

G. Environmental Assessment

1. **Date** August 17, 2001
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 polyacrylic acid homopolymer, or copolymer of acrylic acid and up to 10% alkyl (C₁₀-C₃₀) methacrylate, cross-linked with either allyl sucrose or allyl pentaerythritol, which contains a block copolymer surfactant of fatty acid (C₁₂-C₁₈) and polyethylene glycol.

The products that are the subject of this notification are marketed under the name interpolymers. The subject materials will be used at levels up to 0.5% as a component of hand sanitizers used in food service establishments.

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.

interpolymers 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' home as a result of the employees of these establishments washing their hands. 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 polymers are either (1) polyacrylic acid, i.e., acrylic acid homopolymers or (2) copolymers of acrylic acid and up to 10% alkyl (C₁₀-C₃₀) methacrylate. Either of these polymers is crosslinked using either (a) allyl sucrose (CAS Reg. No. 68784-14-5) or (b) allyl pentaerythritol (CAS Reg. No. 91648-24-7). In addition, a block copolymer surfactant of fatty acid (C₁₂-C₁₈) and polyethylene glycol is blended with the crosslinked polymer; the finished blend contains up to 7% block copolymer surfactant of fatty acid (C₁₂-C₁₈) and polyethylene glycol.

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

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

We believe that the introductions of the subject substances into the environment will take place primarily via release in wastewater treatment systems. The mode by which the substances are introduced into the environment from use of the substances as 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 _____ interpolymers into the environment from its disposal to wastewater treatment systems. These studies indicate that _____ 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.* Consequently, the expected introduction concentration (EIC) of the subject substances that may enter the terrestrial environment has been calculated

¹² A discussion of these studies is contained in a document entitled "Biotreatability of _____ Polymers," March 1995, TDS **164**, that may be found at _____

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 interpolymers, 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 1.2 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.¹³ Based on this distribution, as well as the EIC calculation, introductions into the environment from these routes of disposal are expected to be minimal.

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 interpolymers. The polymers are of high molecular weight and do not volatilize. Thus, no significant quantities of any substances will be released upon the use and disposal of hand sanitizers containing these polymers.

¹³ *Biosolids Generation, Use, and Disposal in the United States*. United States Environmental Protection Agency 530-R99-009; September 1999.

The products of complete combustion of the polymer 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 polymers 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 copolymers. No significant quantities of any substance will be added to these water systems upon the proper incineration of the polymers, nor upon its disposal in landfills due to the extremely low levels of aqueous migration of polymer components.

Using the maximum EIC calculated above, 1.2 ppm, the maximum terrestrial expected environmental concentration (EEC) has been estimated by employing the following dilution factor for biosolids mixed with soils:

$$\text{Dilution Factor}^{14} = (4.5 \text{ kg/m}^2) \div (0.15 \text{ m} \times 1200 \text{ kg/m}^3) = 0.025$$

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

$$\text{EEC} = \text{EIC} \times 0.025 = 1.2 \text{ ppm} \times 0.025 = 0.03 \text{ ppm}$$

¹⁴ The Dilution Factor uses the assumptions 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 calculation, no significant quantities of any of the subject substances will be added to terrestrial systems from soils amended with biosolids containing the subject substances.

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 interpolymers. In particular, the maximum EEC noted above is very low at 0.03 ppm. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of the polymers.

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 CarbopolB interpolymers as components of hand sanitizers used in food service establishments.

8. Environmental Effects of Released Substances

As discussed previously, the only mode by which the subject substances may be expected to be released to the environment upon the use and disposal of interpolymers 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 interpolymers 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 substances 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 0.03 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 copolymers 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 substances will not have a significant impact on energy usage because the amounts of the substances used in hand sanitizers used in food service establishments represents small fractions of the total amounts of these substances that are 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 polymers. This is primarily due to the minute EIC determined for the subject substances. Thus, the use of the subject polymers 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 Petition. 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 interpolymers for use in food-contact applications, the fact that the polymer constituents are 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 their use, the clearance of the use of interpolymers 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: August 17, 2001

Joan Sylvain Baughan



Counsel for Noveon, Inc.