



FOOD CONTACT SUBSTANCE NOTIFICATION

March 26, 2001

ATOFINA PETROCHEMICALS, INC.

Page 1

APPENDIX IX

ENVIRONMENTAL ASSESSMENT

- 1. Date: March 26, 2001
- 2. Name of Notifier: ATOFINA Petrochemicals, Inc.
- 3. Address: All communications on this matter are to be sent in care of Counsel for Notifier, George G. Misko, Keller and Heckman, 1001 G Street, N.W., Washington, D.C. 20001. Telephone: (202)434-4170

4. Description of the Proposed Action

The action requested in this notification is to permit the safe use of a new rubber-modified polystyrene copolymer as a component of food-contact articles; and, to provide for the safe use of octadecyl 3,5-di-tert-butyl-4-hydroxyhydrocinnamate () as a stabilizer in food-contact articles prepared from the subject rubber-modified polystyrene resin.

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 no less than 71% by weight of polymer units derived from styrene monomer. The rubber-modified polystyrene copolymer is referred to hereinafter as :

is composed of two polystyrene block end caps, and a poly-butadiene mid-block with a random butadiene/

FOOD CONTACT SUBSTANCE NOTIFICATION

March 26, 2001

ATOFINA PETROCHEMICALS, INC.

Page 2

styrene portion. The random block functions by improving the elongation properties of the polymer, thus conveying high impact strength 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 the toughness of high impact polystyrene. Articles that may be prepared with the use of the polymer include such items as transparent meat trays, egg containers, blow-molded containers, and films for food-contact use. is expected to compete in these applications primarily with high impact polystyrene and/or general purpose polystyrene, and to a degree with polyesters and cellulose. While exhibits a desirable combination of toughness and clarity, it is essentially similar in technical properties to cleared styrene block polymers. Consequently, the notification as proposed is not expected to open significant new markets for styrene block polymers in the area of food packaging. Rather, in those applications for which styrene block polymers are 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 (cellulose, polyesters), the availability of may result in some increase in the percentage of the market packaged in styrene-based polymers. As noted above, however, in light of the similarity of the polymer to currently cleared styrene block polymers, significant new food packaging applications which previously have not made use of polystyrene are not expected as a result of the use of

000029

In addition, Fina has determined that the random block improves processing characteristics of the polymers,^{1/} thus leading to lower rejection rates of finished articles. Consequently, the use of as proposed could lead to a slight reduction in the amount of polymer needed for certain applications.

also contains a stabilizer that is cleared for use in styrene block polymers complying with Section 177.1810, but not for the conditions of use proposed herein. Since the stabilized is intended to compete with and replace stabilized polymers that are currently cleared under Section 177.1810, the use of the stabilizer in will be in place of its use in other styrene-based polymers. For this reason, there will be little or no increase in the use of in food-contact applications as a result of the commercial use of. Since the stabilizer is proposed for use at a maximum level of 0.25 percent by weight of the polymer, information regarding the stabilizer will be presented herein in an abbreviated format.

The polymer will be manufactured by the Notifier at its production facilities located in . 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 copolymer is expected to be used by container producers at a number of different production sites throughout the United States. Food-contact materials containing Finaclear® 520 will be used in patterns corresponding to national population density,

^{1/} See the report in Appendix V entitled: Influence of a Random Styrene-Butadiene Block on Properties and Rheological Behavior of GPPS/Clear SBS Blends.

FOOD CONTACT SUBSTANCE NOTIFICATION

March 26, 2001

A TOFINA PETROCHEMICALS, INC.

Page 4

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

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

000031

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

The additives that are the subject of this notification are a styrene/butadiene copolymer (CAS Reg. No.: 9003-55-8) containing a minimum of 71% styrene monomer, and a stabilizer, octadecyl 3,5-di-tert-butyl-4-hydroxyhydrocinnamate (CAS Reg. No.: 2082-79-3).

The stabilized polymer will be marketed by the Notifier under the tradename

An illustrative structural formula for the styrene/butadiene copolymer is shown in Section A of the Petition from which this notification was converted.

typically contains styrene and butadiene moieties in a ratio of 73:27 (w:w). The styrene content of the product is limited to a minimum of 71% by weight.

has a weight-average molecular weight of 120,000 KDa, a density of 1.01, and a melt flow of 7.5 g/10 min.

The finished rubber-modified polystyrene contains residual styrene monomer at levels below 100 parts per million (ppm) and residual 1,3-butadiene at levels below 5 parts per billion (ppb).

6. Introduction of Substances Into the Environment

Notifier considers the details of its manufacturing process for 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 middle polybutadiene block with a random styrene/butadiene portion. The polymer contains a stabilizer,

that is cleared for use in polymers complying with Section 177.1810, but not for use under the conditions proposed for the subject polymer.

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 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.

When food packaging materials containing Finaclear[®] 520 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. This conclusion is based on the extremely low levels of migration of polymer constituents from packaging materials tested under exposure conditions representative of the intended conditions of use as shown in Section B of this notification.

These studies were conducted on two different grades of rubber-modified polystyrene; (containing 71% styrene) and (containing 74% styrene). The test plaques were cut into squares with a length of 6.5 cm and were 0.2 cm in thickness. Sets of 8 test plaques were exposed to 8% ethanol at 122°F for 10 days. The resulting extracts were evaporated to dryness and the residues were fractionated with dichloroethane to separate inorganic from organic components. No measurable organic residue was detected; the sensitivity of the gravimetric procedure employed was 0.1 mg, or 0.0125 mg per test plaque.

This sensitivity may be converted to the corresponding fraction of the material extracted as follows. The test plaques were 6.5 cm square and 0.2 cm in thickness, for a volume per plaque of 8.45 cm³. At a density of about 1.0 g/cc, for a weight of 8.45 g per plaque, a maximum migration level of less than 0.0125 mg per plaque represents approximately $1.5 \times 10^{-4}\%$ of the weight of the plaque. This value includes both potential migration

of oligomeric species from the basic rubber-modified polystyrene as well as migration of the subject stabilizer.

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 X, 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 X, the concentration of extractable species from _____ 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 manufacture of generates two waste streams: activated carbon charged with inorganic and organic compounds, and a mixture of antioxidants. These waste streams are 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. Information provided in Item 6 of this Environmental Assessment demonstrates 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

000036

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 due to the extremely low levels of migration of resin components, as demonstrated in Section B 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 indicates that virtually no leaching of these substances may be expected to occur, either when small quantities of plant scrap or larger amounts of 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 _____.

000037

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. As demonstrated by the extraction studies described in Section B of this notification, no constituents of the copolymer may reasonably be expected to leach at more than trace levels from finished packaging materials placed in landfill sites.

Toxicological data presented in Section E of this notification demonstrate that the rubber-modified polystyrene copolymer is of a low degree of acute toxicity. In particular, the copolymer has an acute oral LD₅₀ in rats of greater than 5000 milligrams per kilogram body weight (g/kg b.w.), the highest dosage level that could be administered.

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.

000038

9. Use of Resources and Energy

As is the case with other food-packaging materials, the production, use and disposal of _____ 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 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 _____ 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.

000039

FOOD CONTACT SUBSTANCE NOTIFICATION

March 26, 2001

ATOFINA PETROCHEMICALS, INC.

Page 13

As discussed previously, 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.

000040

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 Finaclear® 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.

000041

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 block polymers; such action would have no environmental impact. However, in view of the excellent qualities of the _____ 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 Finaclear® 520 as a component of articles intended for use in contact with food is environmentally safe in every respect.

000042

FOOD CONTACT SUBSTANCE NOTIFICATION

March 26, 2001

ATOFINA PETROCHEMICALS, INC.

Page 16

12. List of Preparers

- a. Robert H. Burr, Specialist Technical Services, Finaclear[®] Polymers, Fina Oil and Chemical Company, Post Office Box 1200, Deer Park, Texas 77536.
- b. Justin P. McCarthy, Attorney, Keller and Heckman, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001.
- c. Charles V. Breder, Ph.D., Staff Scientist, Keller and Heckman, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001.
- d. Holly H. Foley, B.S., Staff Scientist, Keller and Heckman, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001.

000043

13. Certification

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

Date: March 26, 2001



George G. Misko

COUNSEL FOR: ATOFINA Petrochemicals,
Inc.

14. References

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

000045

15. Appendices

- a. Letter certifying compliance of production facilities with all applicable environmental regulations.

000046
