DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 184

[Docket No. 90G–0412]

Lipase Enzyme Preparation From Rhizopus Niveus; Affirmation of GRAS Status as a Direct Food Ingredient

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to affirm that lipase enzyme preparation derived from *Rhizopus niveus* is generally recognized as safe (GRAS) for use as a direct human food ingredient. This action is in response to a petition submitted by Fuji Oil Co., Ltd.

DATES: The regulation is effective May 4, 1998. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of a certain publication listed in § 184.1420 (21 CFR 184.1420), effective May 4, 1998.

FOR FURTHER INFORMATION CONTACT: Linda S. Kahl, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3101.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the procedures described in 21 CFR 170.35, Fuji Oil Co., Ltd., submitted a petition (GRASP 7G0330) requesting that lipase-protease enzyme preparation from *R. niveus* be affirmed as GRAS for use as a direct human food ingredient. FDA published a notice of filing of this petition in the **Federal Register** of June 18, 1992 (57 FR 27256), and gave interested persons an opportunity to submit comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. FDA received no comments in response to the filing notice.

Although the petitioner proposed that the subject enzyme preparation be called by the common or usual name ''lipase-protease,'' the proposed use of the enzyme preparation is solely for its lipase activity. The GRAS exemption described in section 201(s) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(s)) specifies that a GRAS substance must be generally recognized as safe ''under the conditions of its intended use.'' Thus, affirmation of GRAS status pertains to the particular use of a substance. Accordingly, FDA considers the enzyme preparation that is the subject of this document to be ''lipase enzyme preparation.'' To avoid confusion between lipase, the enzyme, and the lipase-containing enzyme preparation, which contains lipase as its characterizing enzyme activity, but which also contains diatomaceous earth as a carrier and may contain other enzyme activities and impurities, this document will henceforth use the terms ''lipase'' to refer to the enzyme and ''lipase enzyme preparation'' to refer to the fermentation-derived lipase enzyme preparation, including the carrier diatomaceous earth.

II. Standards for GRAS Affirmation

Under § 170.30 (21 CFR 170.30), general recognition of safety may be based only on the views of experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food. The basis of such views may be either scientific procedures or, in the case of a substance used in food prior to January 1, 1958, experience based on common use in food. General recognition of safety based upon scientific procedures requires the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation and ordinarily is based upon published studies, which may be corroborated by unpublished studies and other data and information (§ 170.30(b)). General recognition of safety through experience based on common use in food prior to January 1, 1958, may be determined without the quantity or quality of scientific procedures required for approval of a food additive regulation, and ordinarily is based upon generally available data and information.

FDA has evaluated Fuji Oil Co., Ltd.'s petition on the basis of scientific procedures to establish that the use of lipase enzyme preparation as an enzymatic catalyst for the interesterification of fats and oils is GRAS. In evaluating the petition, FDA considered: (1) Published and unpublished data and information relating to the identity and function of the enzyme component (i.e., lipase) (Refs. 1 through 5); (2) published and unpublished data and information relating to the production organism (Ref. 6); and (3) published and unpublished information, methods, and principles relating to the methods and processing aids used in the manufacture of the enzyme preparation (Refs. 4 and 7 through 10).

III. Safety Evaluation

A. Introduction

Commercial enzyme preparations that are used in food processing typically are not chemically pure but contain, in addition to the enzyme component, other components that derive from the production organism and the fermentation media, residual amounts of processing aids, and substances used as stabilizers, preservatives or diluents. Issues relevant to a safety evaluation of the enzyme preparation therefore include the safety of the enzyme component, the safety of the enzyme source, and the safety of processing aids and other substances added during the manufacturing process. As with all substances added to food, a safety evaluation of an enzyme preparation also includes consideration of dietary exposure to that preparation.

B. The Enzyme Component

Triglycerides are fats or oils comprised of fatty acids linked by ester bonds to each of the three hydroxyl groups of glycerol. Triacylglycerol lipases catalyze the hydrolysis of these ester bonds and can be grouped according to their specificity. The lipase produced by *Geotrichum candidium*, for example, preferentially cleaves triglycerides containing long-chain fatty acids with a cis double bond in the 9-position, but such specificity for the hydrolysis of esters containing a particular type of fatty acid is unusual. Several other lipases (e.g., the lipase derived from *Candida cylindracae*) are nonspecific with respect to either the chemical structure of the fatty acid moiety, or the position of the ester bond, that is hydrolyzed; these lipases catalyze the complete breakdown of triglycerides into glycerol and free fatty acids, and the mono- and diglycerides that are intermediates in the reaction do not normally accumulate (Refs. 2 and 4).

The largest group of triacylglycerol lipases exhibits specificity with respect to the position of the ester bond that is cleaved, i.e., only bonds at the 1- or 3-position of the glycerol component are hydrolyzed. Most of the lipases that are commonly used in food processing (e.g., animal lipase, esterase-lipase from *Mucor miehei*, and lipases derived from *Aspergillus niger*, *M. javanicus*, and *R. delemar*), including the *R. niveus*-derived lipase that is the subject of this document, belong to this group (EC No. 3.1.1.3; CAS Reg. No. 9001–62–1) (Refs. 2, 4, and 11).

Although the petitioner did not address the detailed molecular structure of lipase from *R. niveus*, most lipases that have been characterized at the

molecular level are glycoproteins that contain between 2 and 15 percent carbohydrates, with mannose as the major glycoside (Ref. 4). Lipases from animal and microbial sources have a long history of use in food. Animal lipase (21 CFR 184.1415) is affirmed as GRAS based on its common use in food prior to January 1, 1958. Esterase-lipase from the fungus *M. miehei* (21 CFR 173.140) is approved for use as a food additive. These enzymes are commonly used to enhance flavor production in cheese and in butterfat (Refs. 1, 12, and 13). In addition, lipases from animal sources (e.g., bovine stomach and hog or porcine pancreas) and microbial sources (including *R. arrhizus*, *R. delemar*, and *R. niveus*) have been listed in the Codex Alimentarius Commission ''Inventory of Processing Aids'' (Ref. 14).

The reaction product of the *R. niveus*-derived lipase is a mixture of mono- and diglycerides and free fatty acids (Refs. 2 through 5). The reaction catalyzed by this lipase is reversible and, therefore, under appropriate conditions the enzyme can catalyze the synthesis of triglycerides from a mixture of glycerides and free fatty acids. When this combination of hydrolysis and synthesis occurs within a mixture of triglycerides, or within a mixture of triglycerides and fatty acid esters, the reaction products are triglycerides that have been interesterified, i.e., triglycerides in which the fatty acid components have been exchanged between triglyceride molecules or between triglyceride molecules and fatty acid esters (Refs. 1 through 5). For example, the GRAS food ingredient ''cocoa butter substitute primarily from palm oil'' may be manufactured by the lipase-catalyzed interesterification of partially saturated palm oil-derived triglycerides with the fatty acid ester ethyl stearate (21 CFR 184.1259).

Interesterification also can be achieved through the use of chemical catalysts such as sodium methylate. Such chemical catalysis results in random interesterification, in which fatty acid interchange occurs at all three positions on the glycerol backbone. In contrast, enzymatic catalysis with a lipase, such as the lipase that is the subject of this document, results in selective interesterification at the 1- and 3-positions only. Random interesterification is used commercially in the manufacture of margarines and shortenings, but lipase-catalyzed selective interesterification, which allows an unsaturated fatty acid to remain at the 2-position, is important in the manufacture of fats and oils used in confectionery, such as cocoa butter substitute primarily from palm oil (Refs. 2 through 4). The petitioner stated that one of the primary uses of *R. niveus*-derived lipase enzyme preparation would be in the manufacture of cocoa butter substitute primarily from palm oil.

In general, issues relevant to a safety evaluation of proteins such as the enzyme component of an enzyme preparation are potential toxicity and allergenicity (Ref. 15). Pariza and Foster (Ref. 15) note that very few toxic agents have enzymatic properties, and those that do (e.g., diphtheria toxin and certain enzymes in the venom of poisonous snakes) catalyze unusual reactions that are not related to the reactions catalyzed by enzymes that are commonly used in food processing, such as the lipase that is the subject of this document. Further, the agency has recently noted, in the context of guidance to industry regarding the safety assessment of new plant varieties, that enzymes themselves do not generally raise safety concerns (57 FR 22984 at 23005, May 29, 1992). Exceptions include enzymes that produce substances that are not ordinarily digested and metabolized, or that produce toxic substances.

The catalytic activities of the lipase that is the subject of this document are well known. As already discussed, lipase catalyzes two related reactions: (1) The splitting of commonly consumed triglycerides into smaller components, i.e., fatty acids and mono- and diglycerides; and (2) the synthesis of triglycerides from fatty acids and mono- and diglycerides. The reaction products (i.e., fatty acids, mono- and diglycerides, and triglycerides) from both of these reactions are readily metabolized by the human body and do not have toxic properties (Ref. 16).

The agency is not aware of any reports of allergic reactions associated with the ingestion of enzymes derived from *Rhizopus* species. There have been, however, some reports of allergies and primary irritations from skin contact with enzymes or from inhalation of dust from concentrated enzymes (e.g., proteases used in the manufacture of laundry detergents) (Refs. 17 through 19). These reports relate primarily to workers in production plants (Ref. 18) and are not relevant to an evaluation of the safety of ingestion of such enzymes in food. Moreover, Pariza and Foster (Ref. 15) note that there are no confirmed reports of primary irritations in consumers caused by residues of food processing enzymes in food.

FDA concludes that generally available and accepted data and information establish that the use of lipase in food raises no toxicity or allergenicity concerns. FDA also concludes that generally available and accepted data and information establish that the lipase that is the subject of this document is capable of achieving its intended technical effect. Finally, FDA concludes that generally available and accepted data and information establish that the lipase that is the subject of this document is similar in function to other lipases that are used in food processing to catalyze the hydrolysis of ester bonds at the 1- or 3-position of the glycerol component of a triglyceride.

C. Enzyme Source, Manufacturing Methods, and Processing Aids

The source of the lipase that is the subject of this document is the fungus *R. niveus*. Fungally-derived enzyme preparations used in food processing are usually not chemically pure but contain, in addition to the enzyme component, other components that derive from the production organism and the fermentation media, residual amounts of processing aids, and substances used as stabilizers, preservatives or diluents. The petitioned enzyme preparation meets the general requirements and additional requirements for enzyme preparations in the monograph on Enzyme Preparations in the Food Chemicals Codex, 4th ed. (Ref. 20). When the *R. niveus*-derived lipase enzyme preparation is produced in accordance with current good manufacturing practice (CGMP), it is produced using processing aids that are substances that are acceptable for general use in foods and under culture conditions that ensure a controlled fermentation, thus preventing the introduction of extraneous microorganisms that could be the source of toxic materials and other toxic substances (Ref. 20).

The lipase enzyme preparation is produced in a multistage process by controlled fermentation[1] using a pure culture of the fungus *R. niveus* followed by isolation of the enzyme-containing fraction. Prior to its use in the interesterification of fats and oils, the enzyme-containing fraction is adsorbed onto diatomaceous earth as a carrier. These methods are based upon generally available and accepted methods used for fermentation, for processing fermentation-derived enzyme-containing fractions, and for immobilizing an enzyme-containing fraction on an insoluble carrier (Refs. 4 and 7 through 10).

[1] The stage of the manufacturing process in which the enzyme is being produced by an actively growing culture of microorganisms is referred to as fermentation.

In the initial stage of the fermentation process, the seed cultures of *R. niveus* are checked for purity and classification after growth on a potato-agar medium. The production cultures are suspended in sterile water and added to a previously autoclaved wheat bran culture medium. After growth for 28 to 32 hours, the broth is checked for quality and added to large batch-fermentors containing sterilized growth medium (semisolid wheat bran). The culture is monitored until the water content and pH value of the resulting malt, which is referred to as the ''koji,'' reach standard requirements.

A cell-free extract of the enzymes that are components of the fermentation mixture is prepared by sprinkling and steeping the koji with cold water, filtering the extracted koji through a filter press and a fine filtration apparatus, and precipitating the enzymes that are present in the resulting filtrate with ethanol. After decanting the supernatant and centrifuging the remaining slurry, the sediment containing the extracted enzymes is collected and dried overnight in a vacuum-dryer at 40 to 45 °C. The dried powder is ground, sized, and mixed before storing at room temperature. The finished product is adjusted to a standard activity by mixing the enzyme powder with dextrin as an excipient. The standardized enzyme powder is adsorbed onto diatomaceous earth carrier prior to its use in the interesterification of fats or oils. The petitioner provided a published scientific review article that discusses this immobilization technique with respect to use of lipase enzyme preparations (Ref. 4).

The production strain of *R. niveus* that is the source of the lipase enzyme is nontoxigenic and nonpathogenic. The manufacturing methods completely remove the organism from the enzyme-containing fraction (Ref. 4). Moreover, the petitioner provided documentation, based upon published methods for strain identification (Ref. 6), showing that the production strain was taxonomically identical to the strain used for the production of *R. niveus*-derived amyloglucosidase enzyme preparation, which is approved for use as a secondary direct food additive (21 CFR 173.110).

FDA concludes that the presence of added substances and impurities that are derived from the enzyme source or that are introduced by manufacturing does not present a basis for concern about the safety of the lipase enzyme preparation.

D. Dietary Exposure

FDA considered the estimated dietary exposure to lipase enzyme preparation for the proposed use as an enzymatic catalyst in the interesterification of fats and oils (Refs. 21 through 23). The predominant source of potential exposure to the total organic solids in the enzyme preparation will be baked goods that use interesterified fat at levels up to 30 percent. The petitioner stated that the standardized enzyme powder is adsorbed onto diatomaceous earth carrier prior to its use in the interesterification of fats or oils, so that it can be removed from the modified triglyceride following the enzyme-catalyzed interesterification. Because the adsorbed enzyme preparation is removed from the interesterified product following catalysis, no detectable enzyme remains in the interesterified product.

FDA concludes that dietary exposure to the lipase enzyme preparation is negligible and therefore does not present a basis for concern about use of the lipase enzyme preparation.

IV. Specifications

The agency finds that, because the potential impurities in the lipase enzyme preparation that may originate from the source or manufacturing process do not raise any basis for concern about the safe use of the preparation, the general requirements and additional requirements for enzyme preparations in the monograph on Enzyme Preparations in the Food Chemicals Codex, 4th ed. (1996), which are being incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, are adequate as minimum criteria for food-grade lipase enzyme preparation. Lipase assay can be performed using a method entitled ''Lipase Activity'' (Ref. 24) or by using any appropriate validated method.

V. Conclusions

The agency has evaluated all available information and finds, based upon the published information about the identity and function of lipase, that the enzyme component of lipase enzyme preparation will achieve its intended technical effect and raises no toxicity or allergenicity concerns. In addition, the agency finds, based upon the published information about the identity and function of lipase, that the enzyme component of the lipase enzyme preparation is similar in function to other lipases that are used in food processing to catalyze the hydrolysis of ester bonds at the 1- or 3-position of the glycerol component of a triglyceride. The agency further finds, based upon generally available and accepted information, that when the lipase enzyme preparation is manufactured in accordance with § 184.1420, the source, *R. niveus*, and the manufacturing process will not introduce impurities into the preparation that may render its use unsafe. Finally, the agency finds that dietary exposure to the lipase enzyme preparation from the petitioned use does not present a basis for concern about use of the lipase enzyme preparation. Therefore, the agency concludes, based upon the evaluation of published data and information, corroborated by unpublished data and information, and based upon scientific procedures (§ 170.30(b)), that the lipase enzyme preparation described in the regulation set out below is GRAS for use as an enzymatic catalyst in the interesterification of fats and oils.

VI. Environmental Considerations

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

VII. Analysis For Executive Order 12866

FDA has examined the impacts of this final rule under Executive Order 12866. Executive Order 12866 directs Federal agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). According to Executive Order 12866, a regulatory action is significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million, adversely affecting in a material way a sector of the economy, competition, or jobs, or if it raises novel legal or policy issues. FDA finds that this final rule is not a significant regulatory action as defined by Executive Order 12866. In addition, the agency has determined that this final rule is not a major rule for the purpose of Congressional review.

The primary benefit of this action is to remove uncertainty about the regulatory status of the petitioned

substance. No compliance costs are associated with this final rule because no new activity is required and no current or future activity is prohibited by this rule.

VIII. Regulatory Flexibility Analysis

FDA has examined the impacts of this final rule under the Regulatory Flexibility Act. The Regulatory Flexibility Act (5 U.S.C. 601–612) requires Federal agencies to consider alternatives that would minimize the economic impact of their regulations on small entities. No compliance costs are associated with this final rule because no new activity is required and no current or future activity is prohibited. Accordingly, under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

IX. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Scott, D., ''Enzymes, Industrial,'' Encyclopedia of Chemical Technology, edited by Mark, H. F. et al., John Wiley and Sons, New York, 3d ed., 9:173–224, 1978.

2. MacRae, A. R., ''Lipase-Catalyzed Interesterification of Fats and Oils,'' *Journal of the American Oil Chemists Society*, 60:291–294, 1983.

3. Ratledge, C., ''Biotechnology as Applied to the Oils and Fats Industry,'' *Fette Seifen Anstrichmittel*, 86:379–389, 1984.

4. MacRae, A. R., and R. C. Hammond, ''Present and Future Applications of Lipases,'' *Biotechnology and Genetic Engineering Reviews*, 3:193–217, 1985.

5. IUB, ''Enzyme Nomenclature 1992,'' Academic Press, New York, p. 307, 1992.

6. Inui, T., Y. Takeda, and H. Iizuka, ''Taxonomical Studies on Genus *Rhizopus*,'' *Journal of General and Applied Microbiology*, 11:1–121, 1965.

7. Beckhorn, E. J., M. D. Labee, and L. A. Underkofler, ''Production and Use of Microbial Enzymes for Food Processing,'' *Journal of Agricultural and Food Chemistry*, 13:30–34, 1965.

8. Underkofler, L. A., R. R. Barton, and S. S. Rennet, ''Microbiological Process Report—Production of Microbial Enzymes and Their Applications,'' *Applied Microbiology*, 6:212–221, 1958.

9. Chibata, Ichiro, ed., Immobilized Enzymes—Research and Development, John Wiley and Sons, New York, 1978.

10. Chaplin, M. F., and C. Bucke, Enzyme Technology, Cambridge University Press, New York, 1990.

11. Shahani, K. M., ''Lipases and Esterases,'' Enzymes in Food Processing, edited by Reed, G., Academic Press, New York, 2d ed., pp. 208–214, 1975.

12. Reed, G., ''Industrial Enzymes-Now Speed Natural Processes,'' *Food Engineering*, 24:105–109, 1952.

13. De Becze, G. I., ''Food Enzymes,'' *Critical Reviews in Food Technology*, 1:479–518, 1970.

14. Codex Alimentarius, Joint FAO/WHO Food Standards Programme, Food and Agriculture Organization of the United Nations/World Health Organization, Rome, vol. 1, 2d ed., 1992.

15. Pariza, M. W., and E. M. Foster, ''Determining the Safety of Enzymes Used in Food Processing,'' *Journal of Food Protection*, 46:453–468, 1983.

16. Shils, M. E., J. A. Olson and M. Shike, eds., Modern Nutrition in Health and Disease, Lea & Febiger, Philadelphia, 8th ed., pp. 51–57, 1994.

17. ''Evaluation of the Health Aspects of Papain as a Food Ingredient,'' Select Committee on GRAS Substances, Washington, DC, available through U.S. Department of Commerce, National Technical Information Service, Order No. PB–274–174, 1977.

18. Fulwiler, R. D., ''Detergent Enzymes—An Industrial Hygiene Challenge,'' *American Industrial Hygiene Association Journal*, 32:73–81, 1971.

19. ''Enzyme-containing Laundering Compounds and Consumer Health,'' National Research Council/National Academy of Sciences, National Technical Information Service, Washington, DC, Order No. PB–204–118, 1971.

20. Monograph on ''Enzyme Preparations,'' Food Chemicals Codex, National Academy Press, Washington, DC, 4th ed., pp. 131 and 133–134, 1996.

21. Memorandum dated October 21, 1988, from Food and Color Additives Review Section, FDA, to Direct Additives Branch, FDA, ''Lipase/Protease Enzyme Preparation Derived from *Rhizopus niveus*.''

22. Memorandum dated March 8, 1989, from Food and Color Additives Review Section, FDA, to Direct Additives Branch, FDA, ''Lipase-Protease Enzyme Preparation from *Rhizopus niveus*.''

23. Memorandum dated April 3, 1990, from Food and Color Additives Review Section, FDA, to Direct Additives Branch, FDA, ''Lipase/Protease Enzyme Preparation from *Rhizopus niveus*. Refinement of Estimated Daily Intake (EDI). Submission of 3–6–90.''

24. Monograph on ''Enzyme Preparations,'' Food Chemicals Codex, National Academy Press, Washington, DC, 4th ed., p. 803, 1996.

List of Subjects in 21 CFR Part 184

Food additives, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, and redelegated to the Director, Center for Food Safety and Applied Nutrition, part 184 is amended as follows:

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

1. The authority citation for 21 CFR part 184 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 371.

2. Section 184.1420 is added to subpart B to read as follows:

§ 184.1420 Lipase enzyme preparation derived from Rhizopus niveus.

(a) Lipase enzyme preparation contains lipase enzyme (CAS Reg. No. 9001–62–1), which is obtained from the culture filtrate resulting from a pure culture fermentation of a nonpathogenic and nontoxigenic strain of *Rhizopus niveus*. The enzyme preparation also contains diatomaceous earth as a carrier. The characterizing activity of the enzyme, which catalyzes the interesterification of fats and oils at the 1- and 3-positions of triglycerides, is triacylglycerol lipase (EC 3.1.1.3).

(b) The ingredient meets the general requirements and additional requirements for enzyme preparations in the monograph on Enzyme Preparations in the ''Food Chemicals Codex,'' 4th ed. (1996), pp. 133 and 134, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme as defined in § 170.3(o)(9) of this chapter for the interesterification of fats and oils.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

Dated: April 14, 1998.

L. Robert Lake,

Director, Office of Policy, Planning and Strategic Initiatives, Center for Food Safety and Applied Nutrition.

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