

commission du codex alimentarius



ORGANISATION DES NATIONS
UNIES POUR L'ALIMENTATION
ET L'AGRICULTURE

ORGANISATION
MONDIALE
DE LA SANTÉ



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Item de l'agenda 17

CX/FAC 02/30

PROGRAMME MIXTE FAO/OMS SUR LES NORMES ALIMENTAIRES

COMITE DU CODEX SUR LES ADDITIFS ALIMENTAIRES ET LES CONTAMINANTS

Trente-troisième session

Rotterdam, Pays- Bas, 11-15 Mars 2002

LISTE DES ADDITIFS ALIMENTAIRES, CONTAMINANTS ET SUBSTANCES TOXIQUES NATURELLEMENT

Commentaires reçu de Canada, Cuba, Brésil, Australie, Czech Republic:

CANADA

Point 9: Liste des additifs alimentaires, des contaminants et des substances toxiques naturellement présentes à évaluer en priorité par le JECFA (paragraphe 187 et annexe XVI)

Le Canada passe régulièrement en revue les propositions touchant les additifs alimentaires, les contaminants et les toxines naturelles pour lesquels on peut considérer que l'évaluation en priorité par le JECFA se justifie et, dans chaque cas, nous vérifions aussi la validité de la base de données disponibles. Nous fournirons des renseignements supplémentaires au Comité à mesure que progresseront les travaux de révision.

République de CUBA

Partie B, point 9: Liste des additifs alimentaires, des contaminants et des substances toxiques naturellement présentes à évaluer en priorité par le JECFA (par. 187 et annexe XVI)

Nous sommes d'accord avec la décision d'accorder une première priorité au nitrate et au carbamate d'éthyle, mais nous voudrions joindre les fumonisines à la liste.

BRAZIL (English only)

Priority List of Food Additives, Contaminants and Naturally Occurring Toxicants Proposed for Evaluation by JECFA (para. 187 and Appendix XVI). The Committee agreed to request additional comments for additions or amendments to its Priority List for consideration at its next Session. Brazilian Position: No Comments

AUSTRALIA (English only)

INFORMATION ON THE ADDITIVE TO BE EVALUATED BY JECFA

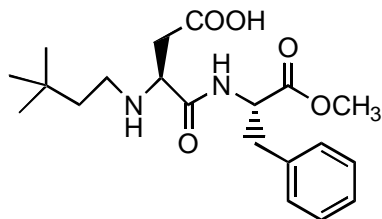
1. Proposal for inclusion submitted by:

Australia

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

Common name: Neotame

Chemical names: L-phenylalanine, N-[N-(3,3-dimethylbutyl)-L- α -aspartyl]-,1-methyl ester
N-[N-(3,3-dimethylbutyl) L- α -aspartyl]-L-phenylalanine 1-methyl ester



CAS registry number: 165450-17-9

3. Names and addresses of basic producers:

The NutraSweet Company
1762 Lovers Lane
Augusta, GA 30901
USA

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

Yes

5. Identification of the manufacturer that will be providing data (contact details).

Dr Wayne Stargel
Senior Vice President
The NutraSweet Company
699 N. Wheeling Road, Suite 103
Mt Prospect, IL 60056
USA

Telephone: +1 (847) 463 1741

Facsimile: +1 (847) 463 1753

E-mail: **Error! Reference source not found.**

6. Justification for use:

Neotame is a new sweetener and flavour enhancer. It is intended for use as a replacement for all or some of the sucrose or other currently approved sweeteners.

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

In both Australia and New Zealand neotame is approved as an additive permitted in processed foods according to Good Manufacturing Practice (GMP) (listed in schedule 2 of standard 1.3.1). This equates to

inclusion in Table 3 of the GSFA with additional entries in Tables 1 & 2 to enable uses in certain foods listed in the Annex to Table 3.

The proposed uses include, but are not limited to, soft drink beverages (both carbonated and non-carbonated), beverage concentrates, beverage mixes, dairy beverages, fruit juice products, alcoholic drinks, non-dairy desserts, gelatin based desserts, ice cream, breakfast cereals and as a tabletop sweetener for use in hot beverages such as tea or coffee. Typical use levels in foods, with GSFA category, are shown in attachment 1.

8. Has the compound been approved for use in 2 or more countries?

Yes, the compound is approved for use in both Australia and New Zealand as a generally permitted food additive for use in accordance with GMP.

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

A complete data set is available. See attachment 2.

Specification: (Australia New Zealand Food Standards Code) – See attachment 3.

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

Full study reports are available now and will be provided to JECFA upon request.

Attachment 1

TYPICAL LEVELS OF USE OF NEOTAME IN FOODS WITH GSFA CATEGORY

Food Group	Food Description	Relevant GSFA categories	Indicative levels of use mg/kg
Tabletop Sweeteners	Table top sweeteners	11.4	GMP
Breakfast cereals	Pre-sweetened cereals	6.3	46
Beverages	Carbonated soft drink	14.1.4	17
	Iced tea drink	14.1.4	8
	Flavoured milks	1.1.2, 1.2.1.2, 1.2.2, 1.3.2	15
	Fruit Juice based drinks	14.1.3	25
	Electrolyte drinks	14.1.4	15
	Cordial, as consumed	14.1.4	17
Desserts; dessert mixes; fillings, filling mixes; toppings; topping mixes	Frozen dairy desserts (ice cream) and novelties (ices)	1.7, 2.4, 3	20
	Gelatin desserts	4.3.7, 16.1	19
	Pudding desserts	1.7, 2.4, 6.5, 10.5	45
	Yoghurt	1.2.1	15
	Pie filling	4.3.7	30
	Whipped toppings	1.4	25
Chewing gum	Chewing gum	5.3	250
Fruit and vegetable spreads: purees and sauces	Jam/Jellies	4.3.4	100
	Fruit purees	4.3.4, 4.3.6	100
	Maple syrup	11.2	70
Salad dressings	Oil/vinegar style dressing	2.2.2, 2.3, 12.6	10
Condiments	Relish	12.2, 12.6	30

Food Group	Food Description	Relevant GSFA categories	Indicative levels of use mg/kg
Peanut/nut spreads	Peanut Butter	12.7	15
Confectionery glazes; coatings	Icings, frostings, cookie fillings	5.1, 5.2	50
	Hard candy	5.2	60
	Soft candy	5.2	28
Bakery products; bakery mixes	Cookies	7.2	60
	Cakes	7.2	35
	Cheese cake	1.7	40
Dairy Products	Fermented and renneted milk products	1.2	15
	Pasteurized cream	1.4.1	GMP
	Clotted cream	1.4.3	GMP
	Cream analogues	1.4.4	GMP

CZECH REPUBLIC

Information on the Additive to be evaluated by JECFA

1) Proposal for inclusion submitted by: CZECH REPUBLIC

2) Name of compound: Anthraquinone natural colour, carmine acid analogue derivated From *Penicillium oxalicum* var. *Anneniaca* (CCM 8242)

3) Trade name: ARPINK RED

4) Chemical names: formula A: 8-ethyl-3,6-dihydroxy-5-[(E)-3 methyl-1,3-butadienyl]-9, 10-dioxo-9, 10-dihydroanthracen-2-carboxylic acid
formula B: 6-ethyl-10-hydroxy-3,3-dimethyl-7,12-dioxo-7-12 dihydro-3H-naphtho [2,3-f] chromene-9-carboxylic acid

5) Name and adress of basic producer: ASKOLOR s.r.o.
Tmovská 246
533 53 Pardubice
CZECH REPUBLIC

6) Justification for use: The colour is produced by a pure culture fermentation of mixed cultivation medium with *Penicillium oxalicum*. Fermentation liquid is then purified by ultrafiltration and nanofiltration. Therefore, it can free of chemical and microbiological contaminants and extraneous natural substances such as proteins etc. This colour differs from carminic acid and carmines, has got a different shade and is heat- and light-stable. It is particularly suitable for food colouring, in which these qualities are sought after.

7) Food products in which the compound is used:

Meat products, meat and meat products analogues, non-alcoholic beverages, alcoholic beverages, dairy products, ice creams, confectionery

8) Has the compound been registered in 2 or more countries?

No, in Czech Republic only

9) Has the manufacturer made a commitment to provide data?

Yes

10) List of data (toxicology, metabolism, specifications) available:

Acute oral toxicity in mice 90-day subchronical toxicological study
Acute dermal Irritation / Corrosion

Acute Eye Irritation / Corrosion
Anti-tumour effectiveness
Micronucleus Test m Mice
AMES test (Salmonella typhimurium Reverse Mutation Assay)
Estimation of Antibiotic Activity
Results of estimation of 5 mycotoxins

11) Date on which data could be submitted to JECFA: 1st of May 2001

To your request of July 12, 2000, we are making the following statement:

After evaluating all your materials, product specification, unexceptionable nature also assessed with regard to its use suggested by the applicant in his/her application and confirmed with the statement of the National Healthcare institute in Prague under reference CZŽP 17-666/99b EX 392152 of November 3, 1999, and under reference CZŽP 16-1831/00 EX 101349 of June 19, 2000, we are making a statement that there will not be any objections to use the red colouring matter **ARPINK RED**

- in meat products in the amount up to 100 mg/kg
- in meat and meat product analogues in the amount up to 100 mg/kg
- in non-alcoholic drinks in the amount up to 100 mg/kg
- in alcoholic drinks in the amount up to 200 mg/kg
- in milk products in the amount up to 150 mg/kg
- in ice creams in the amount up to 150 mg/kg
- in confectionery in the amount up to 300 mg/kg

I am limiting the validity of this statement to December 31, 2002

Motivation: The validity of this statement is limited with regard to the envisaged change of legal regulations.

In order to speed up the proceedings, it will be suitable that the entrepreneur, who asks the Ministry of Healthcare of the Czech Republic for an agreement with release of the aromatic matter in question, makes reference to this statement with mentioning our reference.