

Environmental Assessment

Toho Chemical Industry Co., Ltd., is submitting this Environmental Assessment as part of the Notification for New Use of a Food Contact Substance for Alkylacrylate Alkylmethacrylate Copolymer. Alkylacrylate Alkylmethacrylate Copolymer is to be used in alcoholic and fatty foods packaging as an alternated method for producing petroleum wax.

The intended use for Alkylacrylate Alkylmethacrylate Copolymer is as a processing aid, specifically, a filler aid in the production of petroleum wax that will be used to package food. The petroleum wax will contain not more than 40 parts per million (ppm) by weight of the Alkylacrylate Alkylmethacrylate Copolymer. The petroleum wax will be used in single use scenarios.

The Alkylacrylate Alkylmethacrylate Copolymer will have no technical effect on food. It serves as a processing aid, which improves the filtration rate, dewaxing rate, dewaxed oil yield and oil content in wax in the process of separating wax from the wax-containing hydrocarbon. Dewaxing aids are essential in an auto-chilling type propane dewaxing method.

Processing Aid Identity of the Food Contact Substance

Chemical Name: Alkylacrylate Alkylmethacrylate Copolymer

CAS Name: 2-Propenoic acid, 2-methyl, dodecyl ester, polymer with docosyl 2-propenoate, eicosyl 2-propenoate, , octadecyl 2-propenoate and tetradecyl 2-mehtyl-2-propenoate

CAS No.: 470469-55-7

Other Chemical Names: Docosyl acrylate-eicosyl acrylate-octadecyl acrylate-dodecyl methacrylate-tetradecyl methacrylate

Description of Food Contact Substance

Alkylacrylate Alkylmethacrylate Copolymer is a copolymer of C12 to C14 methacryalate and C18 to C22 acrylate. The C12 to C14 alkyl groups are derived from coconut oil and the C16 to C 18 groups are derived from tallow.

The range of percentage of monomer units in the copolymer is as follows:

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M_w from 100,000 to 200,000

M_N from 30,000 to 60,000

Physical and Chemical Properties

| Physical/Chemical Characterization | |
|--|---|
| Appearance | White Solid at 20 C |
| Boiling Point | >200 C |
| Melting Temperature | 38.3 C |
| Solubility | Insoluble in water |
| Dissociation Constant(s) | |
| Octanol/Water Partition Coefficient | Cannot be determined |
| Vapor Pressure or Henry's Law Constant | |
| Depletion Mechanisms | |
| Sorption/Desorption (K _{oc}) | |
| Hydrolysis | Not hydrolyzable |
| Aerobic Biodegradation | |
| Soil Biodegradation | |
| Photolysis | |
| Metabolism | |
| Environmental Effects | |
| Microbial Inhibition | |
| Acute Toxicity | LD ₅₀ > 2000 mg/kg in female rat |
| Chronic Toxicity | Levels of monomers are not of chronic toxicity concern. |

Stability

The potential degradation products are the monomers used in the preparation of the polymer and oligomers consisting of these structures. These monomers are not of environmental or toxicological importance and are currently regulated in Section 178.3710 of the FD& C Act.

Migration Levels in Food

Due to the use pattern in processing petroleum wax and the low use levels of the FCS, it is not expected to migrate into food products therefore, migration testing was not performed. The FCS concentration will not exceed 40 ppm by weight of the petroleum wax. The maximum levels of petroleum wax used for food packaging is 0.3 g/cm².

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Location of Use and Disposal

The FCS will be used in wax processing plants. Residues of the FCS may be found in oils and waxes that are produced during petroleum wax production. However, these materials are generally reused in the production process and not released to the environment. Almost all of the FCS is removed during the tank sweater stage as Foots Oil. This oil then undergoes fluid catalytic cracking with the resulting products being incorporated into gasoline, diesel oil and banker oil.

In the case of accidental release the FCS is not soluble or volatile and would therefore not be dispersed in the environment. The disposal of the waxes containing trace levels of the processing aid (less than 40 ppm will be present in waxes used in food processing) in landfills or by combustion of municipal waste will similarly not result in the release of the FCS beyond landfills and other disposal sites due to the lack of volatility or water solubility.

Introduction of the FCS into the Environment as the Result of Use and Disposal

No extraordinary circumstances resulting in environmental introduction of the FCS from the use of Alkylacrylate Alkylmethacrylate Copolymer is expected during manufacturing, processing, usage or disposal. FDA has approved structurally related compounds as FSCs. Alkylacrylate Alkylmethacrylate Copolymer and related or degradation compounds are not expected to expose the environment to potentially harmful substances. The attached chart illustrating the process shows that the dewaxed oil is refined and reused as diluent oil. The Footh Oil is combusted as gasoline, diesel oil or banker oil. No FCS is expected to be released during the manufacturing process of petroleum wax. The concentration of FCS in petroleum wax will be very low (<40 ppm) and FCS released as the result of disposal of petroleum wax-containing packages will not be mobile and would be expected to readily degrade at disposal sites.

FSC Use of Resources and Energy

The FCS is intended to compete with other similar regulated processing aids in the manufacturing of petroleum wax. The FCS will not affect the use of natural resources and energy.

Mitigation into the Environment

Due to the lack of water solubility and volatility of this FCS no migration into the environment is expected. With the available information on this product and structural related substances that are already FDA approved, no adverse environmental effects have been identified.

Fate of FCS in the Environment

The FCS is an alkylacrylate alkylmethacrylate copolymer that is expected to readily degrade in the environment. It is not mobile in air or water.

Alternatives to the Proposed Action

The primary alternative to the proposed action is the use of existing processing aids in the production in petroleum wax. Some of these processing aids contain chlorinated hydrocarbons and are of greater concern to the environmental. Similar processing aids to the FCS are already regulated. No potential adverse environmental effects are anticipated from the proposed use of this processing aid due to the lack of water solubility or volatility and the rapid degradation that is expected with this copolymer.

The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of Technology Sciences Group Inc.

Sept. 2, 2004

Date



Signature of Agent

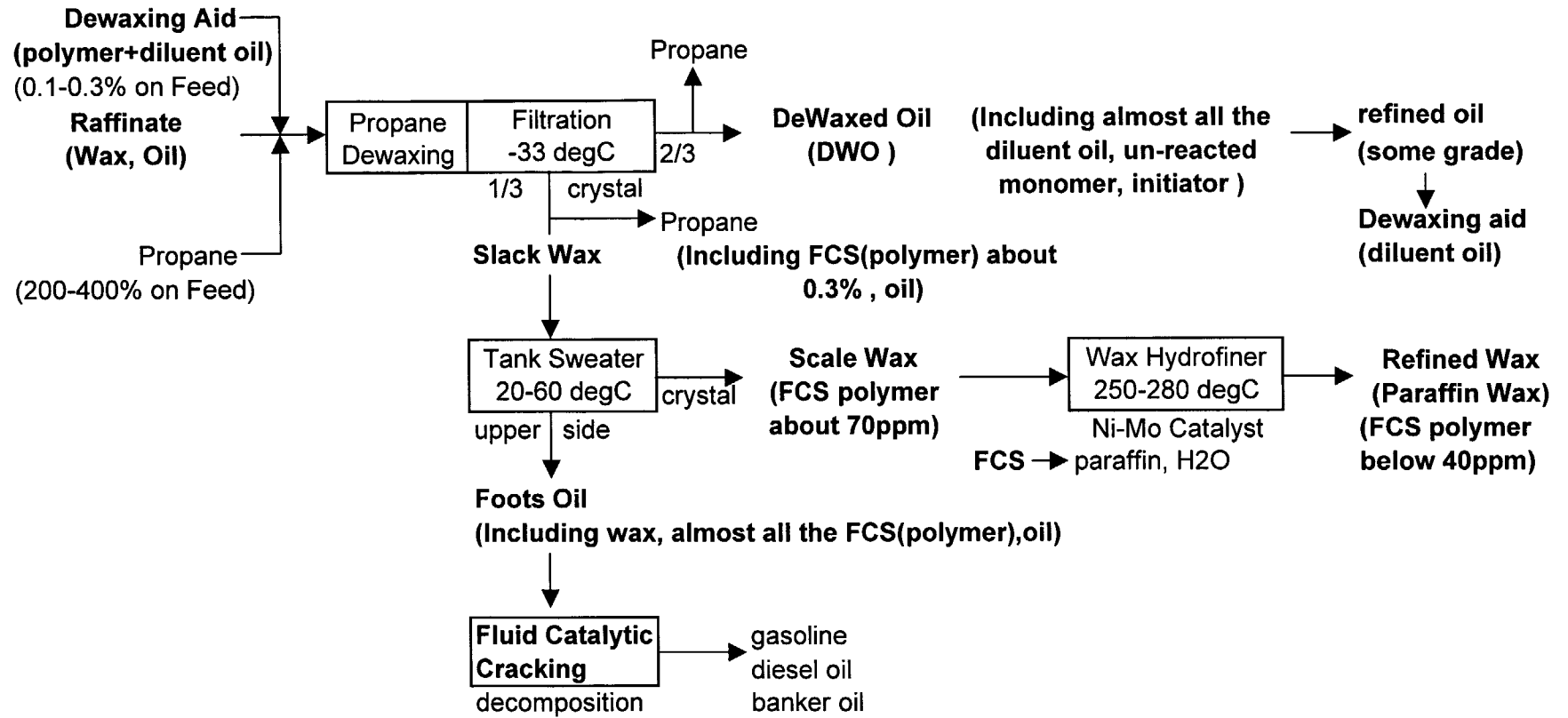
Gary Burin, Ph.D., DABT
Director of Toxicology, Ecotoxicology and Risk Assessment
Technology Sciences Group Inc.
1101 17th Street NW Suite 500
Washington DC
20036

Agent for Toho Chemical Industry Co., Ltd.
Nichrei Akashi-Cho Bldg., No.6-4, Akashi-cho
Chuo-ku, Tokyo 104-0044 JAPAN

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WAX PRODUCTION FLOW

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