NOSB NATIONAL L. FILE CHECKLIST allowed 9 No 4

Bleveleed Syn

PROCESSING

| MATERIAL NAME | : Lecithin, Soy, Vegetable | | | |
|------------------|------------------------------|--|--|--|
| CATEGORY: unknow | Complete?: 3/16 | | | |
| | NOSB Database Form | | | |
| | References | | | |
| | MSDS (or equivalent) | | | |
| | FASP (FDA) | | | |
| | Date file mailed out:2/14/95 | | | |
| | TAP Reviews from: | | | |
| | Richard Thour | | | |
| | Steva Harper | | | |
| | Supplemental Information: | | | |
| 1.00 6/0 70 | | | | |

NOSB/NATIONAL LIST COMMENT FORM/BALLOT

Use this page to write down comments and questions regarding the data presented in the file of this National List material. Also record your planned opinion/vote to save time at the meeting on the National List.

| Name of Material | Lecith | in, Soy | |
|------------------|------------|---------|--|
| Type of Use: | | | |
| TAP Review by: | | | |
| R_{12} | and Thever | | |
| 2. Stee | ve Harper | | |
| 3. | | | |
| Comments/Questic | ons: | | |
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| My Opinion/Vote | is: | | |
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| Signature | | Date | |
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USDA/TAP REVIEWER COMMENT FORM

Use this page or an equivalent to write down comments and summarize your evaluation regarding the data presented in the file of this potential National List material. Attach additional sheets if you wish.

| This file is due back to us within 30 days of: Feb 14 |
|---|
| Name of Material: Lecithin (Veretable) |
| Reviewer Name: Steven Harper |
| Is this substance Natural or Synthetic? Explain (if appropriate) |
| Naturally derived substance. |
| Please comment on the accuracy of the information in the file: |
| Accurate |
| This material should be added to the National List as: Synthetic Allowed Prohibited Natural |
| or, \underline{X} This material does not belong on the National List because: Lecithin is a naturally derived substance fround in soybean oil. |
| Are there any restrictions or limitations that should be placed on this material by use or application on the National List? |
| Chemically modified lecithins are synthetic substances and should not be allowed under this classifications. However, they fit in the synthetic allowed category. |
| Any additional comments or references? |
| There is certainly a chance that trace amounts of hexane can be found in lecithin. Optimally lecithin from cold pressed oils would be a preference in the organic industry. However, the quality of these lecithins has been very poor. |
| Signature Story North Date 3/10/95 |

USDA/TAP REVIEWER COMMENT FORM

Original mailing date: 14 Feb 1995.

Material: Lecithin

Reviewer: Richard C. Theuer

NATURAL Lecithin is the substance isolated as a gum following hydration of solvent-extracted soy, safflower or corn oils. No chemical modification or structural alteration occurs in this process, so unbleached lecithin is natural. SYNTHETIC Most commercial lecithins are bleached with hydrogen peroxide or benzoyl peroxide to improve color. In this reviewer's judgment, bleached lecithin is thus synthetic.

The remainder of this review will focus entirely on natural,

unbleached lecithin.

COMMENTS RE SECTION 2119(m) CRITERIA:

1. Lecithin is removed from vegetable oils in a "degumming" step. Having end uses for his by-product of vegetable oil refining keeps this substance out of the waste stream and so supports sustainable agricultural production and processing.

2. Lecithin is Generally Recognized As Safe (GRAS)

[21CFR184.1400].

3. Lecithin acts as an emulsifier; there are no limitations on its use other than good manufacturing practice.

The following natural substance should be allowed as an ingredient in organic foods. It should not be added to the National List of natural substances prohibited for use as ingredients or processing aids in Organic Food:

lecithin (natural, unbleached).

12 Mar 1995

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NOSB Materials Database

Identification

Lecithin, Soy Common Name

Chemical Name

Other Names

Code #: CAS

Code #: Other

N. L. Category

unknown

MSDS

Oyes Ono

Chemistry

Family

Composition

Complex mixture of alcohol-insoluble phosphatides. Found in all living organisms.

Properties

Plastic to fluid consistency. Light yellow to brown with no odor or slightly nut-like odor and bland taste.

Partially soluble in water but readily hydrates to form emulsions. Soluble in fatty acids but practically

insoluble in fixed oils. Partially soluble in alcohol and practically insoluble in acetone.

How Made

Extracted from soybeans and other plant sources. Soybeans are dried, flaked and the crude soybean oil is extracted almost universally with the use of hexane. Some expeller pressed oil is processed. The crude oil is filtered, hydrated, centrifuged, dried and cooled. Standardized lecithin is the fraction centrifuged. Some chemically modified lecithins are produced but are typically labeled as such. Most

commercial lecithins are bleached with hydrogen peroxide or benzoyl peroxide to improve color.

Use/Action

Type of Use

Processing

Specific Use(s) Emulsifier, Surface active agent, antioxidant, wetting agent, viscosity agent.

Action

Lecithin owes its specific functional qualities to its amphiphilic chemical composition. The surface-active phospholipic molecules, which form the major constituent of lecithin, have both a

hydrophobic (water repelling) and hydrophilic (water attracting) portion.

Combinations

Status

OFPA

N. L. Restriction

EPA, FDA, etc

Directions

Safety Guidelines

State Differences

Historical status

Internation | status

Allowed by IFOAM, EU and Codex.

NOSB Materials Database

OFPA Criteria_

2119(m)1: chemical interactions

Not Applicable

2119(m)2: toxicity & persistence

Not Applicable

2119(m)3: manufacture & disposal consequences

Lecithin is a by-product of making vegetable oils and as such is creating an end use which will keep this substance out of the waste stream.

2119(m)4: effect on human health

None that have been detected.

2119(m)5: agroecosystem biology

Not Applicable

2119(m)6: alternatives to substance

Egg yolks, and other synthetic emulsifiers such as mono-di glycerides. None perform the same functions as well.

2119(m)7: Is it compatible?

It is compatible because of historic acceptance and the fact that it is a naturally derived substance. (SH).

References

AU: Claughton,-S.M.; Pearce,-R.J.

TI: Protein enrichment of sugar-snap cookies with sunflower protein isolate.

SO: J-Food-Sci-Off-Publ-Inst-Food-Technol. Chicago, III.: The Institute. Mar/Apr 1989. v. 54 (2)p. 354-356

CN: DNAL 389.8-F7322

AU: Bell,-J.M.; Slotkin,-T.A.

TI: Perinatal dietary supplementation with a commercial soy lecithin preparation: effects on behavior and brain biochemistry in the developing rat.

SO: Dev-Psychobiol. New York, N.Y.: John Wiley & Sons. Sept 1985. v. 18 (5) p. 383-394. ill.

CN: DNAL QP351.D4

AU: Bell,-J.M.; Lundberg,-P.K.

TI: Effects of a commercial soy lecithin preparation on development of sensorimotor behavior and brain biochemistry in the rat.

SO: Dev-Psychobiol. New York, N.Y.: John Wiley & Sons. Jan 1985. v. 18 (1) p. 59-66. ill.

CN: DNAL QP351.D4

AU: Hirotsuka,-M.; Taniguchi,-H.; Narita,-H.; Kito,-M.

TI: Increase in emulsification activity of soy lecithin-soy protein complex by ethanol and heat treatments.

SO: J-Food-Sci. Chicago, III.: Institute of Food Technologists. July/Aug 1984. v. 49 (4) p. 1105-1110. ill.

CN: DNAL 389.8-F7322

AU: Beane,-M

TI: Vitamin Q in soy lecithin

SO: Prevention, Apr 1974, 26 (4): 59-66.

CN: DNAL 449.8-P92

Boyd Foster, 1994, written communication. Arrowhead Mills, Texas

U.S. FOOD AND DRUG ADMINISTRATION FOOD ADDITIVE SAFETY PROFILE

JUNUMEZ Z Z S S

| (ETABLE) | |
|----------|--|
| (VEG | |
| CITHIN | |
| m | |

977092242 2285 NUL

HUMAN CONSUMPTION:
MARKET DISAPPEARANCE:
MARKET SURVEY:
JECFA:
JECFA ADI:
JECFA ESTABLISHED:
LAST UPDATE:

MG/KG BW/DAY/PERSON LBS/YR

MG/KG BW/DAY/PERSON

1991

DENSITY:

LOGP:

PRUCTURE CATEGORIES: A06

OMPONENTS: 000141435 ETHANOAMINE

(NONYMS:

ტ HEMICAL FUNCTION:

CHNICAL EFFECT:

ANTIOXIDANT DRYING AGENT

184.1400 REG NUMBERS:

INIMUM TESTING LEVEL:

MMENTS:

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