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**REVISED ENVIRONMENTAL ASSESSMENT  
FOR FOOD ADDITIVE PETITION 3B4354**

1. Date: January 7, 2000
  
2. Name of Applicant/  
Petitioner: Asahi Chemical Industry Co., Ltd.  
Synthetic Rubber Technology Service/  
Application and Technology Service
  
3. Address: 1-3-1, Yakoh, Kawasaki-ku, Kawasaki City  
Kanagawa, Japan 210-0863
  
4. Description of the Proposed Action:
  - a. Amend 21 CFR 177.1810 (a) to permit the use of maleic anhydride modified hydrogenated styrene butadiene block polymer (Tuftec M) in blends with such other FDA approved resins such as: polypropylene, polystyrene, polyamide (nylon resins), polyphenylene ether (poly(2,6-dimethyl-1,4-phenylene)oxide resins, polyethyleneterephthalate , and polyvinyl alcohol at not more than 10 wt%.

The use of Tuftec M in repeat use applications meets the criteria for categorical exclusion under 21 CFR 25.32(j). Therefore, in accordance with section 25.15 we hereby state that we are in compliance with 21 CFR 25.32(j) and that to the best of our knowledge and belief there are no extraordinary circumstances that require further analysis in this EA of any repeat use applications for Tuftec M.

The remainder of this EA addresses the potential impact of the single-service use of Tuftec M.

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**b. Need for action:**

By blending Tuftec M to other resins their impact strength is enhanced. The enhancement of impact strength by blending elastomers are generally recognized in the industry. Grafted with maleic anhydride, Tuftec M possesses superior compatibility to other resins, hence it is used as impact strength enhancer for variety of resins, such as polyethylene, polypropylene, polystyrene, polycarbonate, polyamide modified PPE, PET, PBT PPS, etc. Exploiting this property Tuftec M features to have crack resistance, particularly the low temperature impact strength is increased because the brittleness temperature of Tuftec M is as low as minus 40 C. Accordingly, Tuftec M is useful as low temperature impact strength enhancer for such applications as household utensils as food containers placed in the refrigerator.

**c. Locations of use:**

Maleic anhydride modified hydrogenated styrene butadiene block polymer (Tuftec M) will be incorporated into food-packaging materials at production locations throughout the United States. Food-packaging materials are expected to be used by consumers in patterns corresponding to national population density and to be widely distributed across the country.

**d. Location of Disposal:**

Disposal of food-packaging materials containing the proposed additive is expected to occur nationwide; the materials ultimately will enter municipal solid waste landfills, be combusted, or (where possible) be recycled.

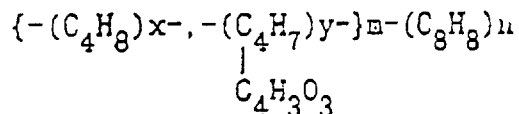
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5. Identification of Chemical Substances That Are The Subject Of The Proposed Action

Chemical Name: Maleic anhydride modified hydrogenated styrene butadiene block polymer

Chemical Structure:



(Inside of { } seems to be random polymer structure.)

Molecular Weight: 25,000 - 200,000

CAS #: 113569-15-6

Commercial Product - A range of Tuftec M grades will be offered. These are all of the same basic molecular structure but the grades vary depending upon styrene content, total molecular weight or content of maleic anhydride as per the following description:

<u>Component</u>	<u>Composition</u>
Styrene	18 - 40 wt%
Hydrogenated butadiene	58 - 80 wt%
Maleic anhydride	0.1 - 2 wt%

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6. Introduction Of Substances Into The Environment

a. Introductions that occur as a result of manufacture

Tuftec M will not be manufactured in the United States. It will be manufactured in Japan and exported to the United States.

In terms of production in Japan, the undersigned hereby certifies that it is being manufactured in accordance with all applicable Japanese environmental laws, rules and regulations.

List of National Environment Control Laws In Japan

- Basic law for environmental pollution control
- Air pollution control law
- Water pollution control law
- Law relating to the prevention of marine pollution and maritime disaster
- Waste disposal and public cleansing law
- Law for the promotion of utilization of recycled resource
- Law concerning the protection of the ozone layer through the regulation of specified substances and other measure

List of An Environment Control Regulation In the Prefecture Where The Manufacturing Plant Is Located

- Pollution control ordinance

Emitted substances - the following materials are likely to be emitted; please refer to the attached Table 1 for details of chemical name, CAS Reg. No. and other information.

- Additives Stabilizer A  
Stabilizer B  
Anti-blocking agent  
White mineral oil
- Impurities - Residual monomer 1  
Residual monomer 2  
Residual monomer 3  
Solvent

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Site of production - Oita Prefecture, Japan  
- Hiroshima Prefecture Japan

Controls exercised - Compliance with Oita Prefectural emission control regulations  
Compliance with Hiroshima Prefectural emission control regulations.

Effect of the approval of the proposed action having upon compliance with current emission requirement at site of production - Since Tuftec M production at the production site has been in compliance with the local (prefectural) emission control requirement, the approval of the proposed action will not affect anything further.

b. Introductions that occur as a result of use

Little or no introduction of maleic anhydride modified hydrogenated styrene butadiene block polymer into the environment will result from its use because it is almost completely incorporated into food-packaging materials and essentially all of it is expected to remain with the packaging throughout use of the product.

c. Introductions that occur as a result of disposal

1. Disposal by landfilling: Only low levels of substances are expected to leach in landfills from food-packaging materials containing maleic anhydride modified hydrogenated styrene block polymer based on the migration studies [or on calculations] for these materials that were performed to demonstrate the additive's safety.
2. Disposal by combustion: Maleic anhydride modified hydrogenated styrene butadiene block polymer is composed of carbon, hydrogen, and oxygen, elements commonly found in municipal solid waste. The complete combustion of this additive will produce carbon dioxide and water. Adding maleic anhydride hydrogenated styrene butadiene block polymer to waste that is combusted will not alter significantly the emissions from municipal waste combustors because its market volume is a small fraction of the municipal solid waste generated and disposed in the United States.

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7. Fate of substances released into the environment

No information need be provided on the fate of substances released into the environment as the result of use and/or disposal of maleic anhydride hydrogenated styrene butadiene block polymer, because, as discussed under Format item 6, only small quantities of substances, if any, will be introduced into the environment as a result of its use and/or disposal.

8. Environmental effects of released substances

No information need be provided on the environmental effects of substances released into the environment as a result of use and/or disposal of maleic anhydride hydrogenated butadiene styrene block polymer, because, as discussed under Format Item 6, only small quantities of substances, if any, will be introduced into the environment as a result of their use and/or disposal. Therefore, we do not expect the use and disposal of the maleic anhydride hydrogenated butadiene styrene block polymer will threaten a violation of applicable laws and regulations, e.g. the Environmental Protection Agency's regulation in 40 CFR parts 60 and 258.

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a. Use of Resources:

Market Volume

Please see information submitted in Confidential Section of This EA.

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Types Of Food contact articles and food applications

See following table:

Description of the food-contact articles and food applications affected by the proposed action				
Articles to be made with packaging the food additive	Types of food applications	Amount of food container holds (if applicable)	Container mass (if applicable)	Type of packaging currently used for those applications
Modifier for Plastics container. (PP, PS, PET, PA, m-PPE PVA etc. ) (refrigerator container)	Frozen food (meat, fish, vegetables, cooked food such as spaghetti and meat sauce, pizza and Chinese dish )	50g - 2000g	50cc - 3000cc	Plastics container (PP, PS, PET, PA, m-PPE, PVA etc. )  (refrigerator container)
Modifier for Plastics Bags or Wraps. ( PP, PS, PET, PA, m-PPE, PVA etc. )	meat, processed foodstuffs ( ham, sausage, bacon )	50g - 2000g	50cc - 3000cc	Plastics Bags or Wraps.( PP, PS,PET, PA, m-PPE, PVA etc. )

PP: polypropylene, PS: polystyrene, PET: polyethylene-terephthalate.

PA: polyamide, m-PPE: modified polyphenylene ether,PVA:polyvinyl alcohol

Disposal Patterns:

Tuftec M is going to be used in the production of food storage containers. These containers will not displace any existing containers nor change any use patterns. The addition of Tuftec M to the manufacture of these articles is intended not to displace or replace any existing polymer uses but to enhance the physical properties of the manufactured articles. Therefore, the use of Tuftec M will not result in any changes in energy requirements, recycling or resource depletion.

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b. Impact on landfill volume

As explained in 9a above, Tuftec M will not be displacing existing materials nor affect existing use, disposal or recycling practices. Therefore, there is no anticipated impacts on landfills.

10. Mitigation measures:

There should be no adverse environmental effects based upon our review of the available data and, therefore, no mitigation measures are required.

11. Alternatives to the proposed action:

As indicated under Format Item 10, we believe that there are no potential adverse environmental effects based on the proposed data and, therefore, no alternatives to the proposed action are required.


12 List of preparers:

Mr. Kiyoshi Tanada  
General Manager  
Asahi Chemical Industry Co., Ltd.  
Synthetic Rubber Technology Department/  
Application and Technical Service

Educational Background: Tokyo University (Graduated Bachelor of Chemistry)

Mr. Tetsuo Masubuchi  
Manager  
Asahi Chemical Industry Co., Ltd.  
Synthetic Rubber Technology Department/  
Application and Technical Service

Educational Background: Waseda University (Graduated Master of Polymer Chemistry)

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13. **Certification**

The undersigned certifies that the information presented herewith is true, accurate and complete to the best of the knowledge and belief of Asahi Chemical Industry Co., Ltd.

[Redacted Signature]

*Jan. 7, 2000*  
Date

Mr. Kiyoshi Tanada  
General Manager, Synthetic Rubber Technology Dept/  
Application and Technical Service

14. **References:**

None

15. **Attachments:**

None

