EA for Styrene maleic anhydride copolymer, sodium salt as a surfactant in the manufacturing process of styrene block polymer with 1,3-butadiene and 1,3-butadiene hydrogenated.

Form 3480, Part IV-B-Environmental Assessment

1. **Date**: August 2004

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**:

   a. **Requested action:**
   This environmental assessment is submitted for review of a food contact notification for the use of 2,5-Furandione, polymer with ethenylbenzene, sodium salt (commonly referred to as styrene-maleic anhydride copolymer, sodium salt) for use in the manufacture of styrene block polymer with 1,3-butadiene and 1,3-butadiene hydrogenated complying with 21 CFR 177.1810 at a residual level not to exceed 1100 parts per million (ppm) of the finished food-contact article.

   b. **Need for action:**
   The EA is prepared on the basis that the substance is used as a processing aid at the site of manufacture of the finished food packaging material, and that a significant portion of the food contact substance is removed from the food packaging material prior to its use.

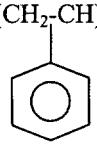
   c. **Locations of use/disposal:**
   The use of this FCN material will be exclusively at the production plant located in Japan. Any waste resulting from the use of an excess amount of the FCN substance in the manufacturing process will not enter the United States. Waste disposal related to the use of the FCN substance as a processing aid is in accordance with the regulation of the country of manufacture, processing and use. The residual level of the FCN substance in polymers imported to the United States will be less than 1100 ppm, which is much less than 5% by weight of the finished food packaging, and is expected to remain with the finished food packaging through use by consumers, as is described in categorical exclusion regulation. 21 CFR 25.32(i). In the manufacturing operation, the wastewater from the styrene block polymer with 1,3-butadiene and 1,3-butadiene hydrogenated manufacturing process, enters the industrial /commercial waste treatment processes. With treatment and dilution, extremely small amounts of the food contact substance will eventually be released into the ocean.

   Food-contact materials produced with the use of the styrene block polymer with 1,3-butadiene and 1,3-butadiene hydrogenated will be utilized in patterns corresponding to the national population density and will be widely distributed across the country. We do not anticipate that food-contact materials containing the subject of this notification will be collected for recycling after use by consumers. Therefore, we anticipate that disposal will occur nationwide, with about 79% of the materials being deposited in land disposal sites, and about 21% combusted.[1]

[1] Municipal Solid Waste in the United States: 2001 Facts and Figures, EPA 530-R-03-011, US. Environmental Protection Agency (5305W), Washington DC, 20460

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

Chemical Abstract Service Name: 2,5-Furandione, polymer with ethenylbenzene, sodium salt
CAS Registry No. 25736-61-2
Molecular Weight: 70,000-400,000
Chemical Formula: $[C_8H_8][C_2H_2(COONa)_2]$)
Chemical Structure: ----$(CH_2$-CH)---- $(C_2H_2(COONa)_2)$—



Physical Description: Aqueous solution

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

a. **Introduction of substances into the environment as a result of manufacture:**
The FCN submitter has reviewed the use and disposal of the FCN substance and has determined that there are no extraordinary circumstances pertaining to the manufacturing, use, and disposal of the FCN substance.

b. **Introduction of substances into the environment as a result of use/disposal:**

1) Use: The expected concentration of the food contact substance in the wastewater is estimated to be 200 ppm. The amount of wastewater from the manufacturing process that involves the food contact substance is approximately 50,000 kg/hour. The total quantity of wastewater from the chemical complex including operations not related to the food contact substance is approximately 50,000,000 kg/hour, thus, the concentration of the substance in the wastewater is diluted to approximately 0.2 ppm. .

2. Disposal by the ultimate consumer of food-contact materials produced from the subject copolymers will be by conventional municipal solid waste disposal and, hence, primarily by landfill or incineration. The subject copolymers consist of carbon, hydrogen, oxygen, and sodium. No toxic combustion products are expected as a result of the proper incineration of the polymers. Only extremely small amounts, if any, of the copolymer or its constituents are expected to enter the environment as a result of the landfill disposal of food-contact articles, in light of Environmental Protection Agency (EPA) regulations governing municipal solid waste landfills.[2] In addition, the use and disposal of food-contact articles containing the subject FCS are not expected to threaten a violation of applicable laws and regulations, e.g., EPA regulations in 40 C.F.R. part 60 pertaining to municipal solid waste combustors and part 258 pertaining to landfills.

3) Material Safety Data Sheet (MSDS) is provided for the substance (see Attachment 1).

[2] 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 ground-water monitoring systems (40 C.F.R. Part 258). 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 collections systems, they are required to monitor groundwater and to take corrective action as appropriate.

7. Fate of substances released into the environment:

a. **Physical/chemical properties:** The food contact substance is soluble in water, insoluble in non-polar solvents including octanol, toluene and olive oil. The solubility in organic solvents is less than 1.0 gram/liter. The substance is non-volatile being a high molecular weight polymer.

b. **Concentration:** As discussed in 6. b. the concentration of the food contact substance in the effluent from the chemical complex is estimated to be 0.2 ppm, which is further diluted by water in the effluent receiving streams.

c. **Environmental depletion mechanisms**: Since the food contact substance is soluble in water and insoluble in non-polar solvents. There is no likelihood of bioaccumulation of the substance. The polymer in the food contact substance is of polymeric nature, being the sodium salt of a common copolymers, styrene-1,3-butadiene, and styrene-1,3-butadiene hydrogenated. The degradation of this polymer is likely to be similar to other chemically related polymeric substances.

8. **Environmental effects of released substances:** An extremely small amount of food contact substance is released into the ocean, at a very small percentage and a very small quantity. There is no unusual toxicity of the FCN substance, i.e., the constituents used in the production of the substance is commonly used in polymers. There is no evidence of adverse effects of low concentrations of the substance or related substances in the environment. As reported in the MSDS, the TLM for the food contact substance as 2,5-furadione polymer with 2,2,4-trimethylpentene, sodium salt as determined to be 0.25 v/v% in a 48-hour study with *Oryzias Laptipes*. This concentration is approximately 2500 ppm. Thus, there is a greater than 1000 fold difference between the effluent concentration from the manufacturing facility and the toxicity to aquatic organisms.

   Studies of a related substance, 2,5-furandione polymer with ethylene benzene, (CAS No. 9011-13-6), similar to the food contact substance excepting not the sodium salt have been reported by E. P Shcherban, Institute of Hydrobiology, National Academy of Science of Ukraine. This study, Toxicity of Surfactants for *Daphnia magnia*, J. Hydrobiol, 15(3:61-65), 1979, reported mortality at 10,000 ug/L, which is a concentration of 50X the concentration expected in effluent from the manufacturing facility.

   There also is reported in this FCN a battery of genetic toxicity studies, including Bacterial mutation assay, In vitro mammalian chromosome aberration assay, and Mammalian cell mutation assay. The conclusion was that the substance did not demonstrate mutagenic potential under any of the experimental conditions either with or without metabolic activation.

9. **Use of resources and energy:** The proposed use of styrene-maleic anhydride copolymer, sodium salt in this notification will replace other processing aids currently used to manufacture styrene block polymer with 1,3-butadiene and 1,3-butadiene hydrogenated complying with 21 CFR 177.1810. The proposed use of styrene-maleic anhydride copolymer, sodium salt will not create new markets for styrene block copolymers. Instead, styrene block polymer with 1,3-butadiene and 1,3-butadiene hydrogenated manufactured using the subject of this notification are expected to compete with and replace other styrene-butadiene block copolymers on the market. That being the case, we do not expect a significant change in the use of natural resources or energy from the proposed use of styrene-maleic anhydride copolymer, sodium salt.

10. **Mitigation measures:** No potential adverse environmental impacts have been identified for the proposed action; therefore, mitigation measures need not be discussed.

11. **Alternatives to the proposed action:** No potential adverse environmental impacts have been identified for the proposed action; therefore, alternatives to the proposed action need not be discussed.

12. List of preparers:

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

13. Certification:

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

(Date) _____ (Date) _____

(signed) _____
Syuji Yahiro, Manager
Synthetic Rubber Development Department
Asahi Kasei Chemicals Corporation

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

14. Attachments:
Attachment 1 - Material Safety Data Sheet

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