GR

ORIGINAL SUBMISSION

GRAS Exemption Notification

PGPR
Polyglycerol polyricinoleic acid for Use in Margarines, Low Fat Margarines, Spreads, Creamers and Dairy Analogs

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OFFICE OF
FOOD ADDITIVE SAFETY

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PROPOSED

GRAS Notice

GRN No.	Notifier	Substance	INTENDED USE	GRP #	*BASIS*	*Date* of Filing	*Closure*
	Stepan Company	Polyglycerol polyricinoleic acid	As an emulsifier in the production of margarines, low fat margarines, spreads, creamers, and dairy analogs at levels no greater than 1.0%.		Scientific procedures	***July* 19,** 2005	

Stepan

Stepan Company

Northfield, Illinois 60093
Telephone 847 446 7500

Office of Premarket Approval (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

Dear Sir or Madam:

SUBJECT: GRAS Notification – Exemption Claim for Polyglycerol polyricinoleic acid

In accordance with FDA proposed rule of April 17, 1997 (62 FR 18938), relating to the filing of a generally recognized as safe (GRAS) notification, we hereby claim that the use of Polyglycerol polyricinoleic acid as an emulsifier in the production of margarines, low fat margarines, spreads, creamers, and dairy analogs is generally recognized as safe and exempt from premarket approval requirements of the Federal Food, Drug, and Cosmetic Act. In conformity with the requirements outlined in the proposed rule, the following information is included (*in triplicate*) with this exemption claim.

GRAS EXEMPTION CLAIM

We hereby claim that the use of Polyglycerol polyricinoleic acid as an emulsifier in the production of margarines, low fat margarines, spreads, creamers, and dairy analogs is exempt from the premarket notification requirements of the Federal Food, Drug, and Cosmetic Act because of determination that such use of Polyglycerol polyricinoleic acid is generally recognized as safe.

(1) Identification of the notifier:

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(2) Common or usual name of the substance:

Polyglycerol polyricinoleic acid

(3) Applicable conditions of use:

(a) Foods in which the substance is to be used:

Polyglycerol polyricinoleic acid is intended to be used in the production of margarines, low fat margarines, spreads, creamers, and dairy analogs.

(c) Purposes for which the substance is used:

Polyglycerol polyricinoleic acid as an emulsifier.

(d) Description of the population expected to consume the substance:

Polyglycerol polyricinoleic acid is expected to be used by the general public.

(4) Basis for GRAS determination, i.e., through experience based on common use in food (pre-1958) or through scientific procedures:

The basis of the GRAS determination is through scientific procedures.

(5) Availability of Data and Information (references)

The referenced material that is the basis for this GRAS determination are available for the Food and Drug Administration's review and copying at reasonable times at the Product Safety and Compliance Department of Stepan Company, 22 Frontage Road, Northfield, IL 60093, or will be sent to FDA upon request.

Stepan Company

ATTACHMENT No. 1

Identity of the Substance

A. Chemical Name:

9-octadecenoic acid, 12-hydroxy-, (9Z, 12R)-, polymer with 1,2,3-propanetriol (9CI)
CAS Registry No. 29894-35-7

B. Common Name:

Polyglycerol polyricinoleic acid

C. Trade Name:

DREWPOL® PGPR

D. Other Names:

Polyglycerol esters of interesterified ricinolic acid
Polyglyercol polyricinoleate

E. Definition:

Polyglycerol Polyricinoleic Acid occurs as a clear, light brown, viscous liquid. It is prepared by esterification of polyglycerol with condensed castor oil fatty acids. The castor oil fatty acids are mainly composed of 80% to 90% ricinoleic acid. It is soluble in ether, in hydrocarbons, and in halogenated hydrocarbons. It is insoluble in water and in alcohol.

F. Assay:

Food Chemical Codex, Fifth Edition, page 344, Specifications

G. Description:

Clear light brown viscous liquid

H. Identification Test:

Food Chemical Codex, Fifth Edition, page 344, Identification, Fatty Acids, and Ricinoleic acid.

I. Purity:
Food Chemical Codex, Fifth Edition, page 344, Specifications

Manufacture, Specifications, and Stability

Polyglycerol polyricinoleic acid, PGPR, has been reported in several scientific articles and a previous GRAS Notification, #0009, for use as a rheology modification agent in molten chocolate mass. PGPR is defined as an interesterified polymer of polyricinoleic acid and polyglycerol.

Polyglycerol polyricinoleic acid is a polymer created by the self-condensation of the 12-hydroxy, 9-octadecenoic acid fraction within the fatty acids obtained from castor oil. The condensation reaction is typically carried out by heating castor oil fatty acids to about 200°C, with or without catalyst, and removing water of reaction. Acceptable catalysts are those known in the art and include acids such as phosphoric acid, bases such as sodium hydroxide and lipase enzymes; all of which are currently used to interesterify food grade fats and oils.

Polyglycerol is obtained either by the controlled polymerization of substituted propyl-1, 2-oxirane, or through the direct condensation of glycerin under highly basic conditions.

A full description of PGPR is given in the Fifth Edition of the Food Chemical Codex (FCC), published by the Institute of Medicine. Specifications and all analytical chemistry associated with this food additive are included in this reference text. The FCC monograph, "Polyglycerol polyricinoleic acid" is incorporated by reference with this submission.

Stability tests of physical and chemical parameters were performed between 1986 to 1988 over a 32-month period. This was reported in GRN #0009. The substance was held at a constant temperature of 15°C in a 200 kg drum. No significant change was observed. The stability of Polyglycerol polyricinoleic acid is shown to be excellent.

Use Information

Anticipated Uses in Margarine and Low Fat Spreads

Margarine came into existence as a low cost butter substitute but by the 1960's was considered a more healthy spread due to the absence of cholesterol and the incorporation of polyunsaturated fats. In recent years, the level of saturated fat and most recently the levels of trans fatty acids in margarines have become issues of concern. The consumption of stick margarine, requiring 80%+ fat, has been on a constant decline through the 1980's and today low fat spreads are finding favor among health-conscious consumers. This trend is expected to continue and today the per capita consumption of margarine and low fat spreads is on the order of about 10 pounds per year.

Helping consumers reduce fat in their diet while providing aesthetically pleasing consumables is of paramount importance. On the whole, consumers tend to avoid unpleasing foods regardless of the health benefit the food may provide. PGPR has been found to be an effective water-in-oil emulsifier, which when incorporated with Lecithin in low fat spreads allows for a greater reduction in overall fat content and enhances the pleasing characteristic – creaminess and low splatter when used to fry foods.[2] This is of paramount importance in low fat spreads where the fat content approaches 40% of the composition; PGPR is an essential emulsifier in the effort to reduce dietary fat.

Lecithin is the primary emulsifier used in spreads. It is reported to prevent syneresis, improve browning of fried food, and improve the shortening of baked goods. Lecithin will function successfully in classic high fat margarine, but when formulated to reduce the fat, lecithin alone cannot build a sufficient interfacial network to stabilize the emulsion system. Classically, solid fat crystals found in plastic and partially hardened fat contribute to stability in margarine emulsions. The solid fat crystals combine with the lecithin at the water/oil interface forming a structured network and aggregate within the continuous phase of the emulsion extending the network; this combination of emulsifier and particulate contributes to both rheological characteristics and emulsion stability.[14] In an effort to reduce saturated fat and especially trans fat in low fat spreads, there is not enough volume of fat crystals to build a network sufficiently strong to prevent coalescence of the water droplets by lecithin alone. The higher water content requires greater packing of the water droplets and reduces the void volume of the continuous phase. The end consequence is that lecithin alone cannot prevent ice formation, cannot impart enough microstructure to maintain rheological characteristics and cannot prevent agglomeration of what limited fat crystals exist in the low fat compositions. What the consumer sees is a hard (difficult to spread), grainy product that is prone to splatter when frying.

To overcome the difficulties associated with making low fat spreads, several emulsifiers have been employed individually and in combination with lecithin. The α-form fat crystals that develop in margarine and low fat spreads can only stabilize water-in-oil emulsions in the presence of food emulsifiers. In addition to lecithin, any of the food-grade emulsifiers in the ester class will function to greater or lesser degree provided the quantity of fat crystals is sufficient to fill the interfacial regions and the emulsifier is capable of forming vesicle structures. Food emulsifiers of this class are partial esters of polyols; sorbitol, glycerol or polyglycerol. Whereas sorbitan esters and mono- and diglycerides require four to six percent of the continuous phase to achieve multilamellar vesicles, polyglycerol esters form an α-crystalline gel just above the Critical Micelle Concentration (< 1.0%). Significantly less emulsifier is necessary for the formulation when polyglycerol esters are used and there exists a synergism between polyglycerol esters and lecithin; the swelling behavior of diacyl phosphatidyl choline is equivalent to monoesters of diglycerol.[23]

Polyglycerol esters by their very nature are excellent emulsifiers for forming structured emulsions and spontaneously form vesicles when used in emulsion systems. They have been shown to be superior to other esters in building microstructure in food emulsion systems. Garti, Binyamin and Aserin demonstrated the superior characteristics of PGPR in stabilizing mixed emulsions with liquid and solid-dispersed phases in a vegetable oil continuous phase.[10] They concluded that PGPR, "was very helpful in decreasing the aggregation and flocculation process," for both the solid particles and the liquid droplets in food emulsions. This characteristic is beneficial for low fat spreads.

It is the dual polymeric structure of PGPR that makes it so efficient. The elongated hydrophobic tail gives this material greater reach in colloidal interactions.[9] The dual polymeric structure of PGPR bridges the voids in the continuous phase distribution of solid particles, something other esters cannot do. At the same time, the higher molecular weight ensures greater interfacial stability at the water oil interface because interfacial concentration is maximized by a significant increase if adsorption energy.[12] Emulsion systems tend to be stabilized by forces that lead to a visco-elastic gel structures; i.e. rheological characteristics that are a combination of viscous forces and elastic forces. By balancing viscosity and elasticity, a plastic fat can be developed which is thick enough, viscous, to remain stable on the shelf while at the same time elastic enough to prevent phase separation. If viscosity is too high the fat will not provide a pleasing spread. If viscosity is too low the fat becomes an unpleasing liquid. However, thin emulsions tend to destabilize so elastic character is critical to maintaining at rest stability. If the elastic character is too low, the emulsion system will phase separate in too rapid a time; unstable.

If elastic character is too high, the fat will be too brittle and again not pleasing to spread. In low fat spreads, the total volume of the continuous phase is limited by the greater reach of PGPR, when compared to all other emulsifiers, distributes the solid fat particles more evenly and this greater reach allows for greater elasticity. The formulation can therefore be thinner, a more pleasing spread, yet is capable to maintaining shelf stability because of its improved elastic characteristics.

The consequence of the characteristics found for PGPR is greater emulsion stability, improved spreadability without hardening and the reduction of splatter in frying as observed by Anon[2]. In our effort to reduce dietary fat and especially trans fat, PGPR has the functional characteristics necessary for the production of healthy spreads. It should be approved for use in margarines, low fat margarines, spreads, creamers and dairy analogs in combination with Lecithin up to and including 10% of the oil phase (0.4 – 0.8% as a function of total weight of the formulation).

Polyglycerol Esters in Margarine and Spreads

Polyglycerol esters are unique among food-grade emulsifiers because under current approval [21CFR172.854] the potential number of different compositions exceeds options available to any other class of food emulsifiers. As a class, polyglycerol esters, can be prepared across a broad range of HLB values; thus, being capable of utility as both hydrophilic and hydrophobic emulsifiers. As a class, polyglycerol emulsifiers find use in: batter, both leavened and unleavened dough; dessert fillings and toppings; anti-splatter agents for oils, margarines and spreads; emulsifiers for creamers and dairy products to name but a few applications.

Margarines and spreads are generally prepared following the following sequence:

1. Preparing the liquid fat phase.
    a. Completed in the melt and incorporating both solid and liquid fats.
    b. Adding the lipophilic emulsifiers
2. Preparing the water phase
    a. Combining water, milk & milk solids
    b. Adding flavors and stabilizers
    c. Adding the hydrophilic emulsifiers
    d. Pasteurizing
3. Preparing the emulsion
    a. With agitation slowly adding the water phase to the fat phase
4. Chilling under agitation
5. Crystallization and further agitation; churning
6. Packaging and tempering

Typical low fat spreads are formulated using 40 to 75% fat on a weight-to-weight basis. Where as margarine with 80% fat and higher typically uses the lecithin and milk protein as the emulsifier package. Spreads being lower in fat usually avoid milk protein because it lacks efficiency in promoting water-in-oil emulsions. At the higher levels of water in spreads, emulsion stability is more difficult to achieve. Phase inversion and therefore emulsion instability, especially during freeze thaw cycles is prevalent when milk protein is present in spreads. Emulsifier systems for spreads usually rely on a package of lecithin and mono & diglycerides to provide the base emulsification power. Polyglycerol esters add anti-splatter capability and improve water binding to the oil phase; improving stability and allowing for increased water levels. PGPR is the most efficient polyglycerol ester found for this application because of its exceptionally low HLB.

Lecithin in spreads is usually used at a level of 0.1 - .02% to achieve stability of the cold emulsion. Lecithin contributes to emulsion instability in the melt; allowing for quicker oil release in frying applications and quicker flavor release in the mouth. A combination of 0.4 – 0.6% mono & diester with 0.1 – 0.3% polyglycerol ester in a spread formulation has been found to synergistically increase stability; reducing the chances of weeping at room temperature. The ideal hard fat must be of a β' crystalline form; any tendency to form β crystals leads to grainy appearance. PGPR, because of its unique ability to separate crystals at greater colloidal distances than other emulsifiers, is ideal at providing inhibition to crystal growth. When crystals are isolated during the cooling process the bulk liquid phase has a greater capacity to dissipate heat; leading to a retardation of β crystal formation and helping to promote β' crystalline form. Polyglycerols have been used in this way in many fat applications and PGPR is simply more efficient due to the polymeric nature of the hydrophobic tail.

As the level of fat decreases in a spread formulation, more and more surface area is produced by the increased volume of the water, discontinuous phase. As a consequence, greater levels of emulsifier are required to cover the surfaces to achieve satisfactory stability. A spread with 75% oil phase will typically require 0.5% mono & diglycerides with 0.2% PGPR to achieve the ideal emulsion stability where as a spread with 45% oil will require 1.5% mono & diglycerides and 0.6% PGPR; the typical US formulation usually falls between these levels. In addition, PGPR is well known for its ability to affect rheology and spreadability, i.e. its current common use in coco powder dispersions. For this reason, it also has a place in margarine formulations where the addition of 0.2 to 0.4% can improve the spreadability of margarine. The current practice is to use saturated or trans fats to control the plastic nature of margarine. Margarines are predominantly stabilized by the presence of fine solid fat crystals dispersed along the water / liquid fat interface. Incorporation of small amounts of PGPR spaces out these fine crystals in the liquid fat matrix, allowing for a reduction in total solid fat without sacrifice of emulsion stability. Both spreadability and elasticity improve making the margarine with lower solid and trans fat more palatable and pleasing to the consumer.

To some extent other polyglycerol esters will achieve some of the technological advantages of PGPR but on the whole PGPR is superior for use in margarines and low fat spreads. At a time where reducing saturated and trans fats in the diet is critical, PGPR approved for use in margarines and spreads will allow the manufactures of these products to incorporate more water into their formulations without sacrifice of quality from the prospective of the consumer. If the consumer sees equivalent quality and taste with the lower fat product we believe they will opt for that product, as it is perceived as healthier. If the healthier product is perceived as having lesser quality we believe the consumer will opt for the less healthy product. For these reasons, we believe PGPR should be approved for use in margarines, low fat margarines, spreads, creamers and diary analogs.

Safety Evaluation

Stepan Company has made the determination that Polyglycerol polyricinoleic acid is Generally Recognized As Safe as an emulsifier in the production of margarines, low fat margarines, spreads, creamers and dairy analogs at levels no greater than 1% by weight. This determination was based upon scientific procedure following review of the information on the manufacture, applications, exposure, animal toxicology and metabolism, and human use experience.

Previously, Polyglycerol polyricinoleic acid has been determined as GRAS as an emulsifier in chocolate and the information relating to that GRAS determination was submitted to the US Food and Drug Administration as GRAS Notification #0009, Quest International, which was reviewed by the agency (Closure Date: March 2, 1999).

Polyglycerol polyricinoleic acid is described in Food Chemical Codex, Fifth Edition, which also describes methods of preparation and specifications for the Polyglycerol polyricinoleic acid.

The product as prepared by Stepan Company is consistent with the manufacture and specifications as established in the Food Chemical Codex.

Polyglycerol polyricinoleic acid has been recognized as an effective emulsifier which forms stable emulsions. The stability of the emulsions permits water and oil emulsions with high ratios of water to fat.

Estimated Daily Intake (EDI)

Polyglycerol polyricinoleic acid previously has been determined to be GRAS in chocolates at levels up to 0.3% (GRN #0009).

Polyglycerol polyricinoleic acid is effective in the type of products for this notification at approximately 0.4%.

Use of Polyglycerol polyricinoleic acid at levels greatly exceeding 0.4% would not be technologically required or economically feasible. Therefore, this GRAS notification suggests a maximum use level of 1.0% for the use in low fat spreads and related products. The use concentration is self-limiting.

Polyglycerol polyricinoleic acid has been reviewed by the Joint Experts Committee on Food Additives with information and conclusions presented in the 17th Report of the Joint FAO/WHO Expert Committee on Food Additives, World Health Organization, Technical Report Series 1974, No. 539, and the FAO Nutrition Meetings Report Series 1974, No. 53.

With respect to the evaluation of EDI in the GRAS Notification submitted for use of Polyglycerol polyricinoleic acid in chocolate, the maximum intake estimates were for persons 12-19 years of age, the 90th percentile intake for these persons was 112 grams of chocolate per estimated 60 kg person. The EDI for the previous GRAS Notification for Polyglycerol polyricinoleic acid was calculated to be 4.7 mg/kg/day for the 90th percentile of consumers or for average consumers a value of 2.4 mg/kg/day.

There was higher consumption of chocolate on a weight basis by infants in the 1-2 years of age group, however, it is expected that for low fat spreads and other foods that are the subject of this GRAS Notification there is not expected to be significant consumption by infants or children under 5 years of age.

The United States Department of Agriculture, Economic Research Service Market and Trade Economics Division, has published the Intake Values for Fats and Oils in Domestic Consumption in Food Products for the Years 1980-1999. In this report, the consumption of butter has been relatively static with consumption in the last report period being 4.8 pounds/person/year (2.2 kg/person/year). The intake for margarine has been reduced during the period 1980-1999, to the current estimate of 8.1 pounds/person/year (3.7 kg/person/year). It is estimated that the average consumption for all food types under the subject of this GRAS Notification to be approximately 13 pounds/person/year (5.9 kg/person/year, or 16grams/person/day).

This consumption would calculate to be approximately 270 mg/kg/day of food products containing Polyglycerol polyricinoleic acid. Using a maximum concentration of 1% addition to these foods, the EDI for additional Polyglycerol polyricinoleic acid would be 2.7 mg/kg/day.

Therefore, the use level when added to the average calculated intake of Polyglycerol polyricinoleic acid from chocolate use in the critical age group of 12 to 19 years of age would be 2.4 mg/kg to give a estimated Cumulative Estimated Daily Intake of consumption including the uses in this GRAS Notification of 5.2 mg/kg/body weight. (2.4 + 2.7 mg/kg).

If one assumes the 90th percentile of intake of Polyglycerol polyricinoleic acid from the highest chocolate consumers in the 12-19 years of age (4.7 mg/kg) plus the expected average intake of Polyglycerol polyricinoleic acid from this GRAS Notification, the cumulative daily intake would be 7.5 mg/kg/body weight, i.e., equivalent to the ADI for the substance.

The estimates as made are assumed to be greatly in excess of those ever likely to be actually achieved.

Average Daily Intake (ADI)

The International Acceptable Daily Intake for Polyglycerol polyricinoleic acid is 7.5 mg/kg/day, based upon the review of the toxicological data. The information on Polyglycerol polyricinoleic acid which was considered by JECFA included toxicological studies in non-rodent species, acute, subchronic, and chronic. There has been publication of the results of the toxicological studies conducted with the substance, as well as publication of safety reviews. These publications are listed in attachment 5 of this notification.

Carcinogenicity for the life-time of rats has been conducted including introduction of three generation studies, metabolic fate studies in rats, mice, and humans. There were no-effects observed in dietary exposures of up to 2% in the feeding studies and the no-effect level in the reproduction study was 1.5%, the only level tested.

It was the reproduction study that resulted in the no-effect level of 1.5% equivalent to 750 mg/kg/day, thus, establishing the ADI of 7.5 mg/kg/day. This ADI has been accepted by international regulatory authorities since 1974.

Conclusion

Stepan Company, after critical review and analysis of the available information on Polyglycerol polyricinoleic acid has concluded that the body of data supports their proposed use of Polyglycerol polyricinoleic acid.

ATTACHMENT No. 5

Bibliography

Safety Data / Biological Studies Summaries

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Submission End