



Memorandum

Date • June 3, 2003

From Toxicology-Group 1, Division of Food Contact Notification (DFCN)

Subject Addendum memorandum #2 to Final Toxicology Memorandum (Young to Peiperl, 3/08/02) for FAP No. 8A4610, regarding revised exposure estimates

To Division of Petition Review
Attn: Martha Peiperl

Through: Garfield N. Biddle, Ph.D. Garfield N. Biddle
Director, Division of Petition Review

FAP No. 8A4610

Related FAPs:
SFAE:

1A3564 9A4166
2A3590 0A4183
3A3708 2A4321
5A3839 5A3859
6A3914

Higher esters: 6T3900

Olestra: 7A3997

Keller and Heckman, LLP
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Suite 500 West
Washington, D.C. 20001


On behalf of: Mitsubishi Chemical Co.
Tokyo 100, Japan



Toxicology previously determined, in their memoranda for this petition dated March 8, and July 18, 2002, that there were no safety concerns regarding the proposed regulation of SOE as described in this food additive petition. This determination was based on reviews of information related to: a) sucrose fatty acid esters, b) the exposure estimate of 110 mg/p/d for the proposed uses of SOE at the 90th percentile (Chemistry memorandum from M. DiNovi to L. Lin, dated October 13, 1998), and c) exposure estimates for various sucrose ester components in SOE described in an e-mail from Dr. DiNovi on March 6, 2002 and presented in the Toxicology memorandum dated March 8, 2002.

Chemistry has provided a revised estimate of exposure to SOE at the 90th percentile, 98 mg/p/d, which is slightly lower than the earlier estimate of 110 mg/p/d. Further refinements in exposure estimates for each of the fatty acid ester components of SOE (mono through octa) have also been provided. This information is provided in a memorandum from Dr. DiNovi, dated June 2, 2003, which is attached.

Toxicology concludes that this reduction in exposure does not change our previous conclusion that we have no safety concerns regarding the proposed regulation of SOE as described in this food additive petition. However, Toxicology reiterates, that if an increase in exposure to the sucrose fatty acid ester components of SOE is proposed in the future, additional safety studies may be needed.


Carolyn Young, Ph.D.

Attachment: Chemistry memorandum June 2, 2003 from M. DiNovi

cc: (Lin, Edwards, Biddle, Varner, Zajac, Twaroski, M.)
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**Memorandum**

Date June 2, 2003

From Division of Biotechnology & GRAS Notification Review, HFS-255

Subject FAP 8A4610: Mitsubishi Chemical Corp. Sucrose Oligoesters (SOE) in Butter-substitute Spreads and Chocolate.

To M. Peiperl
Division of Petition Review, HFS-265

We have refined the estimate of exposure to SOE through the use of TAsdiet software, which enables us to combine the intakes of SOE from its use in chocolate and butter-substitute spreads. Our previous estimates of exposure to SOE of 55 mg/p/d and 110 mg/p/d for a consumer of these foods at the mean and at the 90th percentile, respectively, was a simple average of the intakes from the two uses¹. The previous estimate was obtained using food consumption data from the 3-day 1989-1992 USDA Continuing Survey of Food Intakes by Individuals (CSFII). The TAsdiet software calculates the combined intakes using modeling with the same CSFII food intake data. The use of the combined food intakes for chocolate and butter-substitute spreads improves the reliability of the exposure estimate because it is more representative of the actual intake of these foods than a simple average.

Using the typical use level of 0.5%, as reported by the petitioner and as used in our previous exposure estimate, we calculate the probable intake of SOE as follows:

	Food Intake (g/p/d)			SOE Intake (mg/p/d)	
	% Eaters	Mean	90 th Pctle	Mean	90 th Pctle
All ages					
Butter-substitute Spreads	13.0%	7	14.8	35	74
Chocolate	4.5%	15	30.6	75	153
Butter-substitute Spreads + Chocolate	17.1%	9	19.6	45	98
2 - 5 years					
Butter-substitute Spreads	12.5%	4	9.5	20	48
Chocolate	4%	7	13.5	35	68
Butter-substitute Spreads + Chocolate	16.3%	5	12	25	50

This exposure estimate supersedes that in our October 13, 1998 memorandum. The revised SOE intake for a consumer at the 90th percentile (all ages) is 98 mg/p/d. As the revised SOE

¹Memorandum from M. DiNovi to L. Lin, dated October 13, 1998.

intake is lower than our previous estimate (110 mg/p/d), the probability of health risk from consumption of chocolate and butter-substitute spreads formulated with SOE would be reduced.

The following table contains revised eaters-only intakes for SOE components at or above the 90th percentile, based on the new estimates above².

Intake of SOE Component Esters

Based on Exposure Estimate for SOE of 98 mg/p/d and “% Average” data from: “SOE Product Analysis” - Appendix 3 of FAP 8A4610

Ester	% Average ~50-SOE samples	Exposure from Proposed Use for 90 th pctle., Eaters-only (mg/p/day) ³	Exposure from Regulated Uses for 90 th pctle., Eaters-only (mg/p/day)	Sum of Columns 3 & 4 (mg/p/day)	ADI (mg/p/d)
Mono	1.5	1.5	63	65	1500 ⁴
Di	4.2	4.2	63	67	1500 ⁴
Tri	10	10	63	73	1500 ⁴
Tetra	14	14	12 (SFAE) ⁵	26	110
Penta	19	19	12 (SFAE)+ 35(Olestra)	66	none
Hexa	23	23	70 (Olestra)	93	none
Hepta	20	20	1400	1420	none
Octa	9	9	7000	7009	none

We note that when this petition was initially reviewed a specification for heavy metals was included. In the intervening time, the Food Chemicals Codex committee’s policy on heavy metals specifications has changed. Rather than include a specification for “heavy metals, it is now the policy to include

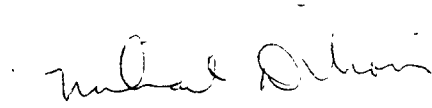
²Rather than estimating a cumulative exposure for the regulated and proposed uses of various sucrose oligoesters, we have simply added the individual estimates for eaters-only at the 90th percentile in columns 3 and 4. These figures will be useful for demonstrating, in a simple fashion, how the contributions of the various components of SOE, based on the proposed use, might impact the safety evaluation.

³Calculated by multiplying the revised eaters-only intake for SOE (98 mg/p/d) by the % average for each ester component.

⁴The ADI of 1500 mg/p/d is a cumulative total ADI for a mixture of mono-, di-, and tri-esters, and not an ADI for each individual ester.

⁵Sucrose Fatty Acid Esters = SFAE

specifications for individual heavy metals when circumstances warrant. For this petition the only heavy metal needing a specification is lead. The Agency concurs with this policy change and is satisfied with the information submitted concerning the lead specification.

A handwritten signature in cursive script, appearing to read "Michael DiNovi".

Michael DiNovi, Ph.D.

HFS-255
HFS-255:MJDiNovi:418-3003:mjd:1-21-03;4-29-03;6-2-03
RD Init:SECarberry, HFS-265:4-30-03