

Environmental Assessment

1. **Date** July 26, 2004
2. **Name of Applicant/Notifier** Noveon, Inc.
3. **Address** All communications on this matter are to be sent in care of Counsel for Notifier, Joan Sylvain Baughan, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001. Telephone: (202) 434-4147.
4. **Description of the Proposed Action**

The action requested in this Notification is the establishment of a clearance to permit the use, in hand sanitizers, of up to 7 percent alcohol ethoxylate, where the alcohol contains from 12-22 carbon atoms and the ethoxylate chain contains between 4 and 20 repeating ethoxylate units, in a mixture with polyacrylic acid homopolymer, or copolymer of acrylic acid and up to 10% alkyl (C₁₀-C₃₀) methacrylate, cross-linked with either allyl sucrose (CAS Reg. No. 68784-14-5) or allyl pentaerythritol (CAS Reg. No. 91648-24-7). The mixture containing up to 7% of the food-contact substance (the alcohol ethoxylate) will be used at levels up to 0.5% as a component of hand sanitizers used in food service establishments. The products that are the mixture containing up to 7% of the alcohol ethoxylate are marketed under the name Carbopol® interpolymers.

Carbopol® interpolymers offer several technical properties that make them useful as components of hand sanitizers. In particular, the crosslinked acrylic polymers are designed to provide excellent thickening efficiency to hand sanitizer formulations. This is achieved as these water soluble or dispersible polymers possess the capacity to greatly increase the viscosity of the liquid in which they are dissolved or dispersed, even when present at concentrations considered quite low. The alcohol ethoxylate acts as a dispersant or surfactant in the crosslinked acrylic polymers.

Carbopol® interpolymers (*i.e.*, containing up to 7% of the food-contact substance) will be a component of hand sanitizers that are used in food service establishments located throughout the United States. The expected route of disposal for the bulk of this substance is the waste water systems of the food service establishment and or their employees' homes as a result of the employees of these establishments washing their hands. Small amounts of the subject substance 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 substance is an alcohol ethoxylate, where the alcohol contains from 12-22 carbon atoms and the ethoxylate chain contains between 4 and 20 repeating ethoxylate units.

The molecular formulas and molecular weights for the individual compounds that bracket the range of alkyl moieties in the food-contact substance are given below:

	Low End of Range	High End of Range
Molecular Formula	(C ₁₂ H ₂₅)-(OCH ₂ CH ₂) ₄ -OH	(C ₂₂ H ₄₅)-(OCH ₂ CH ₂) ₂₀ -OH
Molecular Weight	306	926

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 subject substance. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

We believe that the introductions of the subject substance into the environment will take place primarily via release in wastewater treatment systems. The mode by which the substance is introduced into the environment from use of the substance as a components of hand sanitizers will be as a consequence of use of the hand sanitizers by employees of food service establishments and subsequent transfer of the sanitizer to food and removal to wastewater systems via employees' hand washing. Studies have been performed to determine the mode of introduction of Carbopol® interpolymers into the environment from its disposal to wastewater

treatment systems. These studies indicate that Carbopol® interpolymers (1) are not biodegradable, (2) do not inhibit waste treatment bacteria, and (3) do not pass through typical wastewater treatment to the environments, but are instead removed with the biomass (biosolids) and, thus, disposed or incinerated.¹ Consequently, the expected introduction concentration (EIC) of the subject substances that may enter the terrestrial environment has been calculated when biosolids from publicly owned treatment works are applied to land. As the EIC calculation has relied upon proprietary information, including estimated yearly market volume for the subject substance, the proprietary information and calculations that incorporate this information is contained in a confidential appendix of this Notification. Based on this information, the EIC has been determined to be a maximum of 0.28 ppm.

An estimated 55.5% of biosolids were land applied or composted for land application in 2000; of the 44.5% of sewage sludge that is not land applied, 22% is incinerated, 14% is landfilled, 7.5% is put to other beneficial uses such as daily landfill covers, and 1% is disposed of by other means.² Based on this distribution, as well as the EIC calculation, introductions into the environment from these routes of disposal are expected to minimal.

¹ A discussion of these studies is contained in a document entitled "Biotreatability of Carbopol® Polymers," March 1995, TDS 164, that may be found at <http://www.carbopol.com>.

² *Biosolids Generation, Use, and Disposal in the United States*. United States Environmental Protection Agency 530-R99-009; September 1999.

7. Fate of Emitted Substances in the Environment

No significant effect on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the alcohol ethoxylate. The alcohol ethoxylates are not volatile substances and, therefore, do not vaporize under ambient conditions. Thus, no significant quantities of any substances will be released upon the use and disposal of hand sanitizers containing the subject substance.

The products of complete combustion of the subject substance would be carbon dioxide and water; the concentrations of these substances in the environment will not be significantly altered by the proper incineration of the alcohol ethoxylate in the amounts utilized for food packaging applications.

No significant effects on the concentrations of and exposures to any substances in fresh water, estuarine, or marine ecosystems are anticipated due to the proposed use of the subject substance, as it is not expected to pass through typical wastewater treatment to the environment. No significant quantities of any substance will be added to these water systems upon the proper incineration of the alcohol ethoxylate, nor upon its disposal in landfills.

Using the maximum EIC calculated above, 0.28 ppm, the maximum terrestrial expected environmental concentration (EEC) has been estimated by employing the following dilution factor for biosolids mixed with soils:

$$\text{Dilution Factor}^3 = (4.5 \text{ kg/m}^2) \div (0.15 \text{ m} \times 1200 \text{ kg/m}^3) = 0.025$$

Thus, the maximum terrestrial EEC for soils amended with biosolids containing the subject substances is estimated to be:

$$\text{EEC} = \text{EIC} \times 0.025 = 0.28 \text{ ppm} \times 0.025 = 0.007 \text{ ppm}$$

As a comparison for the calculated EEC, we turn to eco-toxicity on a substance that is a representative of the range of alcohol ethoxylates covered in this Notification. Specifically, we refer to C11-C14, isoalcohols, C13- rich, ethoxylated (Chemical Abstract Service (CAS) Registry No. 78330-21-9). As indicated in the Material Safety Data Sheet (MSDS) for this representative substance, the following eco-toxicity data are indicated:

LC50 (96 hour) (semi-static) rainbow trout	5.6 mg/L (ppm)
LC50 (96 hour) (static) rainbow trout	7.5 mg/L (ppm)
EC50 (48 hour) Daphnia magna	2-10 mg/L (ppm)
EC50 (96 hour) Acartia tonsa	2-10 mg/L (ppm)

³ The Dilution Factor assumes that a maximum annual application rate of 4.5 kg/m², biosolids incorporation to a depth of 15 cm (approximately 6 inches), and a soil density of 1200 kg/m³ (Michael C. Harrass, Charles E. Eirkson, and Lisa Nowel, "Role of plant bioassays in FDA review: scenarios for terrestrial exposure," presented at the Second Symposium on Use of Plants for Toxicity Assessments; sponsored by the American Society for testing and Materials, Committee E47 on biological Effects and Environmental Fate and Subcommittee E47.11 on Plant Toxicity; April 23-24, 1990, San Francisco, California)

Based on the foregoing information, no significant quantities of any of the subject substances will be added to terrestrial systems from soils amended with biosolids containing the subject substance.

Considering the factors discussed above, no significant effects on the concentrations of and exposures to any substances in terrestrial ecosystems are anticipated as a result of the proposed use of the subject alcohol ethoxylate. In particular, the maximum EEC noted above is very low at 0.007 ppm, a level that is orders of magnitude lower than the LC50 or EC50 values determined for a substance that is representative of the subject food-contact substance. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to the subject substance as a result of its proposed use.

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 alcohol ethoxylate as a component of hand sanitizers used in food service establishments.

8. Environmental Effects of Released Substances

As discussed previously, the only mode by which the subject substance may be expected to be released to the environment upon the use and disposal of the alcohol ethoxylate is as a consequence of use of the hand sanitizers by employees of food service establishments and subsequent transfer of the sanitizer to food and removal to wastewater systems via employees'

hand washing. As the Carbopol® interpolymers in which the subject substance will be used do not pass through typical wastewater treatment to the environments, but are instead removed with the biomass (biosolids) and, thus, disposed or incinerated, the terrestrial expected environmental concentration (EEC) of the subject substance that may enter the terrestrial environment has been calculated when biosolids from publicly owned treatment works are applied to land. Based on this information, the EEC has been determined to be a maximum of 0.007 ppm. Based on these considerations, no adverse effect on organisms in the environment is expected as a result of the use and disposal of hand sanitizers used in food service establishments. In addition, the use and disposal of the subject substance are not expected to threaten a violation of applicable laws and regulations, *e.g.*, the Environmental Protection Agency's regulations in 40 C.F.R. part 60 that pertain to municipal solid waste combustors and Part 258 that pertain to landfills.

9. Use of Resources and Energy

The proposed use of the subject substance will not have a significant impact on energy usage because the amount of the substance used in hand sanitizers used in food service establishments represents a small fraction of the total amount of this substance that is produced and marketed.

10. Mitigation Measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of food-contact materials fabricated from the subject substance. This is primarily due to the minute EIC determined for the subject substance. Thus, the use of the subject substance 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 substance would otherwise replace; such action would have no environmental impact. In view of the excellent qualities of the Carbopol® interpolymers (containing the subject substance) for use in food-contact applications, the fact that the subject substance is not expected to enter the environment in more than minute quantities upon the use and disposal of hand sanitizers used in food service establishments, and the absence of any significant environmental impact which would result from its use, the clearance of the use of the alcohol ethoxylate as described herein by allowing this Notification to become effective is environmentally safe in every respect.

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 her knowledge.

Date: July 26, 2004




Joan Sylvain Baughan

Counsel for Noveon, Inc.