

Stepan

Stepan Company

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May 11, 2005

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Dr. Robert Martin
Division of Biotechnology and GRAS Notice Review
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

REC'D MAY 16 2005

Dear Dr. Martin:

SUBJECT: GRAS Affirmation Petition **4G0409** Amendment

This submission is being made on behalf of Stepan Company with respect to the subject GRAS substance, Captrin.

Attached to this letter is replacement page 000003, 000005, 000006 and 00114 with respect to the proposed regulation. This change is to permit a greater range of ratios of C8 and C10 fatty acids.

There are no other changes in the GRAS Affirmation Petition.

Sincerely,

A. Gariepy

Annie Gariepy
Senior Regulatory Chemist
Product Safety and Compliance Department

Enclosure:

Replacement page 000003, 000005, 000006 and 00114

94G-0237

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Replacement Page 000003

Captrin

Section 184.____ Captrin

- (a) Captrin is the common usual name for **glycerides** of linear saturated fatty acids primarily of chain length C₈ or C₁₀. The ingredient is obtained by the hydrolysis of coconut oil or palm kernel oil followed by the fractionation and separation of the desired fatty acids which are esterified with glycerin to form **acylglycerols**.
- (b) The ingredient meets the following specifications. A minimum of **45%** triglyceride not more than **40%** diglyceride and not more than **10%** monoglyceride. The range of weight percent of the fatty acids are as follows:

C ₈	1-99%
C ₁₀	1-99%

Free Fatty Acids as Oleic	not more than 0.05%
Esterified Fatty Acids,	
Other than Caprylic or Capric	not more than 5.5%
Saponification Value	285-360
Unsaponifiable Material	not more than 0.5%
Iodine Value	not more than 1.0%
Hydroxyl Value	not more than 75
Residue on Ignition (Sulfated Ash)	not more than 0.1%
Total Heavy Metals Content (as Lead)	not more than 10 ppm
Arsenic	not more than 0.5 ppm
Lead	not more than 0.1 ppm
Tin	not more than 1 ppm

[c] The ingredient is used as **an acylglycerol** with the following physical or technical functional effects as defined in Section 170.3(o)(8) emulsifiers, (14) formulation aid, (18) lubricant and release agent, (20) nutrient supplement, (24) processing aid, (27) solvents and vehicle, (28) stabilizers and thickeners, (3) surface finishing agent, and (32) texturizer.

(d) The ingredient used in food at levels not to exceed current good manufacturing practice in accordance with Section 184.1(b)(1). The ingredient may be used in the following types of foods as defined in Section 170.3(n)(1) baked goods, (3) beverages, (6) chewing gum, (9) confections and frosting, (10) dairy product analogues, (12) fats and oils, (20) frozen dairy desserts, (35) processed fruits, (37) snack foods, and (38) soft candy; except that the ingredient may not be used in standardized foods unless permitted by the standard of identity.

The ingredient is sold as a technical food ingredient and is not formulated or mixed with other ingredients by the manufacturer.

SECTION (i)
Description of the Substance

(a) Common or Usual Name: Captrin

Captrin is the proposed common name for the randomized *glyceride* of caprylic and capric fatty acids. The term Captrin conforms to acceptable *glyceride* nomenclature for *glyceride* naming, i.e. Stearin is an acceptable name for glyceride tristearate.

The name Captrin is not in conflict with any name in the published literature and it would not be confused or misleading to purchasers of food for which the ingredient would be used.

Other names used:

Caprocapylin triglycerides
Caprylic/capric triglycerides
Caprylin
Neobee® M-5
Neobee® C-10
Medium Chain Triglycerides
Structural lipids

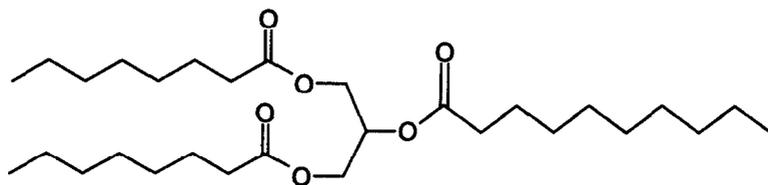
(b) Chemical Name: *Glycerides, mixed decanoyl and octanoyl*

(c) Chemical Abstract Service (CAS) Registry Number: 73398-61-5

The components of Captrin have been assigned the following CAS Registry Numbers:

	CAS	Empirical Formula
<i>Glycerides, mixed decanoyl and octanoyl</i>	73398-61-5	
Glycerin	56-81-5	C ₃ H ₈ O ₃
Caprylic Acid	124-07-2	C ₈ H ₁₆ O ₂
Capric Acid	334-48-5	C ₁₀ H ₂₀ O ₂
<i>Octanoic acid, methyl ester</i>	<i>111-11-5</i>	<i>C₉H₁₈O₂</i>
<i>Decanoic acid, methyl ester</i>	<i>110-42-9</i>	<i>C₁₁H₂₂O₂</i>

(d) Structural Diagram: Captrin has the general structural formula as shown below:



The fatty acids are randomly distributed on the glycerine backbone. The range of fatty acids is as follows:

n = 6 (caprylic acid)	1-99 weight percent
n = 8 (capric acid)	1-99 weight percent

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(e) Description:

Captrin is *obtained by the esterification of fatty acids from coconut oil or palm kernel oil or their derivatives with glycerin to form acylglycerols*. Captrin has exceptional oxidative stability properties, a slightly yellow color, free of suspended matter with a bland taste and odor. The physical and solubility properties are such that the substance has unique technological functions in foods.

The ingredient that contains *glycerides predominantly* consisting of capric acid are solids or paste at room temperature, and those that consist predominantly of caprylic acid are liquid at room temperature.

(f) Specifications for Food Grade Material Including Arsenic and Heavy Metals:

The ingredient meets the following specifications. A minimum of **45%** triglyceride not more than **40%** diglyceride and not more than **10%** monoglyceride. The range of weight percent of the fatty acids are as follows:

C ₈	1-99%
C ₁₀	1-99%

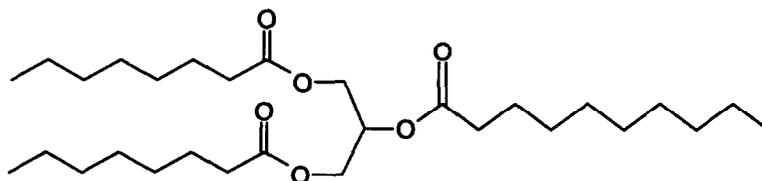
Free Fatty Acids as Oleic	not more than 0.05%
<i>Esterified Fatty Acids,</i>	
<i>Other than Caprylic or Capric</i>	<i>not more than 5.5%</i>
Saponification Value	285-360
Unsaponifiable Material	not more than 0.5%
Iodine Value	not more than 1.0%
<i>Hydroxyl Value</i>	<i>not more than 75</i>
Residue on Ignition (Sulfated Ash)	not more than 0.1%
Total Heavy Metals Content (as Lead)	not more than 10 ppm
Arsenic	not more than 0.5 ppm
Lead	not more than 0.1 ppm
<i>Tin</i>	<i>not more than 1 ppm</i>

(g) Quantitative Composition: i.e., amount of each compound of the mixture and if any other materials used in the formulation the quantity should be given.

The ingredient is sold as a technical food ingredient and is not formulated or mixed with other ingredients by the manufacturer.

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- (1) Identification of the Chemical Substances that are Subject of the Proposed Action:
- (a) Common or usual name: Captrin
 - (b) Chemical Name: **Glycerides** of linear saturated fatty acids primarily of chain lengths C₈ through C₁₀.
 - (c) Chemical Abstract Service (CAS) Registry Number: 73398-61-5
 - (d) Total Molecular Formulas:
 - (e) Structural Formula:



The fatty acids are randomly distributed on the glycerine backbone.

The range of fatty acids is as follows:

n = 6 (caprylic acid) 1-99 weight percent

n = 8 (capric acid) 1-99 weight percent

Captrin consists of two medium chain fatty acids, C₈ or C₁₀ on a glycerine backbone. The components of fatty acids are found in many dietary fats. Captrin is found in coconut and palm kern oils as well as milk and dairy products. Triglycerides that are high in capric acids are solid or paste at room temperature and those high in caprylic acid are liquid at room temperature.

Solubility of Captrin is similar to that of other triglycerides, i.e., it is insoluble in water and soluble in organic solvents. Captrin can be hydrolyzed to yield the components of fatty acids and glycerine.

