ENVIRONMENTAL ASSESSMENT

FOR THE FOOD CONTACT NOTIFICATION

1. Date: December 18, 2007

2. Name of Submitter: Siltech Corporation

3. Address: 225 Wicksteed Avenue
Toronto, Ontario, CANADA
M4H 1G5

4. Description of the Proposed Action:

This action is in conjunction with the Food Contact Notification for the substance "siloxanes and silicones, 3-[3-(diethylmethylammonio)-2-hydroxypropoxyl] propyl methyl, dimethyl, chlorides." This substance is intended for use as a component in emulsion based defoamers that are used in the pulping of lignocellulosic materials. Such lignocellulosic materials can be used to make food-contact paper and paperboard that may come into contact with all types of food.

The food contact substance (FCS) will be marketed under the trade name Silquat AO, which is a 70% solution of the FCS. The use rate for the FCS will range from 3.5 to 14 grams per metric ton of dry pulp (3.5 to 14 ppm).

Siltech does not manufacture the pulp that will use the FCS as a defoamer. Instead, Siltech plans to market the FCS to other companies for use as a component in defoamers that are used in pulp manufacturing.

The FCS is not expected to be released to the environment at the pulping site. This is due to its presence in the "black liquor", which is recycled and reprocessed under conditions that are expected to cause the FCS to decompose. It is also expected that less than 2% of the FCS that is added during pulp processing will be present in waste water generated during the paper manufacturing process. Based on the worst-case calculation presented in Item 6 below, the resulting concentration of the FCS in waste water will less than 2 parts per billion (ppb) and the maximum expected environmental concentrations will be less than 0.2 ppb. Ecological toxicity data on a substance similar to the FCS indicates that this concentration will not pose any adverse environmental effects.

Food-contact articles made with paper containing the FCS will be utilized in patterns corresponding to the national population density and will be widely distributed across the country. Therefore, it is anticipated that disposal will occur nationwide, with about 80% of the materials ultimately being deposited in land disposal sites, and about 20% being incinerated.[1]

5. Identification of Chemical Substance that is the Subject of the Proposed Action

Chemical Name

Siloxanes and silicones, 3-[3-(diethylmethylammonio)-2-hydroxypropoxyl] propyl methyl, dimethyl chlorides.

CAS Registry Number

Molecular Weight

The number average molecular weight for the subject chemical substance is 460.

6. Introduction of Substances Into the Environment

- Production Releases

The submitter is not aware of any information that suggests any significant environmental releases and/or adverse environmental impacts related to the manufacture of the FCS. Consequently, manufacturing site information and compliance with relevant emission requirements are not being included in this EA.

[1] Characterization of Municipal Solid Waste in the United States, 1994 Update @ EPA/530-S-94-042, U S Environmental Protection Agency, Washington, DC 20460

- Use Releases

As noted above, the FCS will be used as a component of defoamers that are used in the pulping of lignocellulosic materials. The EA associated with Food-Contact Notification (FCN) Number 303 contains a comprehensive summary of the pulping process. According to this EA, pulp processing results in a mixture of cellulose fibers and lignins. This mixture is then washed (the step at which defoamers are added) to remove the lignins. The pulp is then sent through a series of washers to remove impurities and to recover the cooling liquor. The water from the washer series is recycled through the process; due to the recycling of the water from the washes, there are no environmental releases at this stage.

The waste stream from the pulp washing process flows out from the first of the series of washers. This liquid is known as the "black liquor". The black liquor is recycled as follows: it is first concentrated by evaporating the water. The concentrated black liquor is then burned to recover energy and chemicals in the combustion chamber. The ash that remains after burning the black liquor is dissolved in water to form the "green liquor". The green liquor is then treated with calcium oxide to form the "white liquor." The white liquor is recycled back to the digester. Thus, no environmental releases are expected from processing the black liquor.

Once the washing is complete, the pulp (cellulose fibers) goes to the bleaching line. The pulp is then isolated, dried and sold in fluff form. To make papers from this pulp, the pulp fluff first must be redispersed in water. This involves subsequent isolation and drying of the paper and paperboard.

The FCS is not substantive to the cellulose fibers. Therefore, it is expected that the substance will be dissolved in the pulp wash water so that only a very small fraction of the substance, if any, will remain in the pulp when it is isolated. It is estimated that no more than about 2% of the defoamer added with the incoming wash water will remain with the pulp. This is consistent with the amount of water-soluble wet-end additives that may remain in finished paper and paperboard based on standard FDA assumptions[2]; given the large volume of water used in the production of pulp, it is reasonable to conclude that the defoamers will be removed to at least as great an extent as in the wet end[3]. Thus, at least 98% of the FCS is expected to be lost with the black liquor and this will be disposed of by means of incineration.

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[2]See FDA's guidance for estimating migration of wet-end additives used in paper production, "*Guidance for Industry, Preparation of Food-Contact Notifications and Food Additive Petitions for Food-Contact Substances Chemistry Recommendations*" (April, 2002).

[3]A typical pulp mill uses approximately 64 cubic meters (64,000 liters, or kg) of water per metric ton (1000 kg) of pulp. Thus, the mass of water is 64 times that of the pulp. Assuming the FCS partitions equally between the water and pulp phases, the amount of the FCS remaining in the isolated pulp will be 1/64th, or less than 2% of the amount added

To produce the paper, the pulp must be redispersed in water to produce a slurry. It is expected that the small amount of the FCS that may have been retained in the pulping process will be liberated from the fibers at this stage. Typically, the pulp is dispersed at a consistency of approximately 0.5% to 1%. In isolating the wet paper, the consistency typically is increased to approximately 33% pulp and 67% water[4]. This represents a reduction in the water content of the paper of about 98%. Due to the lack of substantivity for the paper fiber, it is expected that 98% or more of the FCS will remain in the "white water" from the paper production

While the white water is typically recycled through the process, the water will ultimately be released to the waste water treatment facility. The frequency of such releases will vary from plant to plant.

The maximum concentration at which the FCS may be present in the waste water from the paper manufacturing plant may be calculated as follows As noted above, only 2% or less of the amount of the FCS initially added is expected to be present in the pulp; of this amount, 98% is expected to enter the white water. Thus, based on a maximum addition level of 14 grams per metric ton of pulp, the amount in the white water will be (14 g/metric ton) (0.98)(0.02) or 0.27 g/metric ton. This is equivalent to (0.27 g/metric ton)(1 metric ton/2204 lbs) (1 lb/453 g) or 2.7×10^{-7} g/g pulp. If the pulp slurry contains 0.5% pulp, then the concentration of the FCS in the slurry is (2.7×10^{-7} g/g pulp) (0.5%) or 1.3×10^{-9} g FCS /g slurry. This is equivalent to a concentration in the slurry of 1 3 ppb. This also represents the concentration of the FCS that will remain in the water after isolation of the paper.

Most, if not all, of the paper mills that will use pulp made with the FCS are expected to operate on-site treatment facilities. The submitter does not have information on the extent to which the FCS may be broken down by either chemical or biological waste treatment facilities. Therefore, we assume that the FCS will not be degraded. It is further expected that due to its affinity for water and lack of substantivity to solids, the FCS will remain in the waste water after removal of the solid wastes, or sludge, from the waste water treatment process. Thus, at a worst-case, it may be assumed that the aqueous effluent from the waste water treatment facility will contain the FCS at approximately the concentration calculated in the white water above or 1.3 ppb.

It should also be noted that the subject FCS is a substitute for other defoaming agents that are currently used in the production of pulp for food-contact paper and paperboard. Some of these substances are siloxane defoamers that are similar to the FCS discussed in this notification. Thus, the use of the FCS in place of these materials will not result in any meaningful change in the nature or the amount of substances released into the environment.

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[4]See FDA Chemistry Recommendations

7. Fate of Emitted Substances in the Environment

The FCS will be released into aquatic bodies as part of waste water effluent from papermaking production facilities. As indicated above, the maximum expected introduction concentration (EIC) is estimated to be approximately 1.3 ppb.

The submitter is not aware of any studies that have addressed the environmental behavior or characteristics of the FCS. However, the EIC of 1.3 ppb is expected to be significantly reduced by dilution in river water It is estimated that this dilution is at least ten-fold. Consequently, the maximum expected environmental concentration (EEC) of the FCS will be approximately 0.13 ppb.

8. Environmental Effects of Released Substances

Environmental releases of the FCS are not expected to result in any adverse environmental effects since the predicted environmental releases (into aquatic bodies) are extremely low. Moreover, the aquatic toxicity data on a similar substance indicates that the environmental concentrations are much lower than levels are much aquatic toxicity is observed.

An acute toxicity study in the water flea (*Daphnia magna*) was conducted with the product Silquat 3180, which is a high molecular weight version of the FCS. The water flea is considered a very sensitive indicator organism for potential aquatic toxicity.

The water flea study with Silquat 3180 is attached as Appendix 1 to this EA. Under the conditions of the study, the 48-hr EC_{50} for Silquat 3180 is 6.6 mg/L and the 48-hr No-Observable Effect Level (NOEL) is 2 5 mg/L. These levels are approximately 10,000 times greater than the maximum EEC estimated for the FCS. Consequently, it can be reasonably concluded that no significant adverse effects will result from the anticipated environmental releases of the FCS.

9. Use of Resources and Energy

The FCS is expected to compete with, and to some degree replace, other defoamers that are already used in the manufacture of paper and paperboard. Other siloxane defoamers are listed in 21 CFR 176.210 and have also been subject to food contact notifications. Therefore, the use of the FCS in the production of pulp used to produce food-contact paper and paperboard is not expected to result in a net increase in the use of energy and resources.

10. Mitigation Measures

As discussed above, no significant adverse environmental impacts are expected to result from the manufacture of food-contact paper and paperboard from pulp using the FCS. This is largely due to the very low levels at which the FCS may be introduced into the environment. Therefore, the use of the FCS, as proposed, is not expected to result in any new environmental risks requiring mitigation.

11. Alternatives to the Proposed Action

Since no potential adverse environmental effects have been identified no alternatives to the proposed action need be considered

12. List of Preparers

This assessment was prepared by Eliot Harrison of Lewis & Harrison. Mr. Harrison's background is in biology and chemistry.

13. Certification

The undersigned official certifies that the information presented is true, accurate and complete to the best of his knowledge.

Signed:

Date:

December 18, 2007