ENVIRONMENTAL ASSESSMENT
GENERAL ELECTRIC COMPANY FOOD CONTACT NOTIFICATION

1. **Date:** September 12, 2003

2. **Name of Applicant:** General Electric Company

3. **Address:** 771 Old Saw Mill River Road
Tarrytown, New York 10591-6728

All communications on this matter are to be sent in care of
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4. Description of the Proposed Action

The action requested in this submission is the notification of the use of siloxanes and silicones, di-Me, polymers with silica-1,1,1-trimethyl-N- (trimethylsilyl)silanamine hydrolysis products and silicic acid trimethylsilyl ester (hereinafter "food-contact substance (FCS)"). The FCS is intended for use as a defoamer in the pulping of lignocellulosic materials that will be used to make food-contact paper and paperboard that may come into contact with all types of food under Conditions of Use A-H. In such applications, the FCS is intended for use at levels not to exceed 2500 grams per metric ton of dry pulp (0.25%).

General Electric Company (GE) does not manufacture the pulp that will use the FCS as a defoamer. Rather, GE plans to market the FCS to other companies for use as a defoamer in pulp manufacturing.

As discussed more fully below, none of the FCS is expected to be released to the environment at the pulping site. This is due to its being present in the "black liquor" produced during pulping which is recycled and processed under conditions that are expected to cause the FCS to decompose. Further, it is expected that less than 2% of the FCS that is added during pulp processing will be present in waste water generated in the paper manufacturing process. Based on worst-case calculations presented in Item 6 below, the resulting concentration of the FCS in the waste water will be less than 250 parts per billion (ppb). The available toxicological information does not suggest the possibility of any adverse environmental impact as a result of the substance's potential presence in effluent from the paper production process at this low level.

Food-contact articles made with paper pulp 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% incinerated.[1] The types of environments present at and adjacent to the disposal locations are the same as for the disposal of any other food-contact material in current use. Consequently, there are no special circumstances regarding the environment surrounding either the use or disposal of food-contact materials prepared using the FCS.

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

Chemical Name:	Siloxanes and silicones, di-Me, polymers with silica-1,1,1-trimethyl-N- (trimethylsilyl)silanamine hydrolysis products and silicic acid trimethylsilyl ester
Common or Trade Name:	Tradenames for representative products are and

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

CAS Registry Number:	159002-21-8
CAS Registry Name:	Siloxanes and silicones, di-Me, polymers with silica-1,1,1-trimethyl-N- (trimethylsilyl)silanamine hydrolysis products and silicic acid trimethylsilyl ester

The starting monomers are identified in the following table:

The structural formula for the FCS is provided in Attachment 1 to Form 3480.

Typical physical properties of the FCS are provided in confidential Attachment 1 to this Environmental Assessment (tab 8.1).

6. Introduction of Substances into the Environment

1. Introduction of substances into the environment as a result of manufacture of the polymer

FDA has indicated that an EA ordinarily should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA regulated articles. Moreover, information available to GE 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 regarding the manufacturing site and compliance with the relevant emissions requirements is not provided here.

[redacted]

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

As noted above, the FCS is intended for use as a defoamer in the pulping of lignocellulosic materials that are 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 2500 grams per metric ton (0.25%) of dry pulp. The pulp is sent through a series of washers to remove impurities and recover the cooking liquor. The water from the washer series is recycled through the process, where the incoming (fresh) water initially enters the final washer (where the pulp is most pure) and then travels through the preceding washers in reverse order to the pulp, so that the water ultimately goes through the first wash following the digester. A flow diagram depicting this process is provided as Attachment 2 to this Environmental Assessment (tab 8.2). Due to the recycling of the water from the washes, there is no release at this stage.

As indicated by the attached diagram, 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 CaO to form the white liquor. The white liquor is then recycled back to the digester. Thus, no environmental release is expected from processing of the black liquor.

[redacted]

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 paper 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. We estimate 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 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 thus will be disposed of by means of incineration. During this burning process, the FCS is expected to be broken down into silica and oxides of carbon.

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

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[2] See FDA guidance for estimating migration of wet-end additives used in paper production, set forth in FDA's *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. *See* Koch, Gerhard H., et al., *Corrosion Cost and Preventive Strategies in the United States*, Appendix W, p. Wiii (2001). 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 $1/64^{th}$, or less than 2%, of the amount added.

approximately 0.5% to 1%. In isolating the wet paper, the consistency typically is increased to approximately 33% 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 concentration of the FCS remaining in the white water may be estimated as follows.

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 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 2500 grams per metric ton of pulp, the amount in the white water will be (2500 g/metric ton) (0.98) (0.02), or 49 g/metric ton. This is equivalent to (49 g/metric ton)(1 metric ton/2204 lb)(1 lb/453 g), or 4.9×10^{-5} g/g pulp. If the pulp slurry contains 0.5% pulp, then the concentration of the FCS in the slurry is (4.9×10^{-5} g/g pulp) (0.5%), or 2.5×10^{-7} g FCS/g slurry. This is equivalent to a concentration in the slurry of 250 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 Notifier does not have information on the extent to which the FCS may be broken down by either chemical or biological waste water treatment facilities. Thus, for the sake of this EA, we will assume that the FCS will not be degraded. It is

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[4] See, FDA Chemistry Recommendations.

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, as 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 250 ppb. This is a conservative assumption as it does not account for dilution of the white water with other aqueous wastes from the plant and does not allow for the possible degradation of the FCS during waste water treatment.

It should be noted that the subject FCS is expected to be used in place of other defoaming agents that are currently used in the production of pulp for food-contact paper and paperboard. These substances may include 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 upon the use of the product in the manufacture of food-contact paper and paperboard.

7. **Fate of Emitted Substances in the Environment**

As shown in Item 6 above, the primary means by which the food-contact substance is expected to be released into the environment is as a component of effluents from waste water treatment facilities. The expected introduction concentration (EIC) is estimated to be no more than 250 ppb.

This concentration, of course, will be greatly diluted once the effluent enters the receiving water. The resulting concentration of the FCS is expected to be exceedingly low. For conservatism's sake, we will estimate the expected environmental concentration (EEC) based on a river dilution factor of 10; that is, we will assume there will be a 10-fold dilution in the concentration of FCS upon entering the receiving water. This will result in an EEC of 25 ppb.

We respectfully submit that the concentration at which the FCS may be released in effluent from waste water treatment facilities is so low as to warrant no substantive concern.

8. **Environmental Effects of Released Substances**

The potential release of the FCS at the worst-case level calculated above is not expected to result in any significant environmental effects. This expectation is based on the low levels at which the substance may be introduced into the environment and on available data which do not suggest that the substance is toxic to aquatic organisms.

Because the Notifier does not have any aquatic toxicity data on the FCS, and none was located in our searches, we conducted a search for aquatic toxicity data on the starting reactants used to make the FCS. Enclosed as Attachment 3 to this Environmental Assessment (tab 8.3) is an Environmental Protection Agency (EPA) summary of the ecotoxicity data available on siloxanes and silicones, di-Me (CAS Reg No. 63148-62-9), one of the starting materials used to make the FCS. The results of several aquatic toxicity studies in Bufowoodhousei fowleri (Fowler's toad), daphnia magna (water flea), ictalurus punctatus (Channel catfish), lepomis microlophus (Redear sunfish), and rana pipiens (Leopard frog), are summarized. The LC_{50} values ranged from 3160 µg/L (ppb) in the Channel catfish, to 134,760 µg/L (ppb) in Fowler's toad. The lowest LC_{50} value, 3160 ppb, is more than 126 times the EEC calculated above. Because the FCS would not be expected to be of greater toxicity than its starting reactants, this LC_{50} represents a conservative estimate of toxicity.

As noted previously, this release will not represent a new environmental introduction of siloxanes but, rather, a substitution for the corresponding release of other siloxane defoamers that would otherwise be used for the same purpose. We respectfully submit, therefore, that no adverse environmental effects are expected as a result of this release.

9. **Use of Resources and Energy**

The notified use of 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 that are specifically listed in Section 176.210 of the food additive regulations for this purpose include, *e.g.,* siloxanes and silicones, dimethyl, methylhydrogen, reaction products with polyethylene-polypropylene glycol monoallyl ether (CAS Reg. No. 71965-38-3). For this reason, 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 made using the FCS. This is largely due to the low levels at which the FCS may be introduced into the environment and the available data suggesting an absence of toxicity to organisms in the environment. Thus, the use of the FCS as proposed 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 which would necessitate alternative actions to that proposed in this request. Therefore, alternatives to the proposed action need not be considered.

12. **List of Preparers**

Chuck V. Breder, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Washington, D.C. 20001.

[redacted]

13. **Certification**

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

Date: 9/12/03

Catherine R. Nielsen
Counsel for General Electric Company

14. **References**

None

15. **Attachments**

1. Typical physical properties – **CONFIDENTIAL**
2. Flow diagram representing pulp processing
3. EPA ecotoxicity summary

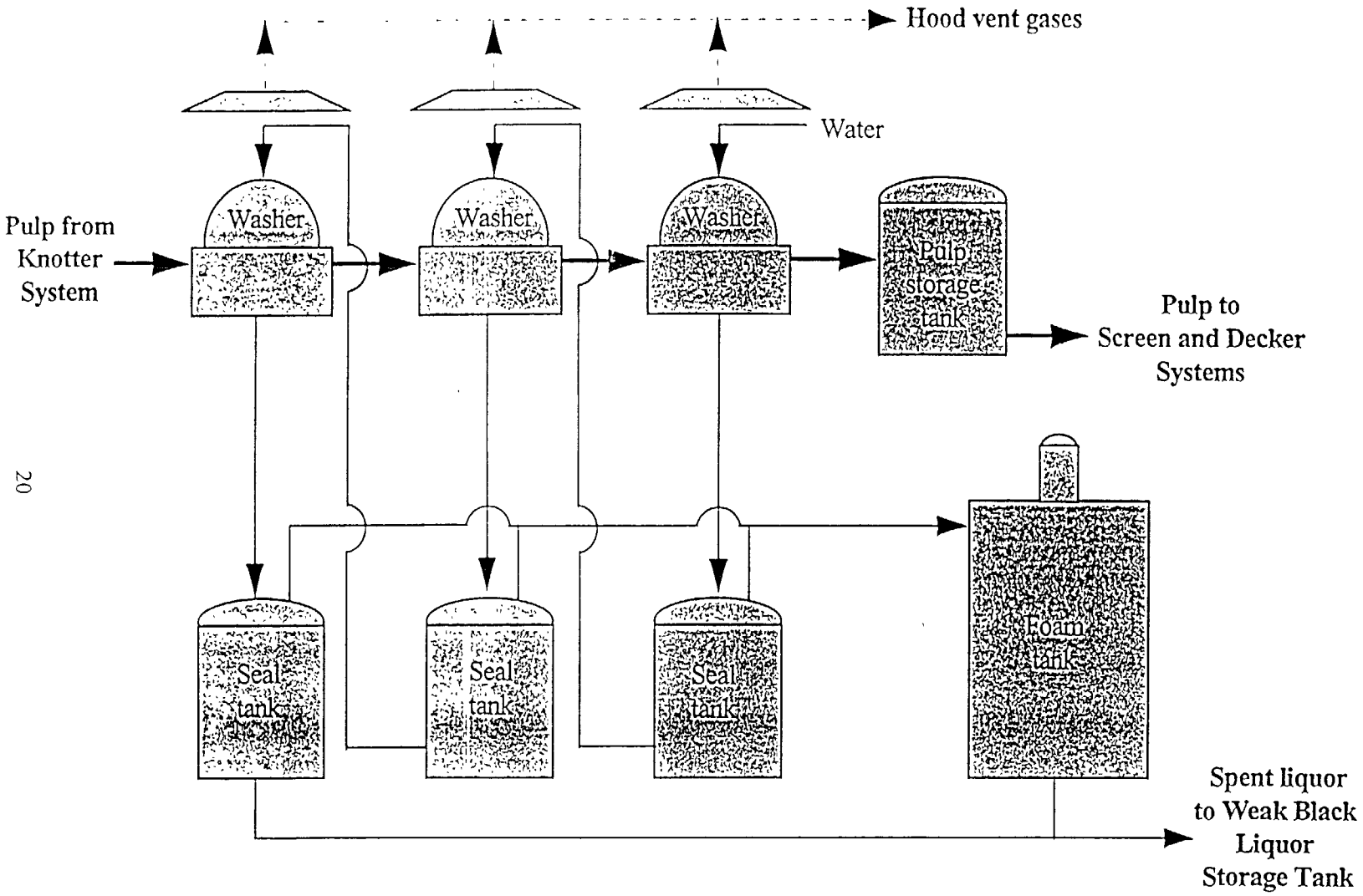

Figure 7.

Brown Stock Washing System (Rotary Vacuum)

ECOTOX:Ecotoxicology Database
USEPA/ORD/NHEERL
Mid-Continent Ecology Division

Contact: T:218-529-5225 F:218-529-5003
E-mail: ecotox.support@epa.gov

It is recommended that users consult the original scientific paper to ensure an understanding of the context of the data retrieved from the ECOTOX database.

Report Generated: Tue Jul 15 16:20:03 2003

Aquatic records found: 9

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Laboratory Data References

NR = Not Reported

000072

Scientific name, Common name	Endpoint	Effect	Effect Measurement	Trend / Effect %	Media Type	Duration / Exp Typ	Conc (ug/L)	Signif / Level	Response Site / BCF	Ref #
Test Loc: LAB										
CAS #/Chemical: 63148629, Dimethyl siloxanes and silicones										
Bufo woodhousei fowleri Fowler's toad	LC50	MOR	MORT		FW	7 - 8 d / R	F 7680, 6240 - 9370		------	6772
Bufo woodhousei fowleri Fowler's toad	LC50	MOR	MORT		FW	96 h / R	F 7680, 6240 - 9370		------	6772
Bufo woodhousei fowleri Fowler's toad	LC50	MOR	MORT		FW	72 - 96 h / R	F 134760, 83970 - 253010		------	6772
Daphnia magna Water flea	LC50*	MOR	MORT		FW	48 h / S	F 44500		------	504
Ictalurus punctatus Channel catfish	LC50	MOR	MORT		FW	96 h / R	F 3160, 2360 - 4150		------	6772
Lepomis microlophus Redear sunfish	LC50	MOR	MORT		FW	96 h / R	F 37790, 26270 - 56730		------	6772
Rana pipiens Leopard frog	LC50	MOR	MORT		FW	7 - 8 d / R	F 6950, 5730 - 8400		------	6772
Rana pipiens Leopard frog	LC50	MOR	MORT		FW	96 h / R	F 6950, 5730 - 8400		------	6772
Rana pipiens Leopard frog	LC50	MOR	MORT		FW	72 - 96 h / R	F 17550, 13570 - 22960		------	6772

Reference Number:	504
Author(s):	Hobbs, E.J., M.L. Keplinger, and J.C. Calandra
Publication Year:	1975
Title:	Toxicity of Polydimethylsiloxanes in Certain Environmental Systems
Reference Source:	Environ.Res. 10:397-406 (Author Communication Used)

Reference Number:	6772
Author(s):	Birge, W.J., J.A. Black, and A.G. Westerman
Publication Year:	1978
Title:	Effects of Polychlorinated Biphenyl Compounds and Proposed PCB-Replacement Products on Embryo-Larval Stages of Fish and Amphibians
Reference Source:	Res.Rep.No.118, Water Resour.Res.Inst., University of Kentucky, Lexington, KY :33 p. (U.S.NTIS PB-290711) (Author Communication Used)

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Laboratory Data References

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