ENVIRONMENTAL ASSESSMENT

Part 1. Public Information

1. Date: January 11th, 2007

2. Name of Notifier: 3. BASF Aktiengesellschaft

3. Address: All communications on this matter are to be sent to
BASF Aktiengesellschaft
Dr. Martin Klatt, KS/KS – E 100,
D-67056 Ludwigshafen,
Germany

4. Description of the Proposed Action

The action requested in this notification is to allow the safe use of a rubber-modified polystyrene copolymer as a component of food-contact articles, for all food types. This rubber-modified polystyrene copolymer is comparable to polymers described in 21 CFR §177.1810 (3)(b)(1.i) but differs with respect to the Tg1 due to the random PSB – mid-block.

More specifically, the polymer, which is the subject of this notification is a rubber-modified polystyrene resin prepared by the polymerization of 1,3-butadiene and styrene such that the resulting product contains between 60 to 75 % by weight of polymer units derived from styrene monomer. The rubber-modified polystyrene copolymer is referred to herein-after as: Styroflex®.

Styroflex® is composed of two polystyrene block end caps, and a randomized copolybutadiene/styrene mid-block. The random block functions by improving the elongation properties of the polymer, thus conveying high elasticity to the finished article. Accordingly, the polymer is expected to be employed primarily in the production of food-contact articles that require the clarity of general-purpose polystyrene and an improved the elasticity. Articles that may be prepared with the use of the polymer include such items as films or coatings for food-contact use. Styroflex® is expected to compete in these applications primarily with high impact polystyrene (HIPS), where a high elasticity is required, and to a degree with plasticized PVC cling films. While Styroflex® exhibits a desirable combination of elasticity and clarity, it is essentially

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similar in technical properties to HIPS. Consequently, the notification as proposed is expected to open new markets for styrene block polymers in the area of food packaging.

The above-mentioned use as coating might be a minor application in future where only negligible amounts will be used. The effect on the environment will not substantially differ whether the FCS is used as a film or as an even thinner coating. For this reasons it is not separately considered in the following assessment

Rather, in those applications for which HIPS polymers are technologically suited, Styroflex® is expected to replace HIPS-based polymers with less desirable overall characteristics. However the availability of Styroflex® may increase the percentage of the market packaged in styrene-based polymers only by insignificant amounts, because the scheduled amount of Styroflex® to be used in food contact applications will be [redacted], which is [redacted] of the market volume of HIPS polymers. As noted above, in light of the similarity of the polymer to currently cleared styrene block polymers, new food packaging applications which previously have been made of HIPS are expected as a result of the use of Styroflex®.

In addition, BASF Aktiengesellschaft has determined that the random block improves processing characteristics of the polymers, thus leading to lower rejection rates of finished articles. Considering also the difference in mechanical properties between Styroflex® and HIPS, the use of Styroflex® as proposed could lead to a reduction in the mass of polymer needed for certain applications.

The polymer will be manufactured by the Notifier at its production facilities located in Ludwigshafen (Germany), Antwerp (Belgium), and Altamira (Mexico). The Notifier does not manufacture finished food-contact articles containing the resin; rather, it will sell resin to compounders or to processors that are involved in the manufacture of food-contact articles. Thus, the co-polymer is expected to be used by film producers at a number of different production sites throughout the United States. Food-contact materials containing Styroflex® 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, and with 80% being disposed of by means of sanitary landfill or, to some extent, by recycling.

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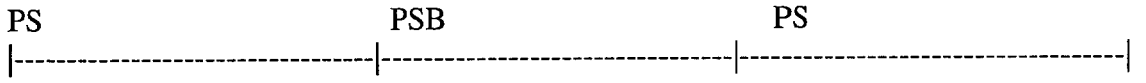
5. Identification of Chemical Substance that is the Subject of the Proposed Action

The polymer will be marketed by the Notifier under the trade name Styroflex®.

An illustrative structural formula for the styrene/butadiene copolymer is shown:



PS = polystyrene
PSB = styrene-butadiene-copolymer

Styroflex® typically contains styrene and butadiene moieties in a ratio of 65:35 (w/w). The styrene content of the product is limited to a minimum of 60 % by weight.

6. Introduction of Substances Into the Environment

Notifier considers the details of its manufacturing process for Styroflex® to be a valuable trade secret. In accordance with 21 C.F.R.§ 25.30(b), this information is provided in Section A of this notification, not as a part of the Environmental Assessment. The information included in Section A should be protected from unauthorized disclosure in accordance with FDA's Public Information Regulations.

To summarize the information provided in Section A, the subject polymer is produced by the reaction of a mixture of styrene and 1,3 butadiene. The reaction is carried out by polymerization of the monomers dissolved in a hydrocarbon solvent. The polymer consists of two polystyrene end blocks and a randomized copolybutadiene styrene middle block. The polymer contains a mixture of stabilizers that are cleared for use in all polymers.

We have determined that no extraordinary circumstances apply to the manufacture of the food-contact substance. Therefore, information regarding production of the food-contact substance is not provided.

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

The rubber-modified polystyrene copolymer is prepared from only carbon and hydrogen containing materials. Thus, no toxic combustion products are expected as a result of the incineration of this product in a properly operated incinerator.

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When food-packaging materials containing Styroflex® are added to sanitary landfills, no significant amount of leaching of either oligomeric components or the subject stabilizer from these materials into the environment is anticipated because of a lack of solubility in water.

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 Styroflex®.
The manufacture of Styroflex® generates as waste stream activated carbon charged with inorganic and organic compounds. This waste stream is sent to a licensed industrial waste treatment facility for incineration. Consequently, no significant volatile emissions are anticipated at the site of production of the rubber-modified polystyrene copolymer.

Moreover, 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 packaging 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. We expect that the information, which will be provided later in Item 6 of this Environmental Assessment demonstrate that no substance will be emitted to aqueous compartments of the environment at levels that could cause any adverse environmental impact. More specifically, all wastewater from the production of is collected and treated in a central facility. Sampling of the wastewater occurs 24 hours a day to ensure compliance with the applicable discharge permits. 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.

(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, either when small quantities of plant scrap or larger amounts of

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finished packaging 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 containing include minute levels of oligomeric species and/or stabilizers from the landfilling of materials containing the additive, and small quantities of carbon dioxide and water from its incineration. No constituents of the copolymer may reasonably be expected to leach at more than trace levels from finished packaging materials placed in landfill sites.

Since the substance is not expected to leach significantly from finished packaging 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.

9. Use of Resources and Energy

As is the case with other food-packaging materials, the production, use and disposal of Styroflex® involves the use of natural resources such as petroleum products, coal, and the like. However, the manufacture of the subject polymer will not result in an increase in the use of such natural resources since the product is intended to compete with and replace HIPS other rubber-modified polystyrene copolymers currently on the market for use in food packaging applications, which require the expenditure of the same or similar quantities of resources to produce. Furthermore, the use of the subject resin in food-contact articles will not significantly alter the applications for which such articles are suitable.

The use of Styroflex® is also not expected to have any impact on current or future recycling efforts. The polymer is expected to be used primarily or solely in food packaging applications that currently employ styrene-based polymers, including such articles as meat trays, egg cartons, and food packaging film. To the extent that currently cleared rubber-modified polystyrene is recycled after consumer use, is equally recyclable with this material since the polymers are identical with the exception of a slight difference in comonomer ratios. Moreover, is not expected to compete with non-styrene based polymers or other materials in applications in which the currently used materials are widely recycled. For example, 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.

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As discussed previously, Styroflex® exhibits improved processing characteristics over those of traditional polystyrene. Consequently, somewhat lower rates of rejection, and lower volumes of plant scrap, may be expected upon the use of the polymer, resulting in additional savings in resource and energy consumption. 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

As shown above, no significant effects on the environment are anticipated from the use and disposal of articles containing the subject polymer. 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 notification, as well as the close similarity between Styroflex® and the currently cleared styrene-based polymers with which it is intended to compete. Thus, the use of the FCS 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 HIPS polymers; such action would have no environmental impact. However, in view of the excellent qualities of the Styroflex® for food packaging, the fact that resin components are not expected to migrate in more than minuscule amounts from finished food packaging 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, allowing this notification to become effective to permit the safe use of Styroflex® as a component of articles intended for use in contact with food is environmentally safe in every respect.

12. List of Preparers

a. Dr. Martin Klatt, KS/KS, Head of Product Safety and Regulatory Affairs, BASF Aktiengesellschaft, D-67056 Ludwigshafen

b. Dr. Ruth Zschiesche, KS/KS, Manager Product Safety and Regulatory Affairs, BASF Aktiengesellschaft, D-67056 Ludwigshafen

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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.

Head of Product Safety and Regulatory Affairs: Date: 29.1.07

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