Environmental Assessment in support of FCN

1) **Date:** 05/11/2005

2) **Submitter:** Dow Corning Corporation

3) **Address:** P.O. Box 994
Midland, MI 48686-0994

4) Description of Proposed Action

a. **Requested action:** To allow the use of Siloxanes and Silicones, di-Me, 3-hyroxypropyl Me, ethers with polyethylene and polypropylene glycol mo-Me ether as a component of a defoamer used in the manufacture of paper and paperboard in accordance with 21 CFR 176.210(d)(3). This is from a general class of materials called Polyethermethylsiloxane (PEMS). This material will be used as an ingredient in making an emulsion to be used for defoaming.

b. **Need for Action:** The addition of the additive in the defoamer formulation will enhance paper-making by reducing foam in the digester process to allow more energy efficient circulation of the mill liquors.

c. **Locations of use /disposal:** The antifoam emulsion which the subject additive is part of will be used in the paper making process. Dow Corning manufactures the PEMS additive that is the subject of this FCN at its manufacturing plant in [redacted] This site is a large chemical complex located within an urban setting. All wastes generated in the production of the PEMS additive are collected and taken off site of incineration by a licensed waste disposal company.

The PEMS additive is then sold to formulators who produce silicone emulsions with a solid content of 30%. The PEMS product would make up about 1/3 of the solids to improve performance of the defoamer. The formulation would then consist of 10% of PEMS, 20% silicone oil and or compound and 70% water. These formulators are located throughout the world and must follow all local and national environmental and safety regulations.

The Emulsion is then used as antifoam in the paper making process within paper mills located around the world. The emulsion is added at 0.02 to 0.09% as regards to the fibers into the paper making process. This means that the amount of the PEMS added is up to 0.009% based on the dry weight of the fibers.

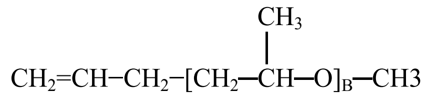
Based on assumption provided in part II.F.2 of the FCN, 98% of the PEMS product will be disposed off along with the black liquor and another 98% will be disposed of with the white liquor at the paper mill. Therefore 99.96% of the PEMS product will be disposed of at the paper mill.

5) **Identification of substances that the subject of the proposed action:** The subject of this Food Contact Notification is the reaction products of Polyethylene glycol monoallyl monomethyl ether (CAS No. 27252-80-8), (reactant A) which is represented below:

$$CH_2{=}CH-CH_2-[CH_2-CH_2-O]_A-CH3$$

(where A is the number of repeating EthyleneOxide groups.)

Polypropylene glycol monoallyl monomethyl ether (CAS No. 62744-60-9), (reactant B) which is represented below:



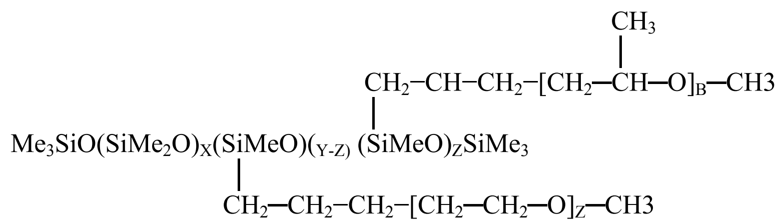
(where B is the number of repeating Propylene Oxide groups.)

And Dimethyl, methylhydrogen siloxane, trimethysiloxy terminated (CAS No. 68037-59-2), (reactant C) which is represented below:

$$Me_3SiO(SiMe_2O)_X(SiMeHO)_YSiMe_3$$

(where X and Y are repeating groups)

To form Dimethyl, methyl(propyl(poly(EO))acetate) siloxane (CAS No. 70914-12-4) (Product D) which is represented below:



The resultant mixture is a clear to cloudy amber liquid.

6) Introduction of substances into the Environment

a. Introduction of substance into the environment as a result of manufacture:

No extraordinary circumstances apply to the manufacture of this processing aid additive. The proposed manufacturing currently takes place for the same material in non food use and is compliant with all applicable emission and occupational safety requirements.

b. Introduction of substances into the environment as a result of use/disposal.

The FCS will be used as a defoaming agent in the pulping of lignocellulosic materials that will be used in the manufacture of paper and paperboard. Pulp processing begins with the addition of wood chips and process chemicals to the digester. The resulting mixture of cellulose fibers and lignins exit the digester. This mixture is washed to remove the lignins. The FCS is added to the process as a defoamer during this washing step. The addition level will not exceed 90 grams per metric ton (0.009%) of dry pulp.

Based on a report put out by the U.S. EPA,[1] we understand that there are mainly four processes used in chemical pulping (Kraft, sulfite, neutral sulfite, semi chemical and soda), out of which the Kraft process accounts for over 80% of the chemical pulp produced in the United States. The waste stream from the Kraft pulp washing process, known as the weak black liquor, is concentrated by evaporation and the concentrated liquor, or strong black liquor, is then combusted. The lava-like smelt or ash that remains is mixed in water to form green liquor; to which lime (calcium oxide CaO) is added to form the white liquor that is then recycled back to the digester.[2,3,4] For other pulping

[1]U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, AP 42, Fifth Edition, Compilation of Air Pollution Emission Factors, Volume 1: Stationary Point and Area Sources, Chapter 10: Wood Products Industry (10.2-Chemical Wood Pulping), available at http://www.epa.gov/ttn/chief/ap42/ch10/final/c10s02.pdf.

[2] Ibid.

[3]See www.rfu.org/KraftPulp.htm, and the EA for effective FCN 303 (http://www.cfsan.fda.gov/~acrobat2/fnea0303.pdf)

[4]Bryd, J.F., Ehrke, M.D. and Whitfield, J.I. 1984. New bleached kraft pulp plant in Georgia -state of the art environmental control. Journal WPCF, 56(4);378-385.

processes, the spent liquor (called the red liquor for the sulfite pulping process) is usually recycled back when chemical recovery is practical.

We expect that the proper combustion of the spent liquor would cause the FCS to decompose to carbon dioxide (CO_2), carbon monoxide (CO), silica dioxide (SiO_{2}), and water (H_2O). These combustion by-products from the FCS would not be a significant component of any air emissions. As for the silica oxides, their introduction in the environment will not have a significant environmental impact since silica compounds are prevalent in the environment.

Based on the above discussion, we expect that there are negligible environmental releases of the FCS and its breakdown products from processing of the black liquor. This accounts for 98% of the FCS used.

2% of the FCS added to the digester process is expected to be retained in the pulping process. It will be dispersed in the headbox and then remain in the white water of the paper making process. The white water will eventually be disposed of through the plant waste water system.

The concentration of the FCS in the waste white water from the paper making step may be calculated as follows. As indicated above, only 2% or less of the amount of 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 the addition level of 90 grams per metric ton of pulp, the amount in the white water will be (90 g/metric ton) (0.98) (0.02), or 1.8 g/metric ton. This is equivalent to (1.8 g/metric ton)(l metric ton/2204 lb)(l 1b/453 g), or 1.8 x 10^{-6} g/g of pulp. If the pulp slurry contains 0.5% pulp, then the concentration of the FCS in the slurry is (1.8 x 10^{-6} g/g of pulp)(0.5%) or 9 x 10^{-9} g of FCS/g of the slurry or a concentration 9 ppb of FCS in the water sent to the waste water treatment plant.

A study conducted at Dow Corning Corporation for the Silicones Environmental, Health and Safety Council of North America (SEHSC) looked at two different PEMS products. One of which was insoluble in water (SPE–D) and while the other was stated to be soluble (SPE-B). The partitioning studies were conducted at solids concentrations of 2080-8700 mg/L, depending on sludge type and SPE copolymer, with SPE copolymer loading concentrations of: 1, 10, 50, and 100 mg/L. The Freundlich isotherm and a linear isotherm were used to calculate adsorption coefficients to describe sorption of the SPE copolymers to the sludge. Calculated solid-liquid partition coefficients, or K_d values, for municipal waste water treatment plant (WWTP) activated sludge ranged from 650 to 11,070 for SPE B and from 4,430 to 7174 for SPE D. Generally, K_d increased with decreased loading of SPE B but slightly decreased with decreased loading of SPE D. The conclusion of this study was that both water soluble and water insoluble PEMS materials are extensively absorbed in the activated sludge and effectively removed from the waste water.

i) Mode of introduction into the Environment:

Based on the discussion above it is estimated over 97% of the material that is sent to the wastewater treatment plant will stay with the sludge. This sludge from the paper mills will be either land filled, incinerated or land applied. Land filled or land applied PEMS material will be expected to have the same fate as polydimethylsiloxane (PDMS) materials. These are expected to be soil catalyzed into volatile silanols and glycol ethers. The glycol ethers are readily degraded in a variety of soils under aerobic conditions[5]. Biological oxygen demand (BOD) data show substantial biodegradation of glycol ethers[6]. This suggests that these compounds are not persistent in the environment.

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5 Gonsio SJ, West RJ (1995) Evriron Toxicol Chem 14:1273

6 Dow Chemical Company (1990) The Glycol ethers handbook, Report 110-00363 Midland, MI

The concentration of the FCS expected to be released through the aqueous effluent from the waste water treatment plant will be 0.3 ppb. This is a conservative assumption as it does not take into account other waste aqueous waste streams from the paper production plant.

ii) Material Safety Data Sheets

See Attachment.

7) Fate of Substances released in the Environment:

As shown in item 6 above, the primary means by which the FCS substance is expected to be released into the environment is as a component of effluents from the wastewater treatment plant. The conservative concentration in this stream is estimated to be 0.3 ppb.

This concentration will be greatly diluted once the effluent reaches the receiving water. Based on a conservative river dilution factor of 10 the environmental concentration would be less than 0.03 ppb. Based on this low level of material in the effluent we conclude that there will be no significant adverse impact to the environment.

8) Environmental effects of released substances:

Although we do not have any data for the environmental effect of the FCS, information on the Environmental effects of the several similar PEMS can be found in *The Handbook of Environmental Chemistry Vol 3-H Organosilicon Materials,* Grish Chandra Ed., Chapter 8. Table 1 of this chapter summarizes the toxicity of PEMS material to various freshwater aquatic organisms. The lowest concentration presented to have any adverse effect for PEMS 1, 2 or 3 is >10ppm using freshwater organisms. Thus the 0.03 ppb concentration is 300,000 times below concentrations observed to have any adverse biological effect toward freshwater organisms.

Unpublished Dow Corning tests were also conducted using marine organisms. The lowest concentration determined to have any adverse effect for same PEMS 1, 2 or 3 listed above was >0.5 ppm marine diatom organisms. Thus the 0.03 ppb concentration is >15,000 times below concentrations observed to have any adverse biological effect toward marine organisms. Therefore it may be concluded that the low levels of potential release will not lead to any significant adverse environmental impact

9) Use of resources and energy:

The proposed PEMS process aid is intended to replace a like silicone oil in the antifoam emulsion. Therefore there should be no essentially no effect on the use of natural resources and energy.

10) Mitigation Measures:

No adverse environmental effects have been identified therefore there is no need to discuss mitigation measures.

11) Alternatives to the proposed action:

No adverse environmental effects have been identified therefore there is no need to discuss alternatives to the proposed action.

12) List of preparers:

Name: Charles A. McCourt

Title: FDA Regulatory Specialist
Degree: B.S. Chemical Engineering – University of Wisconsin - Madison

13) Certification:

"The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of Dow Corning Corporation."

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(Date)

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(Signature of Responsible Official)
Charles A. McCourt,
FDA Regulatory Compliance Specialist

14) Attachments:

MSDS for FCN

Title: FDA Regulatory Specialist
Degree: B.S. Chemical Engineering – University of Wisconsin - Madison

13) Certification:

"The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of Dow Corning Corporation."

May 11, 2005
(Date)

(Signature of Responsible Official)
Charles A. McCourt,
FDA Regulatory Compliance Specialist

14) Attachments:

MSDS for FCN