APPENDIX VIII

ENVIRONMENTAL ASSESSMENT

1.	**Date:**	May 8, 2000
2.	**Name of Notifier:**	Kuraray America, Inc. Kuraray Co., Ltd. Kuraray Europe, GmbH[1/]
3.	**Address:**	All communications on this matter are to be sent in care of Counsel for Notifier, Ralph A. Simmons, Keller and Heckman, 1001 G Street, N.W., Washington, D.C. 20001. Telephone: (202) 434-4120

4. Description of the Proposed Action

The action requested in this Petition is the amendment of an existing Food Additive Regulation, 21 C.F.R. §§ 177.1810. Its purpose is to permit the safe use of a new substance, hydrogenated styrene block copolymer with 2-methyl-1,3-butadiene and 1,3-butadiene as a component of food-contact articles. This block copolymer is known generally as SEPTON®, and more specifically by its tradename, Septon-4033.

1/ As this Petition has been converted into a Food Contact Substance Notification, the references to Petitioner and Petition within the document should be understood to mean Notifier and Notification.

As discussed in Item 9 below, the block copolymer is expected to be employed primarily in the production of food-contact articles that require the clarity of general purpose polystyrene and the toughness of high impact polystyrene. Articles that may be prepared with the use of the hydrogenated styrene block copolymer include such items as closure liners, vending machine tubing, water tank gaskets, food trays, etc.

is expected to compete in these applications primarily with high impact polystyrene and/or general purpose polystyrene, and to a degree with polyesters, cellulosics and rubber. While exhibits a desirable combination of toughness, clarity and heat resistance to degradation, it is essentially similar in technical properties to cleared rubber-modified polystyrene of higher polystyrene content. Consequently, amendment of Section 177.1810 as proposed is not expected to open significant new markets for styrene-based polymers in the area of food-contact articles. Rat'her, in those applications for which polystyrene is technologically suited is expected to replace other styrene-based polymers with less desirable overall characteristics. In areas where polystyrene currently competes with other packaging materials (cellulosics, polyesters, and rubber), the availability of may result

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in some increase in the percentage of the market contacting styrene-based polymers. As noted above, however, in light of the similarity of the polymer to currently cleared styrene-based copolymers, significant new food packaging applications which previously have not made use of styrene containing polymers are not expected as a result of the use of .

The hydrogenated styrene block copolymer will be manufactured by the Petitioner at its production facilities located in n. The Petitioner does not manufacture finished food-contact articles containing this resin; rather, it 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,[2/]

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

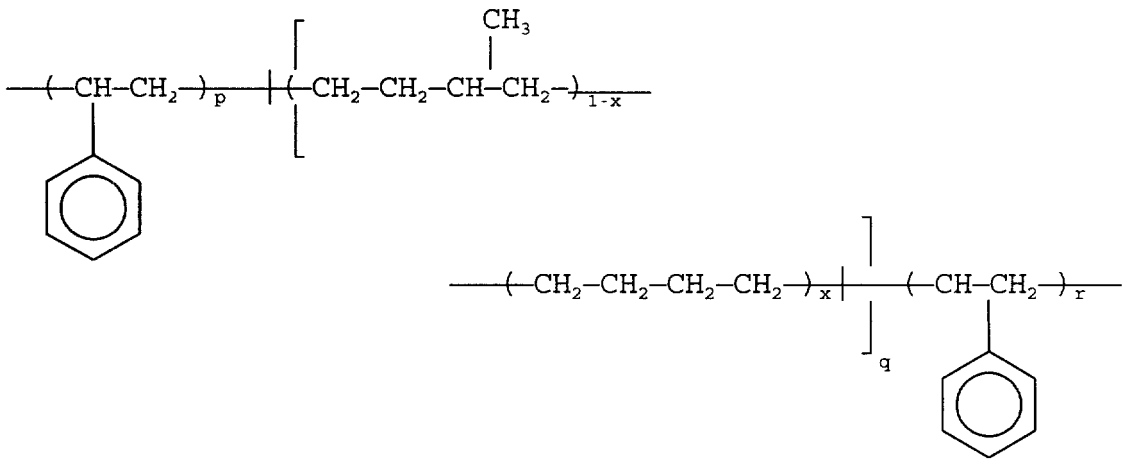
and with 80% being disposed of by means of sanitary landfill or, to some extent, by recycling.

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

The additive that is the subject of this Petition is hydrogenated styrene block copolymer with 2-methyl-1,3-butadiene and 1,3-butadiene (CAS Reg. No.: 132778-07-5).

The block copolymer will be marketed by the Petitioner under the tradename .

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



For the typical composition described above, x equals 50 mole-%.

typically contains, before hydrogenation, styrene, 2-methyl-1,3-butadiene, and 1,3-butadiene in a ratio of 30:38.5:31.5 (w:w:w). The block copolymer has a weight-average molecular weight of 92,900 KDa, a density of 0.91-0.93, and a melt flow of 0.3-3.0 g/10 min (200°C, 10 kg).

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

6. Introduction of Substances Into the Environment

In Section A of the Petition, we provide information on the manufacture of thi that should be maintained as confidential in accordance with **FDA's** Public Information Regulations. However, there are no extraordinary circumstances which pertain to the manufacture **of** 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 Appendix IX, Confidential Environmental Information.

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 open dump, sanitary landfill or incineration.

The hydrogenated styrene block copolymer is prepared from only 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 containin are added to open dumps and sanitary landfills, no significant amount of leaching of components from these materials into the environment is anticipated. This conclusion is based on the extremely low levels of migration of polymer constituents from food-contact materials shown in Section B of this Petition when tested under highly exaggerative exposure conditions compared to the conditions found in a landfill.

The total amount of that might enter the environment in landfill leachate per year is calculated as follows. The percentage of that migrated into 8% ethanol is multiplied by the total pounds of food-contact

produced per year. This number is then multiplied by 0.8 to represent the amount deposited in landfills.

To summarize the pertinent extraction studies that were conducted on , the test plaques were exposed to 8% ethanol at 212°F for 2 hours followed by 10 days at 120°F. The resulting extracts were taken to dryness and the residue dissolved in chloroform for HPLC/GPC analysis. No measurable levels of were found in the extracts using a method sensitivity of 0.0005 mg/in^2, or 50 parts per billion, ppb, assuming 10 g of food contacts each square inch of package surface area.

This sensitivity may be converted to the corresponding fraction of the material extracted as follows. The test plaques were 121 cm square (18.76 in^2) and 0.2 cm in thickness, for a volume of 24.2 cm^3 per plaque. At a density of about 0.92 g/cc, each plaque weighed about 22.3 g. A maximum migration level of less than 0.0005 mg/in^2 for the oligomers represents approximately 8.41 x 10^{-5}% of the weight of the plaque (18.76 in^2/side x 2 sides x 0.0005 mg/in^2 x 100% ÷ 22.3 x 10^3 mg/plaque = 8.41 x 10^{-5}%).

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This fraction may be multiplied by 80% of the total estimated market volume for in food-contact applications to determine the maximum quantity of polymer constituents that may possibly enter land disposal-site leachate per year. These calculations are shown in Appendix IX, Confidential Environmental Information, since they make use of trade secret market information. Based on the extraction data discussed above and the calculations shown in Appendix IX, the concentration of extractable species fro in land-disposal site leachate is expected to be virtually nil.

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, nor upon its disposal in landfills due to the extremely low levels of migration of resin components, as demonstrated in Section B of this Petition 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 indicates that virtually no leaching of these substances may be expected to occur when finished food-contact materials are disposed of. 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 containin 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 B of this Petition, 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 E of this Petition demonstrate that the hydrogenated styrene block copolymer is of a low degree of acute toxicity. In particular, the copolymer has an acute oral $LD_{,}$, 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, Petitioner 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.

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 is also not expected to have any impact on current or future recycling efforts. The polymer is expected to be used primarily cr 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, polyethylene terephthalate (PET) bottles for carbonated beverages, or high-density polyethylene milk jugs.

For all these reasons, approval of this Petition 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 Section B of the Petition, 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.

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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 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, the promulgation of a Food Additive Regulation to permit the safe use of as a component of articles intended for use in contact with food is environmentally safe in every respect.

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12. List of Preparers

a. Harumasa Doi, Vice President, Marketing and Technology, Chemicals, Kuraray America, Inc.

b. Charles V. Breder, Ph.D., Staff Scientist, Keller and Heckman, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001.

c. Holly H. Foley, B.S., Staff Scientist, Keller and Heckman, 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: May ***8, 2000***

Ralph A. Simmons

COUNSEL FOR:

Kuraray America, Inc.
Kuraray Co., Ltd.
Kuraray Europe, GmbH

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14. References

All data referred to in this Environmental Assessment are presented elsewhere in this Petition.

15. Appendix

a. List of potential food-contact applications for

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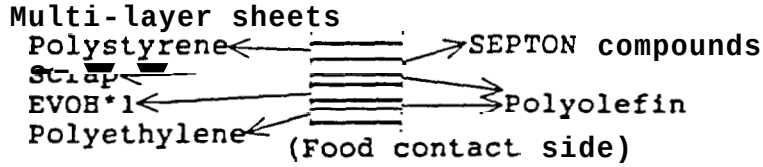
Food packaging applications

1.Food packaging films

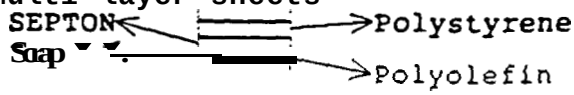
Item	Content
Application	Shrinkable film
Formulation	Polypropylene 65 (parts by weight) Resin*1 20 SEPTON 4033 15
Film thickness	20 to 30μm
Competing materials	PVC(flexible polyvinyl chloride)
Effect of	A high shrink speed such as PVC
Comment	No poisonous gases are generated when the compound is Incinerated.

fn. *1)Hydrogenated terpene resins or alicyclic hydrocarbon resins

2.Food packaging sheets(1)

Item	Content
Application	Cup and tray for yogurt,juice and coffee
Formulation	Multi-layer sheets  *1)Ethylene-vinylalcohol copolymer
Sheet thickness	1 to 3mm
Competing materials	
Effect of	a.Reuse of plant scrap b.Adhesion of PS to PO
Comment	This sheet has a good gas barrier ability.

3.Food packaging sheets(2)

Item	Content
Application	Tray
Formulation	Multi-layer sheets  (Food contact side)
Sheet thickness	0.5mm
Competing materials	A adhesive such as epoxy resins
Effect of	Reuse of plant scrap(compatibilizer)
Comments	There is a PO layer for getting oil resistance of sheets.

4.Gasket

Item	Content
Application	Water tank gasket
Formulation	SEPTON 4055 60 (parts by weight) Paraffin oil 11 Polyisobutylene 17 Polypropylene 12
Sheet thickness	3mm
Competing materials	Vulcanised rubber(IIR)
Effect of	a.High-elasticity b.Process ability c.Reuse of plant scrap
Comment	

5.Closure

Item	Content
Application	Liner of closure
Formulation	A: Polyethylene 90 to 80; Polypropylene -; SEPTON 4033 10 to 20 B: Polyethylene -; Polypropylene < 50; SEPTON 4033 > 50 (parts by weight)
Thickness	0.5 to 3mm
Competing materials	PE/EPR, Polyvinyl chloride paste
Effect of	Elasticity and non-plasticizer
Comment	Formulation: A: for a aluminum bottle cap B: for a polypropylene bottle cap

6.Tube

Item	Content
Application	Tube for vending machine
Formulation	SEPTON compounds(maximum content= 65%)
Thickness	2mm
Competing materials	Vulcanised rubber(Silicone rubber)
Effect of	Elasticity
Comment	