Food Contact Substance Notification No. 732

ENVIRONMENTAL ASSESSMENT

1. Date: May 31, 2007

2. Name of Notifier:
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4. Description of Proposed Action

The action requested in this Notification is the establishment of a clearance for the food-contact substance (FCS), poly(alkyl methacrylate). Specifically, the notification seeks to clear poly(alkyl methacrylates) made from one or more C_{12}-C_{18} alkyl methacrylates (where the alkyl groups may be branched or linear and may be even- or odd-numbered in chain length), polymerized alone or in combination with alkyl methacrylate monomers permitted as reactants for poly(alkylmethacrylates) under 21 C.F.R. § 172.886(c)(2). The poly(alkyl methacrylates) are intended for use as processing aids in the manufacture of petroleum wax that is used as a direct food ingredient under 21 C.F.R. § 172.886 and as a food-contact substance under 21 C.F.R. § 178.3710. The concentration of poly(alkyl methacrylates) remaining in the finished wax will not exceed 1,050 parts per million (ppm).

Petroleum wax and lubricating oils are both derived from petroleum fractions. To separate the oil from the wax, the oil/wax mixture is diluted with an appropriate dewaxing solvent and chilled to crystallize and precipitate out the wax. The crude wax is then removed

from the oil by filtration. The wax is further de-oiled and refined as necessary to produce an essentially oil-free finished product.

Poly(alkyl methacrylate) processing aids, or filtration aids, facilitate the efficient separation of the wax from the oil. The filtration aid is intended to be added to the wax/oil mixture just before the mixture is diluted with the dewaxing solvent. Upon chilling, the polymer crystallizes out of the oil with the wax. Addition of the dewaxing aid can improve the filtration speed and oil yield, as well as reduce the oil content in the finished wax.

The utility of poly(alkyl acrylates) and poly(alkyl methacrylates) as processing aids in the production of petroleum wax has been established in the petitions that led to the current clearances for this use of the polymers under 21 C.F.R. Sections 172.886 (petroleum wax as a direct food ingredient) and 178.3710 (petroleum wax as a component of food-contact materials). The polymers described in this FCN will be used for the same purpose as a substitute for the polymers that are currently cleared in the regulations.

Specifically, under 21 C.F.R. § 172.886 ("Petroleum wax"), petroleum wax used as a component of food may contain either poly(alkyl acrylate) made with long-chain C_{16}-C_{22} alcohols and acrylic acid, or poly(alkyl methacrylate) made with C_{18}-C_{22} methacrylate esters, provided the polymers meet the applicable specifications set forth in the regulation. Similarly, under Section 178.3710, petroleum wax used in food-contact applications may contain either the C_{16}-C_{22} poly(alkyl acrylate) cleared under Section 172.886 or poly(alkyl methacrylate) produced from any combination of C_{12}, C_{14}, C_{16}, and C_{18} *n*-alkyl methacrylates, where the C_{12} and C_{14} alkyl chains are derived from coconut oil and the C_{16} and C_{18} groups are derived from tallow.

The purpose of this FCN is to permit the use of closely related poly(alkyl methacrylates) for the same purpose for which the listed polymers are now permitted for use in the production of wax that is used in compliance with either Section 172.886 or 178.3710. The subject polymers differ from the cleared polymers only in that the FCS polymers explicitly may contain both branched and linear alkyl groups that may be even- or odd-numbered in chain length. Moreover, the subject polymers will be used at the same levels as the currently listed polymers, with a proposed maximum residual concentration in the finished petroleum wax of 1050 ppm, i.e., the same level that is currently specified in Section 172.886 for poly(alkyl acrylate) and poly(alkyl methacrylate).

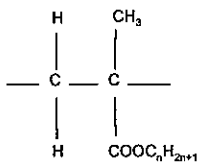
The FCS polymers will be sold to refineries or other industrial processors of lubricating oil basestocks for use in oil dewaxing. Thus, the polymer will be used by various manufacturers located throughout the United States.

Food products made with petroleum wax containing residues of poly(alkyl methacrylate) are expected to be consumed, and food-contact materials made with wax containing residues of the FCS polymer are expected to be used, in patterns corresponding to the national population density and will be widely distributed across the country. Disposal of food-contact materials containing the subject FCS will occur nationwide as a consequence of its intended uses.

5. Identification of Substances that are the Subject of the Proposed Action

The polymers that are the subject of this notification are poly(alkyl methacrylates) made from one or more C_{12}-C_{18} alkyl methacrylates (where the alkyl groups may be branched or linear and may be even or odd-numbered in chain length), polymerized alone or in combination with alkyl methacrylate monomers permitted as reactants for poly(alkylmethacrylate) under 21 C.F.R. Section 172.886(c)(2). The polymers are sold by the notifier under the trade name Viscoplex®.

Because of the variable composition of the polymer, a single chemical name, CAS Reg. No., molecular formula, etc. cannot be provided. A representative molecular structure for the alkyl methacrylate repeating unit is as follows:



where: n may equal 12, 13, 14, 15, 16, 18, 20, 22

Representative CAS Reg. Numbers and names for alkyl methacrylate monomers falling within this range include the following:

Chemical Name	CAS Registry Number
n-Dodecyl (C_{12}) methacrylate	142-90-5
Tridecyl (C_{13}) methacrylate	2495-25-2
Tetradecyl (C_{14}) methacrylate	2549-53-3
Pentadecyl (C_{15}) methacrylate	6140-74-5

Hexadecyl (C_{16}) methacrylate	2495-27-4
Octadecyl (C_{18}) methacrylate	32360-05-7
Eicosyl (C_{20}) methacrylate	45294-18-6
Docosyl (C_{22}) methacrylate	16669-27-5

Representative polymers made by the notifier are described in **Attachment 1** of the FCN. The starting monomers used in the production of the polymers are described further in **Attachment 2** of the FCN. The polymers have a kinematic viscosity (KV100) at 100°C for a 3.54% polymer solution of 13 to 20 cSt, and contain total residual alkyl methacrylate monomer at a maximum level of 14%. Samples of the polymers have been found to contain less than 4% of oligomers with molecular weight below 2000 Daltons.

A technical data sheet for a representative product is set forth in **Attachment 7** of the FCN. As indicated there, the polymer is supplied as a concentrate of poly(alkyl methacrylate) in a highly refined neutral oil. Typical physical properties of the commercial formulation include the following:

Typical Physical Properties of Poly(alkyl methacrylate) Dewaxing Aid Formulation	
Visual appearance	Clear to slightly hazy, viscous liquid
Color (ASTM D 1500)	1.5
Viscosity at 100°C, mm^2/s (ASTM D445)	270
Density at 15°C, g/mL (ASTM D 4052)	0.88
Pour point °C (ASTM D 97)	6
Flash point °C (ASTM D 3278)	160

6. Introduction of Substances into the Environment

a. Introduction of Substances into the Environment as a Result of Manufacture

Under 21 C.F.R. § 25.40(a), an environmental assessment ordinarily should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated substances. Moreover, information available to the Notifier does not suggest that there are any extraordinary circumstances in this case indicative of any adverse environmental impact as a result of the manufacture of the FCS. Consequently, information on

the manufacturing site and compliance with relevant emissions requirements is not provided here.

b. Introduction of Substances into the Environment as a Result of Use/Disposal

Possible releases to the environment as a result of use and disposal of the FCS polymer will be the same as those for the currently cleared poly(alkyl methacrylates) and poly(alkyl acrylates) with the exception of the minor compositional differences in the various polymers. Therefore, environmental releases as a result of use and disposal may be addressed by referencing the relevant information set forth in the food additive petitions that resulted in the existing clearances for these polymers. We specifically cite, and include below, the information that was set forth in FAP Nos. 2A3653 and 7A4524, which led to the current clearances for poly(alkyl acrylates) and poly(alkyl methacrylates), respectively, in 21 C.F.R. Section 172.886.

As discussed previously, the FCS polymer will be added to oil/wax mixtures to facilitate dewaxing of the oil. The dewaxing process typically involves diluting the oil/wax mixture in a solvent that has an affinity for oil, then chilling to precipitate the wax, followed by filtration to remove the wax. The FCS polymer functions by precipitating out with the wax, while the solvents used to dilute the oil/wax mixture remain with the oil fraction. Both the oil and wax fractions are recovered for subsequent use, so that there is little opportunity for the polymer to be released to the environment in more than insignificant quantities at the site of its use. The oil may be further processed to produce other petroleum products, such as lubricating oils, that are not intended for use with food.

The wax obtained in the dewaxing process may be further purified by percolating over clay, which results in some of the poly(alkyl methacrylate) being absorbed onto the clay. Data presented in FAP 2A3653 indicate that the dewaxing aid is typically present in the purified wax at levels below 200 ppm. Disposal of the polymer that is thus removed from the wax is accomplished by incineration in regenerating the clay. The incineration will be subject to applicable federal, state, and local environmental laws and regulations.

The refined wax may be used in a range of food ingredient and food packaging applications. To the extent the wax is used in food packaging materials, disposal of the packaging materials after use by the consumer will be the same as for other packaging materials, and will occur primarily by sanitary landfill and/or incineration. No significant release of the

FCS into the environment would result from this disposal based on the controls placed on such facilities. In particular, no significant environmental release from landfills would be expected based on the Environmental Protection Agency's (EPA) regulations governing municipal solid waste landfills, i.e., 40 C.F.R. Part 258. Moreover, due to the low concentration at which the FCS would be present (generally, < 200 ppm in the refined wax, which itself would represent only a coating on a substrate or an otherwise minor component of the finished food package), the incineration of a portion of the food packaging materials containing FCS residues would not be expected to cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations, i.e., EPA's regulations in 40 C.F.R. Parts 60 and local government air emission regulations.

As for food ingredient uses of refined wax that may contain the FCS, the most significant of these is chewing gum. The wax typically constitutes about 15% of the gum by weight. Assuming that the FCS is present in the refined wax at about 200 ppm (as suggested by the data presented in FAP 2A3653), FCS polymer residues would be present in the chewing gum at a concentration of about 30 ppm. The polymer will either be extracted from the gum during chewing by the consumer or will remain present in the gum when it is disposed of after chewing. If the polymer is extracted during chewing, it will be ingested; in this case, it is expected to be excreted unchanged, as is typical of high-molecular weight, inert polymers. In this scenario, the polymer ultimately would be released to publicly owned treatment works (POTWs). The concentration released to POTWs would be expected to be vanishingly low, given the low concentration of FCS polymer residues expected to be present in the chewing gum. If the polymer remains in the chewed gum, disposal will occur by standard means for solid waste, i.e., by means of sanitary landfill or incineration. Disposal of the polymer by these means is addressed above.

7. Fate of Emitted Components in the Environment

No significant effects on the concentrations of and exposures to any substances in the environment are expected due to the proposed use of the FCS. As shown in Section 6 above, the polymer will not be directly released to the environment. Rather, it will be released – due to disposal of polymer residues removed from the wax during refining or disposal of food

packaging materials containing the wax – primarily by sanitary landfill or incineration. These disposal means are adequately controlled by federal, state, and local requirements, as discussed in Section 6 above, and the concentration of FCS residues in the materials disposed of will be so low that there is no risk of a violation of the applicable environmental release requirements.

To more specifically address the fate of released substances on the environment, no significant effect on the concentrations of any substances in the atmosphere is expected due to the fact that the FCS is not volatile, and because incineration of waste polymer would not significantly alter the concentrations of its complete combustion products, carbon dioxide and water, which are the same as for many other polymers.

Similarly, no significant effects on the concentrations of any substances in fresh water, estuarine, or marine ecosystems are anticipated due to the proposed use of the FCS polymer. Based on the information in Section 6 above, no substance will be emitted to aqueous compartments at levels that could cause adverse environmental impact, either upon use of the polymer in the oil dewaxing process or upon the disposal of the polymer in the manner envisioned.

FDA has previously calculated a worst-case poly(alkyl acrylate) concentration of 0.185 ppb in waste water entering POTWs as a result of ingestion of the polymer in food followed by excretion. (See environmental review for FAP 2A3653.) Due to low water solubility, FDA estimated that most of the polymer would become associated with suspended solids in sewage; the ultimate concentration in the sludge was estimated at 4.76 ppb. Because the polymers that are the subject of this FCN are very closely related to the previously evaluated polymers, and will be used for the same purpose and at the same levels, FDA's previous calculations are also relevant here. Moreover, there will be no net increase in release of dewaxing aid residues, as the FCS polymer will merely be used in place of the cleared polymers.

Finally, considering the factors discussed above, no significant effects on the concentrations of any substances in terrestrial ecosystems is expected as a result of the proposed use of the FCS.

8. Environmental Effects of Released Substances

The notifier is not aware of any data that would suggest that the FCS polymer may be toxic to organisms in the environment at the minute levels at which it may be released. As noted previously, the FCS is a high molecular weight polymer that is expected to be inert, and, thus, is expected to be without appreciable toxicity to organisms in the environment.

In addition, FDA has previously evaluated a large volume of toxicological data on the polyacrylates that are currently cleared for use in the production of petroleum wax. These include acute toxicity data showing an oral LD_{50} in rats of greater than 3200 mg/kg for a 40% dilution in corn oil; subchronic feeding studies in rats and dogs; a two-generation reproductive toxicity study in rats; teratology studies in rats and rabbits; and a battery of mutagenicity assays. The data demonstrate a no-observed effect level of 1000 mg/kg. Due to the similarity of the FCS polymers to the currently cleared polymers, these data may be relied on to predict a low degree of toxicity for the FCS.

FDA also has previously reviewed toxicity data on the C_{12}-C_{18} alkyl methacrylate monomers from which the currently cleared poly(alkyl methacrylates) are produced. These studies demonstrated an LD_{50} in rats of >21.5 ml/kg and established no-observed effect levels in rats and dogs of 750 mg/kg and 600 mg/kg, respectively, upon subchronic exposure. Considering the magnitude of the NOELs established for the methacrylate monomer mixture, the data suggest that high molecular weight poly(alkyl methacrylates) are of very low toxicity.

The previously submitted data are supplemented by additional toxicity data submitted herewith. These include an Ames test in *Salmonella typhimurium* TA1535, TA1537, TA98, TA100 and TA102, and an *in vitro* chromosome aberration test in Chinese hamster V79 cells, conducted on a mixture of monomers from which the subject polymers will be produced. Both of these studies yielded negative results, i.e., there was no evidence of genotoxic activity.

Considering the very low levels at which the polymer may be released to the environment and the data indicating that the polymer is of a low degree of toxicity, the Notifier respectfully submits that the proposed use of poly(alkyl methacrylate) is not reasonably expected to have any adverse effect on organisms in the environment.

9. Use of Resources and Energy

As is the case with other food-contact substances, the production, use and disposal of poly(alkyl methacrylate) requires the use of natural resources such as petroleum products, etc. This energy consumption is offset, however, by the benefits offered by the use of the processing aid in oil dewaxing processes, which include improvements in efficiency of the wax/oil separation process and in the quality of the oil, as well as economic advantages.

Moreover, the use of the subject poly(alkyl methacrylate) in place of the currently cleared processing aids will have no impact on the use of energy and resources. This is because the manufacture and use of these closely related polymers involve the consumption of the same quantities of raw materials and energy.

10. Mitigation Measures

As discussed above, no significant adverse environmental impacts are expected to result from the use and disposal of the FCS. Thus, the use of the subject additive is not reasonably expected to result in any new environmental problem requiring mitigation measures of any kind.

11. Alternatives to the Proposed Action

No potential adverse environmental effects are identified herein that would necessitate alternative actions to that proposed in this Food Contact Notification. The alternative of not approving the action proposed herein would simply result in the continued use of currently cleared dewaxing aids.

12. List of Preparers

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13. Certification

The undersigned official certifies that the information provided herein is true, accurate, and complete to the best of her knowledge.

Date: May 31, 2007

Catherine R. Nielsen

Counsel for RohMax U.S.A., LP, RohMax Canada Inc., RohMax France S.A.S., RohMax Additives GmbH, and RohMax Asia Pacific Pte Ltd.