



USDA Foreign Agricultural Service

# GAIN Report

Global Agriculture Information Network

Voluntary Report - public distribution

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## Japan

### Sanitary/Phytosanitary/Food Safety

### Information Request on Food Additives

**2003**

**Approved by:**

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U.S.Embassy

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**Report Highlights:**

The Government of Japan (GOJ) is seeking information on the use of additives selected for expedited review, including use standards and information on the scope of foods for which these additives. The information will be used to establish use limitation standards for additives including polysorbates, calcium stearate, magnesium biphosphate, hydroxypropyl cellulose and modified starches.

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Includes PSD Changes: No  
Includes Trade Matrix: No  
Unscheduled Report  
Tokyo [JA1]  
[JA]

The Ministry of Health, Labor and Welfare (MHLW) is seeking information on the use of additives selected for expedited review. MHLW has requested countries provide their use standards and, to facilitate review, asked countries, organizations, and companies to provide the information on the quantity and type of foods for which the additives are used, to insure that the new standards cover appropriate uses in food products.

The Food Sanitation Subcommittee is responsible review of food additives on behalf of MHLW's Pharmaceutical and Food Sanitation Committee. On July 27, 2002 the Subcommittee decided to expedite approval of food additives not approved in Japan but widely used internationally and recognized as safe. Minimum requirements for inclusion in this expedited approval were a safety evaluation by the Joint Evaluation Committee on Food Additives and approval in both the U.S. and EU.

MHLW categorized the additives into 3 groups. MHLW's committee began discussion on the standards for the additives in the Group 1 in April 2003. Groups 2 and 3 are forecast to begin review in July and October, respectively.

USDA will assist submission of the use information to MHLW through the Food Safety and Technical Service Division at:

Roseanne Freese  
 Food Safety and Technical Services  
 International Trade Policy division  
 USDA Foreign Agricultural Service  
 Fax: 202-690-0677  
 Email: [FreeseR@fas.usda.gov](mailto:FreeseR@fas.usda.gov)

Following are the document and tables distributed by MHLW.

(Begin document)

**The list of food additives for expedited approvals by MHLW**

General name	US CFR number
Ammonium alginate	21CFR184.1133
Potassium alginate	21CFR184.1610
Calcium alginate	21CFR184.1187
Hydroxypropyl cellulose (HPC)	21CFR172.870
? -apo-8'-carotenal	21CFR73.90
? -carotene (from <i>Blakeslea trispora</i> )	21CFR73.95, 184.1
Calcium ascorbate	21CFR182.3189
Sodium aluminosilicate	21CFR182.2727
Carmine	21CFR73.100
Canthaxanthin	21CFR73.75
Calcium silicate	21CFR172.410
Calcium saccharin	21CFR180.37
Acidic sodium aluminum phosphate	21CFR182.1781
Magnesium hydroxide	21CFR184.1428(c)
Sodium stearolactate	21CFR172.849c9
Nicin	GRN0064
Polyvinylpyrrolidone	21CFR173.55

Potassium lactate	21CFR184.1639
Calcium stearate	21CFR172.863c
Polysorbate20	21CFR172.515b
Polysorbate60	21CFR172.836c
Polysorbate65	21CFR172.838c
Polysorbate80	21CFR172.840c
Magnesium biphosphate	21CFR184.1434
Acetylated adipic acid starch*	21CFR172.892
Acetylated phosphate starch*	21CFR172.892
Acetylated oxidized starch*	21CFR172.892
Sodium octenyl succinate starch*	21CFR172.892
Hydroxypropyl starch*	21CFR172.892
Hydroxypropyl phosphate starch*	21CFR172.892
Phosphate mono-ester phosphate starch*	21CFR172.892
Phosphoric starch*	21CFR172.892
Phosphate starch*	21CFR172.892
Oxidized starch*	21CFR172.892
Acetyl starch*	21CFR172.892
Isopropanol	21CFR172.515b

\* Modified starch items allowed distribution in Japan as foods.

**Group 1: Those already consulted or additives with similar chemical structures have been examined by the committee - 18 additives**

Polysorbate group

Polysorbate20  
Polysorbate60  
Polysorbate65  
Polysorbate80

Stearate group

Calcium stearate

Magnesium phosphate

Magnesium biphosphate

Hydroxypropyl cellulose

Hydroxypropyl cellulose (HPC)

Modified starch group (those starch are allowed distribution as foods.)

Acetylated adipic acid starch  
Acetylated phosphate starch  
Acetylated oxidized starch  
Sodium octenyl succinate starch  
Hydroxypropyl starch  
Hydroxypropyl phosphate starch  
Phosphate mono-ester phosphate starch  
Phosphoric starch  
Phosphate starch  
Oxidized starch  
Acetyl starch

**Group 2: Those having designated additives with similar chemical structure - 12 additives**

Alginate group – 3

Ammonium alginate

Potassium alginate

Calcium alginate

- carotene (from Blakeslea trispora)

Calcium ascorbate

Calcium saccharin

Magnesium hydroxide

Sodium stearolactate

Potassium lactate

Polyvinylpyrrolidone

Calcium sorbate

L-ammonium glutamate

**Group 3 – 4**

Silicate group

Sodium aluminosilicate

Calcium silicate

Calcium aluminosilicate

Magnesium silicate (synthetic)

- apo-8'-carotenal

Carmine

Canthaxanthin

Acidic sodium aluminum phosphate

Nicin

Calcium acetate

Calcium oxide

Potassium sulfate

Tri-ethyl citrate

Isopropanol