



# Sucrose Acetate Isobutyrate Food Regulatory Clearances

March, 2003

## Acceptable Daily Intake:

Joint FAO/WHO Expert Committee on Food Additives (JECFA): 20 mg/kg body weight/day

U.S. Food and Drug Administration (FDA): 20 mg/kg body weight/day

## SAIB Regulatory Clearance

Government/ Authoritative Body	Maximum Level (mg/kg or mg/l)	Food Restrictions	Regulation/Citation
Food Standards Australia/ New Zealand	1,000	Cordials, syrups, and toppings	Standard O1 (1)(b)(ii)(c) (3)(b)(ii)(c) (6)(b)(ii)(c)
	200	Soft drinks and soft drink products	Standard O4 2.(1)(o)
	200	Fruit drinks	Standard O9 Part 1; 2.(2)(I)
	120	Electrolyte drink bases and electrolyte drinks	Standard R9 Part 3; 8(6)
Bahamas	Not specified		The Bahamas accepts the U.S. Standards for Food Additives
Bermuda	Not specified		Bermuda has no food additive regulations and relies on the country of origin requirements for additives.
Bolivia	300	See United States listing	Current local regulations follow United States FDA. Final product formulations require local registration indicating ingredients used and their U.S. FDA approvals.
Bulgaria	300	Nonalcoholic beverages	Order No. 45, 1 December 1995. Health Regulations and Requirements for Additives, Appendix 7
Canada	300	Citrus or spruce flavored beverage  Citrus or spruce flavored alcoholic beverages such as flavored cocktail products, wine coolers, and malt beverage coolers.	B.16.100 Table VIII, S.16
Chile	200	As a clouding or turbidity agent	Decree No. 977, Article 148
China, Peoples Republic	140	Carbonated beverages	Hygienic Standard for Uses of Food Additives, GB 2760-1996, December 1996

<b>Government/ Authoritative Body</b>	<b>Maximum Level (mg/kg or mg/l)</b>	<b>Food Restrictions</b>	<b>Regulation/Citation</b>
Codex Alimentarius	500	14.1.4 Water-based flavored drinks, including “sport” or “electrolyte” drinks	INS 444 Approved at Step 8 23 <sup>rd</sup> Session; July 1999
Colombia	Not specified	Permitted as a diluent to aid the incorporation of flavors into food products	ICONTEC (1417). C.10.170/76
Costa Rica	Follows codex alimentarius		Codex Alimentarius
Croatia	300	Nonalcoholic beverages	Regulation on Additives for Use in Foodstuffs. No. 1598, Table 10, 6 October 1998
Czech Republic	300	Nonalcoholic beverages	Adopted European Directive 95/2/EC
Estonia	300	Cloudy flavored drinks	Decree No. 193, 9 October 1997. Limits and Labeling of Food Additives Permitted in Foodstuffs, Section 9.14.1.4
European Union Member States <sup>a</sup>	300	Nonalcoholic beverages	Directive 95/2/EC; Annex IV; E444
Hong Kong	GMP		
Hungary	300	Cloudy refreshment drinks	Hungarian Food Codex Provision No. 1-2-95/2 Food Additives other than Colors and Sweeteners, Annex IV
Iceland	300	In alcoholic drinks that are a blend of beer, cider, wine, or spirits with a nonalcoholic drink, in cloudy products only. Cloudy flavored drinks	Regulation on Additives in Foodstuffs No. 579/1993, as amended by regulation No. 767/1997, Appendix 1, Section 14.3 and Section 14.1.4
India	300	Nonalcoholic beverages	The Gazette of India; 27 May 1999; GSR 396(E)2(e)
Indonesia	GMP		
Israel	150	Nonalcoholic carbonated beverages	Israeli Standard I.S. 594 (1983), as amended 1985 and 1987. Israel Emulsifier and Stabilizer Amendments (1983)
Japan	GMP	Sucrose esters of fatty acids (which includes sucrose acetate isobutyrate) are generally permitted as emulsifiers in foods	Japanese Standard for Food Additives, March 1997
Kenya	300	Soft drinks	Food Drugs and Chemical Substances Regulations 1978 and 1992
Korea, South	Not specified	Sucrose esters of fatty acids (which includes sucrose acetate isobutyrate) <sup>b</sup>	Public Code on Food Additives, 1995. Part 203, p428
Latvia	300	Nonalcoholic flavored cloudy drinks	Standing Order for Food Additives, Regulation No. 170, 6 May 1997, Annex 4, Section 18.1.3
Lithuania	300	Cloudy flavored drinks	Lithuanian Hygiene Norm HN 53:1998, Approved Food Additives, Article 8.2, Section 14.1.4

<sup>a</sup>Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden, and United Kingdom.

<sup>b</sup>Per Korean Chemical Material Dictionary (1994), Volume II, Chapter 23:Food Additives, 3093-3095.

Government/ Authoritative Body	Maximum Level (mg/kg or mg/l)	Food Restrictions	Regulation/Citation
Madagascar (Malagasy) Republic	300		Gazette of Madagascar, April 14, 1979
Malaysia	Not specified	Sucrose esters of fatty acids (includes SAIB, and therefore can be used in foods wherever "may contain permitted food conditioner" is mentioned. <sup>c</sup>	Food Quality Control Division, Ministry of Health Malaysia, Regulation 25 (Food Regulations 1985). Eleventh Schedule, Table 1: Emulsifiers
Malta	300	Nonalcoholic flavored cloudy drinks	Permitted Food Additives Regulations, 1998 (L.N. 256 or 1998), Fourth Schedule
Mercosur	300	Nonalcoholic beverages	
Argentina	300	Nonalcoholic beverages	Capitulo 12; Bebidas Analcohólicas
Brazil	300	Nonalcoholic beverages	Resolution No. 389, 5 August 1999
Paraguay	See Mercosur		
Uruguay	300	Nonalcoholic beverages	Decree 476/000 Implementing Mercosur, Group 16.2
Mexico	300	Nonalcoholic beverages	Bebidas no alcohólicas
New Zealand	See Australia	See Australia	See Australia
Norway	300	Cloudy flavored drinks and similar products	Regulation No. 1378, 21 December 1993. Permitted Additives List 1999, Annex 3, Section 14.1.4
Peru	300	See United States listing	Current local regulations follow United States FDA. Final product formulations require local registration indicating ingredients used and their FDA approvals
Poland	300	In flavored nonalcoholic opalescent drinks	Ordinance No. 72, Ministry of Health, Annex 2, Part 6. 27 December 2000
Russia	Not specified	Permitted for use as an emulsifier and stabilizer in foodstuffs	Sanitary Rules and Standards, SanPiN 2.3.4.560 – 96, Annex 9, List of Permitted Additives
Singapore	300	Nonalcoholic drinks	Regulation 21(2A) per letter from Food Control Department; Ministry of the Environment; 22 July 2000
Slovak Republic	300	Cloudy soft drinks	Slovak Food Code, June 1996, Head III, Part 2, Annex 1, Additives and Technological Auxiliary Compounds in Foods, Part F
Slovenia	300	Nonalcoholic beverages	Regulation on Additives for Foodstuffs, Annex 6. 12 January 2000
South Africa, Republic of	500	Soft drinks	G.N. R. 2527/1987 13 November 1987
Switzerland	Currently None	<b>Authorizations for food additives on a need to basis based on requests from the food industry</b>	
Taiwan	As practically needed (GMP)	Sucrose esters of fatty acids (includes SAIB, and is allowed to be used in food products as an emulsifier with appropriate amount under GMP. <sup>d</sup> )	Department of Health, Taiwan. Food Sanitation. 1.3. Scope and Application Standards of Food Additives. Section 16: Emulsifiers.
Thailand	220		Under license
Turkey	300	Nontransparent, nonalcoholic aromatic drinks	Turkish Food Codex Regulation, Exhibit 1 (1997)

<sup>c</sup>Per communication with Nik Shabnam Nik Mohd of the Ministry of Health Malaysia (October 15, 2002).

<sup>d</sup>Per letter from Lu-Hung Chen, Ph.D., Director-General, Bureau of Food Sanitation (October 30, 2002).

<b>Government/ Authoritative Body</b>	<b>Maximum Level (mg/kg or mg/l)</b>	<b>Food Restrictions</b>	<b>Regulation/Citation</b>
Ukraine	Not specified	Not specified	Decree No. 342, 17 February 2000
United States	300	Nonalcoholic beverages  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.	21 CFR 172.833, 64 FR 29949; 1999  GRAS Notice No. GRN 000104. Letter of no questions from FDA dated August 16, 2002.
Venezuela	Not specified	Soft drinks	COVENIN Standard No. 2182:1995
Zambia	300	Beverages	Food and Drugs Regs. 1978

## **EASTMAN**

### ■ NORTH AMERICA

#### **Eastman Chemical Company Corporate Headquarters**

P.O. Box 431  
Kingsport, TN 37662-5280 U.S.A.

Telephone:  
U.S.A. and Canada, 800-EASTMAN (800-327-8626)  
Other Locations (1) 423-229-2000  
Fax: (1) 423-229-1673

<http://www.eastman.com>

### ■ LATIN AMERICA

#### **Eastman Chemical Latin America**

9155 South Dadeland Blvd.  
Suite 1116  
Miami, FL 33156 U.S.A.

Telephone: (1) 305-671-2800  
Fax: (1) 305-671-2805

### ■ EUROPE / MIDDLE EAST / AFRICA

#### **Eastman Chemical B.V.**

Customer Service Center  
Weena 159-161  
3013 CK Rotterdam  
NETHERLANDS

Telephone: (31) 10 2402 111  
Fax: (31) 10 2402 100

### ■ ASIA PACIFIC

#### **Eastman Chemical Japan Ltd.**

AIG Aoyama Building 5F  
2-11-16 Minami Aoyama  
Minato-ku, Tokyo 107-0062 JAPAN

Telephone: (81) 3-3475-9510  
Fax: (81) 3-3475-9515

#### **Eastman Chemical Asia Pacific Pte. Ltd.**

#05-04 Winsland House  
3 Killiney Road  
Singapore 239519 SINGAPORE

Telephone: (65) 6831-3100  
Fax: (65) 6732-4930

Material Safety Data Sheets providing safety precautions that should be observed in handling and storing Eastman products are available online or on request. You should obtain and review the available material safety information before handling any of these products. If any materials mentioned are not Eastman products, appropriate industrial hygiene and other safety precautions recommended by their manufacturers should be observed.

*Neither Eastman Chemical Company nor its marketing affiliates shall be responsible for the use of this information, or of any product, method, or apparatus mentioned, and you must make your own determination of its suitability and completeness for your own use, for the protection of the environment, and for the health and safety of your employees and purchasers of your products. No warranty is made of the merchantability or fitness of any product, and nothing herein waives any of the Seller's conditions of sale.*

Eastman is a trademark of Eastman Chemical Company.

© Eastman Chemical Company, 2003.

Publication Z-101  
March 2003

Printed in U.S.A.