **Dioxins/Furans/WHO-12 PCBs	Completed - see attached eurofins Analysis Report

Microbiological Tests

Analyte	Result	Units
1 Aerobic Plate Count (APC)	<10	CFU/g
2 Coliform, Plate Count	<10	CFU/g
3 E Coli, Plate Count	<10	CFU/g
4 Listeria Genus (by PCR)	Negative	
5 Mold	<10	CFU/g
6 Salmonella (by PCR)	Negative	
7 Yeast	<10	CFU/g

Minerals / Metals Screen

Analyte	Result	Units	LOQ
1 Arsenic	ND	ppb	10
2 Cadmium	ND	ppb	10
3 Lead	10	ppb	10
4 Mercury	ND	ppb	5

**This analysis is outside the scope of OMIC USA operations and has been subcontracted to eurofins laboratory. Their report analysis is attached in its entirety. OMIC USA assumes no responsibility for its interpretations or use.

Negative = < 10 CFU/g; CFU=Colony Forming Unit; ppb=parts per billion (mcg/Kg or mcg/L); ppm=parts per million (mg/Kg or mg/L)
LOQ= Limit of Quantification; ND=Not Detected; N/A=Not Applicable; Trace=Qualitative result < LOQ; * = Analysis subcontracted

ANALYTICAL REPORT

Mycotoxins Screen

Analyte	Result	Units	LOQ
1 Aflatoxin B1	ND	ppb	5.0
2 Aflatoxin B2	ND	ppb	5.0
3 Aflatoxin G1	ND	ppb	5.0
4 Aflatoxin G2	ND	ppb	5.0

PAH'S Screen

Analyte	Result	Units	LOQ
1 *Acenaphthene	ND	ppm	140
2 *Acenaphthylene	ND	ppm	130
3 *Anthracene	ND	ppm	220
4 *Benz(a)anthracene	ND	ppm	160
5 *Benzo(a)pyrene	ND	ppm	110
6 *Benzo(b)fluoranthene	ND	ppm	130
7 *Benzo(g,h,i)perylene	ND	ppm	130
8 *Benzo(k)fluoranthene	ND	ppm	130
9 *Chrysene	ND	ppm	110
10 *Dibenzo(a,h)anthracene	ND	ppm	180
11 *Flouranthene	ND	ppm	140
12 *Fluorene	ND	ppm	230
13 *Indeno(1,2,3-cd)pyrene	ND	ppm	160
14 *Naphthalene	ND	ppm	140
15 *Phenanthrene	ND	ppm	130
16 *Pyrene	ND	ppm	110

Solvent Screen

Analyte	Result	Units	LOQ
1 Hexane	ND	ppb	10

Negative = < 10 CFU/g; CFU=Colony Forming Unit; ppb=parts per billion (mcg/Kg or mcg/L); ppm=parts per million (mg/Kg or mg/L)
LOQ= Limit of Quantification; ND=Not Detected; N/A=Not Applicable; Trace=Qualitative result < LOQ; * = Analysis subcontracted

REVISED

Sample Description: AB81761:Rice Bran Wax Composite Solid
OMIC USA INC

LL Sample # G5 7957463
LL Group # 1574979
Account # 30091

Project Name: OMIC USA

Collected: 07/06/2015 10:00 by DF

OMIC USA Inc.

3344 NW Industrial St
Portland OR

Submitted: 07/08/2015 08:10

Reported: 07/27/2015 11:00

CAT No.	Analysis Name	CAS Number	As Received Result	As Received EDL	Dilution Factor
Dioxins/Furans EPA 1613B modified					
12963	2378-TCDD	1746-01-6	< 0.112	0.112	1
12963	2378-TCDF	51207-31-9	< 0.0576	0.0576	1
12963	12378-PeCDD	40321-76-4	< 0.0818	0.0818	1
12963	12378-PeCDF	57117-41-6	< 0.0375	0.0375	1
12963	23478-PeCDF	57117-31-4	< 0.0367	0.0367	1
12963	123478-HxCDD	39227-28-6	< 0.0430	0.0430	1
12963	123678-HxCDD	57653-85-7	< 0.0441	0.0441	1
12963	123789-HxCDD	19408-74-3	< 0.0469	0.0469	1
12963	123478-HxCDF	70648-26-9	< 0.0392	0.0392	1
12963	123678-HxCDF	57117-44-9	< 0.0381	0.0381	1
12963	123789-HxCDF	72918-21-9	< 0.0434	0.0434	1
12963	234678-HxCDF	60851-34-5	< 0.0367	0.0367	1
12963	1234678-HpCDD	35822-46-9	< 0.0339	0.0339	1
12963	1234678-HpCDF	67562-39-4	< 0.0306	0.0306	1
12963	1234789-HpCDF	55673-89-7	< 0.0315	0.0315	1
12963	OCDD	3268-87-9	< 0.0703	0.0703	1
12963	OCDF	39001-02-0	0.277	0.0723	1
D/F Toxic Equivalents EPA 1613B modified					
12963	WHO2005 PCDD/F TEQ Lower Bound	n.a.	0.0000830		1
12963	WHO2005 PCDD/F TEQ Upper Bound	n.a.	0.242		1
WHO 12 PCBs EPA 1668 modified					
12942	PCB77	32598-13-3	< 0.0845	0.0845	1
12942	PCB81	70362-50-4	0.164	0.0864	1
12942	PCB105	32598-14-4	6.15	0.0927	1
12942	PCB114	74472-37-0	0.503	0.106	1
12942	PCB118	31508-00-6	36.9	0.0984	1
12942	PCB123	65510-44-3	< 0.0989	0.0989	1
12942	PCB126	57465-28-8	0.332	0.0849	1
12942	PCB156	38380-08-4	5.53	0.0765	1
12942	PCB157	69782-90-7	0.655	0.0736	1
12942	PCB167	52663-72-6	4.48	0.0901	1
12942	PCB169	32774-16-6	< 0.0710	0.0710	1
12942	PCB189	39635-31-9	0.493	0.0442	1
PCB Toxic Equivalents EPA 1668 modified					
12942	TEQ PCB WHO 2005 -EDLx0.0	n.a.	0.0349		1
12942	TEQ PCB WHO 2005 -EDLx1.0	n.a.	0.0370		1

General Sample Comments

WHO(2005)-PCDD/F + DLPCB TEQ (lower-bound) = 0.0350 pg/g
WHO(2005)-PCDD/F + DLPCB TEQ (upper-bound) = 0.279 pg/g

REVISED

Sample Description: AB81761:Rice Bran Wax Composite Solid
OMIC USA INC

LL Sample # G5 7957463
LL Group # 1574979
Account # 30091

Project Name: OMIC USA

Collected: 07/06/2015 10:00 by DF

OMIC USA Inc.

3344 NW Industrial St

Portland OR

Submitted: 07/08/2015 08:10

Reported: 07/27/2015 11:00

Laboratory Sample Analysis Record

CAT No.	Analysis Name	Method	Trial#	Batch#	Analysis Date and Time	Analyst	Dilution Factor
12963	Solid Dioxins and Furans	EPA 1613B modified	1	15190001	07/10/2015 22:52	Joseph D Anderson	1
12942	Solid WHO12 + 6 Indicators	EPA 1668 modified	1	15190001	07/10/2015 19:23	Joseph D Anderson	1
12961	Dioxins/Furans/PCBs in Oil	EPA 1613B modified	1	15190001	07/09/2015 06:25	Ginelle L McQuaid	1

The following defines common symbols and abbreviations used in reporting technical data:

RL	Reporting Limit	BMQL	Below Minimum Quantitation Level
N.D.	none detected	MPN	Most Probable Number
TNTC	Too Numerous To Count	CP Units	cobalt-chloroplatinate units
IU	International Units	NTU	nephelometric turbidity units
umhos/cm	micromhos/cm	ng	nanogram(s)
C	degrees Celsius	F	degrees Fahrenheit
meq	milliequivalents	lb.	pound(s)
g	gram(s)	kg	kilogram(s)
µg	microgram(s)	mg	milligram(s)
mL	milliliter(s)	L	liter(s)
m3	cubic meter(s)	µL	microliter(s)
		pg/L	picogram/liter
<	less than		
>	greater than		
ppm	parts per million - One ppm is equivalent to one milligram per kilogram (mg/kg) or one gram per million grams. For aqueous liquids, ppm is usually taken to be equivalent to milligrams per liter (mg/l), because one liter of water has a weight very close to a kilogram. For gases or vapors, one ppm is equivalent to one microliter per liter of gas.		
ppb	parts per billion		
Dry weight basis	Results printed under this heading have been adjusted for moisture content. This increases the analyte weight concentration to approximate the value present in a similar sample without moisture. All other results are reported on an as-received basis.		

Laboratory Data Qualifiers:

- B - Analyte detected in the blank
- C - Result confirmed by reanalysis
- E - Concentration exceeds the calibration range
- J (or G, I, X) - estimated value \geq the Method Detection Limit (MDL or DL) and the $<$ Limit of Quantitation (LOQ or RL)
- P - Concentration difference between the primary and confirmation column $>40\%$. The lower result is reported.
- U - Analyte was not detected at the value indicated
- V - Concentration difference between the primary and confirmation column $>100\%$. The reporting limit is raised due to this disparity and evident interference...

Additional Organic and Inorganic CLP qualifiers may be used with Form 1 reports as defined by the CLP methods. Qualifiers specific to Dioxin/Furans and PCB Congeners are detailed on the individual Analysis Report.

Analytical test results meet all requirements of the associated regulatory program (i.e., NELAC (TNI), DoD, ISO17025) unless otherwise noted under the individual analysis.

Measurement uncertainty values, as applicable, are available upon request.

Tests results relate only to the sample tested. Clients should be aware that a critical step in a chemical or microbiological analysis is the collection of the sample. Unless the sample analyzed is truly representative of the bulk of material involved, the test results will be meaningless. If you have questions regarding the proper techniques of collecting samples, please contact us. We cannot be held responsible for sample integrity, however, unless sampling has been performed by a member of our staff.

This report shall not be reproduced except in full, without the written approval of the laboratory.

Times are local to the area of activity. Parameters listed in the 40 CFR Part 136 Table II as "analyze immediately" are not performed within 15 minutes.

WARRANTY AND LIMITS OF LIABILITY - In accepting analytical work, we warrant the accuracy of test results for the sample as submitted. THE FOREGOING EXPRESS WARRANTY IS EXCLUSIVE AND IS GIVEN IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED. WE DISCLAIM ANY OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING A WARRANTY OF FITNESS FOR PARTICULAR PURPOSE AND WARRANTY OF MERCHANTABILITY. IN NO EVENT SHALL EUROFINS LANCASTER LABORATORIES ENVIRONMENTAL, LLC BE LIABLE FOR INDIRECT, SPECIAL, CONSEQUENTIAL, OR INCIDENTAL DAMAGES INCLUDING, BUT NOT LIMITED TO, DAMAGES FOR LOSS OF PROFIT OR GOODWILL REGARDLESS OF (A) THE NEGLIGENCE (EITHER SOLE OR CONCURRENT) OF EUROFINS LANCASTER LABORATORIES ENVIRONMENTAL AND (B) WHETHER EUROFINS LANCASTER LABORATORIES ENVIRONMENTAL HAS BEEN INFORMED OF THE POSSIBILITY OF SUCH DAMAGES. We accept no legal responsibility for the purposes for which the client uses the test results. No purchase order or other order for work shall be accepted by Eurofins Lancaster Laboratories Environmental which includes any conditions that vary from the Standard Terms and Conditions, and Eurofins Lancaster Laboratories Environmental hereby objects to any conflicting terms contained in any acceptance or order submitted by client.

Appendix C. Stability Testing Results

Stability Data for Wax 224 Rice Bran Wax

Batch	Date tested	Acid Value	Date tested	Acid Value	Date tested	Acid Value	Date tested	Acid Value	Date tested	Acid Value
11935	1/28/09	4.6	8/24/11	4.8	6/12/13	4.9				
13115	2/17/10	5.3	9/14/11	5.5	9/26/12	6.1	6/28/13	5.9	2/24/15	5.5
15010	9/9/11	6.7	6/3/13	6.2	9/10/15	6.8				
16139	7/9/12	6.1	6/11/13	6.4	12/4/14	6.4	9/2/15	6.1		
17399	6/3/13	8.5	6/11/15	8.3						

Appendix D. Intake Assessment Report

Estimated Daily Intake of Rice Bran Wax

MARCH 10, 2016

ToxStrategies

Innovative solutions
Sound science

Estimated Daily Intake of Rice Bran Wax

MARCH 10, 2016

PREPARED FOR:

J.M. Smucker Co.
1 Strawberry Lane
Orrville, Ohio 44667

PREPARED BY:

ToxStrategies, Inc.
9390 Research Blvd
Suite 100
Austin, Texas 78759

Table of Contents

List of Tables	47
List of Acronyms and Abbreviations	48
1.0 Executive Summary	49
2.0 Data	49
2.1 Proposed Uses and Use Levels of Rice Bran Wax	49
2.2 Dietary Survey Data	49
2.3 Recipe Data	50
3.0 Methods	50
3.1 Identification of Foods and Their Components to Which Rice Bran Wax May Be Applied	50
3.2 Calculation of Individual Intake of Rice Bran Wax for Individual Survey Participants	51
3.3 Calculation of Population Statistics Describing Rice Bran Wax Estimated Daily Intake	51
4.0 Results	52
5.0 References	54
Appendix: List of Food Codes	55

List of Tables

Table 1. Proposed use and use level of rice bran wax	49
Table 2. Estimated daily intake for rice bran wax (g/day) at a 3% use level	52
Table 3. Estimated daily intake for rice bran wax (g/day) at a 4% use level	52
Table 4. Estimated daily intake for rice bran wax by body weight (g/kg BW/day) at a 3% use level	53
Table 5. Estimated daily intake for rice bran wax by body weight (g/kg BW/day) at a 4% use level	53

List of Acronyms and Abbreviations

ARS	Agricultural Research Service
CDC	Centers for Disease Control and Prevention
EDI	estimated daily intake
FNDDS	Food and Nutrient Database for Dietary Studies
g/day	grams per day
g/kg BW/day	grams per kilogram body weight per day
NHANES	National Health and Nutrition Examination Survey
USDA	United States Department of Agriculture
WWEIA	What We Eat in America

1.0 Executive Summary

ToxStrategies, Inc. (ToxStrategies) has conducted an intake assessment to estimate the mean and 90th percentile daily intake of the ingredient rice bran wax based on its new proposed use in foods. The proposed use of rice bran wax is as a texturizer in peanut butter, allowing peanut butter to be the primary ingredient in new nutritional/snack bars. It was assumed for the purpose of this estimate that consumers of nutritional/snack bars would replace the consumption of all existing bars with the proposed peanut butter-based bars, in order to produce the highest (most conservative) estimate of potential rice bran wax consumption.

Use levels of both 3% and 4% of rice bran wax in peanut butter were estimated. Analyzing dietary survey data from the National Health and Nutrition Examination Survey (NHANES) at 3% yielded a *per user* mean and 90th percentile estimated daily intake (EDI) of rice bran wax for the US population ages 2 and over of 0.76 and 1.29 g/day (0.013 and 0.028 g/kg BW/day, respectively). For the total US population ages 2 and over, the *per capita* mean and 90th percentile EDI were 0.08 and 0.32 g/day (0.001 and 0.004 g/kg BW/day), respectively.

Analyzing dietary survey data from NHANES at 4% yielded a *per user* mean and 90th percentile EDI of rice bran wax for the US population ages 2 and over of 1.02 and 1.72 g/day (0.018 and 0.037 g/kg BW/day, respectively). For the total US population ages 2 and over, the *per capita* mean and 90th percentile EDI were 0.11 and 0.42 g/day (0.002 and 0.005 g/kg BW/day, respectively).

2.0 Data

To calculate the EDI of rice bran wax, information about its proposed use in a new peanut butter nutritional/snack bar was combined with up-to-date, publicly available dietary intake survey data. Data sources are described in the following sections.

2.1 Proposed Uses and Use Levels of Rice Bran Wax

J.M. Smucker Co. proposes to use rice bran wax (the vegetable wax extracted from the bran oil of rice) at the following use levels in a peanut butter-based nutritional/snack bar (Table 1).

Table 1. Proposed use and use level of rice bran wax

Food Category	Proposed Technical Use of Rice Bran Wax	Minimum Proposed Use Level (%)	Maximum Proposed Use Level (%)
Nutritional/snack bar	Texturizing agent	3	4

2.2 Dietary Survey Data

Dietary survey data was obtained from What We Eat in America (WWEIA), the dietary interview portion of NHANES. NHANES is carried out in two-year cycles by the Centers for

Disease Control and Prevention (CDC) in order to characterize the general health and nutritional status of children and adults across the US. The two most recent biennials for which dietary intake data are available were included in this analysis (2009-2010, 2011-2012).

The first day of the WWEIA dietary questionnaire was administered in person, in conjunction with the participants' interviews and examinations for the other NHANES lifestyle and laboratory assessments. The second day of the survey was collected via a phone interview at some point three to ten days after the first survey day. Data collected during the dietary interview includes foods as consumed by the participant, encoded by a US Department of Agriculture (USDA) food code, and amount eaten.

Respondents who provided complete records for both days were designated reliable by WWEIA, and only those respondents were considered in this analysis (N = 2,332). A small percentage of participants (approximately 1%) did not provide body weight information and were therefore excluded from the statistics estimating intake on a per kilogram body weight basis.

2.3 Recipe Data

Recipe data were obtained from the Food and Nutritional Data for Dietary Studies (FNDDS), released by the Agricultural Research Service (ARS) of USDA as a companion to NHANES WWEIA. For each food, the most recent available recipe was applied (*i.e.*, foods reported in the 2009-2010 WWEIA survey were analyzed using recipes from the 2011-2012 release of FNDDS, if possible). As the contents of FNDDS are continually updated and refined, this method ensures that EDI estimates reflect the most up-to-date information about foods consumed in the US.

3.0 Methods

To estimate the intake of rice bran wax from its proposed use, ToxStrategies performed the following steps:

- Step 1: Identified foods and their components to which rice bran wax may be applied
- Step 2: Calculated individual intake of rice bran wax for individual survey participants
- Step 3: Calculated population statistics estimating intake of rice bran wax

Details of each step are provided in the following sections.

3.1 Identification of Foods and Their Components to Which Rice Bran Wax May Be Applied

To identify the new foods that are proposed to contain rice bran wax, ToxStrategies performed a thorough search of food codes reported in WWEIA. Food code descriptions from WWEIA and associated ingredients listed in FNDDS were queried for keywords pertaining to nutritional/snack bars and breakfast bars. In order to generate the most conservative estimate, J.M. Smucker Co. assumed that all consumption of these would be replaced by consumption of the new peanut butter bar products stiffened with rice bran wax. Food codes included in the analysis are listed in the appendix.

In some cases, the peanut butter bar component would be a subcomponent of a reported food (e.g., a nutrition bar covered in a chocolate or yogurt coating). Relevant proportions of each food were determined by reviewing the recipe for that food item from FNDDS, with further development by ToxStrategies. An asterisk in the appendix indicates that stiffened peanut butter was present as a subcomponent of that food item, *i.e.*, the technical use of rice bran wax applied to less than 100% of the reported food.

3.2 Calculation of Individual Intake of Rice Bran Wax for Individual Survey Participants

Only those respondents designated as reliable were included in this assessment. Both days of the NHANES WWEIA dietary interviews from the 2009-2010 and 2011-2012 biennials were analyzed. Participants' consumption of the rice bran wax was averaged over the two response days, *i.e.*, (Day1 consumption + Day2 consumption)/2. Raw consumption of rice bran wax was calculated using the grams of the relevant food consumed as reported in NHANES, multiplied by the proportion of the food that was relevant to the technical use of rice bran wax (see Section 3.1), multiplied by its proposed use level. For example, for the food "53714300 Granola bar, high fiber, coated with non-chocolate yogurt coating", the relevant proportion of that food, the bar itself, was 0.78, and the use level was 0.05. Thus, for a survey participant who consumed 28.3g (1 oz.) of this food, approximately 1.10g, or $(28.3 * 0.78 * 0.05)$, of rice bran wax would be consumed.

For the calculations of intake per kilogram body weight, individuals' own body weights as reported in NHANES were used rather than any general assumption of adults' or children's body weights.

3.3 Calculation of Population Statistics Describing Rice Bran Wax Estimated Daily Intake

To ensure that the most up-to-date data on consumption were used for this analysis, the two most recent NHANES biennials for which there are published dietary survey data available were used: 2009-2010 and 2011-2012. The dietary and sample weighting data from the two biennials were combined according to the NHANES analytic guidelines for combining surveys. From the combined dataset we estimated survey design weighted descriptive statistics for the population consumption per day. Population statistics were estimated using the 'survey' package (Lumley, 2004) in the R 3.1.2 environment for statistical computing (R Core Team, 2015) using the appropriate adjustment to sampling weights for combining biennials, then incorporating survey sampling units and strata from the survey design to ensure that sub-populations and areas were correctly represented. Descriptive statistics (mean, 90th percentile) were calculated for the subset of consumers of rice bran wax and for the entire population, and were broken down by age range and body weight adjustment.

4.0 Results

Tables 2 and 3 present the EDI for rice bran wax in grams per day (g/day), and Tables 4 and 5 the EDI for rice bran wax in grams per kilogram body weight per day (g/kg BW/day), for the following age groups in the US populations: 2 years and older, 2 to 5 years, 6 to 18 years, and 19 years and older. The “number of users” refers to the number of survey participants in a given age group who consumed a food item in the noted food codes. The “% Users” is the percentage of rice bran wax consumers out of the total number of reliable survey participants (consumers and non-consumers) belonging to a given age group.

Table 2. Estimated daily intake for rice bran wax (g/day) at a 3% use level

Nutrition/snack bar	Number Users	% Users	EDI per User (g/day)		EDI per Capita (g/day)	
			Mean	90th Percentile	Mean	90th Percentile
US Population, Ages 2+						
Rice bran wax consumption	1274	8.5	0.76	1.29	0.08	0.32
US Population, Ages 2-5						
Rice bran wax consumption	142	9.9	0.59	1.12	0.08	0.36
US Population, Ages 6-18						
Rice bran wax consumption	392	10.1	0.66	1.11	0.08	0.36
US Population, Ages 19+						
Rice bran wax consumption	740	7.7	0.81	1.46	0.08	0.26

Table 3. Estimated daily intake for rice bran wax (g/day) at a 4% use level

Nutrition/snack bar	Number Users	% Users	EDI per User (g/day)		EDI per Capita (g/day)	
			Mean	90th Percentile	Mean	90th Percentile
US Population, Ages 2+						
Rice bran wax consumption	1274	8.5	1.02	1.72	0.11	0.42
US Population, Ages 2-5						
Rice bran wax consumption	142	9.9	0.79	1.50	0.11	0.48
US Population, Ages 6-18						
Rice bran wax consumption	392	10.1	0.87	1.48	0.11	0.48
US Population, Ages 19+						
Rice bran wax consumption	740	7.7	1.08	1.95	0.11	0.34

Table 4. Estimated daily intake for rice bran wax by body weight (g/kg BW/day) at a 3% use level

Nutrition/snack bar	Number Users*	EDI per User (g/kg BW/day)		EDI per Capita (g/kg BW/day)	
		Mean	90th Percentile	Mean	90th Percentile
US Population, Ages 2+					
Rice bran wax consumption	1270	0.013	0.028	0.001	0.004
US Population, Ages 2-5					
Rice bran wax consumption	142	0.037	0.079	0.005	0.022
US Population, Ages 6-18					
Rice bran wax consumption	391	0.016	0.031	0.002	0.007
US Population, Ages 19+					
Rice bran wax consumption	737	0.010	0.020	0.001	0.003

* Body weight was not reported for ~1% of survey participants. Users with incomplete body weight data were excluded from this analysis.

Table 5. Estimated daily intake for rice bran wax by body weight (g/kg BW/day) at a 4% use level

Nutrition/snack bar	Number Users*	EDI per User (g/kg BW/day)		EDI per Capita (g/kg BW/day)	
		Mean	90th Percentile	Mean	90th Percentile
US Population, Ages 2+					
Rice bran wax consumption	1270	0.018	0.037	0.002	0.005
US Population, Ages 2-5					
Rice bran wax consumption	142	0.049	0.105	0.007	0.029
US Population, Ages 6-18					
Rice bran wax consumption	391	0.022	0.041	0.003	0.009
US Population, Ages 19+					
Rice bran wax consumption	737	0.014	0.026	0.001	0.004

* Body weight was not reported for ~1% of survey participants. Users with incomplete body weight data were excluded from this analysis.

5.0 References

Agricultural Research Service, United States Department of Agriculture (USDA). 2009-2010. Food and Nutrient Database for Dietary Studies. Available at: <http://www.ars.usda.gov/Services/docs.htm?docid=12068>. Last accessed April 1, 2015.

Agricultural Research Service, United States Department of Agriculture (USDA). 2011-2012. Food and Nutrient Database for Dietary Studies. Available at: <http://www.ars.usda.gov/Services/docs.htm?docid=12068>. Last accessed April 1, 2015.

Centers for Disease Control and Prevention (CDC). 2009-2010. National Health and Nutrition Examination Survey. Available at: http://wwwn.cdc.gov/nchs/nhanes/search/nhanes09_10.aspx. Last accessed April 1, 2015.

Centers for Disease Control and Prevention (CDC). 2011-2012. National Health and Nutrition Examination Survey. Available at: http://wwwn.cdc.gov/nchs/nhanes/search/nhanes11_12.aspx. Last accessed April 1, 2015.

Lumley, T. 2004. Analysis of complex survey samples. *Journal of Statistical Software*, 9(1), 1-19.

R Core Team. 2015. R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL <http://www.R-project.org/>.

Appendix: List of Food Codes

Food Code		Main food description
2009-2010	2011-2012	
41435000	NA	Fiber One Fulfill Bar
41435110	53720700	High protein bar, candy-like, soy and milk base
41435120	53720800	Zone Perfect Classic Crunch nutrition bar
41435300	53720100	Balance Original Bar
41435500	53720200	Clif Bar
41435700	53720610	South Beach Living High Protein Cereal Bar
41435710	53720600	South Beach Living Meal Replacement Bar
53540000	53714500	Breakfast bar, NFS
53540200	53714520	Breakfast bar, cereal crust with fruit filling, lowfat*
53540300	53710400	Fiber One Chewy Bar
53540400	53710500	Kellogg's Nutri-Grain Cereal Bar
53540402	53710502	Kellogg's Nutri-Grain Yogurt Bar
53540404	53710504	Kellogg's Nutri-Grain Fruit and Nut Bar
53540500	53714510	Breakfast bar, date, with yogurt coating*
53540600	53710600	Milk 'n Cereal bar
53540700	53710700	Kellogg's Special K bar
53540800	53710800	Kashi GOLEAN Chewy Bars
53540802	53710802	Kashi TLC Chewy Granola Bar
53540804	53710804	Kashi GOLEAN Crunchy Bars
53540806	53710806	Kashi TLC Crunchy Granola Bar
53540900	53710900	Nature Valley Chewy Trail Mix Granola Bar
53540902	53710902	Nature Valley Chewy Granola Bar with Yogurt Coating*
53540904	53710904	Nature Valley Sweet and Salty Nut Granola Bar
53540906	53710906	Nature Valley Crunchy Granola Bar
53541000	53711000	Quaker Chewy Granola Bar
53541002	53711002	Quaker Chewy 90 Calorie Granola Bar
53541004	53711004	Quaker Chewy 25% Less Sugar Granola Bar
53541006	53711006	Quaker Chewy Dipps Granola Bar
53541200	53729000	Meal replacement bar
53541300	53720400	Slim Fast Original Meal Bar
53542000	53712000	Snack bar, oatmeal
53542100	53712100	Granola bar, NFS
53542200	53712200	Granola bar, lowfat, NFS
53542210	53712210	Granola bar, nonfat
53543000	53713000	Granola bar, reduced sugar, NFS
53543100	53713100	Granola bar, peanuts, oats, sugar, wheat germ

53544200	53714200	Granola bar, chocolate-coated, NFS*
53544210	53714210	Granola bar, with coconut, chocolate-coated*
53544220	53714220	Granola bar with nuts, chocolate-coated*
53544230	53714230	Granola bar, oats, nuts, coated with non-chocolate coating*
53544250	53714250	Granola bar, coated with non-chocolate coating*
53544300	53714300	Granola bar, high fiber, coated with non-chocolate yogurt coating*
53544400	53714400	Granola bar, with rice cereal*
53544410	53711100	Quaker Granola Bites
53544450	53720300	PowerBar (fortified high energy bar)
91732000	same	Peanut bar
91732100	same	Planters Peanut Bar
91733000	same	Peanut brittle
91733200	same	Peanut Bar, chocolate covered candy*
91734450	same	Reese's Crispy Crunchy Bar
91780010	53720510	Snickers Marathon Energy bar
91781010	53720500	Snickers Marathon Protein bar

* Rice bran wax was present in a subcomponent of the food item. See section 3.1 of this report.

Exhibit 1. Report of the Expert Panel

OPINION OF AN EXPERT PANEL ON THE SAFETY AND GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF RICE BRAN WAX FOR USE IN FOOD

Introduction

An independent panel of experts (Expert Panel), qualified by scientific training and experience to evaluate the safety of food and food ingredients, was requested by The J. M. Smucker Company (Smucker) to determine the safety and Generally Recognized as Safe (GRAS) status of the use of rice bran wax as an ingredient for use in a specified food for human consumption. Rice bran wax is intended for use as a texturizing agent in peanut butter used in nutrition and granola-type snack bar products. The intended use of rice bran wax is solely in the peanut butter used in these bar products and will allow peanut butter to be the primary ingredient in nutritional/snack bars with a similar form and texture to granola bars and nutritional/energy bars. The rice bran wax ingredient is manufactured in accordance with current Good Manufacturing Practice (cGMP) and meets the proposed specifications.

A detailed review based on the existing scientific literature (through March 2016) on the safety of rice bran wax was conducted by ToxStrategies, Inc. (ToxStrategies) and is summarized in the attached dossier. The Expert Panel members reviewed the dossier prepared by ToxStrategies and other pertinent information and convened on April 13, 2016 via teleconference. Based on an independent, critical evaluation of all of the available information and discussions during the April 13, 2016 teleconference, the Expert Panel unanimously concluded that the intended uses described herein for Smucker's rice bran wax ingredient, meeting appropriate food-grade specifications as described in the supporting dossier (**GRAS Determination of Rice Bran Wax for Use in Food**) and manufactured according to cGMP, is safe, suitable, and GRAS based on scientific procedures. A summary of the basis for the Expert Panel's conclusion is provided below.

Summary and Basis for GRAS Determination

Description

Rice bran wax (CAS No. 8016-60-2) is a hard, crystalline vegetable wax obtained from rice husks. It primarily consists of high molecular weight monoesters ranging from C48 to C64. Rice bran wax is typically yellow to light brown in color with a melting point of 75 - 85.5°C. The rice bran wax that is the subject of this safety evaluation is processed from rice bran oil obtained from rice husks, and is not hydrogenated.

Manufacturing Process

The starting material, crude rice bran wax, is weighed and added to a clean melt tank and melted at a temperature of 220°F. During this process, settling separates out the non-rice bran wax solids. Next, the melted rice bran wax is transferred to a tank, containing one

or more safe and suitable decoloring agents, which is maintained at 240°F and the wax is mixed and recirculated in the tank. Prior to continuing on to the filtration process, a filter medium consisting of common and approved processing aids used in food manufacturing processes is added. Once the filtering medium is adequately incorporated, the mixture is sent through the filter press and then back into the tank until the wax becomes clear. Once the wax is clear, a sample is collected and sent to the laboratory for aesthetics (color and odor) testing. If the wax does not meet aesthetics (color and odor) specifications, it is pumped into another tank and cooling water is turned on until the temperature reaches 180°F, a safe and suitable decoloring agent is added, and the temperature is raised in a controlled method until it reaches 210°F. Once at 210°F, the temperature is raised 2°F every 5 minutes until the temperature reaches 240°F in order to remove the decoloring agent. A sample is again collected and tested for compliance with an aesthetic (color/odor) specification. If the wax meets the aesthetic specification (either with the first or second lab result), it is filtered through a 20-micron cartridge filter made from bleached cotton containing a polypropylene core and sent on to the pastillating (i.e., process of pelleting into uniform half spheres) step. If the wax is tested twice and fails, it is discarded. Once pastillated, the wax is sampled for quality testing, packaged, and labeled. The finished ingredient that passes all quality control measures is released for sale and placed into inventory. If a sample fails established quality parameters, the wax is discarded.

Analytical (chemical and microbiological) results for the rice bran wax product confirm that the finished product meets the proposed analytical specifications as demonstrated by the consistency of production, the lack of impurities and contaminants (e.g., heavy metals, pesticides, mycotoxins, polychlorinated dibenzo-p-dioxins, polychlorinated dibenzofurans, and dioxin-like polychlorinated biphenyls), and is stable for two years past the date of manufacture, if stored under proper conditions.

Rice Bran Wax and Related Data Considered in the Safety Assessment

Due to the limited amount of toxicological data available for rice bran wax, information on carnauba wax was also evaluated due to its chemical compositional similarity to rice bran wax, as both chain length and saturation have been shown to predict physiochemical behavior of waxes and oils (EFSA, 2007; Maru et al., 2012). It is clear, based on the information discussed below, that the monoester fraction in carnauba wax can be considered to be nearly structurally identical to the monoester fraction of rice bran wax; i.e., the monoester fraction in carnauba wax is within a range of 54-84% of total constituents compared to up to 87-98% in rice bran wax. Therefore, published toxicity studies conducted on carnauba wax were deemed suitable for inclusion in the safety assessment of rice bran wax and considered by the Expert Panel in its evaluation of the available data. In addition, it should be noted that in 2007, the European Food Safety Authority (EFSA, 2007) applied a similar approach bridging safety data from carnauba wax to beeswax. In this assessment, the EFSA Panel “noted that experimental biochemical and toxicological studies carried out specifically on beeswax were still lacking and considered that the data on beeswax itself were insufficient to establish an ADI. However, the Panel concluded that the safety of beeswax could be assessed, based

on the available scientific literature on the main constituents of beeswax and plant waxes showing chemical and structural similarities to beeswax, as published since the last SCF evaluation". The Panel concluded, "that the use of beeswax as an additive for the existing food uses and the proposed new food use is not of safety concern." In the US, beeswax is also approved for use in foods at levels not to exceed GMP (21 CFR § 184.1973).

The predominant monoester carbon chain lengths have been reported to be C48-64 and C56 for both rice bran wax and carnauba wax, respectively (Koster Keunen, 2014; Maru et al., 2012; Puleo and Rit, 1992). Carnauba wax is considered to be the most chemically similar to rice bran wax as compared to other plant-based waxes (Koster Keunen, 2014; Puleo and Rit, 1992; Andersen, 2006). This similarity is based on the presence of specific monoesters, which comprise the majority (87-98%) of rice bran wax. In concurrent analyses performed for this GRAS dossier on the rice bran wax product and a carnauba wax product by the same manufacturer, the total monoester fraction was found to account for 87-98% and 54-84% of rice bran and carnauba wax, respectively. The remaining ~2% of the rice bran wax product is made up of long chain fatty alcohols, long chain fatty acids, triglycerides, or rice bran oil. While the monoesters also comprise a major fraction of the carnauba wax samples, a large percentage is also made up of fatty alcohols (19-33%). In addition, carnauba wax has been shown to contain some fatty acids and complex esters that can only be analyzed with additional methods, e.g., via UV analysis; these can include resins and cinnamates (EFSA, 2007; Warth, 1956).

As an approved food additive, the Food and Drug Administration (FDA) has classified carnauba wax (CAS No. 8015-86-9) as GRAS as a direct food substance for human consumption with no specific limitation other than good manufacturing practice (21 CFR § 184.1978). From the data presented above, it is reasonable to also conclude that the use of rice bran wax, which is structurally a much less complex wax compared to that of carnauba wax, could be similarly approved.

The history of use in foods of other vegetable-based waxes, in particular carnauba wax, as well as the available toxicological data on carnauba wax provide sufficient safety data for the intended use of rice bran wax. As such, the available information suggests that rice bran wax should be considered safe for the intended uses proposed herein. Given the structural similarity of carnauba wax and rice bran wax, particularly the similar monoester chain length distribution and nearly identical physio-chemical properties, the available safety data for carnauba wax, primarily from studies on both subchronic and reproductive/developmental toxicity, can be bridged to support the safety of the intended use of rice bran wax in this safety evaluation.

History of Use

Rice, brown rice, and their derivatives have a long history of human consumption, with rice cultivation documented and dating back to prehistoric times, starting in Asia and eventually spreading across Europe around the sixth century (Burlando and Cornara, 2014). Currently, rice is produced in most continents and serves as a dietary staple for a majority of populations across the world (Burlando and Cornara, 2014). Rice bran wax is

used in food as a release agent, brightener, coatings for confectioneries, chocolates, cakes, and tablets, treatment of vegetables and fruits and as a plasticizing material for chewing gum base. Non-food uses include cosmetics, polish for cars, floors, and shoes, office ink, textile oiling agent, and resin lubricant (Andersen, 2006).

Rice bran wax (CAS No. 8016-60-2) has been approved for use in various food applications in the US. It is permitted as a direct food additive (21 CFR §172.890) when used in candy (maximum 50 ppm as a coating), fresh fruits and fresh vegetables (maximum 50 ppm as a coating), and chewing gum (maximum 2.5% in gum when used as a plasticizing material in chewing gum base, 21CFR §172.615). It is also permitted as an indirect food additive as Type VIII in table 1 of 176.170(c), at a maximum level of 1.0 percent by weight of the polymer. After reviewing the available safety data, the Cosmetic Ingredient Review (CIR) Expert Panel concluded that rice-derived ingredients, including rice bran wax, are safe as cosmetic ingredients (e.g., 1% in lip stick) in the practices of use and concentrations as described in their safety assessment (Andersen, 2006). In addition, rice bran wax is eligible for use as an active ingredient or excipient in listed medicines in Australia, with no restrictions (Australian Government, 2007).

Carnauba wax is similarly permitted as a GRAS direct human food ingredient, with no limitation other than cGMP, in baked goods and baking mixes, chewing gum, confections and frostings, fresh fruits and fruit juices, gravies and sauces, processed fruits and fruit juices, and soft candy (21 CFR § 184.1978).

Intended Use and Intake Assessment

The focus of this GRAS assessment is for the proposed use of rice bran wax as a texturizing agent in peanut butter used in nutrition and granola-type bar products. The intended use will allow peanut butter to be the primary ingredient in nutritional/snack bars with a similar form and texture to granola bars and nutritional/energy bars. The proposed use of rice bran wax will be at levels from 3 – 4%.

ToxStrategies conducted an intake assessment in order to estimate the mean and 90th percentile daily intakes of the ingredient rice bran wax based on its new proposed use in foods (ToxStrategies, 2016). It was assumed for the purpose of this estimate that consumers of nutritional/snack bars would replace the consumption of all existing bars with the consumption of the proposed peanut butter-based bars, in order to produce the highest (most conservative) estimate of potential rice bran wax consumption. Two-day average intake data were obtained from the National Health and Nutrition Examination Survey (NHANES) in 2009-2010 and 2011-2012 (Centers for Disease Control and Prevention (CDC), 2009-2010; 2011-2012).

Use levels of both 3% and 4% of rice bran wax in peanut butter used in bar products were estimated. Analyzing dietary survey data at 3% yielded *per user* mean and 90th percentile estimated daily intakes (EDIs) of rice bran wax for the US population ages 2 and over of 0.76 and 1.29 g/day (0.013 and 0.028 g/kg BW/day, respectively). For the total US

population ages 2 and over, the *per capita* mean and 90th percentile EDIs were 0.08 and 0.32 g/day (0.001 and 0.004 g/kg BW/day), respectively.

Analyzing dietary survey data from NHANES at a maximum 4% use level in peanut butter yielded *per user* mean and 90th percentile EDIs of rice bran wax for the US population ages 2 and over of 1.02 and 1.72 g/day (0.018 and 0.037 g/kg bw/day, respectively). For the total US population ages 2 and over, the *per capita* mean and 90th percentile EDIs were 0.11 and 0.42 g/day (0.002 and 0.005 g/kg bw/day, respectively). It should be noted that these intake estimates are extremely conservative and assume complete replacement of the intake of all of the selected bar products with the proposed peanut butter bar product containing rice bran wax.

The background exposure to rice bran wax from its approved uses in gum, candy, and fresh fruit and fresh vegetables is estimated to be approximately 100 mg/day, about half of which is estimated to come from fresh fruit/vegetables and the other half from chewing gum. This estimate is based on reported consumption levels for chewing gum (approximately 30 mg/kg/day for a 60 kg individual or 1.8 g gum/day), candy (mean intake of approximately 40 g candy/day), and fresh fruit and fresh vegetables (approximately 900 g fruits and vegetables/day) (Revolymex Limited, 2011; Cook, 2011; Orlich et al., 2014; Shumow et al., 2012). Given the approved 2.5% maximum use level of rice bran wax in chewing gum, the background exposure estimates for rice bran wax from its use in chewing gum would be higher for heavy users of chewing gum (estimated to be on the order of 2-3x) as compared to mean intake estimates. Therefore, the background exposure to rice bran wax from current approved uses is estimated to be as high as 200 - 300 mg/day.

We believe this background exposure estimate is extremely conservative given that other waxes are more commonly used as confectionery coatings (e.g., confectioners glaze (shellac) and carnauba wax) and as a coating for fruits and vegetables and alternative waxes and plasticizers are approved and used in chewing gum base in the US. In addition, it is generally acknowledged that waxes and plasticizers in gum base remain with the gum cud during chewing and are not released and subsequently ingested.

Safety Data

Brown rice and its derivatives, such as rice bran wax, have a long history of human consumption, with rice cultivation documented back to prehistoric times (Burlando and Cornara, 2014). Rice bran wax has been approved for use in various food applications in the US and is permitted as a direct human food additive when used in candy, fruits and vegetables, and chewing gum (21CFR §172.890).

As discussed above, the monoester fraction in carnauba wax can be considered to be nearly structurally identical to the monoester fraction of rice bran wax; i.e., 54-84% monoester fraction in carnauba wax compared to up to 87-98% of the total rice bran wax composition.

The long-chain fatty acid esters present in rice bran wax and carnauba wax are generally thought to be poorly absorbed in the gastrointestinal tract and as such, any absorption via the oral route of exposure is likely to be negligible (EFSA, 2012 a,b). No published data were identified regarding the acute oral toxicity of rice bran wax; however, the Cosmetic Ingredient Review (CIR) Panel reviewed three unpublished laboratory reports in its assessment of rice bran wax for cosmetic and personal care product use. All of these data suggested that rice bran wax is of low acute oral toxicity with an LD₅₀ of >5 g/kg in rats (Andersen, 2006). Similarly, EFSA (2012b) reviewed two unpublished studies and concluded that carnauba wax is also of low acute oral toxicity. Neither rice bran nor carnauba wax showed mutagenic and/or genotoxic potential in studies (as reviewed in Andersen (2006) and EFSA (2012a,b)) and the EFSA CONTAM Panel determined there is no concern for genotoxicity for carnauba wax based on the available data and the lack of structural alerts (EFSA, 2012a).

While no repeated dose or reproductive/developmental toxicity studies were identified for rice bran wax, several studies evaluating the potential toxicity of carnauba wax via the oral route of exposure were reviewed. Subchronic toxicity studies in rats and beagle dogs reported no treatment-related adverse effects from carnauba wax when administered in the diet, and an EFSA Panel derived No-Observed-Adverse-Effect-Levels (NOAELs) of 8800 mg/kg-bw/day (rat), 1500 mg/kg-bw/day (rat), and 250 mg/kg-bw/day (dog) from these studies (Rowland et al., 1982; Parent et al., 1983a; Edwards, 1998 as cited by EFSA, 2012b). In a developmental toxicity study in rats administered increasing levels of dietary carnauba wax (0.1, 0.3, or 1%, equivalent to 50, 150, or 500 mg/kg-bw/day) no significant treatment-related effects were reported (FDRL, 1977, as cited in EFSA, 2012b). In a reproductive toxicity study, no treatment-related effects were reported following exposure to carnauba wax administered in the diet of male and female rats (Parent et al., 1983b) and an EFSA Panel determined the NOAEL to be 670 mg/kg-bw/day based on the highest dose given to female rats (EFSA, 2012b). In summary, all of the repeated dose and reproductive/developmental toxicity studies of carnauba wax resulted in NOAELs at the highest dose levels administered, the highest of which was a concentration of 10% (equivalent to 8,800 and 10,200 mg/kg-bw/day in males and females, respectively) when administered in the diet of rats for 90 days.

While tests in guinea pigs and rabbits were negative for dermal sensitization, some isolated cases of allergy to rice or its derivatives have been reported (reviewed in Andersen, 2006; Burlando and Cornara, 2014). Given that rice bran wax contains little to no protein, which is the component responsible for imparting allergic potential, rice bran wax is not likely to pose a significant allergenic risk.

Taken together, the available published and unpublished safety data for rice bran wax and the supportive toxicological data publicly available for carnauba wax, which is documented in the publicly available literature to be comprised of nearly identical chemical constituents, demonstrate that rice bran wax has little potential for toxicity.

Brown rice and its derivatives have a long history of human consumption and importantly, the known history of use of rice bran wax in food such as candy, chewing gum, and fresh fruit and vegetables (21 CFR § 172.890 and 21 CFR § 172.615) is

supportive of its safe use in food. While some key studies were not accessible for review, they have been reviewed in detail by authoritative experts or in the case of CIR, well-respected expert panels and deemed sufficient to demonstrate a lack of toxicological potential. The absence of a chronic toxicity study is not considered limiting, as data from the three publicly available subchronic toxicity studies on the structurally similar carnauba wax are considered to be sufficient for supporting the safety of the intended use and use levels of rice bran wax. Given the structural similarity of carnauba wax and rice bran wax, particularly the similar monoester chain length distribution and nearly identical physio-chemical properties, similar safety profiles can be predicted for these two waxes in toxicity studies. While information on the potential carcinogenicity from long-term safety studies of both waxes are not available, there is nothing in the chemical structure of rice bran wax or that of carnauba wax, or based on available genotoxicity data, or on regulatory reviews of carnauba wax to suggest any carcinogenic potential. In addition, the history of use of other vegetable-based waxes, in particular carnauba wax, provide sufficient safety data to support the proposed use and use levels of rice bran wax. The FDA has listed carnauba wax (CAS No. 8015-86-9) as GRAS as a direct food substance for human consumption with no specific limitation other than good manufacturing practice (21 CFR § 184.1978), and as such, the available safety information also suggests that rice bran wax should also be considered to be safe for the intended uses proposed herein.

General Recognition of the Safety of Rice Bran Wax

The intended use of rice bran wax has been determined to be safe through scientific procedures as set forth in 21 CFR§170.3(b), thus satisfying the so-called “technical” element of the GRAS determination and this is based on the following:

- The rice bran wax that is the subject of this notification is a high melting point vegetable wax obtained from rice husks. The rice bran wax product is manufactured consistent with current cGMP for food (21 CFR Part 110). The raw materials and processing aids used in the manufacturing process are food grade and/or approved for use in food.
- Brown rice, and its derivatives have a long history of human consumption with rice cultivation documented back to prehistoric times. Importantly, the known history of use of rice bran wax in food such as candy, chewing gum, and fresh fruit and vegetables (21 CFR § 172.890 and 21 CFR § 172.615) is also supportive of its safe use in food and specifically the intended use and use levels specified in this dossier.
- Safety studies of rice bran wax and/or carnauba wax have been conducted and are publicly available and/or have been previously reviewed and reported in summary form by an authoritative regulatory body. Based on the similar physical-chemical properties of both rice bran wax and carnauba wax, particularly the similar monoester chain length distribution and concentration, the available safety data for carnauba wax obtained from publicly available studies on its subchronic and

reproductive/developmental toxicity, can be appropriately used to bridge the safety of the intended use of rice bran wax in this assessment.

- All of the repeated dose and reproductive/developmental toxicity studies of carnauba wax resulted in NOAELs at the highest dose levels administered. NOAELs ranged from 250 to 10,800 mg/kg/day, the highest of which was a concentration of 10% (equivalent to 8,800 and 10,200 mg/kg-bw/day in males and females, respectively) administered in the diet of rats for 90 days. Estimated mean and 90th percentile intakes of rice bran wax of 18 mg/kg/day and 37 mg/kg/day, respectively were calculated (assuming a maximum 4% use level) for the US population ages 2 and over. This provides margins of exposure (MOEs) of approximately 14x and 7x, respectively for mean and 90th percentile intakes when compared to the lowest NOAEL reported from studies with carnauba wax. However, it should be noted that no adverse effects were reported in the highest dose level tested in these studies and the lower MOEs of 7x and 14x are derived from the published study in dogs with a NOAEL of only 250 mg/kg/day. Importantly, higher dose levels were not administered in this study. When compared to other studies in rodents with NOAELs of 10,800 mg/kg/day, the margins of exposures increase to 560x to 292x for mean and 90th percentile intakes. In addition, since consumption of peanut butter bars with rice bran wax as an ingredient are extremely unlikely to result in 100% market replacement of all nutrition and granola products in bar form, the margins of exposure can be expected to be even higher.
- Given that rice bran wax contains little to no protein, which is the component responsible for imparting any allergic potential, rice bran wax is not likely to pose an allergenic risk.
- The estimated mean and 90th percentile user only intakes of rice bran wax resulting from the proposed new use are below the NOAELs established in numerous toxicity studies, all of which were determined to be the highest dose levels administered.
- The publicly available scientific literature on the consumption and safety of both rice bran wax and carnauba wax is sufficient to support the safety and GRAS determination relative to the intended use and use level of rice bran wax as a texturizing agent in peanut butter used as an ingredient in nutrition and granola-type bar products.

Conclusions of the Expert Panel

We, the undersigned members of the Expert Panel, have individually and collectively critically reviewed the published and ancillary information pertinent to the identification, use, and safety of Smucker's rice bran wax product. We conclude that the rice bran wax ingredient produced under the conditions described in the attached dossier and meeting the proposed specifications is safe.

We further unanimously conclude that the intended use of the rice bran wax as a texturizing agent in peanut butter used in nutrition and granola-type bar products at a maximum level of 4% , meeting the specifications described above, is Generally Recognized as Safe (GRAS) based on scientific procedures and that other experts qualified to assess the safety of foods and food additives, and critically evaluating the same information, would concur with these conclusions.

Michael Carakostas, DVM, PhD
Consultant
MC Scientific Consulting LLC

Date

Stanley M. Tarka, Jr., PhD
Consultant
Tarka Group, Inc.

Date

Thomas Vollmuth, PhD
Consultant
Vollmuth and Associates, LLC

Date

Conclusions of the Expert Panel

We, the undersigned members of the Expert Panel, have individually and collectively critically reviewed the published and ancillary information pertinent to the identification, use, and safety of Smucker's rice bran wax product. We conclude that the rice bran wax ingredient produced under the conditions described in the attached dossier and meeting the proposed specifications is safe.

We further unanimously conclude that the intended use of the rice bran wax as a texturizing agent in peanut butter used in nutrition and granola-type bar products at a maximum level of 4% , meeting the specifications described above, is Generally Recognized as Safe (GRAS) based on scientific procedures and that other experts qualified to assess the safety of foods and food additives, and critically evaluating the same information, would concur with these conclusions.

(b) (6)

Michael Carakostas, DVM, PhD
Consultant
MC Scientific Consulting LLC

4/22/16
Date

Stanley M. Tarka, Jr., PhD
Consultant
Tarka Group, Inc.

Date

Thomas Vollmuth, PhD
Consultant
Vollmuth and Associates, LLC

Date

Conclusions of the Expert Panel

We, the undersigned members of the Expert Panel, have individually and collectively critically reviewed the published and ancillary information pertinent to the identification, use, and safety of Smucker's rice bran wax product. We conclude that the rice bran wax ingredient produced under the conditions described in the attached dossier and meeting the proposed specifications is safe.

We further unanimously conclude that the intended use of the rice bran wax as a texturizing agent in peanut butter used in nutrition and granola-type bar products at a maximum level of 4% , meeting the specifications described above, is Generally Recognized as Safe (GRAS) based on scientific procedures and that other experts qualified to assess the safety of foods and food additives, and critically evaluating the same information, would concur with these conclusions.

Michael Carakostas, DVM, PhD
Consultant
MC Scientific Consulting LLC

Date

(b) (6)

Stanley M. Tarka, Jr., PhD
Consultant
Tarka Group, Inc.

Date

25 April 2016

Thomas Vollmuth, PhD
Consultant
Vollmuth and Associates, LLC

Date

Conclusions of the Expert Panel

We, the undersigned members of the Expert Panel, have individually and collectively critically reviewed the published and ancillary information pertinent to the identification, use, and safety of Smucker's rice bran wax product. We conclude that the rice bran wax ingredient produced under the conditions described in the attached dossier and meeting the proposed specifications is safe.

We further unanimously conclude that the intended use of the rice bran wax as a texturizing agent in peanut butter used in nutrition and granola-type bar products at a maximum level of 4%, meeting the specifications described above, is Generally Recognized as Safe (GRAS) based on scientific procedures and that other experts qualified to assess the safety of foods and food additives, and critically evaluating the same information, would concur with these conclusions.

Michael Carakostas, DVM, PhD
Consultant
MC Scientific Consulting LLC

Date

Stanley M. Tarka, Jr., PhD
Consultant
Tarka Group, Inc. (b) (6)
(b) (6)

Date

Thomas Vollmuth, PhD
Consultant
Vollmuth and Associates, LLC

Date

4/26/2016

References

Andersen, FA. 2006. Amended final report on the safety assessment of oryza sativa (rice) bran oil, oryza sativa (rice) germ oil, rice bran acid, oryza sativa (rice) bran wax, hydrogenated rice bran wax, oryza sativa (rice) bran extract, oryza sativa (rice) extract, oryza sativa (rice) germ powder, oryza sativa (rice) starch, oryza sativa (rice) bran, hydrolyzed rice bran extract, hydrolyzed rice bran protein, hydrolyzed rice extract, and hydrolyzed rice protein. *International Journal of Toxicology*, 25(Suppl 2), 91-120.

Australian Government. 2007. Australian Therapeutic Goods Administration (TGA). Substances that may be used in Listed medicines in Australia.

Burlando, B, Cornara, L. 2014. Therapeutic properties of rice constituents and derivatives (*Oryza sativa* L.): a review update. *Trends in Food Science & Technology*, 40(1), 82-98.

Centers for Disease Control and Prevention (CDC). 2009-2010. National Health and Nutrition Examination Survey. Available at: http://wwwn.cdc.gov/nchs/nhanes/search/nhanes09_10.aspx. Last accessed April 1, 2015.

Centers for Disease Control and Prevention (CDC). 2011-2012. National Health and Nutrition Examination Survey. Available at: http://wwwn.cdc.gov/nchs/nhanes/search/nhanes11_12.aspx. Last accessed April 1, 2015.

Cook, R. 2011. Tracking demographics and US fruit and vegetable consumption patterns. Department of Agricultural and Resource Economics, University of California, Davis.

Edwards, AJ. 1998. A modified 90-day feeding study to investigate the potential for bioaccumulation of carnauba wax in the Fisher 344 rat, Study report from BIBRA International testing laboratory. Project No. 3180/1. Unpublished report. ***Report not available; as cited in EFSA, 2012b.***

European Food Safety Authority (EFSA). 2007. Beeswax (E 901) as a glazing agent and as carrier for flavours. Scientific Opinion of the Panel on Food additives, Flavourings, Processing aids and Materials in Contact with Food (AFC). *The EFSA Journal* (2007) 615, 1-28.

European Food Safety Authority (EFSA). 2012a. Scientific Opinion on the evaluation of the substances currently on the list in the Annex to Commission Directive 96/3/EC as acceptable previous cargoes for edible fats and oils – Part III of III. *EFSA Journal* 2012;10(12):2984.

European Food Safety Authority (EFSA). 2012b. Scientific Opinion on the re-evaluation of carnauba wax (E 903) as a food additive. *EFSA Journal* 2012;10(10):2880.

Food and Drug Research Laboratory (FDRL). 1977. Evaluation of the effects of carnauba wax in FDRL/Wistar derived rats after dietary exposure through one full generation. Unpublished report of July 8, 1977 submitted to Brazilian Embassy, Washington, D.C. ***Report not available; as cited in EFSA, 2012b.***

Koster Keunen, 2014. Waxes for Personal Care Information Sheet.

Maru, AD, Surawase, RK, Bodhe, PV. 2012. Studies on Physico-Chemical Properties of Rice Bran Wax and its Comparison with Carnauba Wax. *International Journal of Pharmaceutical and Phytopharmacological Research*. 1(4), 203-207.

Orlich, MJ, Jaceldo-Siegl, K, Sabaté, J, Fan, J, Singh, PN, Fraser, GE. 2014. Patterns of food consumption among vegetarians and non-vegetarians. *British Journal of Nutrition*, 112(10), pp.1644-1653.

Parent, RA, Cox, GE, Babish, JG, Gallo, MA, Hess, FG, Becci, PJ. 1983a. Subchronic feeding study of carnauba wax in beagle dogs. *Food and Chemical Toxicology* 21:85-87.

Parent, RA, Re, TA, Babish, JG, Cox, GE, Voss, KA, Becci PJ. 1983b. Reproduction and subchronic feeding study of carnauba wax in rats. *Food and Chemical Toxicology* 21:89-93.

Puleo, S, Rit, TP. 1992. Natural waxes: past, present and future. *Lipid Technology*, July/August 1992 Issue.

Revolymer Limited. 2011. GRN No. 374; Maleated isoprenyl polymer with methoxy-polyethylene glycol (MIP-MPEG).
<http://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm269568.pdf>

Rowland, IR, Butterworth, KR, Gaunt, IF, Grasso, P, Gangolli, SD. 1982. Short-term toxicity study of carnauba wax in rats. *Food and Chemical Toxicology* 20, 467-471.

Shumow L, Barraj LM, Murphy MM, Bi X, Bodor AR. 2012. Candy consumption in the United States. *FASEB Journal* 26:1005.3 (abstract).

ToxStrategies, Inc. 2016. Estimated Daily Intake of Rice Bran Wax.

Warth AH. 1956. The chemistry and technology of waxes. New 2nd ed. Reinhold Publishing Co., New York.

SUBMISSION END