

ENVIRONMENTAL ASSESSMENT

- 1. **Date:** January 9, 2003

- 2. **Notifying Party:** Kuraray America, Inc.
Kuraray Co., Ltd.
Kuraray Europe, GmbH
SEPTON Company of America

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4. **Description of the Proposed Action:**

The action requested in this Food-Contact Notification is to permit the safe use of a new substance, hydrogenated styrene block copolymer with 2-methyl-1,3-butadiene, as a component of food-contact articles.

As discussed in item 9 below, is expected to be employed in the production of food-contact articles that require the clarity of high-impact polystyrene. Articles that may be prepared with include such items as closure liners, vending machine tubing, water tank gaskets, food trays and other similar products.

is expected to compete in these applications primarily with high impact polystyrene or other styrene or block polymers, including especially non-hydrogenated styrene-isoprene block copolymer, styrene-butadiene block copolymer, and hydrogenated styrene-butadiene block copolymer. These polymers are cleared at 21 C.F.R. § 177.1810

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for use in contact with the same food types and under the same conditions of use for which _____ s proposed herein.

_____ is not expected to penetrate any new markets, but is expected to replace other currently used styrene-based polymers in those applications for which it is technically suited.

The hydrogenated styrene block copolymer will be manufactured by the Notifiers at production facilities located in, but not limited to,

The Notifiers do not manufacture finished food-contact articles containing this resin;

rather, they will sell resin to compounders or to processors that are involved in the

manufacture of food-contact articles. Thus, the copolymer is expected to be used by

producers at a number of different production sites throughout the United States. Food-

contact materials containing _____ will be used in patterns corresponding to

national population density, and will be widely distributed across the country.

Consequently, it is expected that disposal will occur nationwide, with about 20% of the

materials ultimately being incinerated, according to current Environmental Protection

Agency (EPA) projections,¹ and with 80% being disposed of by means of sanitary landfill

or, to some extent, by recycling.

5. Identification of Chemical Substance that Is the Subject of the Proposed Action

The additive that is the subject of this Notification is hydrogenated styrene block copolymer with 2-methyl-1,3-butadiene (CAS Reg. No.: 68648-89-5).

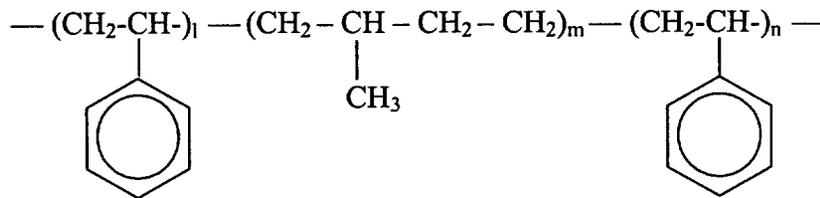
¹EPA Municipal Solid Waste Task Force, The Solid Waste Dilemma: An Agenda for Action (Washington, D.C., U.S. EPA, 1989).

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The block copolymer will be marketed by the Notifiers under the trade name

An illustrative structural formula for the hydrogenated styrene block copolymer is shown below.



The block copolymer has a weight-average molecular weight of 79,100 KDa, a specific gravity of 0.91-0.93, and a melt flow rate of 0.1-1.0 g/10 min (200°C, 10 kg).

contains residual styrene monomer at levels below 1 part per million (ppm), residual 2-methyl-1,3-butadiene monomer at levels below 1 ppm, and residual solvent at levels below 5 ppm.

6. Introduction of Substances into the Environment

In Attachment III of the Notification, we provide information on the manufacture of this [REDACTED] that should be maintained as confidential in accordance with FDA's 21 C.F.R. , Part 20, Public Information Regulations. However, there are no extraordinary circumstances that pertain to the manufacture of [REDACTED] necessitating submission of environmental impact information relating to the production of this substance.

A confidential estimate of the total market anticipated for the subject copolymer in food-contact applications is provided in Attachment 11, Confidential Environmental

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Information. This information confirms that no substantial amount of
will be introduced into the environment from the intended use of the polymer.

To the extent that scrap meeting the specifications is formed,
this material is deposited in land disposal sites or is fed to the incinerator.

Disposal by the ultimate consumer of food packaging materials containing
will be by conventional rubbish disposal and, hence, by sanitary
landfill or incineration.

The hydrogenated styrene block copolymer is prepared only from carbon and
hydrogen containing materials. The products of complete combustion of
are carbon dioxide and water. Thus, no toxic combustion products are
expected as a result of the incineration of this product in a properly operated incinerator.

When food packaging materials containing are added to
sanitary landfills, no significant amount of leaching of components from these materials
into the environment is anticipated. This conclusion is based in part on the extremely low
levels of migration of polymer constituents from food-contact materials shown in
Section F of this Notification when tested under highly exaggerated exposure conditions
compared to the conditions found in a landfill. This expectation is based further on the
Environmental Protection Agency's (EPA) regulations governing municipal solid waste
landfills. EPA's regulations require new municipal solid-waste landfill units and lateral
expansions of existing units to have composite liners and leachate collection systems to
prevent leachate from entering ground and surface water, and to have ground-water
monitoring systems. 40 C.F.R. Part 258. Although owners and operators of existing
active municipal solid waste landfills that were constructed before October 9, 1993 are

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not required to retrofit liners and leachate collections systems, they are required to monitor groundwater and to take corrective action as appropriate.

7. Fate of Emitted Substances in the Environment

(a) Air

No significant effect on the concentrations and exposures to any substances in the atmosphere are anticipated due to the proposed use of _____ The polymer per se is of high molecular weight and does not volatilize. As discussed in Item 5 above, residual monomer levels are extremely low. Finally, the products of complete combustion of the polymer are carbon dioxide and water; the concentrations of these substances in the environment would not be significantly altered by the proper incineration of the polymer in the amounts utilized for food-contact applications.

(b) Water

No significant effects on the concentrations and exposures to any substances in fresh water, estuarine, or marine ecosystems are anticipated due to the proposed use of the subject copolymer. No significant quantities of any substance will be added to these water systems upon the proper incineration of the polymer, or upon its disposal in landfills due to the extremely low levels of migration of resin components, as demonstrated in Section F of this notification and as discussed in Item 6, above.

(c) Land

Considering the factors discussed above, no significant effects on the concentrations and exposures to any substances in terrestrial ecosystems are anticipated as a result of the proposed use of _____ In particular, the extremely low levels of migration of polymer constituents demonstrated by the extraction studies

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indicate that virtually no leaching of these substances may be expected to occur when finished food-contact materials are disposed. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of:

8. Environmental Effects of Released Substances

As discussed previously, substances that may be released to the environment upon the use and disposal of food packaging materials containing _____ include minute levels of oligomeric species from the landfilling of materials containing the additive, and small quantities of carbon dioxide and water from its incineration. As demonstrated by the extraction studies described in Section F of this notification, no constituents of the copolymers may reasonably be expected to leach at more than trace levels from finished food-contact materials placed in landfill sites.

Toxicological data presented in Section G of this notification demonstrate that the hydrogenated styrene block copolymer is of a low degree of acute toxicity. In particular, the _____ copolymer has an acute oral LD₅₀ in rats of greater than 2000 milligrams per kilogram body weight (g/kg b.w.), the highest dosage level that was administered.

Since this substance is not expected to leach significantly from finished food-contact materials deposited in landfill sites, and since it is of such a low order of toxicity, Notifier respectfully submits that no adverse environmental impact can reasonably be anticipated from substances released as a result of the proposed use and subsequent disposal of the subject polymer.

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9. Use of Resources and Energy

styrene block copolymer has a high elasticity and high strength like vulcanized rubber, but without the vulcanization process. Therefore, when is used in place of vulcanized rubber in the manufacture of food-contact articles, many more articles can be injection molded in the same time-frame normally required to manufacture these same food-contact articles by a different process from vulcanized rubber. This results in less energy consumed by the article-formation process.

Since compounds are thermoplastic elastomers, off-specification products can be recycled. Therefore, waste from rejected finished products is decreased.

The use of also is not expected to have any impact on current or future recycling efforts. The polymer is expected to be used primarily or solely in food-contact applications that currently employ styrene-based polymers, including such articles as food trays, food packaging film, etc. To the extent that currently cleared styrene-based polymers are recycled after consumer use, is equally recyclable with these materials. Moreover, where is expected to compete to some extent with non styrene-based polymers, the competitive polymers are usually vulcanized rubber, which is not recyclable. Therefore, as mentioned above, off-spec food-contact articles prepared from can be readily recycled at the converter plant and the rejection rates for finished products are greatly reduced. Finally, the subject polymer is not expected to replace glass bottles or jars, aluminum cans,

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polyethylene terephthalate (PET) bottles for carbonated beverages, or high-density polyethylene milk jugs.

For all these reasons, approval of this notification is not expected to have any adverse impact on the use of natural resources and energy.

10. Mitigation Measures

The only potential adverse environmental impacts would be those resulting from the use and disposal of articles containing the subject polymer. As shown above, no significant effects on the environment are anticipated. This is primarily due to the low toxicity of the polymer and the low levels of migration of polymer constituents as shown in Sections F and G of the notification, as well as the close similarity between and the currently cleared styrene-based polymers with which it is intended to compete. Thus, the use of the _____ 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 currently cleared styrene-based polymers; such action would have no environmental impact. However, in view of the excellent qualities of the _____ for food-contact articles, the fact that resin components are not expected to migrate in more than minuscule amounts from finished food-contact materials into food or into land in which such containers are disposed, and the absence of any significant environmental impact which would result from its use, an effective FCN to permit the safe use of

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is a component of articles intended for use in contact with food is environmentally safe in every respect.

12. List of Preparers

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- b. Ralph A. Simmons, Partner, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001
- c. Holly H. Foley, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001

13. Certification

The undersigned certifies that the information provided in this Environmental Assessment is true, accurate, and complete to the best of his knowledge

/s/

Date: 1/9/03

RALPH A. SIMMONS
Counsel for the Notifiers

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