Attachment 6

FCN Tuftec-EA

Form 3480, Part IV-B-Environmental Assessment

1. Date: March 24, 2008

2. Company: Asahi Kasei Chemicals Corporation

3. Address: 1-3-1, Yako, Kawasaki-ku, Kawasaki-city, Kanagawa 210-0863, JAPAN

4. Description of the Proposed Action:

This environmental assessment is submitted for review of a food contact notification for the use of styrene block copolymer with 1,3-butadiene hydrogenated to be used as a modifier of polypropylene film with maximum thickness of 0.5 mm for use levels up to 40% of the formulation of the food contact surface. The uses permit the production of transparent sheet films with flexibility and absence of hazing and wetting under bending or folding.

The food contact article as manufactured will include single use food containers. The conditions of use with all types of food will be consistent with those currently permitted with polypropylene, 21 CFR 177.1520.

Styrene block polymer with 1,3-butadiene hydrogenated is currently approved and defined in 21 CFR 177.1810(b)(3)(i); meeting all specification excepting the high glass transition point specification due to lower levels of styrene in the polymer. The use of this polymer blend will have the same impact on the environment as existing products. The styrene block polymer with 1,3-butadiene hydrogenated will be manufactured at the notifier's production facilities.

Food packaging materials made from this polymer that are the subject of this notification will be manufactured by various producers of food packaging materials. The resulting films or other food contact articles will be used in patterns that correspond to the national population density and will be distributed across the country. Disposal is expected to occur nationwide with approximately 76% of the materials being mixed with household waste in landfills and 24% being incinerated.[1] The types of environments surrounding the disposal locations remain the same as for any other food packaging material currently in use. There are no special considerations for the environment related to the disposal of these blends of the food contact substance with polypropylene when used as proposed. The manufacture, use, and disposal of food packaging materials from these polymers is not expected to significantly change from, or increase the amount of polypropylene or other olefin polymers currently in use for which the subject blend of polymers is intended to compete and replace. Therefore, there is no significant impact on the environment as a result of the use of this blend of polymers.

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

The contact substance is styrene block polymer with 1,3-butadiene hydrogenated. The FCN is chemically identified as substance as listed in 21 CFR 177.1810(b)(3)(1), with the exception of the glass transition point. All other specifications such as molecular weights, solubility, and extractables meet those as contained specified for styrene block polymers with 1,3-butadiene hydrogenated, 21 CFR 177.1810(b)(3).

[1] *Characterization of Municipal Solid Waste in the United States*: 1997 Update, EPA530-R-98-007, U.S. Environmental Protection Agency (5305W), Washington, DC 20460, May 1998

6. Introduction of the substance into the environment:

No extraordinary circumstances apply to the manufacture of the polymers that are the subject of this notification. Emission circumstances are adequately addressed by general or specific emission requirements promulgated by the Japanese government and Federal, State or local environmental agencies. The proposed action does not threaten a violation of National, State, or local environmental laws or requirements. Production associated with the proposed action does not adversely affect a species or critical habitat of a species determined to be endangered or threatened and entitled to special protection.

Little or no introduction into the environment of the food contact substance at the site of manufacture and processing will result from their use because the substance is almost completely incorporated into food-packaging materials and essentially all of these copolymers are expected to remain with food packaging throughout use of the product. The eventual fate of the substance after incorporation of the substance into food contact formulations is land disposal sites (sanitary landfill) or incineration. Disposal by the ultimate consumer of food packaging material containing the food contact substance will be by conventional rubbish removal, with disposal in sanitary landfill or incineration.

Based on migration studies on the copolymers subject to this action, which were performed to demonstrate the safety of this additive, only very low levels of substances are expected to leach from these materials disposed in landfills. Therefore, the introduction of these substances into the environment will not result in violation of the Environmental Production Agency's regulations in 40 CFR part 258 that pertain to landfills.

The copolymers subject to this action are composed of carbon, hydrogen and oxygen; elements commonly found in municipal solid waste.[2] The complete combustion of these copolymers will produce only carbon dioxide and water. Because these copolymers will be competing with and replacing very similar materials, adding them to waste that is combusted will not alter the emissions from municipal waste combustors. Therefore, we do not expect that the combustion of the additive will cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations, i.e., 40 CFR part 60 or other relevant States and local laws.

7. Fate of emitted substances in the environment:

a: Air
No significant effect of the concentration and exposure to any substance in the atmosphere are anticipated due to the proposed use of the FCN substance. The polymer is of high molecular weight and is not volatile. Residual polymer levels are very low and insignificant with respect to air emmisions. The products of combustion of the polymer are carbon dioxide and water; the concentrations of thee 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 concentration and exposure to any substance 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 Part II, Section F of this notification and as discussed in Item 6 above.

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[2] The levels of carbon, hydrogen and oxygen commonly found in municipal solid waste can be found in *Municipal Waste Combusors – Background Information for Proposed Guidelines for Existing Facilities,* EPA-450/3-89-27e, United States Environmental Protection Agency, Office of Air Quality Planning and Standards, Research Triangle, Park, NC 27711; August 1989; Table 2.2-1.

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 the FCN substance. In particular, the extremely low levels of migration of polymer constituents demonstrated by the extraction studies 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 us of the FCN substance.

The use and disposal of the FCN substance is not expected to threaten a violation of applicable laws and regulations, e.g., the Environmental Protection Agency's regulation in 40 CFR parts 60 and 258.

8. Environmental effects of released substances:

The substances that may be released to the environmental upon the use and disposal of the food contact material are not expected to have detrimental environmental effects. The polymer blends that are disposed of by landfill are similar to those currently authorized. No constituents of the FCN substance may reasonably be expected to leach at more than trace levels from finished food-contact materials placed in landfill sites as demonstrated by the extraction studies included in this notification

Incineration of disposed food contact substances would result only in carbon dioxide and water from the incineration. There is no evidence that the environmental effects relating to the use of this substance to the environment would differ from styrene block copolymer with 1,3-butadiene hydrogenated as currently approved by FDA regulation.

The substance is not expected to leach significantly from finished food contact materials deposited landfill sites. It is not expected that any toxic substance would result from incineration. The notifier's respectively 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 polymer.

9. Use of resources and energy:

The packaging materials currently used in the expected applications, are very similar to the packaging manufactured using the FCN substance. Also, the recycling of food-packaging materials will not change as a result of FDA's approval of the subject FCN. The currently regulated materials are not now recycled nor are articles made with the subject copolymers expected to be recycled,. The FCN substance is not expected to replace glass bottles, jars, or aluminum cans.

The approval of this notification is not expected to have any adverse impact on use of natural resources and energy.

10. Mitigation measures:

There is no potential adverse environmental impact associated with the proposed action. This notification is for a substance that is intended to compete with already regulated and used, chemically similar substance. No new environmental impacts are expected.

11. Alternatives to the proposed action:

No potential adverse environmental impacts have been identified for the proposed action which would necessitate alternative actions to that proposed in this notification. The alternative on not approving the the action proposed would result in the continued use of currently cleared blends; such action would have no environmental impact, but would not permit the production of transparent sheets and film with flexibility and absence of hazing and allowing the bending or folding of the packaging without whitening .

12. List of Preparers:

Kiyoo Katou, Manager, Synthetic Rubber Development Department, Asahi Kasei Chemicals Corporation.
Dr. William A. Olson, President, Center for Regulatory Services, Inc.

13. Certification:

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

(date) March 24, 2008

(signed) _____
Authorized Official
Title General Manager
Asahi Kasei Chemicals Corporation

(date) April 2, 2008

(signed) _____
William A. Olson, Ph.D.
President
Center for Regulatory Services, Inc.

FCN-Tuftec-EA-08
Final