ENVIRONMENTAL ASSESSMENT
CROMPTON CORPORATION FOOD CONTACT NOTIFICATION

1. **Date:** November 4, 2002

2. **Name of Applicant:** Crompton Corporation

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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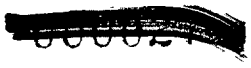
4. Description of the Proposed Action

The action requested in this submission is the notification of the use of siloxanes and silicones, dimethyl, methylhydrogen, reaction products with polyethylene glycol and/or polyethylene-polypropylene glycol monoallyl ether, methyl ether terminated (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 40 grams per metric ton of dry pulp (0.004%).

Crompton does not manufacture the pulp that will use the FCS as a defoamer. Rather, Crompton 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 4 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, dimethyl, methylhydrogen, reaction products with polyethylene glycol and/or polyethylene-polypropylene glycol monoallyl ether, methyl ether terminated.

[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.

[redacted]

Common or Trade Name:	Tradenames for representative products are Y-14441 and Y-14443
CAS Registry Number:	CAS Registry Numbers for two representative products are 68938-54-5 and 67762-85-0
CAS Registry Name:	CAS Registry Names for two representative products are: Siloxanes and silicones, dimethyl, 3-hydroxypropyl methyl, ethers with polyethylene glycol mono-methyl ether, and Siloxanes and silicones, dimethyl, 3-hydroxypropyl methyl, ethers with polyethylene-polypropylene glycol mono-methyl ether.

The starting monomers are identified in the following table:

CAS Registry Number	CAS Name
68037-59-2	Siloxanes and silicones, dimethyl, methylhydrogen
27252-80-8	Poly(oxy-1,2-ethanediyl), alpha-methyl-omega- (2-propenyloxy)-
52232-27-6	Oxirane, methyl-, polymer with oxirane, methyl 2-propenyl ether

The molecular formula for the FCS will vary. Two representative chemical formulas are: ($C_{73\text{-}591}H_{126\text{-}1026}Si_{10\text{-}101}O_{33\text{-}289}$) and ($C_{361\text{-}2752}H_{798\text{-}5722}Si_{67\text{-}416}O_{151\text{-}1157}$).

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

The weight average molecular weight (Mw) of the FCS ranges from 1,810 to 68,906 Daltons.

Typical physical properties of the FCS are provided in confidential Attachment 1 to this Environmental Assessment (tab 9.1).

[redacted]

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 Crompton 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.

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 40 grams per metric ton (0.004%) 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 9.2). Due to the recycling of the water from the washes, there is no release at this stage.

[redacted]

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.

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

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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).

[redacted]

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 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 40 grams per metric ton of pulp, the amount in the white water will be (40 g/metric ton) (0.98) (0.02), or 0.78 g/metric

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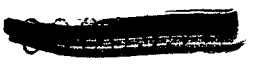
[3] A typical pulp mill uses approximately 64 cubic meters (64,000 liters, or kg) of water per metric ton (1000 kg) of pulp. *See* Koch, Gerhard H., et al., *Corrosion Cost and Preventive Strategies in the United States*, Appendix W, p. Wiii (2001). Thus, the mass of water is 64 times that of the pulp. Assuming the FCS partitions equally between the water and pulp phases, the amount of the FCS remaining in the isolated pulp will be 1/64th, or less than 2%, of the amount added.

[4] See, FDA Chemistry Recommendations.

ton. This is equivalent to (0.78 g/metric ton)(1 metric ton/2204 lb)(1 lb/453 g), or 7.8×10^{-7} g/g pulp. If the pulp slurry contains 0.5% pulp, then the concentration of the FCS in the slurry is (7.8×10^{-7} g/g pulp) (0.5%), or 3.9×10^{-9} g FCS/g slurry. This is equivalent to a concentration in the slurry of 3.9 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 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 3.9 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 3.9 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 0.39 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. The conclusion that there will be no significant adverse impact is further supported by the aquatic toxicity data discussed in Item 8 below.

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.

As documentation of this lack of toxicity, enclosed as Attachments 4-7 to this Environmental Assessment (tabs 9.4 – 9.7) are the reports of four ecotoxicity studies that have been carried out on formulations that include the subject FCS. The compositions of the test formulations are given in confidential Attachment 3 to this Environmental Assessment (tab 9.3).

As indicated by the information provided there, the test formulations contained approximately 6.7% of the defoamer components that are the subject of this FCN.

In the first study, set forth in Attachment 4 (tab 9.4), the toxicity of the test formulation identified as Y-14648 was evaluated in turbot (*Scophthalmus maximus*). In this study, the test fish were exposed to concentrations of the Y-14648 formulation equaling 0 (control), 320 mg/L, 560 mg/L, 1000 mg/L, and 1800 mg/L. No mortality was observed over the course of the 96-hour exposure. Based on these results, the 96-hour LC_{50} to turbot was found to be greater than 1800 mg/L. Considering the 6.7% content of the FCS in the tested material, it may be concluded that the LC_{50} for the FCS is greater than 6.7% of 1800 mg/L, or greater than 120 mg/L (120 ppm). This value is approximately 308,000 times the EEC of 0.39 ppb.

In the second study, set forth as Attachment 5 (tab 9.5), the toxicity of the test formulation identified as TP-40 was evaluated in the calanoid copepod *Acartia tonsa*. In this study, the test organisms were exposed to the TP-40 formulation at concentrations of 300 ppm, 600 ppm, 900 ppm, and 1200 ppm for up to 96 hours. Due to high turbidity of the 900 ppm and 1200 ppm solutions, it was not possible to evaluate the results of the testing at these doses. The 48-hour LC_{50} was found to be 430 ppm, while the 96-hour LC_{50} was 150 ppm. Considering the 6.7% concentration of the FCS in the TP-40 formulation, these values correspond to a 48-hour LC_{50} of $\geq$ 29 ppm and 96-hour LC_{50} of $\geq$ 10 ppm for the FCS.[5] The lower level of 10 ppm is more than 25,000 times the EEC of 0.39 ppb.

The TP-40 formulation also has been evaluated for marine algal growth inhibition in *Skeletonema costatum*; the report of this testing is provided as Attachment 6 to this EA (tab 9.6).

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[5] Because the mortality observed may have been due to other components of the TP-40 formulation, these represent minimal LC_{50} values for the FCS.

[redacted]

The test formulation concentrations ranged from 18 mg/L to 320 mg/L. The average growth rate from start to 72 hours was determined for each exposure level. This testing resulted in an EC_{50} for the test formulation of 120 mg/L. This corresponds to an EC_{50} for the FCS of at least 6.7% of 120 mg/L, or $\geq$ 8 mg/L. This is more than 20,000 times the calculated EEC.

Finally, the toxicity of sediment contaminated with TP-40 was evaluated in the intertidal amphipod *Corophium volutator*; the report of this testing is provided as Attachment 7 to this EA (tab 9.7). In this testing, the amphipods were exposed to solid-phase sediment for 10 days under static conditions, and the resulting mortality evaluated. Concentrations tested were 100, 1000, 10,000, and 100,000 mg per kilogram of dry sediment weight. Based on the results of this testing, the LC_{50} was calculated to be 8802 mg/kg. This corresponds to a minimal LC_{50} for the FCS of 6.7% of this value, or 590 mg/kg. This is more than 10^6 times the calculated EEC.

Based on the foregoing data, it may readily be concluded that the potential release of the FCS at the low levels anticipated will not lead to any significant adverse environmental impacts. Moreover, 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).

[redacted]

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**

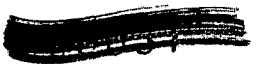
As discussed above, no significant adverse environmental impacts are expected to result from the manufacture of food-contact paper and paperboard from pulp made using the FCS. This is largely due to the low levels at which the FCS may be introduced into the environment and the available data suggesting an absence of toxicity to organisms in the environment. This conclusion is further supported by the close similarity of the FCS to the siloxane defoamers it is intended to replace. 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**

Holly H. Foley, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Washington, D.C. 20001.



13. **Certification**

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

Date: November 4, 2002

Catherine R. Nielsen
Counsel for Crompton Corporation

14. **References**

None

15. **Attachments**

1. Typical physical properties – **CONFIDENTIAL**
2. Flow diagram representing pulp processing
3. Compositional information – **CONFIDENTIAL**
4. Toxicity of Y-14648 formulation to turbot
5. Toxicity of TP-40 to *Acartia tonsa*
6. Marine algal growth inhibition of TP-40
7. Sediment toxicity to *Corophium volutator*

The composition of the TP-40 and Y-14648 test formulations is provided in confidential Attachment 3 to this Environmental Assessment; the information provided there is not to be released to the public.

[redacted]