

Environmental Assessment

1. **Date** December 8, 2003
2. **Name of Applicant/Notifier** E. I. du Pont de Nemours and Company, Inc.
3. **Address** All communications on this matter are to be sent in care of Counsel for Notifier, George G. Misko, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001. Telephone: (202) 434-4170.
4. **Description of the Proposed Action**

The action requested in this notification is the establishment of a clearance to permit the use of a food-contact substance (FCS) that is a mixture of potassium stearyl phosphate, polyoxyethylene lauryl ether phosphate potassium salt, and polyoxyethylene tridecyl ether phosphate potassium salt for use as a finish component on poly (phenyleneterephthalamide) resins cleared in 21 C.F.R. § 177.1632 for repeated-use applications. The finish component is for use at a level not to exceed 1% by weight of the base polymer (aramid fiber) in contact with all types of food at a maximum temperature of 260°C (500°F). The FCS that is the subject of this notification is employed in a formulated product known as

The FCS is intended to facilitate the mechanical manipulation of yarn into fabrics and finished articles; it is effective at reducing static buildup during knitting or weaving operations. The FCS is intended to have a technical effect during manufacture of the aramid fiber, but does not have a technical effect in the finished food-contact article.

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The finish will be used on aramid fibers that will be fabricated into articles, such as gloves, aprons, etc., that are used in food processing facilities located throughout the United States. The expected routes of disposal for the FCS are in the use of the aramid fibers that contain the finish in the manufacturing of fabric and garments at textile manufacturing facilities or during use of the garments at food processing facilities; in these instances, the type of environment that might be affected is surface water receiving liquid production wastes. Small amounts of the subject substances will become incorporated into food and will enter disposal systems along with this food.

5. Identification of Substances that are the Subject of the Proposed Action

The subject FCS is a mixture of (1) potassium stearyl phosphate (CAS Reg. No. 68987-29-1), (2) polyoxyethylene lauryl ether phosphate potassium salt (CAS Reg. No. 58318-92-6), and (3) polyoxyethylene tridecyl ether phosphate potassium salt (CAS Reg. No. 68186-36-7).

A confidential description of the FCS appears in Section B of this Notification.

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6. Introduction of Substances into the Environment

Under 21 C.F.R. § 25.40(a), an environmental assessment 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 the Notifier 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 finish or the fiber to which it is applied; the Notifier does not wash or scour the fibers to which the finish is applied and, therefore, no environmental introductions are anticipated via this means. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

We believe that the introduction of the subject substances into the environment will take place primarily via release into wastewater treatment systems. The mode by which the substances are introduced into the environment from use of the substances as a finish applied to fibers that are subsequently used to manufacture articles that may contact food will be as a consequence of scouring or washing of the fabric at the textile manufacturing facilities and removal of the wash water to wastewater systems employed in the textile facilities. The substances also may be introduced into the environment from laundering of articles, such as gloves, containing the substance used in food processing facilities and removal of the wash water to wastewater systems employed in the food processing/laundry facilities.

The maximum concentration at which the FCS may be present in the wastewater from the textile manufacturing facility or food processing facility may be calculated as follows. As indicated above, the likely source of introduction into the wastewater systems is via scouring or washing of the fabric or articles manufactured from fibers containing the FCS fiber finish. We understand that typical commercial washing machines have a 125 pound capacity and use a four-cycle wash: a pre-soak cycle, a wash cycle, and two rinse cycles, each employing 40 gallons of water. Thus, as the maximum amount of the finish on the fiber is 1%, the maximum amount of finish (the FCS) that could be washed out is $1\% \times 125 \text{ pounds} = 1.25 \text{ pounds} (568 \text{ g})$. The total amount of water for each washing event is 160 gallons, which is equivalent to 605,600 mL. Therefore, assuming that all of the finish is removed, the maximum concentration in the wash water is $(568 \text{ g}) \div (605600 \text{ mL}) = 938 \text{ parts per million (ppm)}$. As detailed in our confidential environmental information, when accounting for dilution of the wash water with other aqueous wastes from the textile manufacturing plant or food processing facility, the adjusted expected introduction concentration (EIC) is equivalent to $938 \text{ ppm}/21$, or 45 ppm. Of course, this EIC is conservative as it assumes that the entire quantity of the FCS expected to be used on fiber intended for food-contact applications in 2008 is removed and discharged in one day, rather than over the course of a year.

Although the washing is expected to take place daily, the EIC calculated here would not be a daily introduction, as the assumption made in the calculation is that 100% of the finish is removed on the first scouring or washing; in this case, there will be no introduction for the subsequent washings. Furthermore, the EIC assumes that the entire concentration would be present in a single day of wastewater from a textile manufacturing facility or a food processing

facility as a worst case; in reality, a portion of the concentration likely would be present in the effluent from each.

It should be noted that the subject FCS is expected to be used in place of other fiber finishes that are currently used in the production of the poly (phenyleneterephthalamide) resins fiber. These substances may include compounds 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 poly (phenyleneterephthalamide) resins fibers and articles made from the fibers. Furthermore, the market volume for the proposed use is an extremely small percentage of the total market volume of all other anionic surfactants used for all uses.

7. Fate of Emitted Substances in the Environment

As shown in Item 6 above, the primary means by which the FCS is expected to be released into the environment is as a component of effluents from wastewater treatment facilities. The EIC is estimated to be no more than 45 ppm. Most, if not all, of the textile manufacturing facilities and food processing facilities are expected to operate on-site treatment facilities. The Notifier has performed studies on the biodegradability of the FCS using the 7-day/28-day Modified Zahn-Wellens Test (Bioelimination Test). Reports of these studies are included in a confidential portion of the FCN. These studies indicate that at least 84% of the FCS is degraded (and/or absorbed) in these studies. It is expected that, due to its affinity for water and lack of substantivity to solids, the FCS will remain in the wastewater after removal of the solid wastes,

or sludge, from the wastewater treatment process. Thus, as a worst-case, it may be assumed that the aqueous effluent from the wastewater treatment facility will contain the FCS at approximately 16% of the concentration calculated in the wash water above, 16% x 45 ppm, or 7.2 ppm.

The water is then discharged into a river where further dilution occurs. We use FDA's suggested river dilution factor of 20¹ in our estimation of the expected environmental concentration (EEC). That is, we will assume there will be a 20-fold dilution in the concentration of the FCS upon entering the receiving water. This will result in an EEC of 0.36 ppm.²

Based on the foregoing calculation, we conclude that only a very small quantity of any of the subject substances will be added to fresh water, estuarine, or marine ecosystems as a result of the proposed use of the subject fiber finish substances.

Considering the foregoing, we respectfully submit that there is no reasonable expectation of a significant impact on the concentration of any substance in the environment due to the proposed use of the FCS, a mixture of potassium stearyl phosphate, polyoxyethylene lauryl ether phosphate potassium salt, and polyoxyethylene tridecyl ether phosphate potassium salt, for use as a finish component at up to 1% by weight of poly(phenyleneterephthalamide) resins cleared in 21 C.F.R. § 177.1632 for repeated-use applications.

¹ We understand that FDA's river dilution factor is based on actual stream flow data from food processing industries, such as poultry processing plants, and paper mills. We believe that this is a conservative estimate.

² 7.2 ppm ÷ 20 = 0.36 ppm

8. Environmental Effects of Released Substances

As discussed under Format Item 7, because only very small quantities of the FCS are expected to end up in the environment as a result of the proposed use, based on a very small market volume, low use level, and biodegradability to non-toxic products, we believe that there will be no significant impact on organisms in the environment. No ecotoxicity data are available for the FCS.

9. Use of Resources and Energy

The proposed use of the subject substances will not have a significant impact on energy usage because the subject FCS is expected to be used in place of other fiber finishes that are currently used in the production of the poly(phenyleneterephthalamide) resin fiber. These substances may include compounds 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 manufactured or distributed in commerce and, hence, will not result in any meaningful change in the use of resources or energy.

10. Mitigation Measures

As shown above, no significant adverse environmental impacts are expected to result from the use of food-contact materials fabricated from fibers employing the subject finish. This is primarily due to the minute EEC determined for the subject substances and the low annual production of the FCS for use in food-contact applications. Thus, the use of the subject 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 Notification. The alternative of not approving the action proposed herein would simply result in the continued use of the materials which the subject substances would otherwise replace; such action would have no environmental impact. In view of the excellent qualities of the FCS for use as intended, the fact that the FCS constituents are not expected to enter the environment in more than minute quantities upon the use of articles manufactured from the fibers containing the FCS, and the absence of any significant environmental impact which would result from their use, the clearance of the use of the FCS as described herein by allowing this Notification to become effective is environmentally safe in every respect.

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12. List of Preparers

Lester Borodinsky, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite
500 West, Washington, D.C. 20001.

13. Certification

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

Date: December 8, 2003



George G. Misko
Counsel for E. I. du Pont de Nemours and Company, Inc.

14. References

None

15. Attachments

None

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