

GR

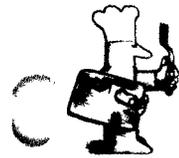


ORIGINAL SUBMISSION

000001

#62932

GRN # 12



Givaudan Roure

Flavors

December 21, 1998

Office of Premarket Approval (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St., SW
Washington, DC 20204

RE: Mesquite Wood Extract

Dear Premarket Approval Reviewer:

Under the Food and Drug Administration's Proposed Rule regarding substances generally recognized as safe (GRAS), 62 Fed. Reg. 18938 (17 April 1997), the below signed is notifying FDA of the determination that mesquite wood alcoholic extract is GRAS under the conditions of use outlined in the attached summary document, specifically as an alternative to the GRAS substance oak chip extract and for the treatment of whiskey.

This GRAS exemption claim is based on common use in food, and pertinent information in support of this claim has been gathered in accordance with the proposed rulemaking guidelines. The detailed information supporting the GRAS notification is available for the FDA review and copying, or could be sent to the FDA upon request.

Based on the information supplied, we request the agency affirm the GRAS status of use of mesquite wood alcoholic extract.

If further information is required and for further correspondence, please do not hesitate to contact me.

Respectfully submitted,

Nancy A. Higley, Ph.D.
Vice President, Product Safety & Regulatory Assurance

/nah
Attachments

1998 DEC 30 P 1:46

General Requirements

Notifier:

Nancy A. Higley, Ph.D.
Vice President, Product Safety and Regulatory Assurance
Givaudan Roure Flavors
1199 Edison Drive
Cincinnati, OH 45216

Notified Substance:

Common or Usual Name: Mesquite wood extract

Conditions of Use

Distilled spirits: 1 lb/400 wine gallons

Exposure limited to adults

Consumption:

1.2 gallons/capita total population

1.8 gallons/capita >21 years

1.7 gallons/capita > 18 years

(Reference: 1995 USDA Economic Research Survey)

and

With projected use, based on the equivalence of the mesquite extract product with oak chip extract, in the following end use categories and average maximum use levels:

Alcoholic beverages: 43.3 ppm

Non-alcoholic beverages: 8.66 ppm

Frozen dairy deserts: 88.6 ppm

Candy: 90.0 ppm

Baked goods: 90.0 ppm

Gelatins & Puddings: 0.561 ppm

(Reference: Results of Second FEMA Survey of Flavoring Ingredients, April 1995)

Possible Average Daily Intake (Based on MRCA mean frequency of eating and USDA mean portion size):

17.45 mg/p/d

Mesquite Wood Extract
GRAS Notification
12/21/98

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Basis of GRAS Determination

This GRAS exemption claim is based on common use in food and pertinent information in support of this claim has been gathered in accordance with the proposed rulemaking guidelines.

Availability of Information

The detailed information and data supporting the GRAS notification are available for the FDA review and copying at reasonable times at the specific address set out in the notice or will be sent to the FDA upon request.

Specific Requirements

Identity and Specifications

Preferred Name: Mesquite wood extract

CAS Number:

93165-66-3 (for Prosopis spicigera extract)

EINECS Number:

296-953-7

Botanical Name:

Prosopis spp.

Varieties in Family Fabacea:

Prosopis julifera

Prosopis glandulosa (honey mesquite)

Prosopis velutina (velvet mesquite)

Prosopis pubescens

Prosopis laevigata

Prosopis pallida

Prosopis chilensis

Prosopis tamarugo

Method of synthesis:

1 lb. mesquite chips/400 gallons alcohol

Stir 2 hours with no heat

Filter out chips

Mesquite Wood Extract

GRAS Notification

12/21/98

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000004

Mesquite Chips Specifications:

Mesquite chips used to produce the extract must not contain detectable levels of pesticides

Alcohol Specifications:

Alcohol used to produce the extract is food grade and undenatured

Alcohol includes, but is not limited to, whiskey

Ethyl alcohol meets the specifications of Food Chemicals Codex, Fourth Edition

Typical Analysis:

Tan to brown liquid

Flashpoint: >50 °F

Refractive Index: 1.395 - 1.392 @20°C

Specific Gravity: 0.84 - 0.86 @ 25/25°C

GLC:

Analysis attached

Self-Limiting Use

As with oak chip extract, the use of the mesquite extract will be self limiting. General experience with wood extracts provides evidence that high concentrations in finished flavor and food result in an undesirable astringent taste.

Basis of GRAS Determination

Traditionally used in Southwest food preparations and seasoning mixes

Native tribes who used mesquite for culinary purposes were, among others, the Hopi, Pima, Papago, Yuma, and Seri. References indicate that whole pods contain a pulpy sweet nutrition material that is ground and made into bread, cakes, mush and porridge. Pods are also used for making a sweet drink (atole) or fermented to beer. (Reference: Ethnobotany Mesquite Database)

Further information indicates that native tribes utilized mesquite extracts as poltices, infusions, and decoctions for the oral and dermal treatment of numerous ailments. (Reference: E.F. Castetter and R.M. Underhill. 1935. The Ethnobiology of the Papago Indians; L.S.M. Curtin. 1949. By the Prophet of the Earch; F. Russel. 1908. The Pima Indians)

Further support of this GRAS notification is found in analysis demonstrating compositional similarity to the GRAS oak chip extract (21 CFR 172.510 and FEMA GRAS 2794).

GLC analysis of oak chip extract attached indicates that the extractable constituents of mesquite wood extract and oak chip extract are identical.

General experience concludes that the overall exposure to mesquite wood extract will be less than the oak chip extract use as distilled spirits are often aged for 3 or more years in oak vessels.

Although not all species of wood are specifically mentioned in FDA's approval of natural smoke flavors, hickory and mesquite are often the hardwoods of choice for the use of wood smoke in approved food products (21 CFR 133.118 and 9 CFR 318.7). Further, Linaloe wood and Western larch wood are cited in 21 CFR 172.510 and 172.610, respectively.

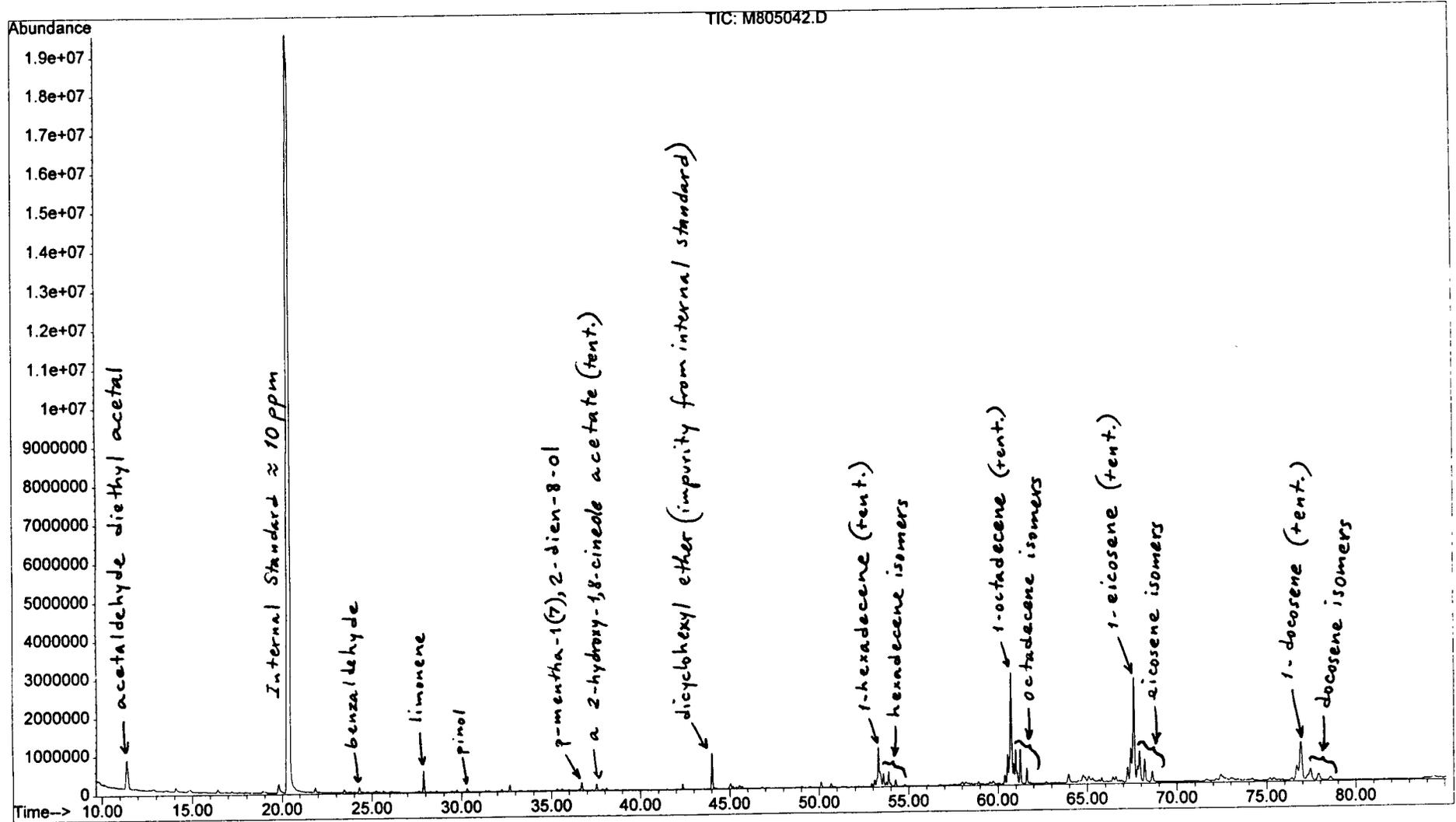
Numerous hardwood species are cited by the Council of Europe (1974, Natural Flavouring Substances, Their Sources, and Added Artificial Flavouring Substances) thus establishing that many hardwoods are known to be added to foodstuffs.

Further, it is recognized that, although not specifically listed in 21CFR, several wood extracts appear on the labels of some alcoholic beverage products, specifically beechwood and maple.

A literature review using CAS 93165-66-3, as well as "mesquite extract" as the search terms, provided no evidence of any relevant toxicity, metabolism or pharmacological studies.

(Search of the STN Express MEDICINE cluster including AIDSLINE, BIOSIS, CANCERLIT, CAPLUS, CEN, DDFB, DDFU, DGENE, DISABS, DRUGB, DRUGLAUNCH, DRUGNL, DRUGU, EMBAL, EMBASE, IFIPAT, IPA, JICST-EPLUS, LIFESCI, MEDLINE, MAPRALERT, NLDB, PHIC, PHIN, PNI, SCISEARCH, TOXLINE, TOXLIT, USPATFULL)

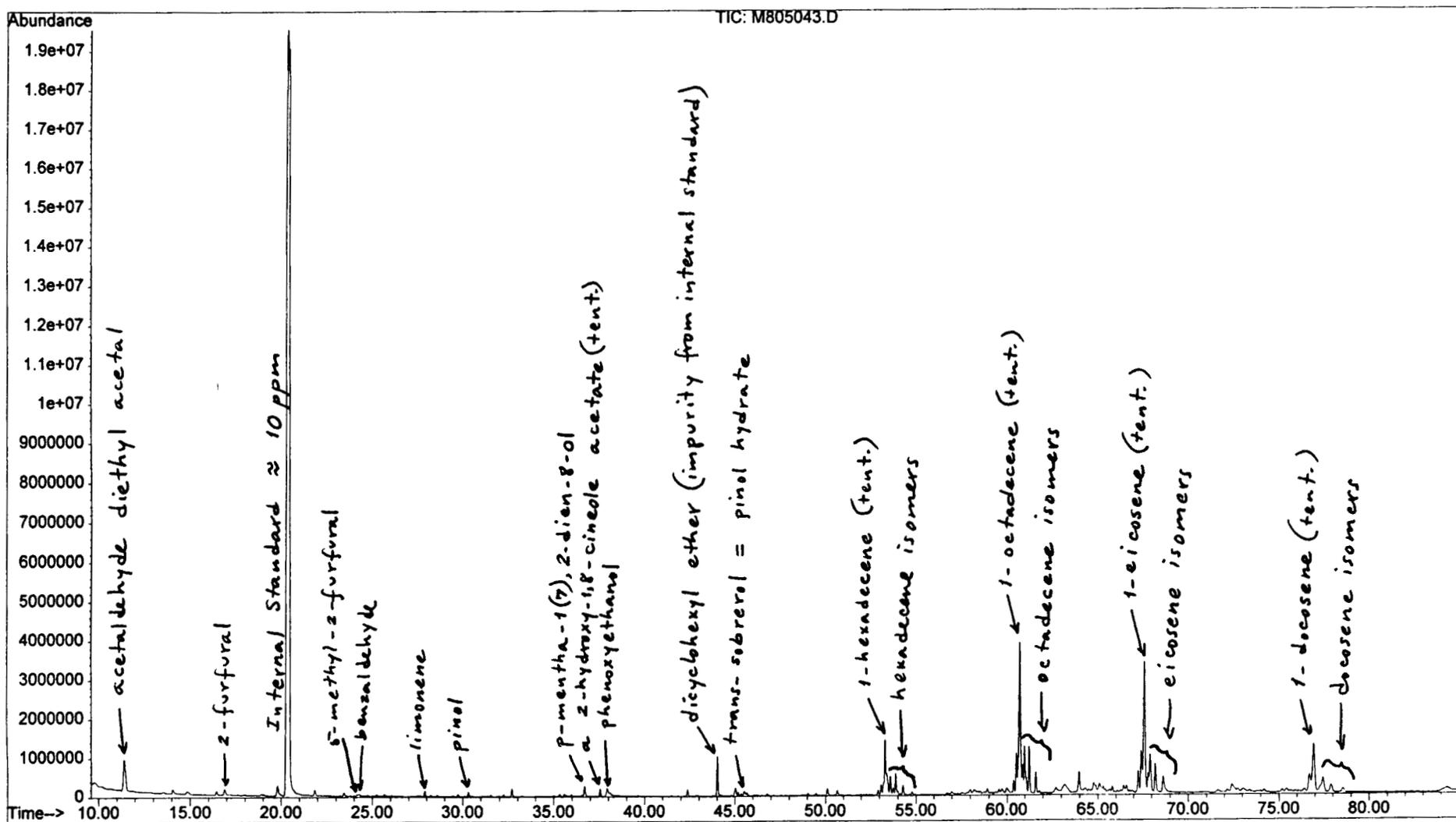
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 Operator : J. Matiella & M. Sunderhaus
 Acquired : 10 Dec 98 19:03 using AcqMethod MCSLESS5
 Instrument : 5890/5972
 Sample Name: 48363 Mesquite Chips in Vodka base, 1lb/400gal, stirred 2 Hr
 Misc Info : 4x(25ml+0.25ml 0.1%CCH+20ml MeCl2), conc.
 Vial Number: 23



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File : S:\ANALYTIC\GCMSDATA\M805043.D
 Operator : J. Matiella & M. Sunderhaus
 Acquired : 10 Dec 98 20:36 using AcqMethod MCSLESS5
 Instrument : 5890/5972
 Sample Name: 48213 Oak Chips in Vodka base, 1lb/400gal, stirred 2 hr
 Misc Info : 4x(25ml+0.25ml 0.1%CCH+20ml MeCl2), conc.
 Vial Number: 24

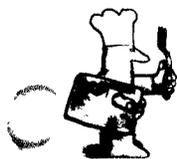
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SUBMISSION END

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Givaudan Roure

Flavors

December 22, 1998

Dr. Alan M. Rulis
Director
Office of Premarket Approval (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St. SW.
Washington, DC 20204

RE: Voluntary GRAS Notification of Mesquite Wood Extract

Dear Dr. Rulis:

We have notified the Office of Premarket Approval regarding the general recognition as safe status (GRAS) of mesquite wood extract in accordance with the Food and Drug Administration's Proposed Rule, 62 Fed. Reg. 18939 (17 April 1997). I am sending a copy to you in an effort to receive an early response from you regarding our customer's ability to use this material prior to the 90 day FDA review period.

My request is due to the fact that the consideration for the use of this substance to impart mesquite flavor, with the subsequent labeling advantages, to whiskey has had an arduous path. First, the submission by United States Distilled Products (USDP) to BATF resulted in a question of the GRAS status of the mesquite extract and subsequent transferal to the FDA for advice. Mr. L. Blum investigated the question and, upon consultation with others at the FDA, determined that the current regulation is specific only for oak chips. My communication with Mr. Blum suggested that our submission of notification of the GRAS status to the Office of Premarket Approval was needed. Although all of this has been completed, some considerable time has transpired between the desired use of this material and a final understanding of what both the BATF and FDA required. This has resulted in an unfortunate delay of over 60 days since this product was submitted for approval. Subsequent communication with Senator elect Jim Bunning, whose response is also attached, was conducted in an effort to elicit assistance in achieving a market introduction. An additional 90 days wait until we receive a response from the FDA will cause a financial burden on Inovatec Corporation and, in fact, result in the loss of the ability to market this product.

Do you believe that there is any avenue by which the FDA could provide an early opinion on the use of this material in such a manner that USDP and Inovatec Corporation can present the affirmative response to BATF and, subsequently, gain approval for the formulation?

If there is any additional information that you require, please do not hesitate to contact me at (513)-848-3549. Your assistance would be greatly appreciated.

Sincerely,

Nancy A. Higley, Ph.D.
Vice President, Product Safety & Regulatory Assurance

cc: Mr. Jim Razzino, Inovatec Corporation (502-253-9413)
Gerry Linkovich, Compliance Associates (502-228-2192)

Attachments:

- (1) Voluntary GRAS Notification, dated December 21, 1998
- (2) Letter to Congressman Bunning, dated December 4, 1998
- (3) Response from Congressman Bunning, dated December 14, 1998

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DUBUOATE



Givaudan Roure
Flavors

December 21, 1998

Office of Premarket Approval (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St., SW
Washington, DC 20204

RE: Mesquite Wood Extract

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Respectfully submitted,

Nancy A. Higley, Ph.D.
Vice President, Product Safety & Regulatory Assurance

/nah
Attachments

000012

DUPPLICATE

General Requirements

Notifier:

Nancy A. Higley, Ph.D.
Vice President, Product Safety and Regulatory Assurance
Givaudan Roure Flavors
1199 Edison Drive
Cincinnati, OH 45216

Notified Substance:

Common or Usual Name: Mesquite wood extract

Conditions of Use

Distilled spirits: 1 lb/400 wine gallons

Exposure limited to adults

Consumption:

1.2 gallons/capita total population

1.8 gallons/capita >21 years

1.7 gallons/capita > 18 years

(Reference: 1995 USDA Economic Research Survey)

and

With projected use, based on the equivalence of the mesquite extract product with oak chip extract, in the following end use categories and average maximum use levels:

Alcoholic beverages: 43.3 ppm

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Frozen dairy deserts: 88.6 ppm

Candy: 90.0 ppm

Baked goods: 90.0 ppm

Gelatins & Puddings: 0.561 ppm

(Reference: Results of Second FEMA Survey of Flavoring Ingredients, April 1995)

Possible Average Daily Intake (Based on MRCA mean frequency of eating and USDA mean portion size):

17.45 mg/p/d

000013

Mesquite Wood Extract
GRAS Notification
12/21/98

Basis of GRAS Determination

This GRAS exemption claim is based on common use in food and pertinent information in support of this claim has been gathered in accordance with the proposed rulemaking guidelines.

Availability of Information

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Specific Requirements

Identity and Specifications

Preferred Name: Mesquite wood extract

CAS Number:

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EINECS Number:

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Botanical Name:

Prosopis spp.

Varieties in Family Fabacea:

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Prosopis velutina (velvet mesquite)

Prosopis pubescens

Prosopis laevigata

Prosopis pallida

Prosopis chilensis

Prosopis tamarugo

Method of synthesis:

1 lb. mesquite chips/400 gallons alcohol

Stir 2 hours with no heat

Filter out chips

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Mesquite Wood Extract

GRAS Notification

12/21/98

DUBUATE

Mesquite Chips Specifications:

Mesquite chips used to produce the extract must not contain detectable levels of pesticides

Alcohol Specifications:

Alcohol used to produce the extract is food grade and undenatured
Alcohol includes, but is not limited to, whiskey
Ethyl alcohol meets the specifications of Food Chemicals Codex, Fourth Edition

Typical Analysis:

Tan to brown liquid
Flashpoint: >50 °F
Refractive Index: 1.395 - 1.392 @20°C
Specific Gravity: 0.84 - 0.86 @ 25/25°C

GLC:

Analysis attached

Self-Limiting Use

As with oak chip extract, the use of the mesquite extract will be self limiting. General experience with wood extracts provides evidence that high concentrations in finished flavor and food result in an undesirable astringent taste.

Basis of GRAS Determination

Traditionally used in Southwest food preparations and seasoning mixes

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Mesquite Wood Extract
GRAS Notification
12/21/98

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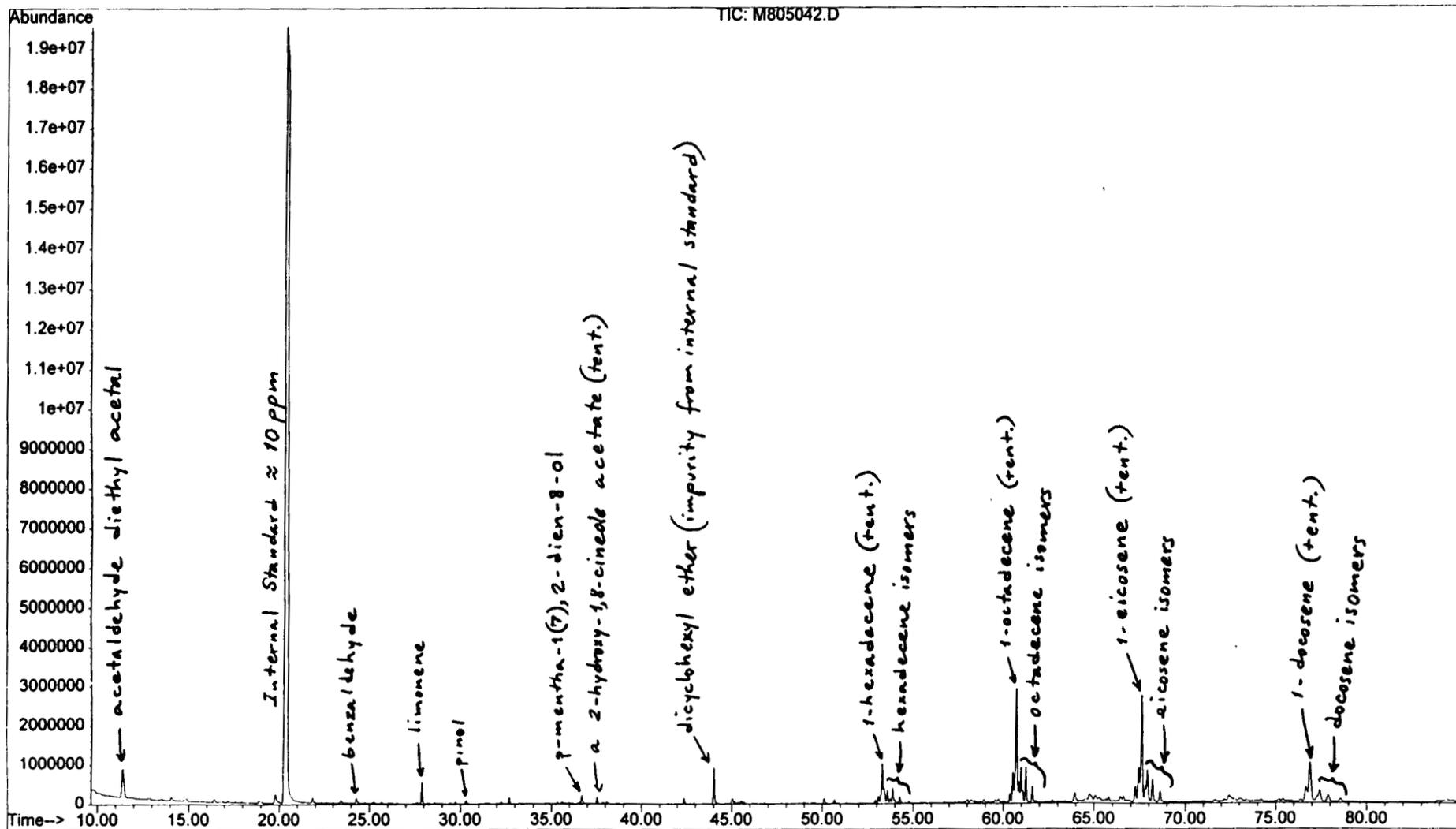
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REPORT

File : S:\ANALYTIC\GCMSDATA\M805042.D
Operator : J. Matiella & M. Sunderhaus
Acquired : 10 Dec 98 19:03 using AcqMethod MCSLESS5
Instrument : 5890/5972
Sample Name: 48363 Mesquite Chips in Vodka base, 1lb/400gal, stirred 2 Hr
Misc Info : 4x(25ml+0.25ml 0.1%CCH+20ml MeCl2), conc.
Vial Number: 23

000017



JIM BUNNING
4TH DISTRICT, KENTUCKY

2437 RAYBURN BUILDING
WASHINGTON, DC 20515
(202) 225 3465

1717 DIXIE HIGHWAY
SUITE 160
FT. WRIGHT, KY 41011
(606) 341-2802

1405 GREENUP AVENUE
SUITE 238
ASHLAND, KY 41101
(606) 325-9898

COMMITTEES:
WAYS AND MEANS
CHAIRMAN, SUBCOMMITTEE
ON SOCIAL SECURITY
BUDGET COMMITTEE
DEPUTY WHIP

Congress of the United States
House of Representatives
Washington, DC 20515-1704

December 14, 1998

Mr. Jim Razzino
Inovatec Corporation
Post Office Box 43368
Louisville, KY 40253-0368

Dear Mr. Razzino:

Thank you for your recent correspondence. I was sorry to learn of the difficulties you are currently encountering.

In an effort to be of assistance to you, I have contacted the appropriate officials of the Food and Drug Administration in Washington, D.C. I have advised them of my interest in your situation and asked that the matter be reviewed to ensure that you are receiving the proper consideration.

Just as soon as I have anything further to report, I will be in touch with you again. In the meantime, if I may be of additional service to you in any way, please feel free to call.

Personal regards,

JIM BUNNING
Member of Congress

JB/psr.ack

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I am not a wealthy person. Most of my funds are now tied up in the start-up expenses/investment in this nascent company.

The delay in approval of this whiskey application is becoming more serious each day. Our capital is invested in consumer research, product development, label and package design, supplies, sales materials, equipment, etc. We are unable to complete advertising and packaging materials until the label is officially approved (the final step after the formula is approved). Vendors are waiting for these approvals to complete their work for us. Customers are waiting to have orders filled and we cannot even guess at when we will be able to ship finished product.

In addition, the Internal Revenue Service has advised us that we must prove that Inovatec Corporation is a going concern in order to expense the over \$100,000 in start-up investment expenditures for 1998. If we cannot document that we have a product, fully approved for sale by the BATF, actively being sold before December 31, 1998, we will be forced to amortize the up-front investment over many years. Very frankly we do not have the funds to do that.

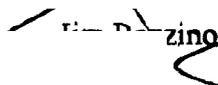
As you know starting a business is fraught with risk. Over two-thirds of new businesses fail within the first two years. We certainly do not want to close down before we ever start-up but we may be forced to do so due to the unresponsive nature of the federal beauracracy.

We would appreciate your intervention with these agencies requesting that the appropriate approvals be expedited. The product is a flavored whiskey not a complex new drug. We have already waited more than 60 days for a response, which is sufficient time to handle a simple matter.

On the last page of this letter are the names and telephone numbers of the all of the people involved.

Thank you very much for your attention to this matter. It means a great deal to us.

Sincerely,

 zino

000019

CONTACTS AND INFORMATION

Product Name: McKendric Whiskey

Bottler: United States Distilled Products Company
1607 S. 12th Street
Princeton, MN. 55371
Attn: Ms. Gail Kenagy, Product Development Manager

Flavorist: Givaudan-Roure
1199 Edison Drive
Cincinnati, Ohio 45216
Attn: Jim Moon, VP Principal Flavorist
Also Ms. Nancy Higley, VP Regulatory Affairs

BATF: Ms. Judy Harrison, Formula Specialist
Tel. 202-927-8140 ext. 78108
Fax. 202-927-8605

Ms. Lynn Gettes, Supervisor Formulas
Same as above

FDA: Mr. Les Bloom
Mr. Marty Stutsman
No telephone numbers available

000020

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Computer Technology Services, Inc.

000021



Givaudan Roure

Flavors

1999 MAR 11 P 12:04

March 8, 1999

Office of Premarket Approval (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, DC 20204

RE: GRAS Notice No. GRN 000012

Dear Reviewer:

On behalf of Givaudan Roure Flavors Corporation, this letter requests the withdrawal of GRN 000012 from consideration in accordance with proposed 21 CFR 170.36 (62 FR 18938; April 17, 1997). If you have any questions regarding this request, please feel free to contact me at (513) 948-3549.

Sincerely,

Nancy A. Higley, Ph.D.
Vice President, Product Safety & Regulatory Assurance

NAH/djc

cc: Dr. Lawrence Lin

Premarkt

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