

**APPENDIX 9**  
**ENVIRONMENTAL ASSESSMENT**  
**for Use of SEBS Polymers**  
**in Food Packaging in Contact With Fatty Foods**

1. **Date:** October 16, 2006
2. **Name of Notifier:** Kraton Polymers LLC.
3. **Address:** World Houston Building,  
15710 John F. Kennedy Boulevard  
Suite 300  
Houston, Texas, 77032

All communications on this matter are to be sent in care of Counsel for Notifier:  
Geraldine Edens  
McKenna Long & Aldridge LLP  
1900 K Street NW  
Washington, DC 20006  
Telephone: 202-496-7371  
Facsimile: 202-496-7756

4. **Description of the proposed action:**

The U.S. Food and Drug Administration (USFDA) has previously approved Styrene Block Polymers with 1,3, Butadiene Hydrogenated ("SEBS Polymers") for use in articles or as components of articles that contact food that does not contain free fat and oils (Food Types I, II, IV-B, VI, VII-B, and VIII). *See* 21 C.F.R. 177.1810(b)(1)(i).

In addition, USFDA has also previously approved these polymers for use as components of closures for sealing gaskets at levels up to 42.4% for foods that do contain free fat and oils (Food Types III, IV-A, V, VII-A, VIII, and IX). *See* 21 CFR 177.1810(b)(1)(ii).

The action requested in this Food Contact Notification (FCN) is to establish a clearance for SEBS Polymers for use in articles or as components of articles that contact food containing free fat and oil (Food Types III, IV-A, V, VII-A, and IX) under Conditions of Use A through H. The FCS is intended for use in both single and repeat use articles. Examples of single use articles include, but are not limited to, stand-up pouches, zipper packs, lids, yogurt cups, deli trays and blow molded containers. Examples of repeat use articles include, but are not limited to, conveyer belts, and flexible tubing for fatty foods.

The use of SEBS Polymers in repeat use applications meets the criteria for categorical exclusion under 21 C.F.R. § 25.32(j). Therefore, in accordance with § 25.15, Kraton submits that it is in compliance with § 25.32(j) and, to the best of Kraton's knowledge and belief, there are no extraordinary circumstances that require further analysis in this EA or any repeat use applications for SEBS Polymers.

000216

The remainder of this EA addresses the potential impact of the single-service use of SEBS Polymers.

SEBS Polymers are typically used with other polymers to improve the elasticity, clarity, impact and puncture resistance of articles in contact with food. They may impart these properties when incorporated as a single layer in a multilayer coextruded structure, or as a blend component in combination with other polymers such as polypropylene, polystyrene or polyolefins and other substances such as white mineral oil or calcium carbonate fillers.

SEBS Polymers are elastic and flexible and, when formulated in food packaging materials, provide a wide range of properties that help improve the performance of the packaging. SEBS Polymers are currently used in a variety of packaging materials for non-fatty foods and as components in sealing gaskets for fatty foods. Because of their ability to enhance the performance of packaging materials, there is a need to use SEBS Polymers in packaging materials used for fatty foods.

The Notifier does not intend to produce finished food packaging articles from the SEBS Polymers. Rather, the SEBS Polymers will be sold to manufacturers engaged in the production of food contact materials. Consequently, SEBS Polymers will be incorporated into food-packaging articles at production locations throughout the United States. The food packaging materials are expected to be used by consumers in patterns corresponding to national population density and to be widely distributed across the county.

Before being used in food contact articles, SEBS polymers are typically fabricated with other polymers such as polypropylene, polystyrene or polyolefins. Other substances such as USP grade white mineral oil, calcium carbonate filler and antioxidants may also be added.

To the best of the Notifier's knowledge, SEBS Polymers are not compounded with polyethylene terephthalate (PET) polymers or High Density Polyethylene (HDPE) in the marketplace.

Disposal of food packaging materials containing SEBS Polymers is expected to occur nationwide with the materials ultimately entering municipal solid waste landfills, being combusted, or (where possible) being recycled. It is expected that approximately 55.4% of the materials will be deposited in solid waste landfills and approximately 14.0% will be combusted.<sup>1</sup> Since SEBS Polymers are typically added to other food contact substances in the manufacture of articles or components or articles in contact with fatty foods, the addition of SEBS Polymers for this use will not affect the amount of polymers now being recycled.

The types of environments present at and adjacent to these disposal locations are the same as for the disposal of any other food-contact material in current use. Consequently,

---

<sup>1</sup> U.S. Environmental Protection Agency, *Municipal Solid Waste in the United States: 2003 Facts and Figures*, available at <http://www.epa.gov/epaoswer/non-hw/muncpl/pubs/msw05rpt.pdf>.

there are no special circumstances regarding the environment surrounding either the use or disposal of food contact articles containing SEBS Polymers.

**5. Identification of substances that are the subject of the proposed action:**

The food contact substance that is the subject of this Notification is benzene, ethenyl-, polymer with 1,3-butadiene, hydrogenated (CAS No. 66070-58-4). The FCS is commonly referred to as SEBS (styrene- ethylene/butylene-styrene), [redacted] polymers, or [redacted] (SEBS). SEBS represents a family of block polymers prepared from styrene and 1,3-butadiene. SEBS are high molecular weight polymers.

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

It is important to remember that SEBS Polymers have been used as components of food contact articles in contact with non-fatty foods for almost 30 years and as closures for sealing gaskets in contact with fatty foods for 15 years. The use of SEBS Polymers in food contact articles in contact with fatty foods is not expected to significantly increase the amounts of, or modify the methods by which, SEBS Polymers are introduced into the environment. Throughout its 30-year history, no adverse environmental effects have been associated with SEBS Polymers being incorporated into food contact articles.

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. Information available to the Notifier does not suggest that there are any extraordinary circumstances indicative of any adverse environmental effects as a result of the manufacture of SEBS Polymers. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

Little or no introduction of SEBS Polymers into the environment will result from its use because it is completely incorporated into food packaging articles, and essentially all of it is expected to remain with these materials throughout the use of the product. Any waste materials generated in this process, *e.g.*, plant scraps, are expected to be disposed of as part of the manufacturer's nonhazardous solid waste in accordance with established procedures.

Disposal by the ultimate consumer of food contact articles containing SEBS Polymers will be by conventional disposal of municipal household waste, and hence, primarily by sanitary landfill or incineration. Since SEBS Polymers are usually compounded with other polymers when used in food packaging, recycling of SEBS itself is usually limited to non-food applications, such as building materials (*e.g.* gaskets for doors, handles for tools) or other household items where the purity of the polymer is not critical (*e.g.* pots for plants, rubber handles for bicycles and tennis rackets, and similar applications).

**Landfills:** Extremely minor amounts, if any, of SEBS Polymers are expected to enter the environment as a result of landfill disposal or food contact packaging

000218

materials, in light of the Environmental Protection Agency (EPA) regulations governing municipal solid waste landfills. See 40 C.F.R. part 258. 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 groundwater monitoring systems. Although owners and operators of existing active municipal solid waste landfills that were constructed before October 9, 1993, are not required to retrofit liners and leachate collection systems, they are required to monitor groundwater and to take corrective action as appropriate. Moreover, SEBS Polymers are high molecular weight polymers that contain only minute levels of extractable material even under conditions that greatly exaggerate environmental exposure conditions.

**Combustion:** SEBS Polymers are composed of carbon and hydrogen, elements commonly found in municipal solid waste. The complete combustion of SEBS Polymers will produce carbon dioxide and water. SEBS Polymers are already approved for use in food packaging in contact with non-fatty foods and for use as sealing gaskets for fatty foods. The additional volume of SEBS Polymers used for food packaging in contact with fatty foods will not significantly alter emissions from municipal waste combustors.

## 7. Fate of Emitted Substances in the Environment

- a. **Air:** No significant effects on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of SEBS Polymers. The polymers have high molecular weights and do not volatilize. Therefore, no significant quantities of any substances will be released into the air upon the use and disposal of food packaging materials manufactured with SEBS Polymers.

As noted above, the complete combustion of the SEBS Polymers will produce carbon dioxide and water. The concentrations of these substances in the environment will not be significantly altered by the proper incineration of SEBS Polymers in the amounts used in food packaging materials.

- b. **Water:** No significant effects on the concentrations of and exposures to any substances in freshwater, estuarine, or marine ecosystems are anticipated due to the proposed use of the SEBS Polymers. No significant quantities of any substance will be added to these water systems through either the proper incineration of the polymers or through their disposal in landfills due to the extremely low levels of aqueous migration of polymer components.
- c. **Land:** 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 SEBS Polymers. As noted above, the extremely low

000219

levels of maximum potential migration of components of the SEBS Polymers, demonstrated by the migration studies, indicate that virtually no leaching may be expected to occur under normal environmental conditions which finished food packaging materials are disposed. Therefore, there is no expectation of any meaningful exposure of terrestrial organisms to the SEBS Polymers as a result of their proposed use in food contact articles in contact with fatty foods.

SEBS Polymers are expected to be remain stable in landfills over a long period of time. The rubber midblock is saturated (does not contain double bonds) and is resistant to aging and ultraviolet (UV) exposure. This same family of polymers are used in other, non-food contact applications such as automotive gaskets due to their stability in the environment and their ability to withstand long outdoor exposure.

Current applications as described above and long shelf life in proper warehouse storage facilities (typically 5+ years without noticeable detriment to product quality) all indicate that these polymers are essentially inert and do not pose a threat to the environment when properly disposed of in landfills.

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

As discussed above, the only substances that may be expected to be released to the environment from the use and disposal of food packaging materials containing SEBS Polymers consist of extremely small quantities of combustion products and extractables. Therefore, no adverse effects on organisms in the environment are expected as a result of the disposal of articles containing the polymers. In addition, the use and disposal of the polymers are not expected to threaten a violation of applicable laws and regulations, *e.g.*, 40 C.F.R. 60 (regulation of municipal solid waste combustors) and Part 258 (regulation of landfills).

#### **9. Use of Resources and Energy**

The production, use, and disposal of SEBS Polymers involve the use of natural resources such as water, petroleum products and coal. The use of SEBS Polymers, however, is not expected to result in a net increase in the use of energy and resources because SEBS Polymers will likely be used in place of similar materials currently used in food packaging materials for fatty foods. These include polyvinyl chloride polymers, thermoplastic olefin polymers and cross-linked natural rubber.

The replacement of currently used materials with SEBS Polymers is not expected to have an adverse impact on the use of energy and resources. Manufacture of SEBS Polymers and their fabrication in food packaging articles will consume energy and resources in amounts comparable to the manufacture and use of materials currently used.

000220

To the best of the Notifiers knowledge, SEBS Polymers are not compounded with either PET or HDPE, and thus the use of SEBS Polymers in food packaging for contact with fatty foods will not affect the recycling activities of these two polymers.

**10. Mitigation measures**

As shown above, no significant environmental impacts are expected to result from the use and disposal of food contact articles fabricated with SEBS Polymers. This is primarily due the minute levels (if any) of leaching of potential migrants from the finished article and the insignificant impact on environmental concentrations of combustion products of SEBS Polymers. Moreover, SEBS Polymers have a 30-year history of use in food contact articles in contact with non-fatty foods and a 15-year history of use in sealing gaskets for fatty foods for which no environmental impacts have been identified. Thus, mitigation measures are not required because of the potential negligible impact SEBS Polymers may have on the environment.

**11. Alternatives to the proposed action**

No potential adverse environmental effects discussed herein would necessitate alternative actions to those proposed in this Notification. The alternative of not approving the proposed action would simply result in the continued use of the materials that SEBS Polymers would likely replace. Because SEBS Polymers are not expected to enter the environment in more than minute amounts (if any) upon the use and disposal of the finished food contact articles, there are no significant environmental impacts which would result from allowing the Notification to become effective.


**12. List of preparers**

**Jonathan Topper • Global FDA and Toxicology Manager, KRATON Polymers LLC • World Houston Building, 15710 John F. Kennedy Boulevard, Suite 300 • Houston, TX 77032-2348**

**13. Certification**

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

DATE: October 16, 2006

  
*Jonathan Topper*

000221