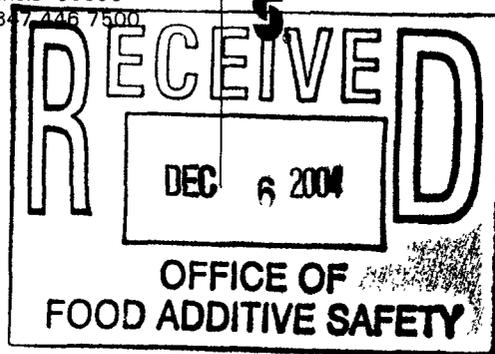


**Stepan**

Stepan Company

Northfield, Illinois 60093  
Telephone 847-446-7500



December 3, 2004

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 12/16/04  
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Dear Dr. Martin:

SUBJECT: GRAS Affirmation Petition 4G0409  
Amendment and update.

This submission is being made on behalf of Stepan Company to update and describe an alternative method of manufacture of the GRAS substance, Captrin.

We are replacing certain pages within the body of the GRAS Affirmation Petition, to reflect changes necessary with this alternative method of manufacture. Enclosed are replacement pages 3, 5, 6, 7, 8, and 19.

We have a new attachment to the GRASP, an R&D Technical Report, with respect to the testing of this alternative method of manufacture, which includes the specification for five alternative method manufactured lots of the GRAS substance, method of manufacture, updated analytical methodology as used in the analytical determinations, and manufacturing standards for ingredients used in the new manufacture, i.e., the methyl ester, glycerin USP, and the catalyst. This Technical Report includes updated analytical methods which have been amended since 1994.

The alternative method of manufacture also will cause some changes in the environmental assessment for the GRAS substance, and enclosed is a copy of the revised Environmental Assessment (November 30, 2004).

Also, enclosed is the revised MSDS for the new starting material, methyl esters, STEPAN® C-25.

The safety of the GRAS substance has been assessed in a peer review paper, *Review of the Toxicologic Properties of Medium-Chain Triglycerides*, Traul, et al., Food and Chemical Toxicology, 38:79-98, 2000. A copy of this review paper is enclosed.

*1994G-0237*

*SUP 1*



We would appreciate if you could place the above described information in the files of the subject GRAS Affirmation Petition. It is understood, as per conversations with Dr. William A. Olson, that there is no active CSO for this GRAS affirmation petition.

We also recognize that the reviews of GRAS affirmation petitions are not given high priority; however, Stepan Company does desire that this GRAS affirmation petition continue as a petition and we are not requesting this to be changed to a GRAS notification.

This letter also authorizes Dr. William A. Olson to communicate directly with the agency with respect to this GRAS affirmation petition.

Sincerely,

Annie Gariepy  
Senior Regulatory Chemist  
Product Safety and Compliance Department

Enclosures:

Replacement pages 3, 5, 6, 7, 8 and 19.  
Replacement Section viii, Pages 113-118, Environmental  
Assessment, Dated November 30, 2004  
Technical Report,  
Stepan Project No. 11651, Stepan GTC for methyl esters  
MSDS - Stepan C-25  
*Review of the Toxicologic Properties of Medium-Chain  
Triglycerides*, Traul, et al., Food and Chemical Toxicology,  
38:79-98, 2000.

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Replacement page 8
  
- B. Replacement page 19  
Revised Analytical Methods:
  - > APHA, Gardner, % Transmission, and Lovibond Color by LCS or LICO 300 Colorimeter, SM 006-A
  - > Hydroxyl Value Determination by Acetylation, SM 053-0
  - > Unsaponifiable Matter, SM 128-0
  - > Sulfated Ash, SM 144-0
  
- C. Replacement Section viii, pages 113-118  
Environmental Assessment, Dated November 30, 2004
  
- D. Technical Report  
Stepan Project No. 11651, Stepan GTC for Methyl Esters
  
- E. MSDS – Stepan C-25
  
- F. *Review of the Toxicologic Properties of Medium-Chain Triglycerides*, Traul, et al., Food and Chemical Toxicology, 38:79-98, 2000.