

Syn

Allowed

# NOSB NATIONAL LIST FILE CHECKLIST

## PROCESSING

MATERIAL NAME: Monoglycerides & Diglycerides

CATEGORY: Synthetic Allowed

Complete?: 3/17

NOSB Database Form

References

MSDS (or equivalent)

FASP (FDA)

Date file mailed out: 2/14/95

TAP Reviews from: \_\_\_\_\_

Richard Theuer

Steve Taylor

Supplemental Information:

restricted to Brown Drying

MISSING INFORMATION: no MSDS available

# 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 monoglycerides & Diglycerides

Type of Use:  Crops;  Livestock;  Processing

TAP Review by:

1. Richard Theuer
2. Steve Taylor
3. Steven Harper

Comments/Questions:

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My Opinion/Vote is:

Signature \_\_\_\_\_ Date \_\_\_\_\_

# 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: 14 Feb

Name of Material: Mono & diglycerides

Reviewer Name: Steve Taylor

Is this substance Natural or Synthetic? Explain (if appropriate)  
Natural

Please comment on the accuracy of the information in the file:

This material should be added to the National List as:  
 Synthetic Allowed       Prohibited Natural

or,  This material does not belong on the National List because:

Are there any restrictions or limitations that should be placed on this material by use or application on the National List?

Method of extraction may be source of considerable concern.

Any additional comments or references?

Signature Steve Taylor

Date 3-5-95



# 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: 14 Feb

Name of Material: Mon- + Di-glycerides

Reviewer Name: Steven Harper

**Is this substance Natural or Synthetic? Explain (if appropriate)**

Synthetic, although some of these substances can be found naturally.

**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,  This material does not belong on the National List because:

**Are there any restrictions or limitations that should be placed on this material by use or application on the National List?**

This substance is critical for some processing operations such as drum dehydrating of vegetables. Other applications are possible using other substances which may or may not be synthetic.

**Any additional comments or references?**

Signature Steven Harper

Date 3/10/95



USDA/TAP REVIEWER  
COMMENT FORM

Original mailing date: 14 Feb 1995.

Material: Mono- and Diglycerides 21CFR184.1505  
Reviewer: Richard C. Theuer

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**SYNTHETIC** Mono- and diglycerides are manufactured by the reaction of glycerin (glycerol) with fatty acids or the reaction of glycerin with triglycerides in the presence of an alkaline catalyst. A molecular transformation takes place which means the processes are synthetic.

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**COMMENTS RE SECTION 2119(m) CRITERIA:**

1. Mono- and diglycerides are the normal digestion products of fat,, so the molecular structures are found in nature (in our small intestines after we eat fat).
  2. Mono- and diglycerides are Generally Recognized As Safe.
  3. These substances are multipurpose food additives [21CFR184.1505(c)(1)]: dough conditioner, emulsifier, lubricant, stabilizer, surface active agent, etc.
  4. Other substances that can replace mono- and diglycerides are even less natural than these substances are.
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The following substances should be added to the National List of Substances as allowed synthetic ingredients in Organic Food:  
mono- and diglycerides.

12 Mar 1995





## Identification

<b>Common Name</b>	<b>Mono- &amp; Di- glycerides</b>	<b>Chemical Name</b>	Mono-Diglycerides
<b>Other Names</b>	Glycerol Monostearate (GMS)		
<b>Code #: CAS</b>	31566-31-1	<b>Code #: Other</b>	
<b>N. L. Category</b>	Synthetic Allowed	<b>MSDS</b>	<input type="radio"/> yes <input type="radio"/> no

## Chemistry

### Family

### Composition Properties

Compounds that are esters of the sweet alcohol glycerin. Mixtures of glycerol mono-esters of edible fats or oils or edible fat-forming fatty acids. They vary in consistency from yellow liquids through ivory-colored plastics to hard, ivory-colored solids having a bland odor and taste. Insoluble in water, but are soluble in alcohol, in ethyl acetate, and in chloroform.

### How Made

Removed from raw oils in the refining process. Extracted primarily from vegetable oils but can be taken from animal fats also. Reaction of soybean oil or other fatty acids and glycerin (glycerol) at high temperatures in the presence of an alkaline catalyst. Molecular transformation takes place.

Processing

## Use/Action

### Type of Use

**Specific Use(s)** Emulsifier, Surface active agent; stabilizer. Used in bakery products to produce "softness". Used as stabilizer in beverages, ice cream, milk, chocolate and shortenings. Release agent for vegetable dehydrating dryers.

**Action** Natural lubricating, emulsifying, binding and defoaming properties. Complex formation with starch to delay retrogradation.

### Combinations

## Status

OFPA

**N. L. Restriction**

EPA, FDA, etc FDA-GRAS

**Directions**

**Safety Guidelines**

**State Differences**

**Historical status**

**International status**

# NOSB Materials Database

5.

## OFPA Criteria

2119(m)1: chemical interactions      Not Applicable

2119(m)2: toxicity & persistence      Not Applicable

2119(m)3: manufacture & disposal consequences

Method of extraction may be cause for concern.

2119(m)4: effect on human health

No effects have been found thus far. Nutrient.

2119(m)5: agroecosystem biology      Not Applicable

2119(m)6: alternatives to substance

None that perform the same functions as well as a release agent.

Lecithin is a good substitute as an emulsifier.

2119(m)7: Is it compatible?

It is compatible for specific applications such as a release agent for dehydrated vegetables which are critical for organic processing (SH).

## References

Boyd Foster, Arrowhead Mills, 1994, written communication.

John Wyatt, Grinsted Products Inc., 1995, written communication.

AU: Lee,-T.; Hastilow,-C.; Smith,-K.

TI: Simple method for derivatization of monoglycerides and diglycerides.

SO: J-Assoc-Off-Anal-Chem. Arlington, Va. : The Association. July/Aug 1988. v. 71 (4) p. 785-788.

CN: DNAL 381-AS7

AU: Doxastakis,-G.; Sherman,-P.

TI: The influence of the interaction of mono- and diglycerides with milk proteins on the rheology and stability of food emulsions [Corn oil-in-water emulsions].

SO: Instrumental analysis of foods / edited by George Charalambous, George Inglett. New York : Academic Press, 1983. v. 2 p. 219-235. ill.

CN: DNAL TX541.Q34-1983

AU: Leonard,-Edward-C.

TI: Production and use of fatty acids.

SO: Cereal-Foods-World. St. Paul, Minn., American Association of Cereal Chemists. Jan 1979. v. 24 (1) p. 12,14.

CN: 59.8-C333

AB: Abstract: Food-grade fatty acids are produced from fats and oils derived from edible sources. Short free fatty acids and their esters are used as synthetic flavoring agents. Salts of stearoyl-2-lactylic acid are used as dough conditioners. Mono- and diglycerides of fatty acids find wide applications as emulsifiers. Metallic salts of fatty acids are used in soaps and greases. Fatty acid amides are good slip agents in polyethylene and polypropylene converters in packaging operations.

CNUM=2415

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

MONO- AND DIGLYCERIDES

S#: 067254733  
 SP#: 2415  
 PE: ASP  
 S#: 0130  
 MA#:   
 AS#:   
 HUMAN CONSUMPTION: 59.03954 MG/KG BW/DAY/PERSON  
 MARKET DISAPPEARANCE: 69666666.666 LBS/YR  
 MARKET SURVEY: 87  
 JECFA: NL-C  
 JECFA ADI:   
 JECFA ESTABLISHED: 1973  
 LAST UPDATE: 931115  
 DENSITY: LOGP:   
 MG/KG BW/DAY/PERSON

RUCTURE CATEGORIES: A3

MPONENTS:

NONYMS:

FATTY ACIDS, EDIBLE, MONO- AND DIGLYCERIDES  
 MONO- AND DIGLYCERIDES OF EDIBLE FATTY ACIDS  
 MONO- AND DIGLYCERIDES OF EDIBLE FATS AND OILS  
 MONO- AND DIGLYCERIDES OF EDIBLE FAT-FORMING ACIDS  
 MONO- AND DIGLYCERIDES OF FAT-FORMING FATTY ACIDS  
 GLYCERIDES, MIXED MONO- AND DI-  
 MIXED MONO- AND DIGLYCERIDES  
 MONO- AND DIGLYCERIDES OF FATTY ACIDS

EMICAL FUNCTION: F

CHNICAL EFFECT:

EMULSIFIER OR EMULSIFIER SALT  
 MASTICATORY SUBSTANCE  
 LUBRICANT OR RELEASE AGENT  
 STABILIZER OR THICKENER  
 TEXTURIZER  
 SURFACE-ACTIVE AGENT  
 FLAVOR ENHANCER  
 FLAVORING AGENT OR ADJUVANT

R REG NUMBERS: 163.123 172.755 184.1505  
 166.40 163.130 136.110  
 136.115 136.130 136.160  
 136.180 163.135 163.140  
 163.145 163.155 163.150  
 163.153

NIMUM TESTING LEVEL: 3

ITEMS: DATA INSUFFICIENT FOR PRIORITY RANKING

9: ORAL TOXICITY STUDIES (OTHER THAN ACUTE)

8 CHRONIC RODENT SOURCE: FOOD RESEARCH 22:529-541  
 YEAR: 1957  
 LEL: > MG/KG BW/DAY  
 SPECIES: SYRIAN HAMSTER  
 DURATION: 196 DAYS HNEL: 14571 MG/KG BW/DAY  
 EFFECTS: NO EFFECTS  
 COMMENTS: MALES ONLY; GLYCERYL MONOSTEARATE TESTED  
 NOT USED FOR PRIORITY RANKING

9 SUBCHRONIC RODENT SOURCE: FOOD RESEARCH 22:529-541  
 YEAR: 1957  
 LEL: 18000 MG/KG BW/DAY  
 SPECIES: SYRIAN HAMSTER  
 DURATION: 154 DAYS HNEL:  
 EFFECTS: BODY WEIGHT DECREASE  
 COMMENTS: ONE DOSE LEVEL ONLY  
 MALES ONLY; GLYCERYL MONOSTEARATE TESTED  
 NOT USED FOR PRIORITY RANKING

3: GENETIC TOXICITY STUDIES

3 COMPLETETENESS: SOURCE:  
 YEAR: MG/KG BW/DAY  
 LEL:  
 HNEL:

5 COMPLETETENESS: SOURCE:  
 YEAR: MG/KG BW/DAY  
 LEL:  
 HNEL:

6 COMPLETETENESS: SOURCE:  
 YEAR: MG/KG BW/DAY  
 LEL:

NUM=2421

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

MONO- AND DIGLYCERIDES, MONOSODIUM PHOSPHATE DERIVATIVES

AS#: 977051323 HUMAN CONSUMPTION: 0.001172 MG/KG BW/DAY/PERSON  
ASP#: 2421 MARKET DISAPPEARANCE: 1383.333 LBS/YR  
CPE: ASP MARKET SURVEY: 87  
AS#: 0135 JECFA:  
CMA#: JECFA ADI:  
CAS#: JECFA ESTABLISHED: 940615 MG/KG BW/DAY/PERSON  
LAST UPDATE:

DENSITY: LOGP:

STRUCTURE CATEGORIES: A6

COMPONENTS:

SYNONYMS:  
SODIUM MONO- AND DIGLYCERIDE PHOSPHATES  
MONOSODIUM PHOSPHATE MONO- AND DIGLYCERIDES  
MONO- AND DIGLYCERIDE PHOSPHATES, SODIUM SALTS

CHEMICAL FUNCTION: G

TECHNICAL EFFECT:  
LEAVENING AGENT  
EMULSIFIER OR EMULSIFIER SALT  
LUBRICANT OR RELEASE AGENT  
SURFACE-ACTIVE AGENT

FORM REG NUMBERS: 184.1521

MINIMUM TESTING LEVEL: 1

REMARKS: NO TOX STUDIES IN SCOGS -30

EX 3: GENETIC TOXICITY STUDIES

STUDY: 2A COMPLETENESS: SOURCE:  
SPECIES: YEAR:  
DURATION: LEL: MG/KG BW/DAY  
EFFECTS: HNEL:  
CELLS:  
REMARKS:

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

NISIN PREPARATION

AS#:	977127335	HUMAN CONSUMPTION:	0.045	MG/KG BW/DAY/PERSON
ASP#:	2448	MARKET DISAPPEARANCE:	53100	LBS/YR
PE#:	EAF	MARKET SURVEY:	FDA	
AS#:		JECFA:	FU	
EMA#:		JECFA ADI:	33000**	MG/KG BW/DAY/PERSON
QAS#:		JECFA ESTABLISHED:	1968	
		LAST UPDATE:		

DENSITY: LOGP:

STRUCTURE CATEGORIES:

COMPONENTS:

NONYMS:

CHEMICAL FUNCTION: G

TECHNICAL EFFECT: ANTIMICROBIAL AGENT

OR REG NUMBERS: 184.1538

MINIMUM TESTING LEVEL:

COMMENTS: \*\*JECFA ADI IS 33000 INTERNATIONAL UNITS OF NISIN  
NISIN IS THE ACTIVE PEPTIDE IN NISIN PREPARATION  
EXPOSURE FROM FDA DIVISION OF CHEMISTRY