

# Environmental Assessment

- 1. Date:** August 7, 2008
- 2. Name of Notifier:** Omnova Solutions, Inc.
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## **4. Description of Proposed Action**

The action requested in this Notification is the establishment of a clearance for the food-contact substance (FCS), a modified styrene/butadiene/acrylic (SBA) copolymer. See Section 5 below for full description of the polymer composition. The FCS will be used as a latex binder at levels not to exceed 20% in paper and paperboard complying with 21 CFR 176.170 ("Components of paper and paperboard in contact with aqueous foods") and 176.180 ("Components of paper and paperboard in contact with dry food").

The technical effect of a self cross-linking SBA copolymer in a coating formulation is to deliver the following advantages: wet, dry, and solvent tensile strength, color stability, pigment receptivity, hand balance, and binding efficiency.

The FCS will be sold to and used in paper mills. The SBA copolymer is primarily intended for use consumer paper products outside the jurisdiction of FDA. The use of the FCS will not change the method of disposal of paper mill waste and will not change the habits of consumers in disposing waste paper.

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

As noted above, the FCS is a modified styrene/butadiene/acrylic copolymer. Specifically, it consists of styrene/butadiene copolymers produced by copolymerizing styrene and butadiene with one or more of the monomers methacrylic acid, 2-hydroxyethyl acrylate,

itaconic acid, acrylic acid, fumaric acid, N-methylol methacrylamide, and methacrylamide, such that the total of methacrylic acid, 2-hydroxyethyl acrylate, itaconic acid, acrylic acid, and fumaric acid does not exceed 10 percent by weight, and the methacrylamide and N-methylol methacrylamide do not exceed 2 percent and 3 percent by weight, respectively.

The copolymers are intended to be used as substitutes for SBA copolymers already cleared under 21 CFR 176.170 of FDA's food additive regulations, and are, therefore, not expected to have any unanticipated effects in the environment. The FCS is identical to the SBA copolymers cleared in Section 176.170 except for the addition of methacrylamide and N-methylol methacrylamide as minor monomers. These monomers are intended to replace acrylamide and N-methylolacrylamide, which are currently permitted for use as minor monomers in formulating SBA copolymers under Section 176.170. The FCS will be sold as an aqueous emulsion containing approximately 50% solids.

## **6. Introduction of substances into the environment**

### **a. Introduction of substances into the environment as a result of manufacture**

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 substances. 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 FCS. There are no extraordinary circumstances pertain to the manufacture of the substance. Both sites of potential manufacture of the FCS (Green Bay, Wisconsin and Mogadore, Ohio) are Synthetic Minor facilities which operate thermal oxidizers (TO) to control air emissions of Hazardous Air Pollutants (HAP) and Volatile Organic Compounds (VOC). Both facilities are subject to federal, state, and local environmental laws and requirements. All polymers produced at both manufacturing facilities are subject to stripping utilizing the TO. Stripping time is roughly 8 hours for all batches at both facilities. There are no extraordinary circumstances where (1) unique emission circumstances are not adequately addressed by general or specific emission requirements (including occupational) promulgated by federal, state, or local environmental agencies and the emissions may harm the environment; (2) a proposed action threatens a

violation of Federal, State or local environmental laws or requirements (40 CFR 1508.27 (b)(10)); and (3) production associated with a proposed action may affect adversely a species or the critical habitat of a species determined under the Endangered Species Act or the Convention on International Trade in Endangered Species of Wild Fauna and Flora to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other federal law.

**b. Introduction of Substances into the Environment as a Result of Use/Disposal**

The FCS is received by paper mills as a latex emulsion consisting of 50% solids. The FCS is very similar in chemical composition to the FCS in Food-Contact Notification No. 244, which was also submitted by the Notifier. The FCS was developed as a latex binder for paper for consumer products not subject to premarket approval by any federal or state agency. OMNOVA is an active participant in the marketing of styrene butadiene latex binders for paper and has approximately 15-20% percent market share of the US latex binder market. However, the Notifier believes that the use of the FCS in food packaging will be for specialty applications because of its cost and unique properties; in fact, the production volume for the FCS for use in food-contact applications will be limited to the amount noted in the Form 3480. *See* Part II, Section G.1 (page 17) of the Form 3480; this information is not repeated here due to its confidential nature.

There will be no difference in the handling of the SBA copolymers at paper mills, whether the copolymer is used to make paper for consumer use or for food-contact use. The FCS is applied to the paper sheet, and essentially 100% of the polymer is expected to be incorporated into the paper.

- A. The FCS has low water solubility and has an affinity for pulp. Therefore, little of the SBA binder is expected to be disposed in the paper mill waste water, and a small percentage will be disposed in the solid waste.
- B. The use and disposal of the FCS at paper mills is expected to be intermittent due to the specialty nature of the uses for food-contact paper. Maximum usage at any one mill is expected to be for a week at a time and should be in use no more than 5 weeks per year. In addition, it should be noted that a primary customer will utilize one or two mills

for the manufacture of non-food contact consumer products, and will likely dedicate 100% production time to manufacturing consumer paper products for non-food contact use exclusively.

- C. The contribution to air emissions is expected to be virtually nil due to the non-volatile nature of the FCS and the low concentration of residual monomers and additives. The contribution to solid waste will be small. Some small concentration is expected in the waste water of water soluble residual monomers and additives. These monomers and additives are commonly used in paper processing, other latex binders, and other paper coatings that are used for both food contact and non-food contact paper.
- D. The MSDS for this product is attached.

Disposal by the ultimate consumer of food contact articles produced with the FCS will be by conventional rubbish disposal, primarily by sanitary landfill or incineration. The total amount of food-contact paper disposed with the FCS will only be a small percentage of paper containing other SBA type latex binders. In addition, the FCS is composed of carbon, hydrogen, oxygen and nitrogen (with a small amount of additives containing small amounts of sulfur) that are commonly found in municipal solid waste. Moreover, due to its proposed use and projected market share, the FCS will constitute only a small fraction of the total municipal waste currently combusted.

Finally, no significant release of the FCS into the environment would result from this disposal based on the controls placed on such facilities. In particular, no significant environmental release from landfills would be expected based on the Environmental Protection Agency's (EPA) regulations governing municipal solid waste landfills, *i.e.*, 40 CFR Part 258. Due to the low concentration at which the FCS would be present, the incineration of a portion of the food-contact materials containing FCS residues would not be expected to cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations, *i.e.*, EPA's regulations in 40 CFR Part 60 and local government air emission regulations

## **7. Fate of substances released into the environment**

Possible releases to the environment as a result of use and disposal of the FCS polymer will be the same as those for the currently cleared SBA copolymers with the exception of the minor compositional differences in the various polymers. Therefore, environmental releases as a result of use and disposal may be addressed by referencing the relevant information set forth in the food additive petitions that resulted in the existing clearances for these polymers.

The fate of the FCS will be well-controlled due to the disposal practices of paper mills and the disposal of food-contact materials by the consumer by sanitary landfill or incineration. These disposal means are adequately controlled by federal, state, and local requirements, as discussed in Section 6 above, and the concentration of FCS residues in the materials disposed of will be so low that there is no risk of a violation of the applicable environmental release requirements. The FCS is chemically similar to other latex binders that are currently used at volumes many folds higher than the expected use of the FCS in paper used for food contact.

To more specifically address the fate of released substances on the environment, no significant effect on the concentrations of any substances in the atmosphere is expected because incineration of waste polymer would not significantly alter the concentrations of its complete combustion products, carbon dioxide and water, which are the same as for many other polymers.

Similarly, no significant effects on the concentrations of any substances in fresh water, estuarine, or marine ecosystems are anticipated due to the proposed use of the FCS polymer, nor are any significant effects on the concentrations of any substances in terrestrial ecosystems expected as a result of the proposed use of the FCS.

## **8. Environmental effects of released substances**

The Notifier is not aware of any data that would suggest that the FCS polymer may be toxic to organisms in the environment at the low levels at which it may be released. Below is a list of attached summaries of published data regarding various monomers and potential impurities that may be present in the FCS. For the Agency's ready reference, these materials are appended herein.

Itaconic acid: ECOTOX Acquire summary

2-Methyl-2-propenamide: ECOTOX Acquire summary

2-Hydroxyethyl acrylate: ECOTOX Acquire and Fat Head Minnow Database  
summary

2-Methyl-2-propenoic acid: ECOTOX Acquire summary

N-Methylol methacrylamide: No data found

Considering the very low levels at which the polymer may be released to the environment and the safety of the low potential exposure to the monomers and impurities of the FCS, the Notifier respectfully submits that the proposed use of subject SBA copolymer is not reasonably expected to have any adverse effect on organisms in the environment.

#### **9. Use of resources and energy**

As is the case with other food-contact substances, the production, use and disposal of the SBA copolymer requires the use of natural resources such as petroleum products, *etc.* This energy consumption is offset, however, by the benefits offered by the use of polymer, which include improvements in wet, dry, and solvent tensile strength, color stability, pigment receptivity, hand balance, as well as binding efficiency. As noted above, the subject copolymers are identical to polymers currently cleared under Section 176.170 except for the substitution of methacrylamide and N-methylol methacrylamide in place of the cleared monomers acrylamide and N-methylol acrylamide. The methacrylamide-containing polymers will be used as a substitute for the acrylamide-containing polymers. This substitution will have no impact on the use of resources and energy.

#### **10. Mitigation Measures**

As discussed above, no significant adverse environmental impacts are expected to result from the use and disposal of the FCS. Thus, the use of the subject polymer 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 that would necessitate alternative actions to that proposed in this Food Contact Notification. The alternative of not

approving the action proposed herein would simply result in the continued use of currently cleared SBA copolymers.

**12. List of Preparers**


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**13. Certification**

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

Date: August 7, 2008

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Counsel for Omnova Solutions, Inc.