

codex alimentarius commission E



FOOD AND AGRICULTURE
ORGANIZATION
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WORLD
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Agenda Item 10

CX/FA 08/40/15

March 2008

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Fortieth Session

Beijing, China, 21-25 April 2008

PRIORITY LIST OF FOOD ADDITIVES PROPOSED FOR EVALUATION BY JECFA

NEW REQUESTS AND INFORMATION ON COMPOUNDS ALREADY INCLUDED IN THE PRIORITY LIST

(in response to CL 2007/27-FA)

The following comments have been received from the following Codex Members and Observers:

Denmark, Japan, The United States of America, EFEMA, ICGMA

Denmark:

In response to CL 2007/27-FA Denmark requests the inclusion of an enzyme on JECFA Priority List applied for by Novozymes in Denmark. The Danish toxicologists have accepted the documentations presented by the company.

Information on the Additive to be Evaluated by JECFA

1. Proposal for inclusion submitted by:

The Danish Veterinary and Food Administration.

2. Name of compound; trade name(s); chemical name(s):

Compound: Branching enzyme from *Rhodothermus obamensis* and expressed in *Bacillus subtilis*.

Trade name: Novozym® 28067.

Chemical name: CAS 9001-97-2, EC 2.4.1.18.

3. Names and addresses of basic producers:

Novozymes A/S
Krogshoejvej 36
DK-2880 Bagsvaerd
Denmark

4. Has the manufacturer made a commitment to provide data?

Novozymes A/S commits to provide data to support the proposal for inclusion of the branching enzyme in the list of substances to be evaluated by JECFA.

5. Identification of the manufacturer that will be providing data (Please indicate contact person):

Novozymes A/S
Krogshøjvej 36
DK-2880 Bagsværd
Denmark

Attn.: Dorthe Helnov
dhel@novozymes.com
+45 4666 0731

6. Justification for use:

The branching enzyme preparation hydrolyzes dextrin chains from amylopectin (branched starch) and amylose (linear starch) and the dextrin chains are thereafter bonded to the main chains through α -1,6-bonds thereby increasing the number of branch points. As a result, starch is modified into dextrans with improved physical properties such as higher solubility, lower viscosity and reduced retro gradation, enabling starch processors to offer improved products for the food industry.

7. Food products and food categories within the GSFA in which the compound is used, including use level(s):

The branching enzyme is intended for use as a processing aid in the starch industry to obtain dextrans with improved properties which can be used beneficially in producing various foods e.g. soft drinks, energy drinks, low fat products and dietetic foods.

The commercial product, Novozym 28067 is standardized to 50.000 BEU/g and will be used in dose ranges of typically 0,1-1%, depending on the desired properties of the modified starch.

8. Has the compound been approved for use in 2 or more countries (please identify the countries)?

A US GRAS (Generally Recognized As Safe) determination under the intended conditions of use will be done, and a GRAS Notification is planned to be submitted to FDA in June 2008.

Submission of Novozym 28067 for approval in Denmark is scheduled for June 2008.

9. List of data (toxicology, metabolism, specifications) available:

To accommodate various registration requirements in different countries world-wide, a full food toxicity program according to the SCF Guidelines¹ for the safety studies has been performed.

The following studies have been conducted and do not give reason to any concerns:

- In vitro cytotoxicity study
- Test for mutagenic activity (Ames Test)
- Human lymphocyte cytogenetic assay (in vitro micronucleus test)
- 13 weeks oral toxicity study in rats

The conclusion of the safety studies can be summarized as follows:

The test preparation is considered non-cytotoxic and it showed no mutagenic activity neither in a bacterial reverse mutation assay nor did it induce micronuclei in human lymphocytes.

Thirteen weeks oral administration in rats caused no dose related findings and therefore the NOAEL is the highest dose level administered.

The safety studies described above were all performed on a liquid branching enzyme concentrate, obtained by mixing of 3 sub batches, each produced in accordance with standard production procedure, omitting stabilization and standardization.

The branching enzyme preparation complies with the purity criteria recommended for enzyme preparations as described in Food Chemicals Codex, 5th edition, 2003.

In addition to this, the product also conforms to the General Specifications and Considerations for Enzyme Preparations Used in Food Processing as prepared by the Joint FAO/WHO Expert Committee on Food Additives at its sixty-seventh meeting for publication in FAO JECFA Monographs 3 (2006).

Furthermore, *Bacillus subtilis* is proposed for QPS status (The EFSA Journal 587, 2007) and the production strain does not contain the potential to produce *Bacillus cereus* like toxins.

10. Date on which data could be submitted to JECFA:

June 2008.

Japan :

In response to Codex Circular Letter CL 2007/27-FA (August 2007), Japan would like to provide information to the Codex Committee on Food Additives (here after CCFA) about “Sucrose Oligoesters Type I and II” and “Aluminum compounds”.

1. Sucrose Oligoesters Type I and II

Last year we had requested the CCFA to include “Sucrose Oligoesters Type I and II” in the priority list of food additives proposed for JECFA evaluation, and it was included in the list at the 39th Session of the CCFA. However, unfortunately this food additive was not noted as “high priority for evaluation” and it was not included in the list of substances scheduled for evaluation at 69th JECFA meeting (June, 2008).

Hereunder we provide additional information about “Sucrose Oligoesters Type I and II” and attach the revised form as Appendix-1.

- (a) All data (Toxicological, Technological and Intake assessment data) required for JECFA evaluation are available at present. We will submit those data to JECFA during March 2008, before the 40th Session of the CCFA.
- (b) We requested the CCFA for addition of “Sucrose Oligoesters Type I and II” to the International Numbering System(INS) for food additives (CX/FA 08/40/12), according to Codex circular letter CL 2007/26-FA.

2. Aluminium compounds

Japan plans to conduct studies of bioavailability and developmental toxicity and a multigeneration study of aluminium-containing compounds, which are required by JECFA for assessment. Japan would like to provide the details including date on which data could be submitted to JECFA as soon as they are available.

Information on the Additive to be Evaluated by JECFA

1. Proposal for inclusion submitted by:

Japan, Ministry of Health, Labor and Welfare

2. Name of compound; trade name(s); chemical name(s):

Name of compound: Sucrose Oligoesters (SOE) Type I and Type II

Trade name: RYOTO® SUGAR ESTER, DK ESTER

Common name: Sucrose fatty acid esters, Sucrose esters of fatty acids, Sucrose esters

3. Names and addresses of basic producers:

(1) Mitsubishi Chemical Corporation

11-1, Shiba-koen 2 chome, Minato-ku, Tokyo 105-0011, Japan

(2) Dai-ichi Kogyo Seiyaku Co., Ltd.

55, Nishi-Shichijo, Higashikubo-cho, Shimogyo-ku, Kyoto 600-8873, Japan

4. Has the manufacturer made a commitment to provide data?

Mitsubishi Chemical Corporation and Dai-ichi Kogyo Seiyaku Co., Ltd. commit to provide data for JECFA.

5. Identification of the manufacturer that will be providing data (Please indicate contact person):

(1) Mitsubishi Chemical Corporation

11-1, Shiba-koen 2 chome, Minato-ku, Tokyo 105-0011, Japan

(2) Dai-ichi Kogyo Seiyaku Co., Ltd.

55, Nishi-Shichijo, Higashikubo-cho, Shimogyo-ku, Kyoto 600-8873, Japan

Contact person:

Mitsubishi Chemical Corporation

11-1, Shiba-koen 2 chome, Minato-ku, Tokyo 105-0011, Japan

(Ms.) Yukino Nagai

MFC0102@cc.m-kagaku.co.jp

Ph:81-3-5403-9152

6. Justification for use:

(1) Sucrose Oligoesters Type I and Type II has been approved as a food additive in some countries (refer to 8.) and used in various foods as a lipophilic emulsifier, stabilizer or tableting aid in various foods (refer to 7.).

(2) "Sucrose Oligoesters Type I and II" can be designed for optimal functionality in specific foods by varying the degree of esterification and the type of fatty acids bonded to sucrose molecule. Especially in reduced-fat foods, such as butter-substitute spreads and reduced-fat chocolate, the performance of "Sucrose Oligoesters Type I and II" is superior to that of other existing emulsifiers.

(3) Functions of Sucrose Oligoesters Type I and II in each food are summarized as follows,

- (a) Controls rate of crystallization of fats and oils and improves creaminess and water holding ability of shortening and margarine. Powerful emulsification ability provides high stability of water-in-oil emulsion in low-fat content butter substitute.
- (b) In chocolate, prevents fat-blooming and sugar-blooming, controls rate of crystallization and lowers viscosity.
- (c) Provides stable emulsion, good stand-up quality, adequate overrun and good texture for whipping cream, coffee whitener and ice cream.
- (d) Increases fluidity of powdered raw materials. It results in good efficiency of filling, easy separation from the machine and strong brightness of tablet form products.
- (e) Prevents caking of hygroscopic powdered seasonings and makes solid type of sauce mixes disperse easily.

7. Food Products and food categories within the GSFA in which the compound is used, including use level(s):

Food Category No.	Food Category	Average level of use (%)	Food Products
01.3.2	Beverage whiteners	0.2	Coffee whitener
01.4.2	Sterilized and UHT creams, whipping and whipped creams, and reduced fat creams (plain)	0.2	Creams for whipping, whipped cream
01.4.4	Cream analogues	0.2	Creams for whipping, whipped cream
01.7	Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	0.2	Ice cream
02.1	Fats and oils essentially free from water	0.3	Fats and oils used as raw materials in foods
02.1.2	Vegetable oils and fats	0.2	Shortening
02.2.1.2	Margarine and similar products	0.2	Margarine, Fat spread
02.2.1.3	Blends of butter and margarine	0.2	Margarine, Fat spread
02.2.2	Emulsions containing less than 80% fat	0.2	Margarine, Fat spread
02.3	Fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions	0.2	Creams for whipping, whipped cream, Coffee whitener
05.1.4	Cocoa and chocolate products	0.3	Chocolate

Food Category No.	Food Category	Average level of use (%)	Food Products
05.1.5	Imitation chocolate, chocolate substitute products	0.3	Chocolate
05.2.1	Hard candy	1.0	Tablet form candy
12.2.2	Seasonings and condiments	1.0	Powder seasoning
12.6.3	Mixes for sauces and gravies	0.2	Solid type of sauce mixes
13.6	Food supplements	1.0	Tablet form supplements

8. Has the compound been approved for use in 2 or more countries (please identify the countries)?

(1) In Japan, China, Korea and Taiwan, this compound has been approved as Sucrose fatty acid esters, which is the family substance.

(2) In the USA, this compound has been approved as Sucrose Oligoesters (CFR 172.869).

Note) Sucrose Oligoesters Type I and Type II is a lipophilic type of sucrose esters, which belongs to the family substance of sucrose fatty acid esters. To date, JECFA and EU have evaluated only the hydrophilic type of sucrose esters, named as "Sucrose Esters of Fatty Acids (INS No.473, E473).

9. List of data (toxicology, dietary exposure, specifications on chemical identity and purity, analytical methods) available:

(1) Toxicological data

(2) Technological data, including specifications and analytical methods

(3) Intake assessment data

10. Date on which data could be submitted to JECFA:

Data are available at present.

United States of America:

This responds to CL 2007/27-FA (August 2007) which requests comments on the Priority List of Food Additives Proposed for Evaluation by JECFA. The United States of America appreciates the opportunity to provide the following comments for consideration at the forthcoming 40th Session of the Codex Committee on Food Additives (CCFA).

Comment on Annex 2

The United States suggests revising the current language for Item 8 of Annex 2 of CL 2007/27-FA. Annex 2 contains a list of 10 information items that should be provided to CCFA and JECFA on the additive proposed for evaluation. Item 8 currently reads as follows:

8. Has the compound been approved for use in 2 or more countries (please identify the countries)?

We believe that this question should be revised in order to focus on establishing that the additive is currently in international trade rather than whether the additive has been formally approved for use in more than one country. Requiring that an additive must be "approved" in 2 separate countries does not adequately cover all instances in which the food additive is used in foods traded internationally. It may be the case that a substance considered a food additive within the context of the Codex definition of a food additive does not require formal approval by a National regulatory authority in order for foods containing the substance to be lawfully sold. Moreover, requiring that 2 countries must have "approved" the use of a food additive also limits Codex's ability to quickly establish safe conditions of use for new additives and thus inhibits product innovation and may unintentionally be an artificial barrier to trade. As such, we believe that Item 8 should be revised as follows:

8. Is the compound currently added to foods in international trade? (please specify)

List of suggested additives for addition to the Priority List

The United States respectfully proposes the addition of three additives as well as a listing of flavours to the Priority List of Food Additives Proposed for Evaluation by JECFA. The additives are:

1) Glycerol ester of gum rosin;

- 2) Sodium acid sulfate;
- 3) Glycerol ester of tall oil rosin; and
- 4) A list of 2478 flavours.

Required information on the additives (as in Annex 2 of CL 2007/27-FA) is included as an Appendix to this comment.

Appendix - Required Information based on Annex 2 of CL 2007/27-FA

Glycerol Ester of Gum Rosin

Information on the Additive to be Evaluated by JECFA

1. Proposal for inclusion submitted by:

United States of America

2. Name of compound; trade name(s); chemical name(s):

Glycerol Ester of Gum Rosin

3. Names and addresses of basic producers:

T & R Chemicals
P.O. Box 330
700 Celum Road
Clint, TX 79836

4. Has the manufacturer made a commitment to provide data?

Yes

5. Identification of the manufacturer that will be providing data (Please indicate contact person):

T & R Chemicals (Contact Dr. Claire Kruger of Spherix Incorporated at 240-565-5501 or ckruger@spherix.com)

6. Justification for use:

Beverage emulsions are a well-known class of foodstuff. They consist of a continuous aqueous phase in which a discontinuous oil phase is dispersed in the form of microscopic droplets. They are thus characterized as oil-in-water emulsions, typically having an opaque or cloudy appearance, which is associated by the consumer with that of natural fruit juice.

Beverage emulsions are thermodynamically unstable two-phase systems that have a tendency to separate into two immiscible liquids. One of the approaches attempting to control the beverage emulsion stability is to minimize the density contrast between the oil phase and the aqueous phase with the use of weighting agents. Those weighting agents, such as glycerol ester of rosins, are typically lipophilic components that serve to increase the density of the oil phase.

Glycerol ester of wood rosin, gum rosin, or tall oil rosin have been approved in the US to adjust the density of citrus oils used in the preparation of beverages [21CFR Sec. 172.735 (b)]

7. Food products and food categories within the GSFA in which the compound is used, including use level(s):

It is proposed to use glycerol ester of gum rosin in “carbonated water-based flavored drinks” [GSFA food category of 14.1.4.1] and in “non-carbonated water-based flavored drinks, including punches and ades” [GSFA food category of 14.1.4.2], whereby the amount of the additive does not exceed 100 parts per million of the finished beverage.

8. Has the compound been approved for use in 2 or more countries (please identify the countries)?

Yes. United States and Mexico.

9. List of data (toxicology, dietary exposure, specifications on chemical identity and purity, analytical methods) available:

All are available (a literature search will be performed to determine if any more current information is available)

10. Date on which data could be submitted to JECFA:

All data are available. We will provide when they are needed.

Sodium acid sulfate**Information on the Additive to be Evaluated by JECFA****1. Proposal for inclusion submitted by:**

United States of America

2. Name of compound; trade name(s); chemical name(s):

Trade name – pHase™, Chemical names - Sodium acid sulfate, Sodium bisulfate, Sodium hydrogen sulfate, Bisulfate of soda, Sulfuric acid monosodium salt

3. Names and addresses of basic producers:

Jones-Hamilton Co., 30354 Tracy Rd, Walbridge, Ohio, USA 43465

4. Has the manufacturer made a commitment to provide data?

Yes

5. Identification of the manufacturer that will be providing data (Please indicate contact person):

Jones-Hamilton Co. 30354 Tracy Rd, Walbridge, Ohio, USA 43465

Carl J Knueven, Corporate Manager - Product Development
Phone 419-662-5277, e-mail cknueven@jones-hamilton.com

6. Justification for use:

Sodium acid sulfate is a new food acid with the unique ability to lower pH without imparting a sour taste. This unique characteristic improves food safety by allowing a lower pH to be achieved without affecting the flavor. Additional benefits include sodium reduction, reduction in thermal processing, and cost reduction.

7. Food products and food categories within the GSFA in which the compound is used, including use level(s):

1.6.4 processed cheese 0.3%, 1.7 dairy based desserts 0.5%, 4.1 fruit 0.4%, 4.2 Vegetables 0.4%, 5.1.1 Cocoa syrups 0.3%, 8 meat 0.5%, 10.3 preserved eggs 0.3%, 11.1 sugar syrups 0.2%, 13.3 dietetic foods 0.2%, 14.0 beverages 0.1%, 16.0 composite foods 0.3%

8. Has the compound been approved for use in 2 or more countries (please identify the countries)?

USA (GRAS Notice No. 000003), European Union (E514ii), Mexico, Thailand

9. List of data (toxicology, dietary exposure, specifications on chemical identity and purity, analytical methods) available:

Toxicology, specifications of chemical identity and purity, analytical methods

10. Date on which data could be submitted to JECFA:

As soon as necessary

Glycerol Ester of Tall Oil Rosin**Information on the Additive to be Evaluated by JECFA****1. Proposal for inclusion submitted by:**

United States of America

2. Name of compound; trade name(s); chemical names(s)

Name of Compound: Glycerol Ester of Tall Oil Rosin

Trade Name: NovaRes™ 1190

3. Names and addresses of basic producers:

Georgia-Pacific Chemicals LLC
133 Peachtree Street NE
19th Floor
P.O. Box 105734
Atlanta, Georgia 30303

4. Has the manufacturer made a commitment to provide data?

Yes

5. Identification of the manufacturer that will be providing data (Please include contact person)

Michael Peck
Georgia-Pacific Chemicals LLC
2883 Miller Road
Decatur, Georgia 30035
e-mail: mcpeck@gapac.com
phone: (770) 593-6854

6. Justification for use:

Glycerol ester of tall oil rosin is used to adjust the density of citrus oils used as flavoring agents in the preparation of soft drink beverages. Since glycerol ester of tall oil rosin is miscible in citrus flavoring oils, the higher specific gravity of the glycerol ester of tall oil rosin increases the specific gravity of the lighter flavoring oils to more closely approximate that of the aqueous phase of the beverage. Decreasing the differences in the specific gravity of the two phases (oil phase and water phase of the beverage) reduces the tendency of the flavoring oils to coalesce and rise to the surface which results in a process called "creaming" or "ringing" in the final beverage and which leads to oxidation of the flavoring oils and an unpalatable product. Glycerol ester of tall oil rosin therefore increases the stability of the flavoring oil and the beverage.

7. Food products and food categories within the GSFA in which the compound is used, including use level(s):

Category 14.1.4 water based soft drinks at a level of 100 mg/kg

8. Has the compound been approved for use in 2 or more countries (please identify the countries)?

United States and Canada

9. List of data (toxicology, dietary exposure, specifications on chemical identity and purity, analytical methods) available:

All data are available. A list of possible references is included as an attachment.

10. Date on which data could be submitted to JECFA:

Available now.

List of 247 flavours**Information on the Additive to be Evaluated by JECFA****1. Proposal for inclusion submitted by:**

United States of America

2. Name of compound; trade name(s); chemical name(s):

List of 247 flavors (see Appendix A for list of chemical names)

3. Names and addresses of basic producers:

Flavor producers are members of IOFI and FEMA. All contacts can be made through FEMA.

4. Has the manufacturer made a commitment to provide data?

Yes

5. Identification of the manufacturer that will be providing data (Please indicate contact person):

The Flavor and Extract Manufacturers Association, Washington, DC 20006, Timothy Adams, Ph.D. (Scientific Director), 202-331-2325, tadams@therobertsgroup.net

International Organization of the Flavour Industry (IOFI) Brussels, Belgium Thierry Cachet, Ph.D. (Science Director)

6. Justification for use:

Flavor ingredient(s) in foods for human consumption.

7. Food products and food categories within the GSFA in which the compound is used, including use level(s):

Natural occurrence, annual poundage data, and food categories and use levels to be submitted as requested.

8. Has the compound been approved for use in 2 or more countries (please identify the countries)?

Yes (e.g., USA, and Japan or, Australia, or New Zealand)

9. List of data (toxicology, dietary exposure, specifications on chemical identity and purity, analytical methods) available:

Relevant toxicity data, dietary exposure and specifications to be submitted as requested.

10. Date on which data could be submitted to JECFA:

December 31, 2008

Appendix A – List of 247 flavours

Priority	Chemical Group	Evaluation Number	Name	FEMA Number	CAS Number
1	32	1	Methyl dihydrojasmonate	3408	24851-98-7
1	32	2	<i>cis</i> -4-(2,2,3-Trimethylcyclopentyl)butanoic acid	4529	CAS Pending
1	32	3	<i>cis</i> - and <i>trans</i> -2-Heptylcyclopropanecarboxylic acid	4130	697290-77-0 (trans) 697290-76-9 (cis)
1	32	4	(2,4) and (3,5) and 3,6-Dimethyl-3-cyclohexenylcarbaldehyde	4505	27939-60-2
1	32	5	Perillaldehyde propyleneglycol acetal	4530	121199-28-8
1	32	6	(+/-) <i>cis</i> - and <i>trans</i> -1,2-Dihydroperillaldehyde	4312	22451-50-9 22451-49-6
1	32	7	(+/-)- <i>cis</i> - and <i>trans</i> -2-Methyl-2-(4-methyl-3-pentenyl)cyclopropanecarbaldehyde	4393	97231-35-1
1	32	8	<i>d</i> -Limonen-10-ol	4504	38142-45-9
1	32	9	<i>p</i> -Menthan-7-ol	4507	5502-75-0

Priority	Chemical Group	Evaluation Number	Name	FEMA Number	CAS Number
1	32	10	<i>p</i> -Menth-1-en-9-ol	4508	18479-68-0
1	32	11	1,3- <i>p</i> -Menthadien-7-al	4506	1197-15-5
2	20	1	Methyl octyl sulfide	4573	3698-95-1
2	20	2	Methyl 1-propenyl sulfide	4574	10152-77-9
2	20	3	Di-(1-propenyl)-sulfide (mixture of isomers)	4386	65819-74-1 37981-37-6 37981-36-5
2	20	4	Ethyl 2-hydroxyethyl sulfide	4562	110-77-0
2	20	5	2-(Methylthio)ethyl acetate	4560	5862-47-5
2	20	6	3-(Methylthio)propyl mercaptoacetate	4561	852997-30-9
2	20	7	Ethyl 3-(methylthio)- (2 <i>Z</i>) -propenoate	4563	136115-65-6
2	20	8	Ethyl 3-(methylthio)- (2 <i>E</i>)-propenoate	4564	136115-65-6
2	20	9	Ethyl 3-(methylthio)-2-propenoate	4565	136115-65-6
2	20	10	4-Methyl-2-(methylthiomethyl)-2-pentenal	4568	40878-73-7
2	20	11	4-Methyl-2-(methylthiomethyl)-2-hexenal	4566	CAS Pending
2	20	12	5-Methyl-2-(methylthiomethyl)-2-hexenal	4567	CAS Pending
2	20	13	1-(3-(Methylthio)-butyryl)-2,6,6-trimethylcyclohexene	4569	68697-67-6
2	20	14	Butyl <i>beta</i> -(methylthio)acrylate	4571	CAS Pending
2	20	15	Ethyl 3-(ethylthio)butyrate	4572	90201-28-8
2	20	16	2-Oxothiolane	4570	1003-10-7
2	20	17	Dodecanethiol	4581	112-55-0
2	20	18	2-Hydroxyethanethiol	4582	60-24-2
2	20	19	4-Mercapto-4-methyl-2-hexanone	4583	CAS Pending
2	20	20	3-Mercapto-3-methylbutyl isovalerate	4584	612071-27-9
2	20	21	(+/-) Ethyl 3-mercapto-2-methylbutanoate	4392	CAS Pending
2	20	22	3-Mercaptohexanal	4585	51755-72-7
2	20	23	Diisoamyl disulfide	4575	2051-04-9
2	20	24	Bis(2-methylphenyl) disulfide	4576	4032-80-8
2	20	25	Mixture of butyl propyl disulfide and propyl and butyl disulfide	4577	72437-64-0
2	20	26	di- <i>sec</i> -Butyl disulfide	4578	5943-30-6
2	20	27	Diisoamyl trisulfide	4580	CAS Pending
2	20	28	Methyl 2-methylphenyl disulfide	4579	35379-09-0
2	20	29	3-Mercaptopropionic acid	4587	107-96-0
2	20	30	Methyl isobutanethioate	4586	42075-42-3
2	20	31	2-Ethylhexyl 3-mercaptopropionate	4588	50448-95-8
2	20	32	Butanal dibenzyl thioacetal	4589	CAS Pending
2	20	33	Methional diethyl acetal	4590	CAS Pending
2	20	34	3-(Methylthio)propyl hexanoate	4436	906079-63-8
2	20	35	(+/-) <i>cis</i> - and <i>trans</i> -2-Pentyl-4-propyl-1,3-oxathiane	4499	59323-81-8
2	20	36	2-Pentenyl-4-propyl-1,3-oxathiane (mixture of isomers)	4526	876748-60-6
3	21	1	Hydroxyacetone	4462	116-09-6
3	21	2	Methyl 3-hydroxybutyrate	4450	1487-49-6
3	21	3	(+/-) Ethyl 3-hydroxy-2-methylbutyrate	4391	27372-03-8
3	21	4	Methyl 3-acetoxy-2-methylbutyrate	4451	139564-42-4
3	21	5	1-Hydroxy-4-methyl-2-pentanone	4463	68113-55-3
3	21	6	Ethyl 2-acetylhexanoate	4452	1540-29-0
3	21	7	3-Isopropenyl-6-oxoheptanoic acid	4461	4436-82-2
3	21	8	Ethyl 3-hydroxyoctanoate	4453	7367-90-0
3	21	9	Methyl 3-acetoxyoctanoate	4454	35234-21-0
3	21	10	5-Oxoocanoic acid	4455	3637-14-7
3	21	11	Ethyl 2-acetyloctanoate	4459	29214-60-6
3	21	12	Ethyl 5-acetoxyoctanoate	4443	35234-25-4
3	21	13	5-Oxodecanoic acid	4456	624-01-1
3	21	14	Ethyl 5-oxodecanoate	4457	93919-00-7

Priority	Chemical Group	Evaluation Number	Name	FEMA Number	CAS Number
3	21	15	Ethyl 5-hydroxydecanoate	4444	6071-25-6
3	21	16	5-Oxododecanoic acid	4458	3637-16-9
3	21	17	Dimethyl adipate	4472	627-93-0
3	21	18	Dipropyl adipate	4473	106-19-4
3	21	19	Diisopropyl adipate	4474	6938-94-9
3	21	20	Diisobutyl adipate	4475	141-04-8
3	21	21	Diocetyl adipate	4476	123-79-5
3	21	22	Ethyl acetoacetate ethyleneglycol ketal	4477	6413-10-1
3	21	23	Methyl levulinate	4478	624-45-3
3	21	24	Propyl levulinate	4480	645-67-0
3	21	25	Isoamyl levulinate	4481	71172-75-3
3	21	26	Ethyl levulinate propyleneglycol ketal	4479	57197-36-1
3	21	27	<i>cis</i> -3-Hexenyl acetoacetate	4489	84434-20-8
3	21	28	Hydroxycitronellal propyleneglycol acetal	4485	93804-64-9
3	21/30	29	Propyleneglycol diacetate	4464	623-84-7
3	21	30	6-(5(6)-Decenoyloxy)decanoic acid	4442	85392-05-8 85392-06-9
3	21/30	31	Propyleneglycol dipropionate	4465	10108-80-2
3	21/30	32	Propyleneglycol monobutyrate	4488	29592-95-8
3	21/30	33	Propyleneglycol dibutyrate	4466	50980-84-2
3	21/30	34	Propyleneglycol mono-2-methylbutyrate	4467	923593-56-0 923593-57-1
3	21/30	35	Propyleneglycol di-2-methylbutyrate	4468	15514-30-0
3	21/30	36	Propyleneglycol monohexanoate	4469	39556-41-7 170678-49-6
3	21/30	37	Propyleneglycol dihexanoate	4470	50343-36-7
3	21/30	38	Propyleneglycol dioctanoate	4471	7384-98-7
3	21/38	39	2-Oxo-3-ethyl-4-butanolide	4460	923291-29-6
4	06	1	4-Hydroxy-2-butenic acid <i>gamma</i> -lactone	4138	497-23-4
4	06	2	5-Pentyl-3H-furan-2-one	4323	51352-68-2
4	06	3	5-Hydroxy-4-methylhexanoic acid <i>delta</i> -lactone	4141	10413-18-0
4	06	4	2-Nonenoic acid <i>gamma</i> -lactone	4188	21963-26-8
4	06	5	4-Hydroxy-2,3-dimethyl-2,4-nonadienoic acid <i>gamma</i> -lactone	4050	774-64-1
4	06	6	Isoambrettolide	4145	28645-51-4
4	06	7	7-Decen-4-olide	4439	67114-38-9
4	06	8	9-Decen-5-olide	4440	74585-00-5
4	06	9	8-Decen-5-olide	4441	32764-98-0
4	06	10	Orin Lactone	4449	134359-15-2
4	06	11	9-Dodecen-5-olide	4445	15456-68-5
4	06	12	9-Tetradecen-5-olide	4448	15456-70-9
4	06	13	<i>gamma</i> -Octadecalactone	4446	502-26-1
4	06	14	<i>delta</i> -Octadecalactone	4447	1227-51-6
5	58	1	<i>N</i> -Ethyl-2,2-diisopropylbutanamide	4557	51115-70-9
5	58	2	Cyclopropanecarboxylic acid (2-isopropyl-5-methyl-cyclohexyl)-amide	4558	958660-02-1 958660-04-3
5	58	3	(+/-) <i>N</i> -Lactoyl tyramine	4550	781674-18-8
5	58	4	<i>N</i> -(2-(Pyridin-2-yl)ethyl)-3-p-menthane-carboxamide	4549	847565-09-7
5	58	5	<i>N</i> - <i>p</i> -Benzeneacetonitrile-menthane-carboxamide	4496	852379-28-3
6	08	1	4-Methylpentyl isovalerate	4347	850309-45-4
6	08	2	5-Methylhexyl acetate	4346	180348-60-1
6	08	3	Ethyl 4-methylpentanoate	4343	25415-67-2
6	08	4	Ethyl 2-ethylbutyrate	4344	2983-38-2
6	08	5	Ethyl 2-ethylhexanoate	4345	2983-37-1
6	08	6	3,7-Dimethyloctanal	4348	5988-91-0

Priority	Chemical Group	Evaluation Number	Name	FEMA Number	CAS Number
7	15	1	<i>alpha, alpha</i> -Dimethylbenzyl isobutyrate	2388	7774-60-9
7	15	2	Dimethyl benzyl carbinyol crotonate	4403	93762-34-6
7	15	3	Dimethylbenzyl carbinyol hexanoate	4404	CAS Pending
7	15	4	Caryophyllene alcohol	4410	56747-96-7
7	15	5	Cubebol	4497	23445-02-5
7	15	6	(-)-Sclareol	4502	515-03-7
7	15	7	(+)-Cedrol	4503	77-53-2
8	18	1	Acetoin propyleneglycol acetal	4532	94089-23-3
8	18	2	3-Hydroxy-5-methyl-2-hexanone or 2-Hydroxy-5-methyl-2-hexanone	3989	163038-04-8
8	18	3	3-Hydroxy-2-octanone	4139	37160-77-3
8	18	4	Octan-2,3-dione	4060	585-25-1
8	18	5	4,5-Octanedione	4533	5455-24-3
8	18	6	3-Methyl-2,4-nonedione	4057	113486-29-6
8	18	7	(+/-) 2-Hydroxypiperitone	4143	490-03-9
9	27	1	4-Hydroxyacetophenone	4330	99-93-4
9	27	2	3-Hydroxy-4-phenylbutan-2-one	4052	5355-63-5
9	27	3	2-Methoxyacetophenone	4163	579-74-8
9	27	4	4-(3,4-Methylenedioxyphenyl)-2-butanone	2701	55418-52-5
9	27	5	2-Aminoacetophenone	3906	551-93-9
9	27	6	2-Methylacetophenone	4316	577-16-2
9	27	7	2-Hydroxy-5-methylacetophenone	4594	1450-72-2
9	27	8	Dihydrogalangal acetate	4555	129319-15-9
9	27	9	2,3,3-Trimethylindan-1-one	4556	54440-17-4
10	36	1	2-(<i>trans</i> -2-Pentenyl)cyclopentanone	4284	51608-18-5
10	36	2	Cyclotene propionate	4511	87-55-8
10	36	3	2-Cyclopentylcyclopentanone	4514	4884-24-6
10	36	4	Cyclohexanone diethyl acetal	4516	1670-47-9
10	36	5	2-Cyclohexenone	4517	930-68-7
10	36	6	3,3,5-Trimethylcyclohexyl acetate	4512	67859-96-5
10	36	7	2,6,6-Trimethyl-2-hydroxycyclohexanone	4531	7500-42-7
10	36	8	8,9-Dehydrotheaspironone	4518	85248-56-2
11	50	1	5-Methyl-3(2 <i>H</i>)-furanone	4176	3511-32-8
11	50	2	Ethyl 2,5-dimethyl-3-oxo-4(2 <i>H</i>)-furyl carbonate	4546	39156-54-2
11	50	3	2,5-Dimethyl-3(2 <i>H</i>)-furanone	4101	14400-67-0
11	50	4	Nerolidol oxide	4536	1424-83-5
11	50	5	2,5-Dimethyl-4-ethoxy-3(2 <i>H</i>)-furanone	4104	65330-49-6
11	50	6	2-Tetrahydrofurfuryl 2-mercaptopropionate	4535	99253-91-5
11	50	7	4-Acetyl-2,5-dimethyl-3(2 <i>H</i>)-furanone	4070	36871-78-0
11	50	8	2-Methyl-3-furyl 2-methyl-3-tetrahydrofuryl disulfide	4545	252736-40-6
12	13	1	(+/-) Octan-3-yl formate	4009	84434-65-1
12	13	2	(<i>R</i>)-(-)-1-Octen-3-ol	4492	3687-48-7
12	13	3	2-Decanone	4271	693-54-9
12	13	4	6-Methyl-5-hepten-2-one propyleneglycol acetal	4400	68258-95-7
12	13	5	2-Pentyl 2-methylpentanoate	4401	CAS Pending
12	13	6	3-Octyl butyrate	4402	20286-45-7
12	13	7	2-Nonanone propyleneglycol acetal	4399	CAS Pending
13	14	1	<i>cis</i> -3-Nonen-1-ol	4412	10340-23-5
13	14	2	(<i>Z,Z</i>)-3,6-Nonadienyl acetate	4551	83334-93-4
13	14	3	<i>trans</i> -2-Nonenyl acetate	4552	30418-89-4
13	14	4	<i>trans</i> -3-Hexenyl acetate	4413	3681-82-1
13	14	5	<i>cis</i> -3-Hexenoic acid	4493	1775-43-5
13	14	6	(<i>Z</i>)-3-Nonenyl acetate	4553	13049-88-2
13	14	7	(<i>Z</i>)-6-Nonenyl acetate	4554	76238-22-7

Priority	Chemical Group	Evaluation Number	Name	FEMA Number	CAS Number
14	24	1	4-Propenylphenol	4062	539-12-8
14	24	2	2-Methoxy-6-(2-propenyl)phenol	4490	579-60-2
14	24	3	2,4,6-Trimethylphenol	4329	527-60-6
14	24	4	Sodium 3-methoxy-4-hydroxycinnamate	3812	24276-84-4
14	24	5	3-(4-Hydroxy-phenyl)-1-(2,4,6-trihydroxy-phenyl)-propan-1-one	4390	60-82-2
14	24	6	Magnolol	4559	528-43-8
15	10	1	Furfural propyleneglycol acetal	4537	4359-54-0
15	10	2	Furfuryl formate	4542	13493-97-5
15	10	3	Furfuryl decanoate	4539	39252-05-6
15	10	4	5-Methylfurfuryl alcohol	4544	3857-25-8
16	38	1	2-(2-Hydroxy-4-methyl-3-cyclohexenyl)propionic acid <i>gamma</i> -lactone	4140	57743-63-2
16	38	2	2-(2-Hydroxyphenyl)cyclopropanecarboxylic acid <i>delta</i> -lactone	4270	5617-64-1
16	38	3	<i>beta</i> -Angelicalactone	4438	591-11-7
16	38	4	Phthalide	4195	87-41-2
17	41	1	Methyl hexyl ether	4291	4747-07-3
17	41	2	Myrcenyl methyl ether	4592	24202-00-4
17	41	3	Dill ether	4315	70786-44-6
17	41	4	Ethyl linalyl ether	4591	72845-33-1
17	41	5	Linalool oxide pyranoid	4593	14049-11-7
18	46	1	1-Octene	4293	111-66-0
18	46	2	2,4-Nonadiene	4292	56700-78-8
18	46	3	<i>alpha</i> -Ionene	4264	475-03-6
18	46	4	2-Methyl-1,3-cyclohexadiene	FDA GRAS	1489-57-2
18	46	5	Mixture of methyl cyclohexadiene and methylene cyclohexene	4311	30640-46-1 1888-90-0
19	59	1	Ethyl 3-(2-furyl)acrylate	4541	53282-12-5
19	59	2	2-Methyl-3-furyl methylthiomethyl disulfide	4320	333384-99-9
19	59	3	di-2-Furylmethane	4540	1197-40-6
19	59	4	Methyl 3-furfuryl-2-mercaptopropionate	4538	94278-26-9
19	59	5	3-[(2-Methyl-3-furyl)thio]butanal	4501	915971-43-6
19	59	6	2-Methylbenzofuran	4543	4265-25-2
20	48	1	<i>dl</i> -Camphor	4513	21368-68-3
20	48	2	<i>l</i> -Fenchone	4519	7787-20-4
20	48	3	2,2,6,7-Tetramethylbicyclo[4.3.0]nona-4,9(1)-dien-8-ol	4521	97866-86-9
20	48	4	2,2,6,7-Tetramethylbicyclo[4.3.0]nona-4,9(1)-dien-8-one	4522	97844-16-1
21	28	1	Benzyl hexanoate	4026	6938-45-0
21	28	2	<i>o</i> -Anisaldehyde	4077	135-02-4
21	28	3	Prenyl benzoate	4203	5205-11-8
21	28	4	(+/-) 2-Phenyl-4-methyl-2-hexenal	4194	26643-92-5
22	29	1	3-Hydroxybenzoic acid	4431	99-06-9
22	29	2	3,4-Dihydroxybenzoic acid	4430	99-50-3
22	29	3	2-Hydroxy-4-methoxybenzaldehyde	4435	673-22-3
23	22	1	Cinnamaldehyde propyleneglycol acetal	4596	4353-01-9
23	22	2	2-Phenylpropanal propyleneglycol acetal	4595	67634-23-5
23	22	3	Ethyl <i>alpha</i> -acetylcinnamate	4597	CAS Pending
23	22	4	3-(3,4-Methylenedioxyphenyl)-2-methylpropanal	4599	1205-17-0
23	22	5	Ethyl 2-hydroxy-3-phenylpropionate	4598	CAS Pending
24	04	1	Paraldehyde	4010	123-63-7
24	04	2	(+/-) Acetaldehyde ethyl isopropyl acetal	4432	25334-93-4
24	04	3	Tridecanal	4335	10486-19-8

Priority	Chemical Group	Evaluation Number	Name	FEMA Number	CAS Number
24	04	4	Acetaldehyde ethyl isobutyl acetal	4528	6986-51-2
24	04	5	Tridecanoic acid	4336	638-53-9
24	04	6	Acetaldehyde di-isobutylacetal	4527	5669-09-0
24	04	7	Pentadecanoic acid	4334	1002-84-2
25	40	1	Citral glyceryl acetal	4486	5694-82-6
26	26	1	Isopropenylpyrazine	3296	38713-41-6
26	26	2	5-Ethyl-2,3-dimethylpyrazine	4434	15707-34-3
26	26	3	3,5 and 3,6-Dimethyl-2-isobutylpyrazine	4100	38888-81-2 70303-42-3
27	05	1	3-Methylhexanal	4261	19269-28-4
27	05	2	6-Methylheptanal	4498	63885-09-6
27	05	3	(+/-) 6-Methyloctanal	4433	30689-75-9
28	11/36	1	Menthyl formate	4509	2230-90-2
28	11/36	2	Menthyl propionate	4510	86014-82-6
28	11/36	3	<i>l</i> -Menthyl butyrate	4524	68366-64-3
29	16/36	1	Pinocarvyl isobutyrate	4525	929116-08-5
29	16/36	2	Carvyl palmitate	4515	929222-96-8
29	16	3	6-Hydroxycarvone	4523	51200-86-3
30	17	1	<i>trans-alpha</i> -Damascone	4088	24720-09-0
30	17	2	<i>beta</i> -Isomethylionone	4151	79-89-0
30	17	3	Pseudoionone	4299	141-10-6
31	30	1	Propyl pyruvate	4484	20279-43-0
31	30	2	Dodecyl lactate	4482	6283-92-7
31	30	3	Hexadecyl lactate	4483	35274-05-6
32	45	1	1-Ethyl-2-pyrrolicarboxaldehyde	4317	2167-14-8
32	45	2	1-Methyl-1 <i>H</i> -pyrrole-2-carboxaldehyde	4332	1192-58-1
32	45	3	2,4-Dimethylpyridine	4389	108-47-4
33	03	1	Allyl valerate	4074	6321-45-5
33	03	2	Allyl crotonate	4072	20474-93-5
34	33	1	Phenethyl decanoate	4314	61810-55-7
34	33	2	Phenethyl benzoate	2860	94-47-3
35	34	1	2-Pentylthiophene	4387	4861-58-9
35	34	2	5-Ethyl-2-methylthiazole	4388	19961-52-5
36	49	1	<i>l</i> -Ornithine monochlorohydrate/Ornithine	4190	3184-13-2
37	52	1	Ethyl maltol isobutyrate	4534	852997-28-5

EFEMA:

Having considered the criteria for inclusion of food additives in the priority list of substances (Annex I of CL 2007/27-FA), EFEMA would like to request that Diacetyltartaric and Fatty Acid Esters of Glycerol (DATEM, INS: 472e) be listed on the priority list of Food Additives Proposed for Evaluation by JECFA, for a **revision of the current JECFA specification**, specifically as concerns the method for fatty acids. EFEMA believes that there are errors in the monograph for DATEM and the method for free fatty acids, which need to be addressed. The issue is outlined in detail below.

The current JECFA monograph for Datem¹ includes a limit for free fatty acids of not more than 3% as oleic acid and includes a reference to the method in Vol 4 of the Combined Compendium of Food Additive Specifications.² However, the method for free fatty acids is not appropriate for the purpose of analyzing the amount of free fatty acids in Datem, as the method includes other acids present in the product. Therefore the results obtained by using this method are not correct.

¹ JECFA monograph on DATEM (2006)

<http://www.fao.org/ag/agn/jecfa-additives/specs/Monograph1/Additive-149.pdf> – Annex I

² Combined Compendium of Food Additive Specifications, JECFA, Vol. 4, p 167 – 168
<ftp://ftp.fao.org/docrep/fao/009/a0691e/a0691e00b.pdf> – Annex II

EFEMA would thus like to propose that JECFA considers the following modification to the JECFA monograph for Datem (472e) under the heading ‘characteristics’ (page 2):

“Free Fatty Acids (~~Vol.4~~): Not more than 3%”

The method for free fatty acid content is also referred to in the Combined Compendium of Food Additive Specifications. It refers to the formula “ VN/W ”, where V is the volume of NaOH solution used to titrate the free fatty acids, N is the normality of the NaOH solution, W is the sample weight and ‘e’ is the equivalence factor given in the monograph. However, there is no ‘e’ mentioned in the formula.

EFEMA would therefore like to propose that JECFA considers the following modification to the paragraph on the Free Fatty Acid method on page 168 of the Combined Compendium of Food Additive Specifications (Vol 4):

“Calculate the percentage of free fatty acids (FFA) in the sample by the formula VNe/W , in which V is the volume and N is the normality, respectively, of the sodium hydroxide used, W is the weight of the sample, in g, and e is the equivalence factor given in the monograph.”

As requested in CL 2007/27-FA, please find enclosed (*Annex III*) the completed form on which information for a revised JECFA evaluation on DATEM is provided.

DATEM

Information on the Additive to be Evaluated by JECFA

1. Proposal for inclusion submitted by:

EFEMA (European Food Emulsifier Manufacturers Association)
Avenue des Gaulois, 9
B-1040 Brussels
Belgium

2. Name of compound; trade name(s); chemical name(s):

Datem (Diacetyltartaric and fatty acid esters of glycerol), INS 472e

3. Names and addresses of basic producers:

See list of EFEMA company members (www.emulsifiers.org)

4. Has the manufacturer made a commitment to provide data?

Yes. The information concerns a revision of the existing JECFA monograph for DATEM.

5. Identification of the manufacturer that will be providing data (Please indicate contact person):

Danisco A/S,
Edwin Rahrs Vej 38,
8220 Brabrand, Denmark.

Contact person: Ms. Lisa Jensen
Email: lisa.jensen@danisco.com
Tel: +45 29484423

6. Justification for use:

JECFA has already assessed DATEM, assigned an ADI of 50 mg/kg/body weight and considers Diacetyltartaric and Fatty Acid Esters of Glycerol safe for their intended uses in food and drinks.

7. Food products and food categories within the GSFA in which the compound is used, including use level(s):

GSFA Provisions for Diacetyltartaric and Fatty Acid Esters of Glycerol (DATEM), as listed on the GSFA Online (2007)

Number	Food Category	Max Level
14.2.7	Aromatized alcoholic beverages (e.g., beer, wine and spirituous cooler-type beverages, low alcoholic refreshers)	10,000 mg/kg
06.6	Batters (e.g., for breeding or batters for fish or poultry)	5,000 mg/kg
01.3.2	Beverage whiteners	5,000 mg/kg

Number	Food Category	Max Level
02.2.1.3	Blends of butter and margarine	10,000 mg/kg
07.1	Bread and ordinary bakery wares	6,000 mg/kg
04.1.2.7	Candied fruit	1,000 mg/kg
06.5	Cereal and starch based desserts (e.g., rice pudding, tapioca pudding)	5,000 mg/kg
01.6.5	Cheese analogues	10,000 mg/kg
05.3	Chewing gum	50,000 mg/kg
14.2.2	Cider and perry	5,000 mg/kg
01.4.3	Clotted cream (plain)	5,000 mg/kg
14.1.5	Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa	500 mg/kg
05.2	Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3 and 05.4	10,000 mg/kg
04.2.2.8	Cooked or fried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds	2,500 mg/kg
01.4.4	Cream analogues	6,000 mg/kg
01.7	Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	10,000 mg/kg
01.1.2	Dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks)	5,000 mg/kg
05.4	Decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	10,000 mg/kg
13.5	Dietetic foods (e.g., supplementary foods for dietary use) excluding products of food categories 13.1 - 13.4 and 13.6	5,000 mg/kg
13.3	Dietetic foods intended for special medical purposes (excluding products of food category 13.1)	5,000 mg/kg
13.4	Dietetic formulae for slimming purposes and weight reduction	5,000 mg/kg
14.2.6	Distilled spirituous beverages containing more than 15% alcohol	5,000 mg/kg
10.2.3	Dried and/or heat coagulated egg products	5,000 mg/kg
04.1.2.2	Dried fruit	10,000 mg/kg
04.2.2.2	Dried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	10,000 mg/kg
03.0	Edible ices, including sherbet and sorbet	1,000 mg/kg
10.4	Egg-based desserts (e.g., custard)	5,000 mg/kg
02.2.2	Emulsions containing less than 80% fat	10,000 mg/kg
02.3	Fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions	10,000 mg/kg
02.4	Fat-based desserts excluding dairy-based dessert products of food category 01.7	5,000 mg/kg
04.1.2.10	Fermented fruit products	2,500 mg/kg
01.2.1.2	Fermented milks (plain), heat-treated after fermentation	5,000 mg/kg
04.2.2.7	Fermented vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweed products, excluding fermented soybean products of food category 12.10	2,500 mg/kg
07.2	Fine bakery wares (sweet, salty, savoury) and mixes	20,000 mg/kg
13.6	Food supplements	5,000 mg/kg
04.1.2.3	Fruit in vinegar, oil, or brine	1,000 mg/kg
04.1.2.8	Fruit preparations, including pulp, purees, fruit toppings and coconut milk	2,500 mg/kg
04.1.2.9	Fruit-based desserts, including fruit-flavoured water-based desserts	2,500 mg/kg
04.1.2.6	Fruit-based spreads (e.g., chutney) excluding products of food category 04.1.2.5	5,000 mg/kg
02.1.3	Lard, tallow, fish oil, and other animal fats	10,000 mg/kg
02.2.1.2	Margarine and similar products	10,000 mg/kg
01.5.2	Milk and cream powder analogues	10,000 mg/kg
01.5.1	Milk powder and cream powder (plain)	10,000 mg/kg
12.4	Mustards	10,000 mg/kg
12.9.5	Other protein products	10,000 mg/kg
06.4.3	Pre-cooked pastas and noodles and like products	10,000 mg/kg
01.6.4	Processed cheese	10,000 mg/kg
15.2	Processed nuts, including coated nuts and nut mixtures (with e.g., dried fruit)	10,000 mg/kg
01.2.2	Renneted milk (plain)	5,000 mg/kg
01.6.2.1	Ripened cheese, includes rind	10,000 mg/kg
12.7	Salads (e.g., macaroni salad, potato salad) and sandwich spreads excluding cocoa- and nut-based spreads of food categories 04.2.2.5 and 05.1.3	5,000 mg/kg
12.1.2	Salt Substitutes	16,000 mg/kg
12.6	Sauces and like products	10,000 mg/kg
15.1	Snacks - potato, cereal, flour or starch based (from roots and tubers, pulses and legumes)	20,000 mg/kg
12.5	Soups and broths	5,000 mg/kg
01.4.2	Sterilized and UHT creams, whipping and whipped creams, and reduced fat creams (plain)	6,000 mg/kg
04.2.2.6	Vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed pulps and preparations (e.g., vegetable desserts and sauces, candied vegetables) other than food category 04.2.2.5	2,500 mg/kg
02.1.2	Vegetable oils and fats	10,000 mg/kg
04.2.2.3	Vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) and seaweeds in vinegar, oil, brine, or soy sauce	2,500 mg/kg
14.1.4	Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks	5,000 mg/kg
14.2.4	Wines (other than grape)	5,000 mg/kg

8. Has the compound been approved for use in 2 or more countries (please identify the countries)?

Yes

9. List of data (toxicology, dietary exposure, specifications on chemical identity and purity, analytical methods) available:

As submitted and included in JEFCA evaluations and reports

10. Date on which data could be submitted to JECFA:

Detailed information is already outlined in the cover letter to this Annex.

ICGMA:

In response to CL 2007/27-FA, August 2007, Request for Comments on the Priority List of Food Additives Proposed for Evaluation by JECFA, the International Council of Grocery Manufacturers Association (ICGMA) submits a request to consider for inclusion as a new compound of the priority list, the following additive:

OSA modified gum acacia: CAS # 455855-22-0

Manufactured by TIC Gums, Inc.

This additive is widely used by food manufacturers in the United States as an emulsifier in a broad range of products and in other countries in flavor systems. More information is included on the required form attached.

OSA modified gum acacia**Information on the Additive to be Evaluated by JECFA****1. Proposal for inclusion submitted by:**

International Council of Grocery Manufacturers Associations (ICGMA)

2. Name of compound; trade name(s); chemical name(s):

OSA modified gum acacia; Ticamulsion; Gum arabic, hydrogen octenylbutanedioate; Gum arabic, hydrogen octenylsuccinate CAS#: 455885-22-0

3. Names and addresses of basic producers:

TIC Gums, Inc.
4609 Richlynn Drive
Belcamp, MD 21017

4. Has the manufacturer made a commitment to provide data?

Yes

5. Identification of the manufacturer that will be providing data (Please indicate contact person):

TIC Gums, Inc.
Janet Jacoby, Chief Compliance Officer
4609 Richlynn Drive
Belcamp, MD 21017

6. Justification for use:

Emulsifier and Microencapsulator

7. Food products and food categories within the GSFA in which the compound is used, including use level(s):

Used as an emulsifier in the following foods up to 10,000 mg/kg: 05.4 Icings, 12.6.1 Sauces, Salad Dressing

Used as an emulsifier in 14.1.4, Water-based flavoured drinks, up to 1000 mg/kg.

Used as an emulsifier up to 500 mg/kg in flavor systems, which are used in a wide range of foods.

8. Has the compound been approved for use in 2 or more countries (please identify the countries)?

It is legal for use as an emulsifier in food products in the USA. It may be legally used in several countries in flavor systems. It is also on the FEMA GRAS list.

9. List of data (toxicology, dietary exposure, specifications on chemical identity and purity, analytical methods) available:

Subchronic Toxicity Study (28 and 90 day studies in rats)

Acute oral toxicity study

Mutagenicity • Bacterial mutation assay of the additive (Ames method)

Dietary exposure

Specifications

Analytical methods

10. Date on which data could be submitted to JECFA:

Immediately
