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Orginial Submission

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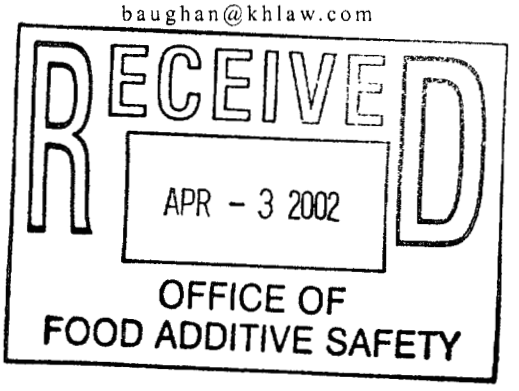
April 3, 2002

Via Hand Delivery



Linda S. Kahl
U.S. Food and Drug Administration
Center for Food Safety & Applied Nutrition
Office of Food Additive Safety
12th Floor
1110 Vermont Avenue
Washington, D.C. 20201

Re: GRAS Notification for Sucrose Acetate Isobutyrate;
Our File No. EA12315-24

Dear Dr. Kahl:

Pursuant to proposed regulation, 21 C.F.R. § 170.36(c), and on behalf of our client, Eastman Chemical Company, we hereby notify the Agency of our determination on the basis of scientific procedures that sucrose acetate isobutyrate (SAIB) is generally recognized as safe (GRAS) when used as a stabilizer of emulsions of flavoring oils used in alcoholic beverages, such as wine coolers. SAIB will be used at levels no greater than 300 parts per million (ppm) in the finished alcoholic beverage. As with all GRAS substances, SAIB, when used in this application, is exempt from the premarket clearance requirement applicable to food additives under Section 409 of the Food, Drug, and Cosmetic Act.

We are submitting this GRAS Notification in triplicate with an additional sanitized version to accommodate any Freedom of Information Act (FOIA) requests should the notification proceed without objection from FDA.

We trust that you will find the enclosed notification acceptable. Should any questions arise during the review process, please do not hesitate to contact us, preferably by telephone, so that we may respond as quickly as possible.

Sincerely yours,

Joan Sylvain Baughan

Enclosure: (GRAS notification in triplicate)

cc: Ms. Donna Jackson, Eastman Chemical Company

000016

Before the
FOOD AND DRUG ADMINISTRATION
Department of Health and Human Services
Washington, D.C.

GRAS NOTIFICATION PETITION

Name of Petitioner:	**Eastman Chemical Company**
Post Office Address:	**All communications on this matter are to be sent in care of Counsel for Petitioner, Joan Sylvain Baughan, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001. Telephone: (202) 434-4147**
Name of Generally Recognized as Safe Substance and Proposed Use:	**Sucrose Acetate Isobutyrate (SAIB) used as a stabilizer of emulsions of flavoring oils in alcoholic beverages**
Dated:	**April 3, 2002**

Joan Sylvain Baughan
Counsel for Eastman Chemical Company

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GRAS Notification for
Sucrose Acetate Isobutyrate

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I. Claim regarding GRAS status

Eastman Chemical Company hereby notifies the agency through its attorneys that its sucrose acetate isobutyrate (SAIB), as described below, is Generally Recognized as Safe (GRAS) when used as a stabilizer of emulsions of flavoring oils used in alcoholic beverages, such as premixed liquid or solid cocktail products, malt beverage coolers including flavored products containing beer, and alcoholic "cooler beverages" or wine coolers, such that the level of SAIB in the finished beverage will be no greater than 300 parts per million (ppm). Accordingly, SAIB is exempt from the premarket approval requirements of the Food, Drug, and Cosmetic Act.

Date: April 3, 2002

Robert A. Mathews, Ph.D.
Staff Scientist
Keller and Heckman, LLP
1001 G Street, N.W.
Washington, D.C. 20001
202-434-4100

Joan Sylvain Baughan
Attorney for the Notifier
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202-434-4100

A. Name and address of the notifier

Eastman Chemical Company
100 North Eastman Road
Kingsport, Tennessee 37662-5054

B. Common or usual name of the subject substance

The proposed common or usual name of the notified substance is sucrose acetate isobutyrate.

C. Conditions of use

Sucrose acetate isobutyrate (SAIB) is intended for use as a stabilizer of emulsions of flavoring oils used in alcoholic beverages, such as premixed liquid or solid cocktail products, malt beverage coolers including flavored products containing beer, and alcoholic "cooler beverages" or wine coolers, such that the level of SAIB in the finished beverage will be 300 parts per million (ppm) or less.

D. Basis for the GRAS determination

The GRAS determination for SAIB is based upon scientific procedures, as described in greater detail in Section IV below.

E. Statement of availability of data and information

The data and information that are the basis for Eastman's GRAS determination are available for review and copying by FDA at the offices of Keller and Heckman, LLP, 1001 G Street, N.W., Washington, D.C. 20001. These documents will be sent to FDA upon request.

II. Detailed Information About the Identity of the Notified Substance

A. Name

SAIB is further identified by the following names:

1. Common or usual name

The common or usual name for the notified substance is sucrose acetate isobutyrate (SAIB). The name under which the notifier will market and label the product for use in alcoholic beverages is EASTMAN® SAIB – FOOD GRADE.

2. Formal chemical name following nomenclature of Chemical Abstracts Service

The Chemical Abstracts Service (CAS) nomenclature for SAIB is alpha-D-glucopyranoside, O-acetyl-tris-O-(2-methyl-1-oxopropyl)-beta-D-fructofuranosyl, acetate tris(2-methyl propanoate).

3. Other names

Sucrose acetate isobutyrate; sucrose diacetate hexaisobutyrate.

B. Chemical description

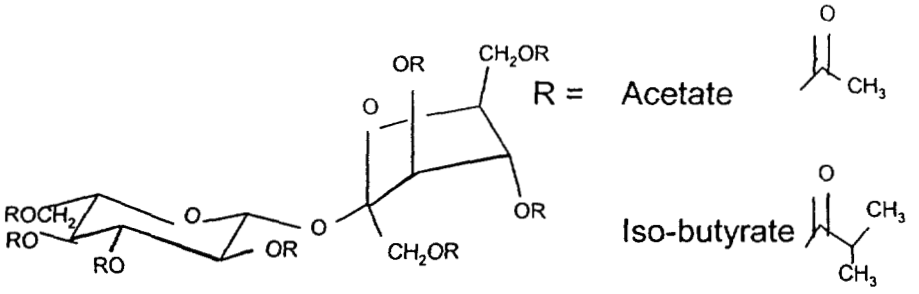
SAIB may be further described chemically as follows.

1. Empirical formula

The emprical formula for SAIB is $C_{40}H_{62}O_{19}$ based on a typical ratio of acetyl:isobutyryl substitution of 2:6.

2. Structural formula

The following is a representative structural formula for SAIB:



3. Chemical Abstracts Service registry number

The CAS Registry Number for SAIB is 27216-37-1.

4. Molecular Weight

Based on the description provided above, the molecular weight of SAIB is calculated to be 846.9.

C. Physical description

SAIB is a clear, viscous liquid, which is slightly yellow in color. It is practically odorless, but has a bitter taste at high levels. This taste is not apparent at the levels at which it would be employed in alcoholic beverage formulations.

D. Method of manufacture

SAIB is produced by a reaction of food grade sucrose with acetic anhydride and isobutyric anhydride in the presence of a catalyst. The esterification product is purified by molecular distillation. Residues of the catalyst used in the manufacture of SAIB are removed in the filtration and distillation (purification) steps.

Substances used

(1) food grade granular sucrose (starch-free sugar)
(2) isobutyric anhydride
(3) acetic anhydride
(4) triacetin (glyceryl triacetate) – used as a pump-shaft lubricant
(5) catalyst
(6) filtration aids

E. Specifications

SAIB that is marketed for use in alcoholic beverages under this notification will comply with the specifications for food-grade SAIB set forth in the *Food Chemicals Codex, Fourth Edition* (FCC IV), *Third Supplement* (2001). The pertinent specifications are shown below; a copy of the monograph for SAIB as it appears in the third supplement to FCC IV is provided as Appendix XII to this notification.

Identification	Passes test when infrared spectrum is compared with a typical spectrum
Assay	Not less than 98.8% and not more than 101.9% of $C_{40}H_{62}O_{19}$
Acid Value	Not more than 0.2
Lead	Not more than 1 mg/kg
Saponification Value	Not less than 524 and not more than 540

SAIB also complies with the additional specifications set forth below.

Appearance	Free from insoluble matter or haze
Color (Platinum – Cobalt Scale)	Not more than 150
Triacetin	Not more than 0.10%

III. Information Relevant to Self-limiting Levels of Use

Not applicable.

IV. Detailed Summary of Basis for Notifier's GRAS Determination

The safety of SAIB as an ingredient in food has been established by a comprehensive series of toxicological studies, including genetic, reproductive, teratogenic, pharmacokinetic, subchronic, and chronic exposures of test animals. In addition, studies involving human exposure have been conducted to confirm that the only adverse effect observed in animal testing, impairment of hepatobiliary excretion in dogs, will not occur in consumers exposed to SAIB.

The Food and Drug Administration has previously evaluated the safety of SAIB as a food ingredient. In the process, the Agency reviewed most, if not all, of the toxicity studies discussed herein. As a result of this evaluation, FDA promulgated 21 C.F.R. Section 172.833, which permits the use of SAIB as a stabilizer of emulsions of flavoring oils in nonalcoholic beverages, provided that the total SAIB content of the finished beverage does not exceed 300 mg per kilogram of beverage.[1] It should be emphasized that the Notifier does not claim that SAIB is generally recognized as safe based on this prior evaluation and clearance by FDA. Rather, the Notifier has concluded that SAIB is GRAS for the intended use described herein based on the Agency's established standards, as discussed below. The current clearance for SAIB under Section 172.833 is mentioned here merely for the sake of completeness and to confirm that no conflicting expert opinions have been expressed with regard to the safety of SAIB.

FDA's GRAS notification proposal states that a GRAS substance is distinguished from a food additive on the basis of the common knowledge about the safety of the substance for its intended use.[2] The Agency has stated further that there are two aspects to this common knowledge. First, the data and information relied on to establish safety must be generally available. Second, there must be a basis on which to conclude that there is a consensus among qualified experts about the safety of the substance for its intended use. The Notifier has concluded that both of these elements of "common knowledge" are satisfied with respect to SAIB, as discussed below.

The toxicological information relevant to the safety assessment for SAIB has been published in the peer-reviewed scientific literature, as shown below. This publication took the form of a series of articles that were jointly published in 1998, more than three years ago. Thus, the data clearly are generally available.

Moreover, several respected bodies of experts have found SAIB to be safe for use in food. Specifically, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) concluded that sufficient data exist for the adoption of a permanent acceptable daily intake (ADI) for SAIB of 20 mg/kg bw/day. In addition, the European Union's Scientific Committee for Food has reviewed the toxicology of SAIB and concluded that it is safe for use as a stabilizer in beverages. (The ADI established by the Food and Drug Administration for SAIB, 20 mg/kg

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1 64 Fed. Reg. 29949 (June 4, 1999).

2 62 Fed. Reg. 18937 (April 17, 1997).

bw/day,[3] is identical to that set by JECFA, further confirming that the toxicology data have been consistently interpreted as ensuring the safety of SAIB as a human food ingredient.)

Thus, both elements of the "common knowledge" requirement for general recognition of safety are satisfied: specifically, the data and information relied on to establish safety are generally available, and there is a basis on which to conclude that there is a consensus among qualified experts about the safety of the substance for the intended use. Finally, the level of exposure to SAIB that is expected to result from its use in alcoholic beverages is discussed in Section IV.D below. This level, when combined with the estimated dietary intake associated with the current use of SAIB in non-alcoholic beverages, is shown to be well below the acceptable daily intake established by consensus opinion. Based on the entirety of the available information, the Notifier has concluded that SAIB is generally recognized as safe for the intended use in alcoholic beverages.

The detailed safety assessment for SAIB is set forth more fully below.

A. General

SAIB has been shown to have very low acute and chronic toxicities in monkeys and rats. In dogs, SAIB was found to decrease the elimination rates of bromosulfophthalein (BSP) and indocyanine green (ICG) following a single exposure, which is indicative of interference with biliary excretion. Repeated exposures to dogs caused increases in the serum levels of alkaline phosphatase, but other serum enzyme levels indicative of toxic effects on the liver were unaffected. After prolonged exposure of dogs to SAIB in their feed, changes in liver morphology as revealed by electron microscopy were reported.

The no observed effect level (NOEL) for liver and biliary effects in dogs was determined to be 5 milligrams per kilogram of body weight per day (mg/kg bw/day). However, no liver or biliary effects were observed in human volunteers who were fed SAIB at levels up to 20 mg/kg bw/day, in monkeys fed up to 10 g/kg bw/day, or in rodents fed up to 4 g/kg bw/day. The JECFA Committee that reviewed the safety of SAIB deemed the liver and biliary response to be unique to the dog and not relevant to humans. Therefore, the committee established its permanent ADI of 20 mg/kg bw day by applying a 100-fold safety factor to the NOEL for long-term ingestion of SAIB in rats.

B. Toxicological studies

All of the key toxicological studies relied on in this Notification have been published in the peer-reviewed literature, specifically, in *Food and Chemical Toxicology*, Vol. 36, no. 2, pp. 81-144 (1998). The specific articles published therein are listed below. Copies of the articles are attached hereto as the indicated appendices.

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[3] 64 Fed. Reg. 29949 at 29957 (1999).

Sucrose Acetate Isobutyrate (SAIB): Historical Aspects of its Use in Beverages and a Review of Toxicity Studies Prior to 1988. Reynolds, R.C., and Chappel, C.I., pages 81-93. (Appendix I)

Subchronic Toxicity Studies of Sucrose Acetate Isobutyate (SAIB) in the Rat and Dog. Procter, B.G., and Chappel, C.I., pages 101-110. (Appendix II)

Four-week Range Finding and one-Year Oral toxicity Studies of Sucrose Acetate Isobutyrate (SAIB) in the Cynomolgus Monkey. Blair, M., and Chappel, C.I., pages 121-126. (Appendix III)

Oral Toxicity and Carcinogenicity Studies of Sucrose Acetate Isobutyrate (SAIB) in the Fischer 344 Rat and B6C3F1 Mouse. MacKenzie, K.M., et al., pages 111-120. (Appendix IV)

Sucrose Acetate Isobutyrate (SAIB): Three-generation Reproduction Study in the Rat and Teratology Studies in the Rat and Rabbit. MacKenzie, K.M., et al., pages 135-140. (Appendix V)

Lack of Genotoxic Effects of Sucrose Acetate Isobutyrate (SAIB). Myhr, B.C., et al., pages 127-134. (Appendix VI)

Effect of Sucrose Acetate Isobutyrate (SAIB) ingestion on the Hepatobiliary Function of Normal Human Male and Female Volunteers. Chiang, M., et al., pages 141-144. (Appendix VII)

Metabolism and Pharmacokinetics of Sucrose Acetate Isobutyrate (SAIB) and Sucrose Octaisobutyate (SOIB) in Rats, Dogs, Monkeys, and Humans: A Review. Reynolds, R.C., pages 95-99. (Appendix VIII)

As noted above, most, if not all, of the studies have been previously reviewed by FDA; thus, we are not relying on substantial new toxicity data requiring additional evaluation. In addition, the studies discussed in these articles served as the bases for the JECFA reviews of SAIB and the permanent ADI adopted by that organization in 1996 (see Section IV.C below). The JECFA evaluation of the toxicological data is published in the following monograph: 797. Sucrose acetate isobutyrate. WHO Food Additives Series 32; 12-18-01; a copy of the monograph is attached as Appendix IX. The monograph also is available at the following internet address: http://www.inchem.org/documents/jecfa/jecmono/v32je15.htm. The JECFA report adopting the permanent ADI is set forth in Joint FAO/WHO Expert Committee on Food Additives (1997). Forty-sixth Report. Evaluation of Certain Food Additives and Contaminants. WHO Technical Report Series 868; World Health Organization, Geneva. The summary report of the JECFA evaluation also is set forth in Appendix IX, and is available at the following internet address: http://www.inchem.org/documents/jecfa/jeceval/jec_s203.htm.

The following discussion summarizes the toxicology studies that are published in the articles referenced above. The citations given in footnotes at the beginning of each section are to the published articles in which the studies are described; the citations included in the individual study summaries are to the primary data sources. A list of these primary sources appears at the end of the Notification.

1. Acute toxicity studies[4]

The oral LD50 of SAIB in the rat is greater than 5 g/kg bw (in WHO, Series 32; Fassett and Reynolds, 1962; Reynolds, 1972a). Single SAIB doses administered by gavage or ip injection at levels equivalent to 25.6 g/kg bw did not cause mortality in rats or mice over a 2-week observation period (Hewing, 1958). No mortalities occurred in cynomolgus monkeys following administration of SAIB by gastric intubation at doses up to 20 g/kg bw (Tierney and Rinehart, 1979).

2. Short-term and subchronic toxicity studies

a) Rodents[5]

Groups of B6C3F1 mice (10/sex/group) received diets containing SAIB at concentrations providing total doses of 0, 0.625, 1.25, 2.5, or 5.0 g SAIB/kg bw/day for 4 weeks. Body weights, food consumption and physical examinations were recorded at initiation of treatment and weekly during the study. Feeding of SAIB at these doses for 4 weeks had no effect on any of the treated animals. No treatment-related observations were noted at the terminal necropsy (MacKenzie, 1987; see Appendix IV).

Groups of Holtzman albino rats (25/sex/group) received SAIB in the diet at concentrations of 0, 1, or 5% for 95 days. Body weight and food intake were determined weekly, and hematological analyses were conducted at selected intervals. At study termination, animals were necropsied, liver and kidney weights recorded, and histological analysis conducted on select tissues. Weight gain was slightly reduced in males fed 5% SAIB, and absolute and relative liver weights were slightly increased in females fed 5% SAIB. No treatment-related histopathological or hematological changes were reported (Fassett, et al., 1962).

Groups of Sprague-Dawley rats (10/sex/group) received SAIB in the diet at concentrations of 0, 0.38, 1.88, or 9.38% for 13 weeks. Body weights were determined weekly, and hematology was conducted at study termination. At autopsy, organ weights were measured and select tissues were examined microscopically. The only adverse clinical sign was mild diarrhea at the top dose. Post-mortem examination did not reveal any adverse macroscopic or microscopic findings (Hint, 1964).

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[4] Reynolds and Chappel, Appendix I; 797. Sucrose acetate isobutyrate; WHO Food Additives Series 32, Appendix IX.

[5] Reynolds and Chappel, Appendix I; Procter and Chappel, Appendix II.

A series of experiments were conducted in Sprague-Dawley rats. Groups of animals (10/sex/group) received SAIB in the diet at concentrations of 1, 2, or 4% for 28 days, for 56 days, or for 28 days followed or preceded by 28 days on control diet. Animals were evaluated for effects on mortality/morbidity, body weight gain, food consumption, blood chemistry, and gross and microscopic pathology. Significant effects were limited to somewhat decreased blood glucose levels among some groups of female rats; the decreases, however, were not related to dose or feeding regimen. (Krasavage and Terhaar, 1971b; Krasavage, et al., 1973).

Groups of Sprague-Dawley rats (40/sex/group) received SAIB in the diet at concentrations of 0, 2.5, 5, or 10%. A positive control group to aid in evaluation of liver enlargement and microsomal enzyme induction received phenobarbital daily by gavage at a dose equivalent to 100 mg/kg bw. One-half of the animals in each group (20/sex) received the test compound for 6 weeks, the other half for 12 weeks. Urinary excretion of ascorbic acid was measured at weekly intervals during treatment. At the end of 6- or 12-week treatment, half the animals in each group were subjected to the Zoxazolamine muscle relaxant test, followed by re-testing after an additional 4 weeks on basal diet. The Zoxazolamine and urinary excretion tests were performed to determine whether SAIB induces hepatic microsomal enzymes. The remaining 10 animals/sex/group were subjected to clinical chemistry and gross and microscopic pathological examination. Absolute and relative weights were measured for liver, heart, kidneys, and adrenals.

None of the SAIB-treated rats died, and no treatment-related adverse clinical signs were reported. There were no significant effects on weight gain among females; body weights were decreased relative to controls at all dose levels; however, these changes were not dose related. Food consumption was generally not affected, though there were some sporadic differences between tested groups and controls. The SAIB-treated rats did not differ from negative controls in their response to the Zoxazolamine muscle relaxant challenge or in urinary excretion of ascorbic acid, while the positive controls demonstrated the expected responses. On this basis, the authors concluded that induction of microsomal enzymes did not occur in SAIB-treated rats.

Upon necropsy, the mean absolute, but not relative, heart weights were decreased among male rats fed SAIB. No other significant treatment-related effect in gross or microscopic pathology was reported. Treatment with SAIB did not affect liver carboxylesterase activity or the liver lipid levels. Liver glycogen content was significantly increased among the high-dose males and females, consistent with consumption of high levels of the metabolizable sucrose derivative SAIB. By contrast, animals fed phenobarbital for 12 weeks had a marked increase in hepatic carboxylesterase activity, had enlarged livers and demonstrated a significant reduction in glycogen and water content and an increase in lipid content. The top dose of 10% in the diet was concluded to be the no-observed adverse effect level (NOAEL) for this study (Procter, et al., 1971a).

b) Dogs[6]

Groups of beagle dogs (4/sex/group) received SAIB in the diet at concentrations of 0.2, 0.6, or 2.0% for 30 days; an additional 6 males and 6 females served as controls. Animals were evaluated for effects on food intake and weight gain, blood chemistry, hematology, urinalysis, gross and microscopic pathology. No effects on any tested parameters were reported with the exception of a slight but significant elevation in serum alkaline phosphatase (SAP) levels in males and females of the 2.0% SAIB group, and a significant increase in liver weights in both sexes of the 0.6% and 2.0% SAIB groups. These changes were not accompanied by compound-related microscopic pathological changes, however (Morgareidge, 1965).

To further study the effect of SAIB on the liver in dogs, groups of beagle dogs (6/sex/group) were fed diets containing SAIB at concentrations of 0, 0.5, 1.0, 2.0, or 4.0% for 12 weeks. Test animals in the 4.0% group were maintained for a further 3 weeks on the basal diet as a recovery period. Body weight and food intake were monitored over the course of the study. Blood and urine samples were taken for hematology, serum chemistry, and urinalysis prior to treatment and at weeks 4, 8, and 12, and standard hematological, biochemical and urinalysis tests were performed. At these intervals, bromosulfophthalein (BSP) and phenosulfophthalein (PSP) retentions were measured. BSP and indocyanine green (ICG) plasma disappearance curves were determined at week 12 for male dogs in the 0 and 4.0% groups. BSP clearance was measured in the 4.0% group at intervals during the 3-week withdrawal period.

At study termination, following gross necropsy, organ weights were determined for the brain, heart, liver, lung, kidneys, adrenals, gonads, prostate, uterus, pituitary, spleen, and thyroid. Samples of six tissues including the liver and small and large intestines were examined microscopically. Histochemical studies were carried out on liver sections from the 0.5, 1, and 2% groups; these included evaluation of succinate dehydrogenase, phosphorylase, glucose-6-phosphate dehydrogenase, glycogen, acid phosphatase, alkaline phosphatase, adenosine triphosphatase, and use of Masson's trichrome stain. Additional samples of liver from these groups were analyzed for protein, glycogen, lipid and water, and carboxylesterase activity.

Apart from a number of changes that were associated with liver function, no adverse treatment-related effects were observed. The changes included marked increases in serum alkaline phosphatase (SAP), which were dose- and duration-related, decreased BSP elimination rates, and dose-dependent increases in liver weights among male dogs. The BSP elimination rates were not found to be related to dose. Week-12 BSP clearance curves in male dogs receiving 4% SAIB were found to have a similar pattern to those in control dogs, but the individual plasma BSP concentration values were much higher in the high-dose dogs than in controls. ICG clearance rates in dogs receiving 4% SAIB were reduced in a manner paralleling the changes observed in the BSP tests. Upon repeated testing of the high-dose dogs during the 3-week recovery period, the BSP elimination rates returned to normal, as did the liver weights, incidating the reversibility of the liver effects.

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[6] Reynolds and Chappel, Appendix I; Procter and Chappel, Appendix II.

As a further test of liver function, at study termination the controls and test groups receiving 0.5%, 1.0%, and 2.0% SAIB were tested for serum ornithine carbamoyl transferase, a highly specific liver enzyme. The 4.0% SAIB group also was tested for ornithine carbamoyl transferase, before the 3-week recovery period. These studies failed to reveal any toxic effect of SAIB on liver function.

Light microscopic examination of liver sections did not reveal treatment-related changes. However, electron microscopic evaluation of the livers of treated dogs showed various morphological changes, the most consistent being an increase in smooth endoplasmic reticulum (SER). The effect was most pronounced in the males. Additionally, high levels of enzyme activity (alkaline phosphatase, adenosine triphosphatase and glucose-6-phosphate dehydrogenase) were found in the bile canaliculi of exposed animals. Liver carboxylesterase levels were increased markedly, and slight but significant liver protein decreases and liver glycogen and fat increases were found; these changes, however, were not dose-related and were not clearly treatment-related.

The authors concluded that the liver effects of SAIB were functional rather than toxic in nature. This conclusion took into account the fact that the liver lesions and increased carboxylesterase activity were consistent with induction of metabolic enzymes reflecting adaptation to overloading, as well as the reversibility of the interference by high doses of SAIB with biliary excretion mechanisms. The authors further speculated that the effect on BSP elimination may be due to competition between BSP and SAIB for a common excretory pathway. Nonetheless, a NOEL was not found for this study (Procter, et al., 1970).

In related testing, an additional group of beagle dogs (4/sex) was fed SAIB at the 2.0% dietary concentration for 12 weeks followed by a 6-week recovery period. During the feeding stage, BSP elimination rates were again decreased and SAP levels slightly increased. However, at the end of the 6-week recovery period, BSP and SAP values had returned to normal. Gross pathology and organ weight measurement revealed no treatment-related changes, further indicating the reversibility of the liver effects. No other effects were found upon analysis for hematological parameters, urinalysis, or microscopic examination of liver or other organs. Histochemical analysis and electron microscopy revealed normal liver function and morphology following 6 weeks of recovery (Procter, et al., 1971b; Procter, et al., 1973).

In another study, 5 male beagle dogs received SAIB at 5.0% in the diet for 91 days, while 5 control dogs received base diet. During the study, ICG half-lives were measured for 3 dogs/group at three week intervals, and blood was collected weekly for analysis. At study termination, animals were necropsied. Treatment-related effects consisted of moderately elevated SAP, prolonged ICG retention time, and significantly increased absolute and relative liver weights. No other adverse effects were found in growth, clinical signs, hematology, or serum chemistry (Krasavage and Terhaar, 1971c; Krasavage, et al., 1973).

c) Monkeys[7]

Two male and two female *Cynomolgus* monkeys received SAIB by intubation in an orange juice vehicle over a period of 14 days. Dosing started at 1.25 g/kg bw/day and increased by a factor of 2 with a 72-h rest period between doses, up to a dose of 20 g/kg bw/day. The animals were observed daily for signs of adverse effects. Body weight and food consumption were recorded daily. Seventy-two hours after the last dose, the animals were sacrificed and gross postmortem examinations were conducted. No deaths occurred during the study. Moderate amounts of yellow, watery emesis and/or yellow/tan watery stools were observed in some males and some females 1 to 5 hours after dosing. Twenty-four hours after dosing, all the animals passed moderate amounts of loose, tan stools. Gross postmortem examinations did not reveal any changes which could be attributed to an effect of treatment (Tierney and Rinehart, 1979).

Six groups of cynomolgus monkeys (1/sex/group) received daily doses of SAIB, via intubation in orange juice, at levels of 0, 0.5, 1.0, 2.0, 5.0, or 10.0 g/kg bw/day, for 15 consecutive days. No significant pathological changes were found upon gross and light microscopic examinations. Examination of livers of the high-dose animals by electron microscopy revealed glycogen aggregation surrounded by scant endoplasmic reticulum. However, no changes were seen in bile canaliculi, bile ducts, or hepatic vascular structure (Tierney and Rinehart, 1980a).

In another study, the effect of SAIB on selected clinical chemical parameters was studied in eight cynomolgus monkeys (1/sex/group) fed doses of 0, 2.0, 5.0 and 10.0 g SAIB/kg bw/day under the same conditions as in the previous study. Dosing error resulted in two mortalities (2.0 g/kg female, 5.0 g/kg male). After recording data for the controls, these animals replaced the dead animals and were then dosed for 15 days. Clinical chemistry values, including SAP, were comparable among the various treatment groups. Differences noted were not dose-related and were within normal ranges. BSP retention rates were not altered by dosing with SAIB at any level (Tierney and Rinehart, 1980b).

Groups of cynomolgus monkeys (1/sex/group) received daily gavage doses of SAIB, at levels of 0, 500, 1450, or 2400 mg/kg bw/day, for 4 weeks. Clinical signs, including appetite, were observed twice daily. Body weight measurements and complete physical examinations were conducted weekly. Hematology and clinical chemistry studies, including 30-minute BSP clearance, were conducted on blood samples collected pretest and at four weeks. Gross necropsy was conducted at sacrifice. Low appetite, which was noted occasionally throughout the study, was the only change noted in physical condition or behavior. Body weights were unaffected except for the high-dose female, which lost weight over the course of the study; this animal was found frequently to lack appetite. Hematological and clinical chemistry studies revealed no treatment-related effects, although a reduced serum phosphorus level was detected in the high-dose female. Gross necropsy did not reveal any treatment-related lesions (Blair, 1986).

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[7] Reynolds and Chappel, Appendix I; Blair and Chappel, Appendix III.

Groups of cynomolgus monkeys (4/sex/dose) received daily gavage doses of SAIB, at levels of 0, 500, 1450, or 2400 mg /kg bw/day, for 1 year. Clinical signs, including appetite, were observed twice daily. Body weights were measurements weekly. Complete physical examinations, including ophthalmoscopic examination, were conducted during months 3, 6, 9, and 12. Blood samples were taken at these same intervals for hematology and clinical chemistry studies. Gross necropsy was conducted at sacrifice, selected organs were weighed, and a wide range of tissues and organs were subjected to histopathological examination.

Physical and ophthalmoscopic examinations did not reveal any treatment-related abnormalities. Body weights remained normal. Hematological and clinical chemistry values did not indicate any treatment-related effects. No SAIB-related gross or microscopic lesions were reported. Examination of liver sections by electron microscopy did not reveal any differences between treated and control animals. Based on these results, the NOEL in this study was the highest dose tested, 2400 mg/kg bw/day (Blair, 1990).

3. Long-term toxicity/carcinogenicity studies[8]

a) Rodents

Groups of Sprague-Dawley rats (10/sex/group) were fed diets containing SAIB at levels of 0, 0.38, or 9.38% for 104 weeks. Three cycles of reproduction were carried out during this period. Body weight and food intake were measured weekly. All animals were autopsied at study end, organ weights were measured, and microscopic examination was carried out on select tissues from rats of the control and 9.38% SAIB groups.

For the 9.38% group, treatment-related effects included decreases in some reproductive parameters (discussed in Section IV.B.4 below), as well as the deaths of four males during the first 10 weeks. Death was due to massive multiple hemorrhages in each case, and may have been treatment-related. However, administration of SAIB did not increase the overall number of mortalities among males (7/10 in control, 11/12 in 0.38%, and 8/10 in 9.38% groups). No other significant inter-group differences were reported. For the group receiving 0.38% SAIB, no treatment-related effects were reported on food consumption, body weight gain, organ weights, or tissue morphology based on gross and microscopic examination (Harper, et al., 1966).

Groups of F-344 rats (20/sex/group) were fed diets that provided SAIB doses of 0, 0.5, 1, or 2 g/kg bw/day for 52 weeks. Animals were observed twice daily for clinical signs, and physical examinations were conducted weekly. Body weights and food consumption were recorded weekly. Ophthalmoscopic examinations were performed on all animals pretest and at 6 months and 12 months. Hematology, clinical chemistry and urinalysis parameters were measured at 6 and 12 months. BSP clearance was evaluated for controls and high-dose animals during weeks 23 and 48. At study end, surviving animals were sacrificed, organ weights (heart, kidneys, liver, gonads, and brain) were measured, and histopathological examination was conducted for a wide range of organs and tissues.

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[8] Reynolds and Chappel, Appendix I; Mackenzie, et al., Appendix IV.

No treatment-related effects on body weight gain, food consumption, or general health were reported. Moroever, no adverse treatment-related effects were indicated by measurement of hematology, clinical chemistry and urinalysis parameters. In particular, BSP retention rates in high-dose rats did not differ from controls. At necropsy, mean and absolute organ weights were unchanged, and there were no treatment-related gross or microscopic lesions. Microscopic examination of liver sections from three high-dose rats of each sex revealed no alterations in hepatocytes, bile canaliculi or other liver structures. The authors concluded that the NOAEL for this study was the high dose, 2 g/kg bw/day (MacKenzie, 1990a).

The carcinogenic potential of SAIB also was investigated in F-344 rats. In this study, 50 rats/sex/group received SAIB in the diet for 104 weeks at concentrations that provided doses of 0.0, 0.0, (*i.e.*, dual control groups), 0.5, 1.0, or 2.0 g SAIB/kg bw/day. Animals were observed twice daily for clinical signs, and physical examinations were conducted weekly. Body weights and food consumption were recorded weekly. Hematological parameters were measured on all surviving rats at study end. All animals were subjected to necropsy, organ weights were measured, and histopathology was carried out on a full range of tissues and organs.

No adverse clinical signs or deaths were attributed to SAIB. Body weights were unchanged in male rats, although occasional decreases in body weight were observed for female rats during the first year. Food consumption was not affected by treatment. No treatment-related effects on hematology, organ weights, or macroscopic and microscopic lesions were reported. No significant trends or differences between test and control animals were found for any tumor type. The NOAEL for the study was determined to be 2 g/kg bw/day (MacKenzie, 1990b).

The carcinogenic potential of SAIB in B6C3F1 mice was studied by administering SAIB in the feed to 50 mice/sex/group at levels equivalent to 0.0, 0.0, (*i.e.*, dual control groups),1.25, 2.5, or 5.0 g/kg bw/day for 104 weeks (MacKenzie, 1990c). Physical examination, body weight and food consumption data were collected weekly. A standard set of hematology parameters was determined for 15 mice/sex from one control group and from the high dose group at 26, 52, 78, and 104 weeks of the study. Necropsy was performed on all animals dying on test or sacrificed. The weights of liver with gall bladder, lungs and kidneys were recorded for all animals sacrificed at 104 weeks. Histopathology was carried out on lungs, liver, kidneys and gross lesions from all animals and on 44 additional organs and tissues, including the GI tract, from animals that died on test and the control and high-dose animals from the terminal sacrifice.

No treatment-related ante-mortem clinical observations or deaths were reported. Survival rates at the various exposure levels ranged from 66-80%. Body weights of male mice fed 2.5 g/kg bw/day – but not in males fed 5 g/kg bw/day – were occasionally significantly lower than those of both control groups. Occasional significant differences in body weights were noted for female mice at the 1.25 g/kg bw/day and 2.5 g/kg bw/day exposure levels, but again not at the 5 g/kg bw/day exposure. The absence of a dose-dependence in body weight decreases suggested that the observations were not treatment related. No treatment-related effects were reported for hematology or clinical chemistry measures in mice exposed up to 5 g SAIB/kg bw/day.

At necropsy, the only treatment-related change in mean organ weights consisted of decreases in mean absolute and relative kidney weights in high-dose males. However, these changes were not associated with significant macroscopic or microscopic changes in the kidneys.

The authors reported that no exposure-induced tumors were observed in mice exposed to SAIB at levels up to 5 g/kg bw/day for two years. The incidence of alveolar-bronchiolar adenomas was the only tumor observed that "qualified," according to the authors, for further statistical analysis. Based on the "Fischer-Irwin" exact test and the Cochran-Armitage trend test the authors concluded that the alveolar-bronchiolar adenomas did not occur at a significantly increased incidence relative to the controls.[9]

Based on a conservative evaluation of the data, the NOAEL for SAIB for two-year exposure of mice was concluded by the authors to be 2.5 g SAIB/kg bw/day for both males and females due to observed body weight changes and kidney weight variations at the high exposure level.[10]

4. Reproduction studies[11]

a) Rats

Groups of Holtzman rats (15 female and 5 male) were maintained on diets containing 0 or 5% SAIB. After one month on the diet, the rats were bred, with a second mating 51 days following parturition. Some progeny of the first mating (F1) also were bred. The test and control diets were fed to parents and offspring throughout the study. Exposure to SAIB at 5% in the diet for one month prior to mating was reported to have no effect on breeding performance or reproductive function. Further, continued ingestion of SAIB by the parental (F0) generation through weaning and for an additional 51 days thereafter did not adversely affect reproductive parameters for the second mating. For the F1 generation mating, reproductive parameters and viability of offspring were reported to be no different than controls. Due to an outbreak of respiratory disease near the end of the study, many F1 parents and pups died during the test, and none of the F2 pups from the mating of the SAIB-fed F1 generation survived post-weaning.

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[9] It is worth noting that, in its review of this study, FDA considered the incidence of bronchiolar/alveolar tumors to be increased in male mice receiving SAIB, although not in female mice. However, the Agency found the tumor incidences to be within the range commonly observed in aged B6C3F1 mice according to historical control data from the National Toxicology Program (NTP) database. FDA concluded, therefore, that the tumors observed in SAIB-fed male mice were not attributable to the test compound. 64 Fed. Reg. 29949 at 29951-52 (1999).

[10] Again, FDA's assessment differed somewhat from that of the authors. The Agency assigned a NOEL of 5 g/kg bw/day for this study, discounting the sporadic body weight changes and the kidney weight effects absent any associated kidney histopathology.

[11] Reynolds and Chappel, Appendix I; Mackenzie, et al., Appendix V.

Gross and microscopic examination of adult rats showed no abnormalities attributed to feeding SAIB. The only change was a slight reduction in liver and kidney weights among SAIB-fed females, which was attributed to an unusually high liver weight among some female controls (Fassett, et al., 1965).

As part of a chronic feeding study of SAIB in rats discussed above (Harper, et al., 1966), reproductive function was investigated for Sprague-Dawley rats (10/sex/group) that were fed diets containing 0, 0.38, or 9.38% SAIB. Three reproductive cycles were carried our during weeks 10-36 of the 104-week study. Pairs of rats from each dose group (10 pairs) were randomly selected and caged together for 19 days, followed by removal of the male. Females reared the young until weaning at 21 days. In each of the three reproductive cycles, each female was paired with a different male. Feeding with SAIB continued throughout mating and weaning.

No significant differences between SAIB-fed and control groups were reported with respect to the mean numbers of pups per litter or pup growth. Examination of pups did not reveal any abnormalities, although the extent of the examination is not clear. However, feeding with 9.38% SAIB did result in a lower percentage of females becoming pregnant and in the percentage of pups reared to weaning. The observed effects may have been due to reduced nutritive value of the feed due to the high concentration of SAIB. Performance of the 0.38% group was comparable to controls (Harper, et al., 1966).

In a three-generation reproduction study, groups of F344 rats (30/sex/group) received SAIB mixed with the diet at concentrations designed to provide 0, 0.5, 1.0, or 2.0 g SAIB/kg bw/day for 10 weeks (males) or 2 weeks (females) prior to mating. F0 females continued to receive SAIB through mating, pregnancy and lactation. The offspring (F1 generation) were exposed to SAIB in utero, during nursing, and through weaning. Feeding with SAIB again continued for randomly selected groups of F1 animals (30/sex/dose) through mating (10 weeks after weaning), gestation, and lactation for the F2a litters and, subsequently, the F2b litters (used for the teratology study discussed in Section IV.B.5 below). Finally, the F2a litters were mated in a similar fashion to produce the F3 litters. In each generation, breeding pairs were randomly selected, avoiding sibling or half-sibling matings. The study was completed with the necropsy of the F2a females on day 14 of the F3 gestation.

All animals were observed daily for general signs of toxicity. Body weight and food consumption were measured weekly during the pre-mating, gestation, and lactation periods. Pregnant females were examined closely for signs of abortion, premature delivery, or difficult parturition. Litters were examined as soon as possible following birth; litter size and numbers of live and dead pups were recorded, and dead pups were examined for visceral abnormalities. Pups were weighed, sexed, and examined for external abnormalities on days 4 and 28 of lactation. Also at day 4, litters were culled as appropriate to yield 5 pups per sex, and culled pups were examined for cervical, thoracic, or abdominal visceral abnormalities. On day 28, one pup per sex was chosen from each litter to continue on test. The F1 females were sacrificed and examined macroscopically on day 20 of the F2b generation. Parameters examined included number and distribution of fetuses in each uterine horn, numbers of resorptions and corpora lutea.

Body weights were reduced among some groups of females during gestation and lactation. However, no differences in body weight gain were observed for any generation throughout the study. Some variability was noted in the fertility index for the high-dose F1 females mated to produce the F2a litter, but not in the mating of this generation to produce the F2b litter, or in the other generations. No other significant treatment-related effects were noted on fertility, gestation or survival indices for any of the generations. The NOAEL was considered to be the highest dose tested, 2.0 g/kg bw/day (MacKenzie, 1990d).

5. Special studies on teratogenicity[12]

a) Rats

The F2b litters from the three-generation reproduction study described above were subjected to teratologic evaluation. Groups of F-344 rats (30/sex) from the F1 generation were subjected to *in utero* and in-life exposure to SAIB in the diet at concentrations yielding 0, 0.5, 1.0, or 2.0 g SAIB/kg bw/day. The animals were bred two weeks after completion of weaning of the F2a litters. Vaginal smears were taken daily and the presence of a copulatory plug or sperm in the vaginal smear was taken as positive evidence of mating and counted as Day 0 of gestation. The F1 dams were sacrificed on Day 20 of gestation and examined for the number and distribution of fetuses, the number of fetuses undergoing resorption and the number of corpora lutea. Live fetuses were removed from the uterus, weighed, sexed and examined for gross abnormalities. Approximately one-half of the pups from each litter were examined for soft tissue abnormalities and the remainder were examined for skeletal abnormalities.

No SAIB-related effects were reported for the mating of the F1 generation to yield the F2b litters used for teratologic evaluation. No differences were reported with respect to percent of females mated, females pregnant, or percent of males siring litters. Examinations from the caesarean sections of the F1 dams revealed no group differences with regard to mean numbers of corpora lutea, implantations, resportions, live fetuses, fetal viability, sex ratios, or fetus weights. Examination of the F2b litters did not reveal any SAIB-related soft tissue or skeletal abnormalities (MacKenzie, 1990d).

b) Rabbits

SAIB was administered by corn oil gavage to groups of 16 inseminated New Zealand white rabbits at doses of 0, 500, 850, or 1200 mg SAIB/kg bw/day on days 7 to 19 of gestation. (The day of insemination was counted as day zero). Animals were observed twice daily for general clinical signs; body weights and food consumption were recorded approximately weekly.

On day 29 of gestation, the dams were sacrificed and the pups delivered by caesarean section. The number and location of viable and nonviable fetuses, early and late resorptions and the number of total implantations and corpora lutea were recorded. Abdominal and thoracic cavities were examined for gross morphological changes. Each fetus was weighed, sexed, and

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[12] Mackenzie, et al., Appendix V.

examined for external malformations, then dissected and examined for visceral malformations, and the carcass prepared for subsequent skeletal examination.

Two high-dose females died during day 17 of gestation; these mortalities were not clearly treatment-related. There were no differences between treated and control animals with regard to weight gain or food consumption. At necropsy, no gross morphological changes were observed. Examinations following the caesarian section did not reveal any effects of treatment on reproductive or fetal development parameters, including corpora lutea, total implantations, post-implantation loss, fetus viability, fetal weights, sex distribution of fetuses, and fetal malformations (Schardein, 1988).

6. Studies on Genotoxicity[13]

SAIB has been extensively tested to investigate its genotoxic potential in a wide range of both *in vitro* and *in vivo* short-term genotoxicity screening assays. These include three independent bacterial mutagenicity assays in Salmonella (i.e., Ames tests); a mammalian cell mutation assay and chromosomal aberration assay in Chinese hamster ovary cells; an assay for unscheduled DNA synthesis in rat primary hepatocytes; and an *in vivo* dominant lethal assay in rats. The results of these studies are summarized in the following table.

Test System	Test Object	Concentration of SAIB	Results	Reference
Ames Test [a]	S. typhimurium TA1535, TA1537, TA1538, TA98, TA100; S. cerevisiae D4	10-2000 µg/plate	Negative	Jagannath & Brusick, 1978
Ames Test [a]	S. typhimurium TA98, TA100	100-10,000 µg/plate	Negative	Bonin & Baker, 1980
Ames Test [a]	S. typhimurium TA98, TA100, TA1535, TA1537, TA1538	333-10,000 µg/plate	Negative	Lawlor & Valentine, 1989
CHO/HGPRT Forward Mutation Assay [a]	Chinese hamster ovary cells	25-1000 µg/ml	Negative	Young, 1985
Unscheduled DNA Synthesis Assay	Rat hepatocytes	0.25-1000 µg/ml	Negative	Cifone, 1985
In Vitro Chromosome Aberration Assay	Chinese hamster ovary cells	400-2000 µg/ml	Negative	Ivett, 1985

[13] Reynolds and Chappel, Appendix I; Myhr, et al., Appendix VI.

In Vivo Dominant Lethal Assay [b]	Rats	20, 200, 2000 mg/kg bw	Negative	Krasavage, 1973

a. With and without metabolic activation. b. Matings every two weeks

As indicated by the foregoing, SAIB has tested negative for genotoxic activity, both in the presence and absence of exogenous metabolic activation, in a wide range of test systems. Based on the results of these assays, SAIB may be concluded to have no genotoxic activity.

7. Special Studies on Liver Function[14]

a) Rats

Groups of rats (15/sex/group) were fed diets containing SAIB at concentrations of 0, 0.5, or 5% for up to 3 weeks. Five rats/sex/group were sacrificed at the end of the first, second, and third weeks of treatment. No adverse effects were reported with respect to body weight or liver weight (both absolute and relative to body weight), and pathological examination did not reveal any other treatment-related effects (Procter and Chappel, 1970a).

Male Wistar rats were fed diets containing 4% SAIB for 7 days. BSP elimination rates were determined before the beginning of treatment and 24 and 48 hours after SAIB administration ended. No effect on the BSP elimination rate was found (Procter and Chappel, 1971).

Groups of Sprague-Dawley rats received either control diet or a diet containing 4% SAIB for 36 days. The average received SAIB dose was 2.8 g/kg bw/day. Plasma indocyanine green (ICG) clearance was determined on at least 2 rats selected from each group on eight days over the course of the 36-day study. The ICG retention half-lives in rats from the SAIB group were not significantly different from those of the controls (Krasavage and Terhaar, 1972; Krasavage, et al., 1973).

b) Dogs

A single groups of beagle dogs (2/sex) received SAIB in one day's food ration (450 g) at concentrations of 0.1, 0.3, or 0.5%. The doses were administered in three separate trials separated by one week. BSP elimination rates were determined before dosing, 24 hours after dosing, and 48 hours post-dosing if BSP elimination was decreased at 24 hours. No BSP retention occurred at the 0.1% SAIB dose level. At the higher doses of 0.3% and 0.5% SAIB, a distinct decrease in the BSP elimination rate was observed; this effect was found to be entirely reversible within 48 hours of dosing (Procter and Chappel, 1971).

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[14] Reynolds and Chappel, Appendix I.

The reversibility of the liver effects in dogs was examined in a study in which six male beagle dogs, approximately 6 years old, received a base diet containing 5% corn oil for 3 weeks, followed by a test diet containing 5% SAIB for 4 weeks. At the end of treatment, the dogs were returned to the control diet for an additional 9 weeks. Hematology and serum chemistry analyses were conducted weekly. Four of the dogs were tested for plasma ICG clearance every 3 weeks starting 3 weeks after placement on the test diet. These same dogs also received a single day's worth of SAIB-containing feed 3 days before study termination at 91 days after dosing began (i.e., day 88). ICG clearance and SAP levels were monitored for 72 hours following dosing.

After 4 weeks on the test diet, SAP levels were 3.7 to 7.3 times pre-treatment levels; these values decreased to 1.2 to 2.2 times pre-treatment values by 9 weeks following the end of treatment. The ICG retention half-lives in the four dogs tested after 21 days on test diet were elevated compared to historical control values. (Pre-test ICG data were not collected.) ICG values returned to normal within 35 days after the end of SAIB treatment. ICG half-lives were again elevated following the additional dose at day 88. These dogs, however, did not have elevated SAP levels at 24, 48, or 72 hours following the single-day's dose of SAIB. With the exception of increased SAP levels and ICG retention times, no significant effects were noted with regard to hematology or serum chemistry values. Histopathological examination of dogs sacrificed on day 91 revealed no effects on any tissue. The study authors concluded that the effects observed in this study constituted functional deficits in the liver that were reversible upon cessation of treatment (Krasavage and Terhaar, 1971a; Krasavage, et al., 1973).

In another study of the effects of SAIB on liver function in dogs, preliminary testing was first conducted to establish a 5-hour optimal interval for measurement of BSP elimination following dosing of beagle dogs (8-9 months old). This was followed by testing in which groups of 2-3 dogs (from a pool of 14) received single SAIB doses in several trials at levels ranging from 5 to 2000 mg/kg bw. Each dog was used in multiple trials, with rest periods of 8 to 22 days between trials.

No significant effects on body weight were reported, although vomiting and soft stools were occasionally observed throughout the study. SAP levels also were unaffected. BSP 15-minute elimination rates were significantly decreased at doses of 25 mg/kg bw and higher. A dose of 5 mg/kg bw was found to represent an approximate NOEL (Dickie, et al. 1980a).

A similar study investigated the effects on BSP elimination in beagle dogs (10-11 months old) of two SAIB component esters, sucrose hexaacetate diisobutyrate (SHADIB) and sucrose octaisobutyrate (SOIB). Dose levels were 0, 100, 200, 500, and 1000 mg/kg bw for each test substance. Groups of 2-3 dogs received single SHADIB doses by intubation in corn oil or orange juice in two trials, 16 days apart, or single SAIB doses in corn oil in a single trial. Again, the dogs were chosen randomly from a pool of 14, and were used in repeated trials.

Dosing with either SHADIB or SOIB in corn oil at 100-1000 mg/kg resulted in reduced BSP elimination rates, though the effect was not dose-related. For SHADIB in orange juice, the BSP elimination rate was affected only at the 1000 mg/kg dose. SAP levels were not affected by a single dose of either SHADIB or SOIB. Upon further examination with SOIB at doses of 5

and 25 mg/kg bw, all dogs demonstrated significantly reduced BPS elimination rates at 25 mg/kg bw, while only 1/3 dogs receiving 5 mg/kg bw were affected (Dickie, et al. 1980b). These results were consistent with those discussed above (Dickie, et al. 1980a), in which SAIB was found to have a NOEL for reduced biliary excretion of close to 5 mg/kg bw.

c) Monkeys

The effect of SAIB on liver function in monkeys has also been investigated. In the first study, a group of 3 male squirrel monkeys received a single dose by intubation, consisting of 1 gram SAIB in cottonseed oil. BSP clearance rates were determined 24 hours after dosing in these animals and in a second group of 3 monkeys that did not receive SAIB. After a 7-day rest period, the three monkeys that did not receive SAIB in the first experiment were given 1 gram SAIB in cottonseed oil, while the previously dosed monkeys were untreated. BSP elimination rates were again determined 24 hours after dosing.

In the first trial, no effect was found on BSP clearance rates for any of the three dosed monkeys. In the second trial, BSP retention was again unaffected for two of the dosed animals. In this trial, however, markedly high BSP retention values were found for one dosed monkey and one non-dosed monkey. These findings were considered unlikely to represent an effect of SAIB on the liver (Procter and Chappel, 1970b).

This experiment was subsequently repeated, but with an increased SAIB dose of 2 g in cottonseed oil. SAIB was found to have no effect on BSP elimination in either trial (Procter and Chappel, 1971).

Liver function was also investigated in a study in young adult male cynomolgus monkeys. In this study, four monkeys per group received a single SAIB or SOIB dose in corn oil equivalent to 5.0 g/kg bw. An additional two monkeys served as controls. Analyses for BSP elimination rates and SAP levels were carried out 24 hours before dosing and 5 hours after treatment. No effect on BSP retention or on SAP levels were found for either treatment with SAIB or SOIB when compared either to pre-treatment values or concurrent controls (Dickie, et al., 1980c).

8. Pharmacokinetics and Metabolism Studies[15]

A series of studies were conducted in which rats, dogs, monkeys, or human volunteers received SAIB or ^{14}C-labelled SAIB to investigate the absorption, metabolism, and pharmacokinetics of SAIB in these species. Studies conducted in rats and humans demonstrated that SAIB is extensively metabolized in the gastrointestinal tract, with likely end products being sucrose and partially de-esterified SAIB. These products are readily absorbed from the gut. Testing using the SAIB component ester SOIB indicated that this ester is less readily absorbed than acetyl-containing esters, and that SOIB is more readily absorbed by rats than by dogs or

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15 Reynolds, Appendix VIII.

cynomolgus monkeys; the absorbed SOIB, however, is more readily metabolized to CO_2 by rats than by dogs. Dogs, by contrast, eliminate the majority of the absorbed material in the bile.

The marked difference in handling of SAIB between rats and dogs was further demonstrated by testing with SAIB. Rats appeared to eliminate primarily sucrose in the bile, while dogs appeared to excrete SAIB or highly acylated sucrose in the bile. In testing with cynomolgus monkeys, it appeared that the monkey was closer to the dog with regard to elimination of SAIB metabolites in the urine and as $^{14}CO_2$, while elimination by monkeys of radioactivity in the bile was closer to that in rats.

Dogs were shown to differ from other species tested in handling of SAIB in several ways. Absorption of SAIB from the GI tract was lower in dogs than in humans or rats, with the majority of the administered dose in dogs being excreted in the feces. In rats and humans, the majority of the SAIB dose was eliminated as CO_2 in expired air. Moreover, SAIB is eliminated in the urine of dogs in a more highly acylated form than in humans or rats. Similarly, SAIB is eliminated in the bile of dogs solely as SAIB or other highly acylated sucrose derivatives, while SAIB is eliminated in rat bile almost exclusively as sucrose with a small amount of intermediate sucrose esters. It was concluded from these findings that dogs absorb and cannot readily degrade fully or highly acylated sucrose, which are handled by the biliary system and liver. Rats, by contrast, do not eliminate highly acylated sucrose moieties in the bile or urine, indicating that they either do not absorb these species or break them down before elimination occurs. Finally, it was concluded that humans handle SAIB in a manner similar to rats and that SAIB handling in dogs is not parallel to that in humans (Noker, et al., 1986; Phillips, et al., 1976; Reynolds, 1963; Reynolds, 1975; Reynolds, et al., 1974).

9. Observations in Humans[16]

The effect of SAIB ingestion on blood chinical chemistry and erythrocyte sedimentation rate was studied in 10 men and 10 women,18-22 years of age. The subjects ingested a 10 mg/kg bw/day daily dose of SAIB, suspended in a beverage, for a period of 14 days. Blood chemical indices, including the following parameters, were measured prior to treatment and at days 7 and 14: serum bilirubin, total protein, albumin, uric acid, blood urea nitrogen (BUN), serum alkaline phosphatase (SAP), alanine aminotransferase (ALAT), aspartate aminotransferase (ASAT), erythrocyte sedimentation rate, sodium, potassium, phosphorus, total CO_2, cholesterol and glucose. No significant differences in any parameters for any individual were observed (Hensley, 1975).

Testing to investigate the possible effect of SAIB on liver function was conducted by administering SAIB in a soft drink vehicle to two groups of 4 men and 4 women, while a third group received the soft drink only as a control. The test groups received a daily SAIB dose of 7.0 or 20.0 mg/kg bw/day for 14 days. Testing to determine the BSP clearance rate was performed prior to dosing and on day 15 (i.e., one day after dosing ceased). Additional blood

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16 Reynolds and Chappel, Appendix I; Chaing, et al., Appendix VII.

indices relevant to liver function were also evaluated on days 7 and 14, including SAP, ALAT, ASAT, and lactate dehydrogenase (LDH). Tests for hematological and urinalysis parameters also were conducted. No discernible effects were found on BSP elimination, clinical chemistry, hematology, or urinalysis. Treatment with SAIB at 20 mg/kg bw/day was found to have no appreciable effect on normal liver function of adult humans (Orr, et al., 1976).

Additional testing to investigate the effect of SAIB on the hepatobiliary function of healthy human volunteers was conducted on a group of 13 men and 14 women. The subjects received SAIB daily doses of 20 mg/kg bw/day in an aqueous/orange juice emulsion for 14 days. For 7 days just prior to treatment, the subjects ingested a placebo emulsion (without SAIB) for control purposes. Blood samples for measurement of routine hematological and clinical chemistry parameters were collected from each subject on the first and last day of placebo treatment (days –6 and 0), on day 7 of SAIB treatment, and on the day following the last SAIB dose (day 15). Analyses specific to examining hepatobiliary function included SAP, ASAT, ALAT, LDH, gamma-glutamyl transferase, total bilirubin, direct bilirubin, bile acids and serum proteins. No changes attributable to treatment with SAIB were detected in any of these or the other evaluated parameters over the 14-day dosing period (Chiang, 1988).

C. JECFA Evaluation of SAIB[17]

In 1996, the FAO/WHO Joint Expert Committee on Food Additives (JECFA) adopted an acceptable daily intake (ADI) for SAIB of 20 mg/kg bw/day.[18] This is equivalent to a total daily intake of 1200 mg/day for a 60-kg individual.

Prior to the review of SAIB by JECFA in 1996, previous JECFA committees had reviewed SAIB four times. At the evaluation meeting immediately prior to the 1996 review, a temporary ADI of 10 mg/kg bw/day had been adopted by JECFA.[19] At that time, JECFA had reviewed virtually all available data on SAIB, but had requested further information:

> information that would clarify the disparate effects of sucrose acetate isobutyrate on hepatobiliary function in the dog compared with other species, in particular humans, is required for review by 1996.

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[17] See Appendix IX.

[18] Joint FAO/WHO Expert Committee on Food Additives (1997). Forty-sixth Report. Evaluation of Certain Food Additives and Contaminants. WHO Technical Report Series 868; World Health Organization, Geneva.

[19] JECFA's evaluation of the toxicology studies on SAIB is set forth in: 797 Toxicological Monographs. WHO Food Additives Series 32. First draft prepared by Ms. E. Vavasour Toxicological Evaluation Division Bureau of Chemical Safety, Food Directorate Health and Welfare, Ottawa, Canada.

However, after reviewing the existing data once again in 1996, the committee was able to conclude that sufficient data existed for the adoption of a permanent ADI for SAIB of 20 mg/kg bw/day. The following summarizes the basis for the JECFA ADI.

In the dog, exposures to SAIB as low as 0.5% of the diet (125 mg/kg bw/day) were associated with the development of increased SAP activity, impairment of biliary excretion as indicated by decreased BSP clearance, a marked increase in the activity of several enzymes in the bile canaliculi, increased liver weights, and microscopic changes in hepatocellular morphology after 12 weeks. All of the observed effects were found to be reversible within three to six weeks after cessation of exposure to SAIB.

A single oral exposure of 25 mg/kg bw was shown to reduce the clearance of BSP and a very slight effect was apparent at 5 mg/kg bw; the latter value was considered by the committee to be a no observed effect level (NOEL) for hepatobiliary function in the dog. Similar hepatobiliary effects were not observed in monkeys or rodents upon exposures as high as 2400 mg/kg bw/day and 2000 mg/kg bw/day and lasting up to one year. Tests specific for evaluating hepatobiliary excretion in monkeys and rats revealed no adverse effects after exposures to SAIB. Humans exposed to SAIB at up to 20 mg/kg bw/day for 14 days did not display signs of adverse hepatobiliary effects, including changes in serum enzymes that are markers for liver damage and modifications of the clearance rate of BSP.

At the JECFA evaluation of SAIB in 1996, the committee concluded that data on the disposition of SAIB in dogs, humans, and rats indicate differences in responses to exposure among the species. Dogs excrete more highly acylated sucrose molecules in the urine and bile than do rats and humans and excrete a higher proportion of the total dose in the bile than does the rat. In humans, there was no effect on indices of hepatobiliary function at an exposure of 20 mg/kg bw/day, an exposure that exceeds the NOEL of 5 mg/kg bw/day for such effects in the dog. The committee concluded that the effects of SAIB on hepatobiliary excretion in the dog were not relevant for humans. Therefore, JECFA disregarded the data from testing in dogs and instead relied on the NOEL of 2 g/kg bw/day for chronic exposure in rats (the lowest NOEL from long-term testing in species other than dogs). Applying a safety factor of 100 to the NOEL yielded an ADI of 20 mg/kg bw/day, equivalent to a total daily intake of 1200 mg/day for a 60 kg reference body weight).

D. Intake Estimate

The intake of SAIB associated with its use in alcoholic beverages such as cocktail premixes, malt beverage coolers, and wine coolers[20] will be a small fraction of the ADI established by JECFA.

SAIB will be used at a maximum level of 300 ppm in alcoholic beverages specifically limited to premixed cocktails, premixes for the preparation of cocktails and in malt-based or

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[20] The beverages of interest include mixed alcoholic fruit beverages and wine coolers. SAIB is not intended to be used in beer, wine, or spirits containing no fruit juice.

wine coolers. The typical alcoholic beverage of interest, e.g., a wine cooler, at the maximum use level would contain about 107 mg SAIB per 12-fluid ounce (355 mL) bottle.[21] For a 60-kg adult, the intake from one bottle of beverage corresponds to 1.8 mg SAIB/kg body weight.

The following table displays the weighted 2-day average intakes of the three "parent" beverages that subsume the class of beverages in which SAIB would be used under this Notification, based on USDA CSFII 1994-96, 1998 data. The table also displays the 2-day average exposures to SAIB from the entire class of parent beverages and the total intake, assuming that all of the beverages contain 300 ppm of SAIB (0.3 mg SAIB per gram of beverage) and that all these beverages would be ingested by the same consumers in a single day.[22]

Beverage	2-Day Weighted Average Intake (g bev./day)	SAIB Level (mg/g bev.)	2-Day Average Intake of SAIB (mg/day)
Beer and Ale	431	0.3	129
Wine Coolers	167	0.3	50
Cocktails	158	0.3	47
Total Intake			226

This worst-case total SAIB intake level of 226 mg/day is well below the ADI established by JECFA (and the identical ADI set by FDA), which is equivalent to 1200 mg/day based on a 60-kg reference body weight. Thus, even if all beer products, wine coolers, and cocktails contained 300 ppm SAIB and the beverages were consumed at a total rate equivalent to the two-day average for each beverage – a highly exaggerated assumption – the intake of SAIB would still be only a small fraction of the allowable exposure.

The above estimated total intake of SAIB, while well below the JECFA ADI, represents a gross exaggeration, since SAIB is not intended to be used in the entire class of parent beverages but, rather, will be used only in alcoholic beverages that contain fruit juice. The average intake of beer and wine coolers is not expected to be a significant fraction of the estimated intake of all beer and wine. For example, the excerpt attached as Appendix X from *The International Market for 'Alternative Drinks'* indicates that the market for wine coolers in the United States has dropped significantly since reaching a maximum in the mid-1980s, and that wine coolers

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[21] 355 mL (or g) x 0.3 mg SAIB/g (i.e., 300 ppm SAIB) = 107 mg SAIB.

[22] Excel Spreadsheets demonstrating the calculation of the two-day averaged intakes for each beverage are attached as Appendix XI.

represented only 1.4% of the total wine market as of 1999.[23] Thus, intake of SAIB in the subset of flavored alcoholic beverages described here is expected to be far less than the values calculated based on assuming SAIB's presence in 100% of the parent beverages.

It is widely accepted that ADIs are intended to apply to the daily intake of a food ingredient averaged over the lifetime. Consequently, estimated daily intakes (EDIs) of ingredients from specific food products ideally should be averaged over long periods for comparison with ADIs. In this regard, it should be noted that long-term average intakes of the specialty beverages in which SAIB will be used is likely to be substantially smaller than the intake calculated based on the USDA two-day CSFII survey. This conclusion is supported by data from the 1977-78 USDA National Food Consumption Survey.[24] This survey, which involved surveying consumers over a three-day period, indicated (similar to the CSFII 1994-96 survey results) that for persons consuming wine only on one day, the average intake was 221 g/day, while the consumption of wine for all persons consuming wine over the three-day survey period was 113 g/day, on average. Thus, by extending the survey to three days, the average intake of wine dropped by approximately one half. This suggests that with a longer survey period, the average intake calculated on a per-day basis will tend to decrease. This phenomenon has been confirmed in reports by Lambe, et al. (2000) for approximately 30 food groups.[25] Specifically, mean consumer-only intakes based on 14-day surveys were found to be just 0.6 times the corresponding intakes from a 3-day diary.

Based on the foregoing considerations, we conclude that the actual exposure to SAIB is expected to be substantially less than that calculated above. First, the average long-term intake of the beverages is likely to be substantially less than suggested by the USDA 1994-96 one-day intake value. Second, due to their special nature as flavored beverages, the intake of SAIB-containing wine coolers and other alcoholic beverages is likely to be a small fraction of the average intake of the entire categories of the parent beverages.

Because SAIB may also be used as a stabilizer of flavor emulsions used in non-alcoholic beverages, as described in 21 C.F.R. Section 172.833, it is appropriate also to consider the potential impact on cumulative intake of the compound that may result from its additional use in alcoholic beverages. The Food and Drug Administration has estimated that the mean dietary exposure associated with the use of SAIB in non-alcoholic beverages is 82 mg/person/day, or

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[23] The International Market for "Alternative Drinks" (2000). Leatherhead Food RA, United Kingdom.

[24] Foods Commonly Eaten by Individuals (March 1982). United States Department of Agriculture. Home Economics Report Number 44.

[25] Lambe, J., et al. (2000). Enhancing the Capacity of Food Consumption Surveys of Short Duration to Estimate Long-Term Consumer-Only Intakes by Combination with a Qualitative Food Frequency Questionnaire. Food Add. Contam., Vol. 17 (3), pages 177-187.

170 mg/person/day for the 90th percentile, all ages.[26] Thus, a conservative (exaggerative) estimate of total SAIB consumption resulting from its use in both alcoholic and non-alcoholic beverages may be calculated by adding the intake levels determined for the two beverage applications.

Towards this end, the maximum intake value calculated here for alcoholic beverage use of SAIB is 226 mg/day based on the total of 2-day average intakes of beer and ale, wine coolers, and cocktails. Adding this to the EDI for non-alcoholic beverages would result in a maximum cumulative intake of 396 mg/day. Again, actual intake is expected to be substantially less than that calculated here for the reasons discussed above.[27]

It is also helpful to note that the Notifier, Eastman Chemical Company, estimates that, for a mature market, the total amount of SAIB sold into the food ingredient market in the United States will be approximately 500,000 pounds of SAIB per year. Based on an approximate U.S. population of 250 million, the per capita intake for SAIB, assuming that all beverages containing SAIB are consumed by just 10% of the population, is estimated as approximately 25 mg per person per day.[28] The available toxicological data on SAIB and the ADI established by JECFA and other expert authorities support this exposure estimate with a substantial margin of safety.

E. Expert Consensus

The use of sucrose acetate isobutyrate in nonalcoholic beverages is widely known and recognized as safe among qualified experts. As noted above, JECFA committees have reviewed the safety of SAIB several times and concluded in 1996 that a daily intake of SAIB of 20 mg/kg bw/day (approximately 1200 mg/day for a 60 kg bw) is safe. SAIB is also cleared for use in nonalcoholic beverages in the European Union (E No. 144). The EU Scientific Committee for Food (SCF) has reviewed the toxicology of SAIB and concluded that it is safe for use as a stabilizer in beverages.[29] SAIB is permitted for use in Canada as an ingredient in citrus- and spruce-flavored drinks at levels up to 300 ppm.[30] Indeed, as of 1998, SAIB was permitted for use in carbonated and non-carbonated beverages in at least 28 countries worldwide.[31] Finally, as

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[26] 64 Fed. Reg. 29949 at 29950 (1999).

[27] Note that the worst-case SAIB intake in alcoholic beverages of 226 mg/person/day is significantly higher than FDA's estimates of intake for SAIB's use in non-alcoholic beverages. It is extremely unlikely that actual long-term average intake of SAIB in alcoholic beverages would exceed that resulting from its use in non-alcoholic beverages.

[28] (500,000 lb)(453,000 mg/lb) ÷ (25 x 10^6 population) ÷ (365 days/year) = 25 mg/person/day.

[29] European Subcommitee for Food. Thirty-second Series (1994) (Cat. No. CO-80-93-589).

[30] See Reynolds and Chappel, Appendix I.

[31] *Id.*

confirmation of the consistency of expert opinion, we note that SAIB is now permitted for use in the United States as a component of non-alcoholic beverages pursuant to FDA's promulgation of 21 C.F.R. Section 172.833. The existing approvals, and the specific consensus reviews by several JECFA committees, indicate that experts qualified by scientific training and experience generally recognize the safety of SAIB for use as a stabilizer in beverages.

F. Toxicological References

Primary sources for the toxicology studies discussed in this Notification are set forth below.

Blair, M. (1986). Exploratory four-week oral toxicity study with sucrose acetate isobutyrate in *Cynomolgus* monkeys. Study no 548-001, International Research and Development Corporation, Mattawan, Michigan, December 18.

Blair, M. (1990). One year oral toxicity study with sucrose acetate isobutyrate in *Cynomolgus* monkeys. Study No. 548-002, International Research and Development Corporation, Mattawan, Michigan.

Bonin, A.M. & Baker, R.S.U. (1980). Mutagenicity testing of some approved food additives with the *Salmonella/*microsome assay. *Food Technology in Australia* 32(12), 608-611.

Chiang, M. (1988). Determination of the effect of single daily ingestion of SAIB on the hepatobiliary function of normal human male and female volunteers. Report No. 2657-001, Hazleton Laboratories Canada, Ltd.

Cifone M.A. (1985). Evaluation of sucrose acetate isobutyrate special lot No. 84-8 in the rat primary hepatocyte unscheduled DNA synthesis assay. Report No. 20991, Litton Bionetics Inc.

Dickie, B.C., et al., (1980a). Effect of sucrose acetate isobutyrate esters on liver excretory function in dogs. Report No. 80004, Raltech Scientific Services.

Dickie, B.C., et al., (1980b). Preliminary study to determine the effect of sucrose hexaacetate diisobutyrate (SHADIB) and sucrose octaisobutyrate (SOIB) esters on liver excretory function in dogs. Report No. 80503, Raltech Scientific Services.

Dickie, B.C., et al., (1980c). Effect of sucrose acetate isobutyrate and sucrose octaisobutyrate esters on liver excretory function in *Cynomolgus* monkeys. Report No. 80540, Raltech Scientific Services.

Fassett, D.W., and Reynolds, R.C. (1962). The fate of sucrose acetate isobutyrate in the rat. Report No. BCH 62-1, of Laboratory of Industrial Medicine, Eastman Kodak Company.

Fassett, D.W., et al. (1962). Sucrose acetate isobutyrate, low acetyl (SAIB) 95 day feeding study. Eastman Kodak Company.

Fassett, D.W., et al. (1965). Reproduction study in rats fed sucrose acetate isobutyrate (61-115-2). Report of Laboratory of Industrial Medicine, Eastman Kodak Company.

Harper, K.H., et al. (1966). Chronic toxicity and effect upon reproductive function of SAIB in the rat (Final Report). Huntingdon Research Lab. (HRC Report No. 1612/66/140).

Hensley, W.J. (1975). A brief report on the use of sucrose acetate isobutyrate in human volunteers. Report prepared for the Food Additives Sub-Committee of the National Health and Medical Research Council, Australia.

Hewing, R.B. (1958). Toxicity report on sucrose acetate-isobutyrate (58-7). Laboratory of Industrial Medicine, Eastman Kodak Company, Rochester, New York.

Hint, H. (1964). Short term toxicity of SAIB in rats. Report submitted to Aktiebolaget Fructus Fabriker, Stockholm, Sweden.

Ivett, J.L. (1985). Mutagenicity evaluation of sucrose acetate isobutyrate special lot No. 84-8 in an *in vitro* cytogenetic assay measuring chromosome aberration frequencies in Chinese hamster ovary (CHO) cells. Final report, project No. 20990, Litton Bionetics Inc.

Jagannath, D.R., and Brusick, D.J. (1978). Mutagenicity evaluation of 78-341 in the Ames *Salmonella/*microsome plate test (sucrose acetate isobutyrate). Report No. 20938, Litton Bionetics Inc.

Krasavage, W.J (1973). A dominant lethal assay of sucrose acetate isobutyrate (SAIB) in the rat. Report No. TOX-73-3, Eastman Kodak Company.

Krasavage, W.J., and Terhaar, C.J. (1971a). Sucrose acetate isobutyrate, 70-339, a preliminary study of the reversibility of effects on liver weight and serum alkaline phosphatase in old beagle dogs. Report No. Tox-70-8, Eastman Kodak Company.

Krasavage, W.J., and Terhaar, C.J. (1971b). Sucrose acetate isobutyrate (70-339), a three part dietary feeding study in rats. Eastman Kodak Company.

Krasavage, W.J., and Terhaar, C.J. (1971c). Sucrose acetate isobutyrate (70-339), a subacute feeding study in beagle dogs. Report No. TOX-7-7, Eastman Kodak Company.

Krasavage, W.J., and Terhaar, C.J. (1972). Indocyanine green plasma clearance rates in rats fed high levels of sucrose acetate isobutyrate (SAIB, 70-339). Report No. Tox-72-1, Eastman Kodak Company.

Krasavage, W.J., et al. (1973). Biological effects of sucrose acetate isobutyrate in rodents and dogs, *J. Agr. Food Chem.*, 21, 473-478.

Lawlor, T.E., and Valentine, D.C. (1989). Mutagenicity test on sucrose acetate isobutyrate in the Salmonella/mammalian-microsome reverse mutation assay (Ames test) with confirmatory assay. Report No. 10977-0-401, Hazleton Laboratories America, Inc.

Mackenzie, K.M. (1987). Short-term palatability study with sucrose acetate isobutyrate (SAIB) in mice. Report No. 6194-103, Hazleton Laboratories America, Inc.

Mackenzie, K.M. (1990a). One year chronic toxicity study with sucrose acetate isobutyrate (SAIB) in rats. Report No. HLA 6194-100. Hazleton Laboratories America, Inc.

Mackenzie, K.M. (1990b). Two-year carcinogenicity study with sucrose acetate isobutyrate (SAIB) in rats. Report No. 6194-101, Hazleton Laboratories America, Inc.

Mackenzie, K.M. (1990c). Carcinogenicity study with sucrose acetate isobutyrate (SAIB) in mice. Study No. 6194-104, Hazleton Laboratories America, Inc.

Mackenzie, K.M. (1990d). Three-generation reproduction and teratology study with sucrose acetate isobutyrate (SAIB) in rats. Report No. 6194-105, Hazleton Laboratories America, Inc.

Morgareidge, K. (1965). Subacute (90-day) feeding studies with SAIB in dogs. Report No. 86501, Food and Drug Research Laboratories.

Noker, P.E. (1982). Pharmacokinetics and metabolism studies of sucrose octaisobutyrate (SOIB) in rats. Report No. 4924-I, Southern Research Institute.

Noker, P.E. (1984a). A pharmacokinetic and metabolism study of sucrose octaisobutyrate (SOIB) in dogs. Report No. 4924-III, Southern Research Institute.

Noker, P.E. (1984b). A pharmacokinetic and metabolism study of sucrose octaisobutyrate (SOIB) in monkeys. Report No. 4924-IV, Southern Research Institute.

Noker, P.E., et al. (1986). Disposition of sucrose octaisobutyrate in rats, dogs and monkeys. *Food Chem. Toxicol.* 24, 1287-1293.

Orr, J.M., et al.. (1976). Fourteen day feeding and tolerance study of sucrose acetate isobutyrate (SAIB) in human volunteers. Report No. 1, project No. 4479, Bio-Research Laboratories Ltd.

Phillips, J.C., et al. (1976). Studies on the metabolism of sucrose acetate isobutyrate in the rat and in man. *Food. Cosmet. Toxicol.* 14, 375-380.

Procter, B.G. and Chappel, C.I. (1970a). An investigation of the effect of sucrose acetate isobutyrate on the liver of the rat. Report No. 1110, Bio-Research Laboratories Ltd.

Procter, B.G., and Chappel, C.I. (1970b). Studies of the effect of bromsulfophthalein plasma clearance rate in the squirrel monkey (*Saimiri sciureus).* Report No. 1570, Bio-Research Laboratories, Ltd., Quebec, Canada.

Procter, B.G., and Chappel, C.I. (1971). Studies of the effect of sucrose acetate isobutyrate on bromsulfophthalein plasma clearance rate in the squirrel monkey (*Saimiri sciureus)*, in the albino rat and in the beagle dog. Report No. 1370, Bio-Research Laboratories Ltd.

Procter, B.G., et al. (1970). A study of the subacute oral toxicity of sucrose acetate isobutyrate (SAIB) in the Beagle dog. Report No. 1, project No. 953, Bio-Research Laboratories, Ltd., Quebec, Canada.

Procter, B.G., et al. (1971a). A subacute study of the effect of ingestion of sucrose acetate isobutyrate on the liver of the rat (a study of the subacute oral toxicity of sucrose acetate isobutyrate in the rat). Report No. 966, Bio-Research Laboratories Ltd., Quebec, Canada.

Procter, B.G., et al. (1971b). A study of the subacute oral toxicity of sucrose acetate isobutyrate (SAIB) in the beagle dog. Report No. 2, project No. 953, Bio-Research Laboratories, Ltd., Quebec, Canada.

Procter, B.G., et al. (1973). Biochemical effects of sucrose acetate isobutyrate (SAIB) on the liver, *Proc. Soc. Expt. Biol. Med.,* 142, 595-599.

Reynolds, R.C. (1963). The *in vivo* absorption of sucrose acetate isobutyrate from the intestine of the rat. Report No. BCH-63-5, Laboratory of Industrial Medicine, Eastman Kodak Company, Rochester, N.Y. 14652-3615.

Reynolds, R.C. (1972a). Physiological fate of sucrose.^{14}C(U) acetate isobutyrate in rats: (1) After single oral doses in corn oil. Raw data report, BDH-72-5, Eastman Kodak Company.

Reynolds, R.C. (1972b). Physiological fates of sucrose.^{14}C(U) acetate isobutyrate and sucrose.^{14}C(U) in rats: (2) After single oral doses in an aqueous emulsion. Raw data report, BCH-72-6, Eastman Kodak Company.

Reynolds, R.C., and Travis, M.G. (1972). Physiological fate of sucrose-^{14}C(U) acetate isobutyrate in dogs. Raw data report, BCH-72-4, Eastman Kodak Company.

Reynolds, R.C., and Ziegler, D.A. (1977). Metabolites of sucrose acetate isobutyrate in the urine of rats, dogs and a man. Report (BC-77-T2), Eastman Kodak Co.

Reynolds, R.C., et al. (1971). The disposition of SAIB in mammals (rat, dog and man). Report No. BCH-71-8. Laboratory of Industrial Medicine, Eastman Kodak Company.

Reynolds, R.C., et al. (1972). Physiological fate of sucrose-^{14}C(U) acetate isobutyrate and sucrose-^{14}C(U) in humans. Report (BCH-72-1), Laboratory of Industrial Medicine, Eastman Kodak Co.

Reynolds, R.C., et al. (1974). Fate and disposition of sucrose-U-^{14}C acetate isobutyrate in humans, rats and dogs. *J. Agr. Food Chem.,* 22, 1084-1088.

Reynolds, R.C., et al. (1975). Elimination of radioactivity in bile of rats and a dog fed sucrose-^{14}C(U) acetate isobutyrate. Report No. BCH-75-6, Health and Safety Laboratory, Eastman Kodak Co., Rochester, N.Y.

Schardein, J.L. (1988). Teratology study in rabbits with sucrose acetate isobutyrate (SAIB). International Research and Development Corporation.

Tierney, W.J., and Rinehart, W.E. (1979). An acute oral tolerance study of sucrose acetate isobutyrate (SAIB) in monkeys. Report No. 78-2187, Bio/dynamics Inc.

Tierney, W.J., and Rinehart, W.E. (1980a). A range-finding study with sucrose acetate isobutyrate (SAIB) in monkeys. Report No. 78-2188, Bio/dynamics Inc.

Tierney, W.J., and Rinehart, W.E. (1980b). Evaluation of selected clinical chemistry parameters in monkeys following administration of sucrose acetate isobutyrate (SAIB) for 15 days. Report No. 79-2431, Bio/dynamics Inc.

Young, R.R. (1985). Evaluation of sucrose acetate isobutyrate special lot No. 84-8 in the CHO/HGPRT forward mutation assay. Report No. 22207, Litton Bionetics Inc.

APPENDIX I

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APPENDIX IX

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APPENDIX IX

SUCROSE ACETATE ISOBUTYRATE

INS:	444
Chemical names:	SUCROSE DIACETATE HEXAISOBUTYRATE (APPROXIMATE)
Synonyms:	SAIB
Functional class:	DENSITY ADJUSTING AGENT; CLOUD-PRODUCING AGENT IN NON-ALCOHOLIC BEVERAGES
Latest evaluation:	1996
ADI:	0-20
Report:	TRS 868-JECFA 46/43
Specifications:	COMPENDIUM ADDENDUM 4/FNP 52 Add.4/155
Tox monograph:	FAS 32-JECFA 41/223
Previous status:	1993, TRS 837-JECFA 41/25, COMPENDIUM ADDENDUM 2/FNP 52 Add.2/125, FAS 32-JECFA 41/223. 0-10 (TEMPORARY). TE. R 1990, COMPENDIUM/1441. R 1985, FNP 34-JECFA 29/217. R,T 1982, TRS 683-JECFA 26/30, FNP 25-JECFA 26/194, FAS 17-JECFA 26/229. NO ADI ALLOCATED. NO. R,T 1977, TRS 617-JECFA 21/28, NMRS 57-JECFA 21/104. NO ADI ALLOCATED. NO. N,T 1975, NMRS 55/TRS 576-JECFA 19/15, NOT PREPARED, NOT PREPARED. NO ADI ALLOCATED. NO. O

See Also:
- Toxicological Abbreviations
- Sucrose acetate isobutyrate (WHO Food Additives Series 32)

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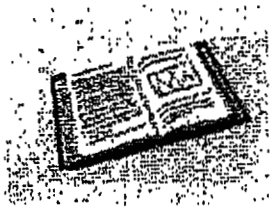
APPENDIX X

APPENDIX X

Search Help

The International Market for "Alternative Drinks"



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The simple process of quenching thirst is becoming increasingly complicated in today's society, as modern consumers are faced with an ever more diverse range of drinks to choose from. Many new product sectors have been developed in recent years, offering consumers a multitude of more interesting and unusual alternatives to standard soft drinks and alcoholic beverages.

This invaluable market report, now in its second edition, looks at trends and developments in some of the more newly developed beverage categories, highlighting market sizes and segmentation, and pinpointing the leading companies and some of the more interesting product developments in recent years.

Key features

- Detailed discussion of nine major international markets in Europe, Asia/Oceania and North America
- 75 tables presenting data on market sizes and company shares
- Analysis of key trends and influences, country-by-country and on an international basis
- Discussion of major manufacturers and recent new product developments

Country coverage:

Australia	Japan
Canada	Spain
France	UK
Germany	US
Italy	

Product coverage:

Energy and sports drinks	Ready-to-drink tea and coffee
Adult fruit drinks	Flavoured water/clear drinks
Functional drinks	Pre-mixed/flavoured alcoholic drinks

Excerpts from the report

"The market for alternative drinks has arisen from a combination of several factors. Perhaps the most fundamental of these has been the general willingness of many younger consumers to experiment with different products and new concepts."

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although, to date, there have been difficulties in obtaining suitable ingredients on a consistent and regular basis.

Examples of fruit-based juices and drinks launched since the beginning of 1998 include Nantucket Nectars' range of Super Nectar vitamin-enhanced fruit drinks, Sobe's Lean Metabolic Enhancer drink incorporating vitamins A, C, E and K and its Orange Tomato Elixir, as well as Day Fresh Foods' Super Sixteen, a blend of grape, apple and orange juices with other fruit, which contains 100% of the RDA of 16 vitamins and minerals in a one-pint serving. In addition to these drinks, Kraft launched its Crystal Light range of vitamin-fortified powdered soft drinks in the spring of 1998, marking the Company's first foray into the functional foods market.

In the functional tea market, Arizona Beverages launched its Asia Plum Green Tea in early 1999, made with green tea, plum juice, ginseng and honey, whilst Triarc's Snapple has launched herbally enhanced green tea and black tea products as part of its Elements range.

10.7 Pre-mixed and Flavoured Alcoholic Drinks

The US market for pre-mixed and flavoured alcoholic drinks was estimated at 300 million litres in 1998, worth in excess of $1.8 billion (£1.1 billion). In the mid-1990s, sales volumes of pre-mixed and flavoured alcoholic drinks declined at an annual rate of around 10-12%, although, since 1998, there have been signs that sales have stabilised. Pre-mixed spirits account for over 80% of total sector volumes; flavoured alcoholic beverages have generally failed to gain widespread acceptance. This is thought to be due to the fact that, in many states, the legal drinking age is 21, considerably higher than that of the typical British alcopop drinker in the mid-1990s; furthermore, there is generally much stricter enforcement of under-age drinking laws (Table 10.X).

TABLE 10.X
US: pre-mixed and flavoured alcoholic drinks market by type, 1998

	Volume (million litres)	Value ($m)
Flavoured alcoholic beverages	50	250
Pre-mixed spirits	250	1,600
Total	300	1,850

Source: Leatherhead Food RA estimates based on trade sources

Although excluded from the scope of this report, the US market for wine coolers, which have traditionally fulfilled a role similar to that of pre-mixed spirits, has continued to suffer from falling sales, having peaked in the late 1980s. In value terms, the wine coolers market is of similar size to that of pre-mixed spirits.

Currently, the most popular products seem to be pre-mixed cocktails, the most notable examples being Jack Daniels Country Cocktails, Southern Comfort's Dixie Jazzberry, Big Easy Punch and Laidback Lemonade cocktails, and José Cuervo Margaritas. Of the other pre-mixed non-cocktail spirit drinks, Bacardi Breezers and Jim Beam & Cola, Jim Beam & Ginger Ale as well as Jim Beam & Lemon Lime also enjoy a prominent position in the marketplace. These products tend to appeal most to the 21- to 30-year-old age group; many of the products primarily appeal to males, although Bacardi Breezers tend to be favoured by younger women.

In contrast, the variety of flavoured alcoholic beverages tends to be more limited, although both Two Dogs and Hooch have been introduced to the US market. In 1999, several lemon- or lemonade-based alcoholic beverages reportedly proved popular, including a drink known as Mike's Hard Lemonade, which is produced by the Mark Anthony Group in Canada and is sold in New England.

Appendix XI

APPENDIX XI

EXPORT OF INTAKE DATA FOR BEER AND ALE:
USDA CSFII 1994-96,98

USDA CSFII 1994-96,98: CONTINUING SURVEY OF FOOD INTAKES BY INDIVIDUALS

RECORD TYPE 30 EXPORT: FOOD CODE 93101000 (BEER AND ALE)

DayCode	Wt4 Day1	Wt4 2 Day	FoodAmt	Weighted One Day Amount	Weighted Two Day Amount	One Day Weighted Average	One Day Weighted Average	Two Day Weighted Average
						Day 1	Day 2	
1	5068	6666	9360	47436480	62393760	854	877	431
1	17720	13676	8640	1.53E+08	118160640	grams/day	grams/day	grams/day
1	13605	20640	7200	97956000	148608000			
1	19762	38232	6720	1.33E+08	256919040			
1	3417	2576	5760	19681920	14837760			
1	42092	36788	5400	2.27E+08	198655200			
1	42092	36788	5400	2.27E+08	198655200			
1	25588	19333	5400	1.38E+08	104398200			
1	20724	35057	5040	1.04E+08	176687280			
1	7923	6405	4800	38030400	30744000			
1	26588	31533	4560	1.21E+08	143790480			
1	3868	3051	4320	16709760	13180320			
1	19527	24397	4320	84356640	105395040			
1	5583		4320	24118560	0			
1	6565	5208	4320	28360800	22498560			
1	20724	35057	4320	89527680	151446240			
1	7412		4320	32019840	0			
1	13613	11840	4320	58808160	51148800			
1	2631	2192	4320	11365920	9469440			
1	16491	12575	4320	71241120	54324000			
1	2436	3240	4320	10523520	13996800			
1	34547	29829	4320	1.49E+08	128861280			
1	8258	17080	4320	35674560	73785600			
1	15228	13097	3840	58475520	50292480			
1	16914		3840	64949760	0			
1	20745	24851	3600	74682000	89463600			
1	33250	38767	3240	1.08E+08	125605080			
1	20796	18183	3000	62388000	54549000			
1	10221	11063	2880	29436480	31861440			
1	21586	24230	2880	62167680	69782400			
1	15576	17769	2880	44858880	51174720			
1	14631	16796	2880	42137280	48372480			
1	28545	31479	2880	82209600	90659520			
1	21704	16763	2880	62507520	48277440			
1	31861	25984	2880	91759680	74833920			
1	3813	4880	2880	10981440	14054400			
1	21838	17487	2880	62893440	50362560			
1	12570	14909	2880	36201600	42937920			
1	12345	23695	2880	35553600	68241600			
1	14995	12693	2880	43185600	36555840			
1	26543		2520	66888360	0			
1	23001	18913	2520	57962520	47660760			
1	20126	13272	2400	48302400	31852800			
1	34216		2400	82118400	0			

EXPORT OF INTAKE DATA FOR BEER AND ALE:
USDA CSFII 1994-96,98

1	23364	19046	2160	50466240	41139360
1	20835	24654	2160	45003600	53252640
1	13072	16178	2160	28235520	34944480
1	12836	11167	2160	27725760	24120720
1	25432	20391	2160	54933120	44044560
1	13956		2160	30144960	0
1	24282		2160	52449120	0
1	19527	24397	2160	42178320	52697520
1	26543		2160	57332880	0
1	26808		2160	57905280	0
1	24052	19580	2160	51952320	42292800
1	15250	11478	2160	32940000	24792480
1	8614	18733	2160	18606240	40463280
1	11554	9742	2160	24956640	21042720
1	10751	13669	2160	23222160	29525040
1	7732	6504	2160	16701120	14048640
1	5194	10118	2160	11219040	21854880
1	17944	25504	2160	38759040	55088640
1	7189	9148	2160	15528240	19759680
1	8435	9103	2160	18219600	19662480
1	9830	12085	2160	21232800	26103600
1	1979	2209	2160	4274640	4771440
1	3326	5666	2160	7184160	12238560
1	14314	17622	2160	30918240	38063520
1	12741	8562	2160	27520560	18493920
1	19125	38699	2160	41310000	83589840
1	18050	20340	2160	38988000	43934400
1	4911	4183	2160	10607760	9035280
1	5001	4632	2160	10802160	10005120
1	7090	4943	2160	15314400	10676880
1	26054	20647	2160	56276640	44597520
1	17720	13676	2160	38275200	29540160
1	14240	12889	2160	30758400	27840240
1	3667	2933	2160	7920720	6335280
1	3426		2160	7400160	0
1	4542	4668	2160	9810720	10082880
1	7321	11093	2160	15813360	23960880
1	24076	19824	2160	52004160	42819840
1	32976		2160	71228160	0
1	13158	16188	2160	28421280	34966080
1	8628	9980	2160	18636480	21556800
1	18634	22046	2100	39131400	46296600
1	23095	19015	2040	47113800	38790600
1	3454	2632	1920	6631680	5053440
1	3647	2897	1920	7002240	5562240
1	17439	13999	1920	33482880	26878080
1	11060	20247	1800	19908000	36444600
1	18986	16388	1800	34174800	29498400
1	14272	12116	1800	25689600	21808800
1	9489	7353	1800	17080200	13235400
1	4579	4870	1800	8242200	8766000
1	6564	5268	1800	11815200	9482400

1	4840	6180	1800	8712000	11124000
1	7689	8661	1800	13840200	15589800
1	23753	19686	1800	42755400	35434800
1	31861	25055	1800	57349800	45099000
1	11597	13966	1800	20874600	25138800
1	19190	25257	1800	34542000	45462600
1	36261	30854	1800	65269800	55537200
1	4259	7610	1680	7155120	12784800
1	27951	39597	1500	41926500	59395500
1	30218	25034	1500	45327000	37551000
1	29807	41692	1440	42922080	60036480
1	22909	18018	1440	32988960	25945920
1	18407	13472	1440	26506080	19399680
1	20472	23322	1440	29479680	33583680
1	20472	23322	1440	29479680	33583680
1	20472	23322	1440	29479680	33583680
1	26293	22731	1440	37861920	32732640
1	24282		1440	34966080	0
1	32097	35419	1440	46219680	51003360
1	12318		1440	17737920	0
1	17528	13603	1440	25240320	19588320
1	30218	25034	1440	43513920	36048960
1	14720	17710	1440	21196800	25502400
1	19065		1440	27453600	0
1	24077	20772	1440	34670880	29911680
1	12599	10450	1440	18142560	15048000
1	17377	14840	1440	25022880	21369600
1	24414	31926	1440	35156160	45973440
1	17654	13877	1440	25421760	19982880
1	34950	28272	1440	50328000	40711680
1	30598	20253	1440	44061120	29164320
1	15161	16109	1440	21831840	23196960
1	17086	20614	1440	24603840	29684160
1	6122	4624	1440	8815680	6658560
1	22038	29720	1440	31734720	42796800
1	31442	33222	1440	45276480	47839680
1	12058	9862	1440	17363520	14201280
1	12910	10415	1440	18590400	14997600
1	39003		1440	56164320	0
1	21553	22501	1440	31036320	32401440
1	9009	7326	1440	12972960	10549440
1	14341	17231	1440	20651040	24812640
1	3470	2620	1440	4996800	3772800
1	23887	27563	1440	34397280	39690720
1	46132	40874	1440	66430080	58858560
1	4787	3838	1440	6893280	5526720
1	17549	33434	1380	24217620	46138920
1	4639	5421	1260	5845140	6830460
1	17549	33434	1260	22111740	42126840
1	24276	37113	1200	29131200	44535600
1	19119	23469	1200	22942800	28162800
1	20003	17447	1200	24003600	20936400

1	26661	23126	1200	31993200	27751200
1	12580	11294	1200	15096000	13552800
1	20796	31496	1200	24955200	37795200
1	24171	37678	1200	29005200	45213600
1	59845	69647	1200	71814000	83576400
1	31581	28145	1200	37897200	33774000
1	21998	17748	1140	25077720	20232720
1	22605	18197	1080	24413400	19652760
1	3549	2792	1080	3832920	3015360
1	3203	2247	1080	3459240	2426760
1	19538	15646	1080	21101040	16897680
1	24627	26029	1080	26597160	28111320
1	30775	26269	1080	33237000	28370520
1	13045	15484	1080	14088600	16722720
1	22022	28656	1080	23783760	30948480
1	11103	9205	1080	11991240	9941400
1	23265	27049	1080	25126200	29212920
1	10402	11749	1080	11234160	12688920
1	9114	6638	1080	9843120	7169040
1	19928		1080	21522240	0
1	28518	65303	1080	30799440	70527240
1	14857	21049	1080	16045560	22732920
1	6852	12916	1080	7400160	13949280
1	32097	35419	1080	34664760	38252520
1	16257	18228	1080	17557560	19686240
1	22894	33392	1080	24725520	36063360
1	6430	11205	1080	6944400	12101400
1	20866	29900	1080	22535280	32292000
1	8087	9803	1080	8733960	10587240
1	27991	21994	1080	30230280	23753520
1	20475	15442	1080	22113000	16677360
1	23566	18533	1080	25451280	20015640
1	23636	19480	1080	25526880	21038400
1	31431	47827	1080	33945480	51653160
1	1980	2098	1080	2138400	2265840
1	23569	17174	1080	25454520	18547920
1	25328	21639	1080	27354240	23370120
1	28432	22000	1080	30706560	23760000
1	17654	13877	1080	19066320	14987160
1	17385	14029	1080	18775800	15151320
1	9414	7646	1080	10167120	8257680
1	17853	14979	1080	19281240	16177320
1	3107	3591	1080	3355560	3878280
1	22323		1080	24108840	0
1	5660	4305	1080	6112800	4649400
1	26731	31253	1080	28869480	33753240
1	3813	4880	1080	4118040	5270400
1	6356	4802	1080	6864480	5186160
1	22038	29720	1080	23801040	32097600
1	22452	19172	1080	24248160	20705760
1	50682	71759	1080	54736560	77499720
1	18435	16277	1080	19909800	17579160

EXPORT OF INTAKE DATA FOR BEER AND ALE:
USDA CSFII 1994-96,98

1	12091	9389	1080	13058280	10140120
1	27282		1080	29464560	0
1	29304	20783	1080	31648320	22445640
1	30870		1080	33339600	0
1	17188	12896	1080	18563040	13927680
1	67722	63357	1080	73139760	68425560
1	36261	30854	1080	39161880	33322320
1	13353	10728	1080	14421240	11586240
1	16458	33847	1080	17774640	36554760
1	23156	28981	1080	25008480	31299480
1	26319	23016	1050	27634950	24166800
1	11931	10037	960	11453760	9635520
1	22066	16898	960	21183360	16222080
1	20472	23322	960	19653120	22389120
1	11303	8843	960	10850880	8489280
1	10239	12336	960	9829440	11842560
1	28557	25713	960	27414720	24684480
1	20449	16402	960	19631040	15745920
1	29475	22817	960	28296000	21904320
1	3454	2632	960	3315840	2526720
1	3647	2897	960	3501120	2781120
1	33317	27900	960	31984320	26784000
1	33587	40253	960	32243520	38642880
1	31440	44814	960	30182400	43021440
1	3324	2189	960	3191040	2101440
1	14756	19467	960	14165760	18688320
1	16829	14207	960	16155840	13638720
1	15937	12183	960	15299520	11695680
1	26633	34514	960	25567680	33133440
1	34750	45501	960	33360000	43680960
1	29111	31282	960	27946560	30030720
1	38967	32442	960	37408320	31144320
1	11463	13427	960	11004480	12889920
1	8103	7172	960	7778880	6885120
1	31373	26921	900	28235700	24228900
1	14589	27831	900	13130100	25047900
1	31455	60811	900	28309500	54729900
1	5823	6675	900	5240700	6007500
1	3238	2705	840	2719920	2272200
1	6458	5363	840	5424720	4504920
1	11439	9827	810	9265590	7959870
1	16699	19224	780	13025220	14994720
1	11303	8843	750	8477250	6632250
1	16201	13347	720	11664720	9609840
1	20213	24540	720	14553360	17668800
1	21463	18345	720	15453360	13208400
1	12685	11556	720	9133200	8320320
1	22908	32522	720	16493760	23415840
1	20782	16997	720	14963040	12237840
1	22909	18018	720	16494480	12972960
1	18407	13472	720	13253040	9699840
1	16812	13591	720	12104640	9785520

000170

1	14438	11077	720	10395360	7975440
1	20876	30088	720	15030720	21663360
1	10631	13720	720	7654320	9878400
1	11833	9681	720	8519760	6970320
1	36764	28888	720	26470080	20799360
1	28455	22127	720	20487600	15931440
1	15768	13011	720	11352960	9367920
1	28327	23876	720	20395440	17190720
1	13352	12029	720	9613440	8660880
1	16032	13442	720	11543040	9678240
1	13330	10812	720	9597600	7784640
1	34917	40222	720	25140240	28959840
1	35797	27697	720	25773840	19941840
1	19787	14208	720	14246640	10229760
1	15970	17733	720	11498400	12767760
1	31288	25784	720	22527360	18564480
1	10412	8558	720	7496640	6161760
1	26105	52182	720	18795600	37571040
1	30205	37659	720	21747600	27114480
1	41035	34964	720	29545200	25174080
1	21926	16993	720	15786720	12234960
1	9609	8049	720	6918480	5795280
1	13903	17673	720	10010160	12724560
1	18732	14896	720	13487040	10725120
1	14561	11056	720	10483920	7960320
1	23370	16784	720	16826400	12084480
1	19079	14765	720	13736880	10630800
1	26186	23326	720	18853920	16794720
1	28557	25713	720	20561040	18513360
1	29475	22817	720	21222000	16428240
1	29475	22817	720	21222000	16428240
1	84664	96170	720	60958080	69242400
1	6852	12916	720	4933440	9299520
1	8644	7375	720	6223680	5310000
1	17900	23062	720	12888000	16604640
1	31416	49120	720	22619520	35366400
1	31416	49120	720	22619520	35366400
1	8336	8881	720	6001920	6394320
1	20014	17372	720	14410080	12507840
1	13572	10833	720	9771840	7799760
1	13572	10833	720	9771840	7799760
1	13337	10418	720	9602640	7500960
1	29761	23620	720	21427920	17006400
1	17561	14214	720	12643920	10234080
1	17561	14214	720	12643920	10234080
1	19711	16849	720	14191920	12131280
1	49926	44156	720	35946720	31792320
1	18263	34295	720	13149360	24692400
1	25043	20431	720	18030960	14710320
1	14601	11887	720	10512720	8558640
1	20847	17744	720	15009840	12775680
1	20398	16051	720	14686560	11556720

1	27678	37267	720	19928160	26832240
1	6547	8325	720	4713840	5994000
1	8677	9988	720	6247440	7191360
1	6773	5851	720	4876560	4212720
1	33596		720	24189120	0
1	12017		720	8652240	0
1	17504	15435	720	12602880	11113200
1	6964	4858	720	5014080	3497760
1	45273	51659	720	32596560	37194480
1	45273	51659	720	32596560	37194480
1	17654	21298	720	12710880	15334560
1	17654	13877	720	12710880	9991440
1	18858	15328	720	13577760	11036160
1	26135	19647	720	18817200	14145840
1	29609	34627	720	21318480	24931440
1	14171	11110	720	10203120	7999200
1	7412		720	5336640	0
1	11265	6771	720	8110800	4875120
1	4911	4183	720	3535920	3011760
1	9977	11394	720	7183440	8203680
1	24035	18484	720	17305200	13308480
1	20209	23545	720	14550480	16952400
1	12150	9156	720	8748000	6592320
1	12150	9156	720	8748000	6592320
1	36397	29520	720	26205840	21254400
1	7411	5499	720	5335920	3959280
1	14783	27093	720	10643760	19506960
1	24592	19582	720	17706240	14099040
1	6101	10016	720	4392720	7211520
1	30147	54269	720	21705840	39073680
1	30147	54269	720	21705840	39073680
1	14700	16029	720	10584000	11540880
1	10379	12300	720	7472880	8856000
1	18352	24114	720	13213440	17362080
1	32019	25471	720	23053680	18339120
1	29170	34096	720	21002400	24549120
1	29666	34212	720	21359520	24632640
1	3277	2448	720	2359440	1762560
1	21579	23196	720	15536880	16701120
1	50682	71759	720	36491040	51666480
1	39585	32143	720	28501200	23142960
1	39585	32143	720	28501200	23142960
1	28850	23287	720	20772000	16766640
1	2753	3417	720	1982160	2460240
1	12392	9669	720	8922240	6961680
1	14091	20415	720	10145520	14698800
1	27551	21794	720	19836720	15691680
1	27846	22673	720	20049120	16324560
1	16688	14238	720	12015360	10251360
1	16335	13390	720	11761200	9640800
1	16335	13390	720	11761200	9640800
1	11986	18566	720	8629920	13367520

1	29784	25457	720	21444480	18329040
1	22351	32708	720	16092720	23549760
1	23112	18537	720	16640640	13346640
1	13710	11814	720	9871200	8506080
1	31196	28954	720	22461120	20846880
1	35731	30425	720	25726320	21906000
1	25683	21400	720	18491760	15408000
1	17574	13864	720	12653280	9982080
1	25662	48300	720	18476640	34776000
1	29927	61752	720	21547440	44461440
1	16035	18288	720	11545200	13167360
1	22846	27261	720	16449120	19627920
1	18559	16016	720	13362480	11531520
1	5905	5000	720	4251600	3600000
1	29292	33843	720	21090240	24366960
1	14640	16145	720	10540800	11624400
1	27443	22847	720	19758960	16449840
1	17792	14067	720	12810240	10128240
1	2659	3001	720	1914480	2160720
1	36036	28361	720	25945920	20419920
1	18539	16169	720	13348080	11641680
1	14703	18241	720	10586160	13133520
1	45003	57939	720	32402160	41716080
1	30296		720	21813120	0
1	30775	26269	660	20311500	17337540
1	6844	5397	660	4517040	3562020
1	11400	12571	660	7524000	8296860
1	18665	15118	660	12318900	9977880
1	23936	17998	600	14361600	10798800
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1	9177	10131	600	5506200	6078600
1	23112	18537	600	13867200	11122200
1	25623		600	15373800	0
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1	32278	26101	540	17430120	14094540
1	17244	17749	540	9311760	9584460
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1	22931	25732	480	11006880	12351360
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1	20803	28052	480	9985440	13464960
1	10833	13140	480	5199840	6307200
1	16682	14096	480	8007360	6766080
1	22967	20581	480	11024160	9878880
1	28557	25713	480	13707360	12342240
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1	14385	11450	480	6904800	5496000
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1	7901		480	3792480	0
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1	11209	8896	480	5380320	4270080
1	27251	21529	480	13080480	10333920
1	27251	21529	480	13080480	10333920
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1	9576	7259	480	4596480	3484320
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1	19542	15284	480	9380160	7336320
1	22057	17418	480	10587360	8360640
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1	39618	31665	480	19016640	15199200
1	11463	13427	480	5502240	6444960
1	7709	5857	480	3700320	2811360
1	35319	26209	480	16953120	12580320
1	12355	15520	480	5930400	7449600
1	11534	13892	480	5536320	6668160
1	22796		480	10942080	0
1	34053	29209	480	16345440	14020320
1	54657	45145	420	22955940	18960900
1	27381	19065	420	11500020	8007300
1	23545	19788	420	9888900	8310960
1	3024	2508	360	1088640	902880
1	28923	36325	360	10412280	13077000
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1	28923	36325	360	10412280	13077000
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1	41505	35048	360	14941800	12617280
1	24902	21141	360	8964720	7610760
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1	21449	15725	360	7721640	5661000
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1	9972	8534	360	3589920	3072240
1	9972	8534	360	3589920	3072240
1	9972	8534	360	3589920	3072240
1	9972	8534	360	3589920	3072240
1	9972	8534	360	3589920	3072240
1	9972	8534	360	3589920	3072240
1	14438	11077	360	5197680	3987720
1	14438	11077	360	5197680	3987720
1	18084	14390	360	6510240	5180400
1	35102	32613	360	12636720	11740680
1	35102	32613	360	12636720	11740680
1	26268	22475	360	9456480	8091000
1	9145	10183	360	3292200	3665880
1	10295	18999	360	3706200	6839640
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1	10295	18999	360	3706200	6839640
1	18841	21856	360	6782760	7868160
1	14395	12809	360	5182200	4611240
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1	42707	37028	360	15374520	13330080
1	33141	37785	360	11930760	13602600
1	20368	15714	360	7332480	5657040
1	28327	23876	360	10197720	8595360
1	7469	8863	360	2688840	3190680
1	5006	3936	360	1802160	1416960
1	4152	9026	360	1494720	3249360
1	20295	16077	360	7306200	5787720
1	15656	31080	360	5636160	11188800
1	11303	9108	360	4069080	3278880
1	11303	8843	360	4069080	3183480
1	22238	19568	360	8005680	7044480
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1	4279	3630	360	1540440	1306800
1	4279	3630	360	1540440	1306800
1	21608	26568	360	7778880	9564480
1	43045	38068	360	15496200	13704480
1	43045	38068	360	15496200	13704480
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1	43045	38068	360	15496200	13704480
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1	16837	15181	360	6061320	5465160
1	31426	26642	360	11313360	9591120
1	10232	15273	360	3683520	5498280
1	18040	14806	360	6494400	5330160
1	13045	15484	360	4696200	5574240
1	74636	99715	360	26868960	35897400
1	12741	9891	360	4586760	3560760
1	25856	52385	360	9308160	18858600
1	17052	13808	360	6138720	4970880

1	47458	36134	360	17084880	13008240
1	18193	14620	360	6549480	5263200
1	25961	19606	360	9345960	7058160
1	25961	19606	360	9345960	7058160
1	28555	22397	360	10279800	8062920
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1	13261	9971	360	4773960	3589560
1	17108	13855	360	6158880	4987800
1	21819	16683	360	7854840	6005880
1	16719	11689	360	6018840	4208040
1	15759	13796	360	5673240	4966560
1	21635	24440	360	7788600	8798400
1	20656	25095	360	7436160	9034200
1	4604	5287	360	1657440	1903320
1	19176	15325	360	6903360	5517000
1	19176	15325	360	6903360	5517000
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1	28518	65303	360	10266480	23509080
1	10519	7897	360	3786840	2842920
1	23368	17542	360	8412480	6315120
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1	30787	23358	360	11083320	8408880
1	11480		360	4132800	0
1	11480		360	4132800	0
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1	12010	9306	360	4323600	3350160
1	12010	9306	360	4323600	3350160
1	40034	34143	360	14412240	12291480
1	28189	37409	360	10148040	13467240
1	17171	20923	360	6181560	7532280
1	46210	57725	360	16635600	20781000
1	23295	37310	360	8386200	13431600
1	12535	9176	360	4512600	3303360
1	25936	21093	360	9336960	7593480
1	15485	13057	360	5574600	4700520
1	20281	37894	360	7301160	13641840
1	11851	14542	360	4266360	5235120
1	11851	14542	360	4266360	5235120
1	25495	29064	360	9178200	10463040
1	17528	13603	360	6310080	4897080
1	9122	11605	360	3283920	4177800
1	27623	22540	360	9944280	8114400
1	45552	35747	360	16398720	12868920
1	27476	24063	360	9891360	8662680
1	27476	24063	360	9891360	8662680
1	7640	8259	360	2750400	2973240
1	20711	18195	360	7455960	6550200
1	25885	29589	360	9318600	10652040
1	25885	29589	360	9318600	10652040
1	30192	26826	360	10869120	9657360

1	30192	26826	360	10869120	9657360
1	31976	40462	360	11511360	14566320
1	20502	22830	360	7380720	8218800
1	30218	25034	360	10878480	9012240
1	33108	29310	360	11918880	10551600
1	26506	38241	360	9542160	13766760
1	26506	38241	360	9542160	13766760
1	7901		360	2844360	0
1	27305	20902	360	9829800	7524720
1	28598		360	10295280	0
1	14693	19345	360	5289480	6964200
1	27632	25179	360	9947520	9064440
1	27841	25006	360	10022760	9002160
1	8313	17479	360	2992680	6292440
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1	17559	22330	360	6321240	8038800
1	26139	20814	360	9410040	7493040
1	23366	26576	360	8411760	9567360
1	25869	33402	360	9312840	12024720
1	28679	38753	360	10324440	13951080
1	26717	20807	360	9618120	7490520
1	17653	14731	360	6355080	5303160
1	21540		360	7754400	0
1	8677	9988	360	3123720	3595680
1	7875	9391	360	2835000	3380760
1	21345	16082	360	7684200	5789520
1	5249	7625	360	1889640	2745000
1	19661	16678	360	7077960	6004080
1	6964	4858	360	2507040	1748880
1	35037		360	12613320	0
1	28601	22373	360	10296360	8054280
1	28601	22373	360	10296360	8054280
1	11535	13939	360	4152600	5018040
1	26186	33564	360	9426960	12083040
1	13084	10785	360	4710240	3882600
1	28302	21507	360	10188720	7742520
1	32116	24483	360	11561760	8813880
1	23135	26661	360	8328600	9597960
1	23135	26661	360	8328600	9597960
1	18858	15328	360	6788880	5518080
1	18663	22797	360	6718680	8206920
1	26135	19647	360	9408600	7072920
1	26709	21164	360	9615240	7619040
1	26709	21164	360	9615240	7619040
1	6901	9331	360	2484360	3359160
1	19925	21374	360	7173000	7694640
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1	18004	13369	360	6481440	4812840
1	2750	2178	360	990000	784080
1	2750	2178	360	990000	784080
1	2750	2178	360	990000	784080

EXPORT OF INTAKE DATA FOR BEER AND ALE:
USDA CSFII 1994-96,98

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1	25555	20970	360	9199800	7549200
1	17317	18516	360	6234120	6665760
1	17317	18516	360	6234120	6665760
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1	10828	12457	360	3898080	4484520
1	9344	17631	360	3363840	6347160
1	14537	11736	360	5233320	4224960
1	15161	16109	360	5457960	5799240
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1	6101	10016	360	2196360	3605760
1	6101	10016	360	2196360	3605760
1	23671	17960	360	8521560	6465600
1	8496	9841	360	3058560	3542760
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1	24520	51610	360	8827200	18579600
1	8656	17295	360	3116160	6226200
1	26731	31253	360	9623160	11251080
1	12051	16076	360	4338360	5787360
1	12592	9506	360	4533120	3422160
1	20445	16068	360	7360200	5784480
1	10877	8090	360	3915720	2912400
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1	10448	9130	360	3761280	3286800
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1	15527	22055	360	5589720	7939800
1	21715	18167	360	7817400	6540120
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1	25830	21042	360	9298800	7575120
1	18084	14328	360	6510240	5158080
1	18084	14328	360	6510240	5158080
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1	50682	71759	360	18245520	25833240
1	28850	23287	360	10386000	8383320
1	42397	33649	360	15262920	12113640
1	24668	20491	360	8880480	7376760
1	27809	38773	360	10011240	13958280
1	27809	38773	360	10011240	13958280

1	8960	10206	360	3225600	3674160
1	18449	15667	360	6641640	5640120
1	27396	19783	360	9862560	7121880
1	27396	19783	360	9862560	7121880
1	21838	17487	360	7861680	6295320
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1	14448	11676	360	5201280	4203360
1	31182	24587	360	11225520	8851320
1	31182	24587	360	11225520	8851320
1	2753	3417	360	991080	1230120
1	31052	28379	360	11178720	10216440
1	32173	31989	360	11582280	11516040
1	33188	28616	360	11947680	10301760
1	13936	14325	360	5016960	5157000
1	47399	41533	360	17063640	14951880
1	3299	2803	360	1187640	1009080
1	3299	2803	360	1187640	1009080
1	10489	8341	360	3776040	3002760
1	20968	15321	360	7548480	5515560
1	16688	14238	360	6007680	5125680
1	11112	8479	360	4000320	3052440
1	41532	35127	360	14951520	12645720
1	16483	14631	360	5933880	5267160
1	31196	28954	360	11230560	10423440
1	14203	11888	360	5113080	4279680
1	18712	38471	360	6736320	13849560
1	17888	16067	360	6439680	5784120
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1	11698	8820	360	4211280	3175200
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1	25683	21400	360	9245880	7704000
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1	17574	13864	360	6326640	4991040
1	9286	10546	360	3342960	3796560
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1	9286	10546	360	3342960	3796560
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1	5738	7524	360	2065680	2708640
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1	30330	36622	360	10918800	13183920
1	30330	36622	360	10918800	13183920
1	10770	8787	360	3877200	3163320
1	10541	13375	360	3794760	4815000
1	9451	18623	360	3402360	6704280
1	2659	3001	360	957240	1080360
1	19845	25128	360	7144200	9046080
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1	36036	28361	360	12972960	10209960
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1	41578	37834	300	12473400	11350200
1	23366	26576	300	7009800	7972800
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1	17865	25313	240	4287600	6075120
1	17046		240	4091040	0
1	22955	18168	180	4131900	3270240

1	3611	7158	180	649980	1288440
1	5921	12305	180	1065780	2214900
1	31426	26642	180	5656680	4795560
1	30218	25034	180	5439240	4506120
1	16197	12709	180	2915460	2287620
1	5782	9768	180	1040760	1758240
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1	7493	6151	180	1348740	1107180
1	28112	38851	180	5060160	6993180
1	7798	6810	180	1403640	1225800
1	8651	10017	120	1038120	1202040
1	14607	13148	120	1752840	1577760
1	6002	8573	120	720240	1028760
1	11588	9267	120	1390560	1112040
1	39292	60261	60	2357520	3615660
1	18446	20621	45	830070	927945
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2	22551	24906	7680		191278080
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2	23833	42720	4320		184550400
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2	4639	5421	4320		23418720
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2	7321	11093	360	3993480
2	20930	24225	360	8721000
2	13192	10159	360	3657240
2	13599	25567	360	9204120
2	13500	11812	360	4252320
2	14375	19725	360	7101000
2	23713	25627	360	9225720

2	29927	61752	360	22230720
2	26999	22155	360	7975800
2	18043	26142	360	9411120
2	8923	7346	360	2644560
2	24994	20398	360	7343280
2	13147	18649	360	6713640
2	24407	17048	360	6137280
2	7709	5857	360	2108520
2	23887	27563	360	9922680
2	29241	40196	360	14470560
2	27443	22847	360	8224920
2	16420	13735	360	4944600
2	46132	40874	360	14714640
2	10541	13375	360	4815000
2	27095	35534	360	12792240
2	21112	31127	360	11205720
2	9763	7804	360	2809440
2	18384	22671	360	8161560
2	21494	41545	360	14956200
2	18539	16169	360	5820840
2	12617	15385	360	5538600
2	27756	19874	360	7154640
2	18188	16723	360	6020280
2	16747	25584	360	9210240
2	30537	36322	360	13075920
2	23275	30360	360	10929600
2	28983	21747	360	7828920
2	8405	6517	360	2346120
2	9556	17705	360	6373800
2	16804	22600	360	8136000
2	50163	41611	359.97	14978712
2	50163	41611	359.97	14978712
2	13789	18893	330	6234690
2	74636	99715	300	29914500
2	23295	37310	300	11193000
2	8962	17551	300	5265300
2	27305	20902	270	5643540
2	16201	13347	240	3203280
2	13731	16701	240	4008240
2	20558	20702	240	4968480
2	28302	21507	240	5161680
2	21143	16497	240	3959280
2	12990	18149	240	4355760
2	20415	22749	240	5459760
2	27173	22121	240	5309040
2	14050	11257	180	2026260
2	13321	12113	180	2180340
2	19401	22973	180	4135140
2	29321	23914	180	4304520
2	29321	23914	180	4304520
2	32824	25542	180	4597560
2	32824	25542	180	4597560

2	32824	25542	180	4597560
2	6854	7765	180	1397700
2	36745	29872	180	5376960
2	15505	12571	180	2262780
2	7798	6810	180	1225800
2	21106	25297	180	4553460
2	10770	8787	180	1581660
2	8651	10017	120	1202040
2	19919	15725	120	1887000
2	20415	22749	120	2729880

EXPORT OF INTAKE DATA FOR COCKTAILS:
USDA CSFII 1994-96,98

USDA CSFII 1994-96,98: CONTINUING SURVEY OF FOOD INTAKES BY INDIVIDUALS

RECORD TYPE 30 EXPORT: ALL COCKTAILS.

FoodCode	DayCode	Wt4 Day	Wt4 2Day	FoodAmt	Weighted FoodAmt
93301500	2	33150	69610	232	16149520
93301360	2	33150	69610	540	37589400
93301090	2	16479	20564	28.5	586074
93301110	1	11594	10256	174	1784544
93301110	1	22162	20655	174	3593970
93301180	1	9258	10924	58	633592
93301090	1	31529	28295	87	2461665
93301090	2	31529	28295	87	2461665
93301160	2	21246	16757	180	3016260
93301190	1	30387	33620	960	32275200
93301150	2	42092	36788	480	17658240
93301170	2	42092	36788	464	17069632
93301200	2	16742	14041	180	2527380
93301140	2	16742	14041	180	2527380
93301110	2	17370	34746	232	8061072
93301090	2	20490	46600	57	2656200
93301450	1	26430	33400	46.65	1558110
93301180	1	18874	15092	174	2626008
93301180	1	13330	10812	232	2508384
93301360	1	30767	22954	2400	55089600
93301180	1	8227	6288	116	729408
93301140	1	13646	11271	480	5410080
93301140	1	12077	10081	480	4838880
93301100	1	23592	18312	186	3406032
93301140	1	26293	22731	240	5455440
93301200	1	24284	16748	180	3014640
93301370	1	49313	61319	120	7358280
93301090	1	14172	28036	348	9756528
93301100	2	33966	23844	248	5913312
93301090	2	20158	31519	116	3656204
93301100	2	74636	99715	310	30911650
93301450	1	12408	8979	93.3	837740.7
93301100	1	13261	9971	186	1854606
93301110	1	17108	13855	58	803590
93301170	2	19404	20927	232	4855064
93301160	1	20028	16703	90	1503270
93301080	1	17771	21793	348	7583964
93301110	1	19094	22375	142	3177250
93301160	1	21188	30260	80	2420800
93301180	2	18732	14896	464	6911744
93301450	2	18732	14896	186.6	2779594
93301180	2	14561	11056	232	2564992
93301100	1	20985	19506	372	7256232
93301150	1	21747	17367	300	5210100
93301100	2	14176	11481	124	1423644

Two Day Weighted Average

158 grams/day

EXPORT OF INTAKE DATA FOR COCKTAILS:
USDA CSFII 1994-96,98

93301360	1	26164	47194	720	33979680
93301250	2	13925	20859	360	7509240
93301100	2	13292	11007	23.25	255912.8
93301270	1	13027	10877	464	5046928
93301220	1	33722	24770	250	6192500
93301190	1	10803	8533	240	2047920
93301190	1	10803	8533	240	2047920
93301100	1	13297	13152	496	6523392
93301160	1	31416	49120	180	8841600
93301040	1	21836	17728	240	4254720
93301170	2	24008	18342	116	2127672
93301100	1	11429	13581	496	6736176
93301180	1	8644	7160	116	830560
93301040	1	12746	9894	120	1187280
93301500	1	30218	25034	522	13067748
93302000	1	25852	30453	232	7065096
93302000	1	25852	30453	232	7065096
93301110	2	14693	19345	232	4488040
93301110	2	14693	19345	232	4488040
93301110	2	16649	20530	116	2381480
93301100	1	36390	32702	154	5036108
93301400	2	26108	35620	52.8	1880736
93301100	1	13133	10881	372	4047732
93301100	1	15913	13329	372	4958388
93301100	2	18504	14638	434	6352892
93301500	2	18189	18817	464	8731088
93301100	2	23724	19821	310	6144510
93301100	1	21618	15259	248	3784232
93301170	2	6786	5061	43.5	220153.5
93301100	1	9932	11516	310	3569960
93301100	1	13677	15071	310	4672010
93301170	1	20558	20702	174	3602148
93301170	2	22265	40366	464	18729824
93301100	1	26365	33833	372	12585876
93301100	2	17882	21232	186	3949152
93301100	1	9520	8505	372	3163860
93301100	1	9295	7397	372	2751684
93301170	1	5561	4016	174	698784
93301090	1	14676		116	0
93301190	1	20137	23349	30	700470
93301110	2	11151	9464	116	1097824
93301100	2	24702	18605	496	9228080
93301090	2	14578	15993	174	2782782
93301090	2	17654	21298	174	3705852
93301360	1	18663	22797	480	10942560
93301450	2	23468	18505	155.5	2877528
93301370	1	23752	18407	420	7730940
93301370	1	23752	18407	840	15461880
93301110	2	14040	11284	174	1963416
93301180	2	23151	31987	1392	44525904
93301110	1	11889	13640	71	968440
93301110	1	11889	13640	71	968440

93301110	1	11889	13640	71	968440
93301110	2	11889	13640	71	968440
93301110	2	11889	13640	71	968440
93301140	1	20724	35057	480	16827360
93301140	2	17439	13999	480	6719520
93301000	2	17439	13999	496	6943504
93301370	2	22449	40970	480	19665600
93301100	1	11990	13101	186	2436786
93301100	1	4478	5868	372	2182896
93301180	1	11140	14693	870	12782910
93301180	1	12209	17892	348	6226416
93301060	1	17695	18857	300	5657100
93301110	2	22627	25652	348	8926896
93301140	2	11776	21830	360	7858800
93301100	2	23510	32000	186	5952000
93301180	1	6598	7910	348	2752680
93301180	2	6598	7910	580	4587800
93301180	1	30341	24104	232	5592128
93301060	1	17476	13164	480	6318720
93301040	2	5115	5448	122	664656
93301200	2	20409	24598	266	6543068
93301100	1	15505	12571	77	967967
93301060	2	15887	11241	225	2529225
93301180	1	2409	3269	348	1137612
93301180	2	2409	3269	2610	8532090
93301190	1	25896	17162	120	2059440
93301180	1	25896	17162	464	7963168
93301190	2	1901	3147	2532	7968204
93301140	2	13934	9918	213	2112534
93301140	1	17720	13676	1200	16411200
93301200	1	14293	18674	480	8963520
93301180	1	3277	2448	696	1703808
93301110	2	19228	22481	174	3911694
93301110	1	10203	11805	116	1369380
93301040	1	15428	18108	120	2172960
93301060	1	58251		270	0
93301180	1	23725	17575	464	8154800
93301140	1	23725	17575	480	8436000
93301110	1	15236	13502	43.5	587337
93301060	1	19225	16898	240	4055520
93301060	1	19225	16898	720	12166560
93301190	1	15716	10895	240	2614800
93301190	1	15716	10895	720	7844400
93301040	1	15999	13075	720	9414000
93301090	1	24098	33019	114	3764166
93301060	1	14091	20415	480	9799200
93301180	1	20298	24067	116	2791772
93301500	1	36228	30400	232	7052800
93301500	1	27324	29835	87	2595645
93301180	1	39618	31665	406	12855990
93301180	1	11589	9809	116	1137844
93301030	1	19731	15010	360	5403600

93301030	1	19731	15010	360	5403600
93301030	1	19731	15010	360	5403600
93301090	2	29679	41894	116	4859704
93301360	1	14561	15579	240	3738960
93301110	2	21531	30705	71	2180055
93301180	1	13404	26372	232	6118304
93301180	1	15878	30573	116	3546468
93301450	1	23852	18371	279.9	5142043
93301050	1	19603	19021	130.5	2482241
93301050	2	19603	19021	130.5	2482241
93301040	1	16959	13000	180	2340000
93301100	1	25599	19080	186	3548880
93301090	1	13242	10333	116	1198628
93301110	2	13242	10333	116	1198628
93301360	2	42331	94650	240	22716000
93301360	2	42331	94650	480	45432000
93301180	1	34636	28709	696	19981464
93301400	1	15720	12750	26.4	336600
93301180	2	26063	22165	696	15426840
93301100	2	20602	15959	372	5936748
93301100	2	27656	32111	496	15927056
93301100	1	28215	24731	992	24533152
93301500	2	23616	18059	232	4189688
93301100	1	23798	16381	186	3046866
93301030	1	34081	28834	120	3460080
93301170	1	39885	37187	232	8627384
93301270	2	19975	14412	696	10030752
93301270	2	19975	14412	348	5015376
93301160	2	19975	14412	120	1729440
93301060	1	23998	28143	150	4221450
93301360	1	41267		300	0
93301100	1	41267		744	0
93301180	1	52756		696	0
93301180	1	52756		348	0
93301100	1	36261	30854	620	19129480
93301110	1	20296	29228	58	1695224
93301110	2	20296	29228	87	2542836
93301110	2	20296	29228	43.5	1271418
93301100	1	17253	15297	77	1177869
93301100	2	13173	10704	744	7963776
93301110	1	10534		232	0
93301180	1	10340	8650	522	4515300
93301360	2	21112	31127	240	7470480
93301360	2	21112	31127	240	7470480
93301100	1	19397		248	0
93301100	1	15757	18524	310	5742440
93301500	2	37999	27898	464	12944672
93301110	1	9038	7650	29	221850
93301110	2	9038	7650	21.27	162715.5
93301110	1	11426	7804	29	226316
93301110	2	11426	7804	38.67	301780.7
93301110	1	9812	8466	116	982056

EXPORT OF INTAKE DATA FOR COCKTAILS:
USDA CSFII 1994-96,98

93301100	1	31878	24787	248	6147176
93301100	2	14964	17514	744	13030416
93301400	1	20830		211.2	0
93301100	1	23417	17577	248	4359096
93301180	1	5319	3785	928	3512480
93301110	2	12839	11325	43.5	492637.5
93301110	2	22152	17653	43.5	767905.5

EXPORT OF INTAKE DATA FOR WINE COOLERS:
USDA CSFII 1994-96,98

USDA CSFII 1994-96,98: CONTINUING SURVEY OF FOOD INTAKES BY INDIVIDUALS

RECORD TYPE 30 EXPORT: WINE COOLERS.

FoodCode	DayCode	Wt4 Day1	Wt4 2Day	FoodAmt	Weighted FoodAmt	Two Day Weighted Average
93404000	1	33041	25758	360	9272880	167
93404000	2	26129	20234	360	7284240	grams/day
93404000	2	21474	14790	360	5324400	
93404000	1	25136	17359	60	1041540	
93404000	1	16172	21667	360	7800120	
93404000	2	19701	17163	240	4119120	
93404000	2	25378	19000	240	4560000	
93404000	2	25378	19000	240	4560000	
93404000	2	21801	21960	720	15811200	
93404000	1	11019	11554	240	2772960	
93404000	2	11019	11554	240	2772960	
93404000	1	16965	24949	360	8981640	
93404000	1	21747	17367	420	7294140	
93404000	1	22574		720	0	
93404000	1	13120	10354	360	3727440	
93404000	2	13120	10354	180	1863720	
93404000	2	11439	9827	720	7075440	
93404000	2	41652	37709	240	9050160	
93404000	1	8391	16624	360	5984640	
93404000	1	8166	8494	240	2038560	
93404000	1	22710	17339	900	15605100	
93404000	1	24077	20772	300	6231600	
93404000	1	11423	20869	360	7512840	
93404000	1	12853	26156	360	9416160	
93404000	2	34938	52451	180	9441180	
93404000	1	28302	21507	480	10323360	
93404000	1	17654	21298	360	7667280	
93404000	2	8355	6734	180	1212120	
93404000	2	6222	6097	180	1097460	
93404000	2	17317	18516	360	6665760	
93404000	1	14052	19228	240	4614720	
93404000	2	14052	19228	360	6922080	
93404000	2	11866	8294	360	2985840	
93404000	1	13934	11398	210	2393580	
93404000	1	31661	22378	360	8056080	
93404000	1	22038	29720	360	10699200	
93404000	1	10565	7368	180	1326240	
93404000	1	7321	5347	180	962460	
93404000	1	22704	17855	360	6427800	
93404000	2	20382	16823	180	3028140	
93404000	1	27666	26598	360	9575280	
93404000	1	20086	15814	360	5693040	
93404000	2	23893	22274	360	8018640	
93404000	2	23417	17577	360	6327720	

Appendix XII

APPENDIX XII

Pages 000202 - 000202 have been removed in accordance with copyright laws. Please see appended bibliography list of the references that have been removed from this request.

End Submission

Reference List for Industry Submission, GRN 000104

Pages	*Author*	*Title*	*Publish Date*	*Publisher*	*BIB_Info*
000054 - 000070	Reynolds, R.C.; Chappel C. I.	Sucrose Acetate Isobutyrate (SAIB): Historical Aspects of its use in Beverages and a Review of Toxicity Studies Prior to 1988	February 1998	Food and Chemical Toxicology	Volume 36, Number 2, pgs 81-93
000073 - 000082	Procter, B.G.; Chappel, C.I.	Subchronic Toxictiy Studies of Sucrose Acetate Isobutyrate (SAIB) in the Rat and Dog	1998	Food and Chemical Toxicology	Volume 36, pgs 101-110
000085 - 000090	Blair, M.; Chappel, C.I.	4-Week Range-finding and 1-Year Oral Toxicity Studies of Sucrose Acetate Isobutyrate (SAIB) in the Cynomolgus Monkey	1998	Food and Chemical Toxicology	Volume 36, pgs 121-126
000093 - 000102	Mackenzie, K.M.; Tisdel, P.J.; Hall, R.L.; Boysen, B.G.; Field, W. E. ; Chappel, C.I.	Oral Toxicity and Carcinogenicity Studies of Sucrose Acetate Isobutyrate (SAIB) in the Fischer 344 Rat and B6C3F1 Mouse	1998	Food and Chemical Toxicology	Volume 36, pgs 111-120
000105 - 000110	Mackenzie, K.M.; Henwood, S.M.; Tisdel, P.J.; Boysen, B.G.; Palmer, T.E.; Schardein, J.L; West, A.J.; Chappel, C.I.	Sucrose Acetate Isobutyrate (SAIB): Three-generation Reproduction Study in the Rat and Teratology Studies in the Rat and Rabbit	1998	Food and Chemical Toxicology	Volume 36, pgs 135-140
000113 - 000120	Myhr, B.C.; Cifone, M.A.; Ivett, J.L.; Lawlor, T.E.; Young, R.R.	Lack of Genotoxic Effects of Sucrose Acetate Isobutyrate (SAIB)	1998	Food and Chemical Toxicology	Volume 36, pgs 127-134
000123 - 000126	Chiang, M.; Gray, K.; Chappel, C.I.	Effect of Sucrose Acetate Isobutyrate (SAIB) Ingestion on the Hepatobiliary Function of Normal Human Male and Female Volunteers	1998	Food and Chemical Toxicology	Volume 36, pgs 141-144
000130 - 000133	Reynolds, R.C.	SAIB metabolism and pharmacokinetics	NA	NA	pgs 96-99

NA- Not applicable

Pages	*Author*	*Title*	*Publish Date*	*Publisher*	*BIB_Info*
000137 - 000157	Vavasour, E.	Sucrose Acetate Isobutyrate	NA	IPCS/INCHEM /WHO Food Additives	Report Series 32, pgs 1-21
000163 - 000163	NA	THe U.S. WIne Market	2000	Beverage Marketing Corporation	pg 164
000202 - 000202	NA	Sucrose Acetate Isobutyrate	NA	FCC	Volume IV, Supplement 3, pg 60

NA- Not applicable

DEPARTMENT OF HEALTH & HUMAN SERVICES. Public Health Service

Food and Drug Administration
Washington, DC 20204

April 29, 2002

Joan Sylvain Baughan
Keller and Heckman LLP
1001 G Street, N.W.
suit's 500 West
Washington, D.C. 20001

Re: GRAS Notice No; GRN 000104

Dear Ms. Baughan:

The Food and Drug Administration (FDA) has received the notice, dated April 3,2002, that you submitted on behalf of Eastman Chemical Company (Eastman) in accordance with the agency's proposed regulation, proposed 21 CFR 170.36 (62 FR 18938; April 17, 1997; Substances Generally Recognized as Safe (GRAS)). FDA received this notice on April 3,2002, filed it on April 17,2002, and designated it as GRN No: GRN 000104.

The subject of the notice is sodium acetate isobutyrate (SAIB). The notice informs FDA of the view of Eastman that SAIB is GRAS, through scientific procedures, for use as as stabilizer of emulsions of flavoring oils used in alcoholic beverages at a level no greater than 300 parts per million (ppm) in the finished alcoholic beverage.

In accatdance with proposed 21 CFR 170.36(f), a copy of the information in the notice that conforms to the information described in proposed 21 CFR 170.36(c)(1) is available for public review and copying on the homepage of the Office of Food Additive Safety (on the Internet at http://www.cfsan.fda.gov/~lrd/foodadd.html). If you have any questions about the notice, contact me at (202) 418-3352.

Sincerely yours,

Jeremian Pasano
DBGNR
Center for Food Safety
and Applied Nutrition

000212

AM

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(202) **434-4158**
grau@khlaw.com

May 6, 2002

Via Facsimile and U.S. Post Office

Jeremiah Fasano
DBGNR
The Food and Drug Administration
Center for Food Safety and Applied Nutrition
Washington, D.C. 20204

Re: April 25,2002 Acknowledgement Letter for GRAS Notice No. GRN 000104; Our File No. EA12315-24

Dear Mr. Fasano:

Thank you for the recent (April 25,2002) acknowledgment letter confirming the Food and Drug Administration's (FDA) receipt of the generally recognized as safe (GRAS) Notification,we filed on behalf of our client, Eastman Chemical Company, for the use of sucrose acetate isobutyrate (SAIB) in alcoholic beverages. As you know, this GRAS Notification informed the Agency of our determination, on basis of scientific evidence, that SAIB may be considered GRAS when used at levels of up to 300 parts per million (ppm) as a stabilizer of emulsions in flavoring oils used in alcoholic beverages.

We appreciate the acknowledgement letter; however, we have noticed an error in the description of the notified substance as it is reported in the April 25, 2002 letter. Specifically, we note that in the first line of the second paragraph of the letter, SAIB is described as "sodium" acetate isobutyrate, rather than sucrose acetate isobutyrate (we have enclosed a copy of the letter for your ease of reference). This being the case, we would respectfully ask that you re-issue the acknowledgement letter using the correct name for the notified substance. In addition, we understand that FDA will post this notification on its website available for public review; we would ask that you please ensure that the notified substance is described accurately in this listing to avoid any potential confusion.

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We appreciate your time and attention to this matter. Should you have any questions, please feel free to contact us.

Sincerely yours,

Caren **A.C.** Grau

Enclosure

cc: Linda Kahl
Paulette Gaynor