comisión del codex alimentarius

ORGANIZACIÓN DE LAS NACIONES UNIDAS PARA LA AGRICULTURA Y LA ALIMENTACIÓN

ORGANIZACIÓN MUNDIAL DE LA SALUD

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Tema 17 del programa **CX/FAC 02/30**

PROGRAMA CONJUNTO FAO/OMS SOBRE NORMAS ALIMENTARIAS

COMITÉ DEL CODEX SOBRE ADITIVOS ALIMENTARIOS Y CONTAMINANTES DE LOS ALIMENTOS
34ª reunión
Rotterdam, Países Bajos, 11-15 de marzo de 2002

LISTA DE PRIORIDADES DE LOS ADITIVOS ALIMENTARIOS, CONTAMINANTES Y SUSTANCIAS TOXICAS NATURALMENTE

Las observaciones siguientes se han recibido Brasil, Australia, Czech Republic e Canada

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**

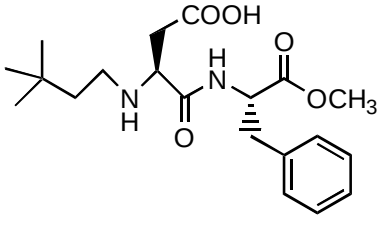
AUSTRALIA (English only)

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
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

CANADA (English only)

Canada suggests that consideration be given to inclusion of the following on the JECFA Priority List:

(1) **Ergot Alkaloids**

Ergot alkaloids are a group of mycotoxins not evaluated before by JECFA. They occur from time to time as a component (variable composition) of ergot in grains such as rye, wheat (especially triticale wheat) and barley infected with the fungus, *Claviceps*. At present, ergot levels in Canada are managed based on technological considerations as part of the grading system. Ergot alkaloids are of acute and chronic concern, and may affect the vascular system as well as the CNS. Health Canada is, at present, evaluating this group of toxicants, with a view towards establishing a group TDI, based on either animal toxicity data or on human data, and a full toxicological database is under development. Health Canada has investigated the occurrence of ergot alkaloids in a variety of foods, including infant cereals, and we are at present estimating Canadian exposure.

In summary, Canada could contribute much toxicological data and exposure and monitoring data for these compounds.

(2) **Polybrominated Diphenyl Ethers**

Brominated diphenyl ether flame retardants can be regarded as an emerging class of world-wide persistent organic pollutants (POPs). While human exposure to other POPs such as DDT and PCBs has declined within the past 15 years, residue analysis of biota, including aquatic food species, and humans indicates continual increased exposure to these chemical contaminants up to the late 1990s.

While Canada would not be able to provide toxicological data on these compounds, we would be able to provide some monitoring data, market basket survey data and human residue data). We also would be able to contribute a draft risk assessment, prepared in connection with a recent meeting of the Joint UNECE/WHO-ECEH Task Force on Health Aspects of Long-Range Transboundary Air Pollution. A WHO Environmental Health Criteria - IPCS monograph prepared in 1994, plus more recent congener-specific data, are available upon which a hazard characterization may be attempted.

CZECH REPUBLIC (English only)

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-[lE)-3 methyl-1,3-butadienyl] -9, l0-dioxo-9, l0-dihydroanthracen-2-carboxylacid
formula B: 6-ethyl-10-hydroxy-3,3-dimethyl-7,12-dioxo-7-12 dihydro-3H-naphto [2,3-f] chromene-9-carboxylacid

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

6) Justification foruse: The colour is produced by a pure culture fermentation of mixed cultivation medium with Penicillium oxalicum. Fermentation liquid is than purified by ultrafiltration and nanofiltration. Therefore, it can free of chemical and microbiological contaminants and extraneous natural substances such as proteins ets. 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 sough after.

7) Food products in vhitch the compound is used:
Meat products, maet and maet 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 m 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 whitch data could be submitted to JECFA: 1st of May 2001

To your reguest 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 astatement 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.