

**Appendix IV**  
**Environmental Assessment**

92F-0285

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**APPENDIX IV**

**ENVIRONMENTAL ASSESSMENT**

1. **Date:** June 9, 1992
2. **Name of Petitioner:** Mitsui Toatsu Chemicals, Inc.
3. **Address:** All communications on this matter are to be sent in care of Counsel for Petitioner, Jerome H. Heckman, Keller and Heckman, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001. Telephone: (202) 434-4110.
4. **Description of the Proposed Action**

The action requested in this Petition is the amendment of an existing Food Additive Regulation. Its purpose is to amend section 178.3295 of the Food Additive Regulations to permit the slightly expanded use of an effective, currently cleared nucleating, or clarifying, agent for polypropylene food packaging materials, to compete with, and to some degree replace, other permitted products.

The additive which is the subject of this Petition is bis(p-ethylbenzylidene) sorbitol, or NC-4, which is manufactured by Mitsui Toatsu at its plant located in Tokyo, Japan for use as a nucleating agent in propylene homopolymer and high-propylene copolymer articles. NC-4 is used to improve the clarity of polypropylene articles.

NC-4 is intended to be added at low levels (0.3% to 0.35%) to polypropylene to improve the clarity (i.e., transparency) of the finished article. The use of the additive in this manner will not affect the potential uses or disposal of the polymers in which it is used or of the packaging materials fabricated from these polymers, particularly since, in the absence of the NC-4, the polypropylene could be clarified with any of the other substances currently permitted for this use. Thus, approval of the action proposed herein may not reasonably be expected to have any significant environmental impact from the standpoint of use and disposal of the finished food-contact article.

The Petitioner does not manufacture finished food-contact articles with the use of the subject additive; rather, the clarifying agent, either alone or as a component of formulated polypropylene resins, will be sold to processors that are involved in the manufacture of food-contact materials. Thus, the additive is expected to be used at a number of different production sites throughout the United States. Food-contact materials containing the subject clarifier 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 80% of the materials ultimately being deposited in land disposal sites

or, to some extent, being recycled, and with about 20% being incinerated.

Clarifying agents are generally required only in thick layers of polypropylene, the plastic being sufficiently clear when used in thin layers. Moreover, many food packaging applications either are not intended to be clear or utilize polypropylene in film form. Thus, only a relatively small portion of polypropylene articles used in FDA-regulated applications may be expected to contain the subject clarifying agent. The maximum level of use of the substance requested in this Petition is 0.35 percent by weight of the polymer.

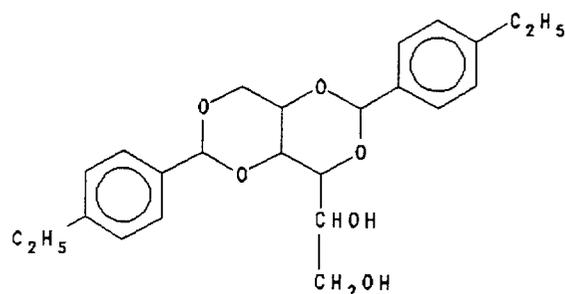
NC-4 is currently listed under Section 178.3295 for use in polypropylene at levels not to exceed 0.3%. The finished food-contact article may be used with all food types with the exception of beverages containing more than 20% of alcohol, and may be utilized under FDA's Condition of Use "B" and below (i.e., boiling-water sterilization conditions or less severe). This Petition is being submitted to bring about the amendment of Section 178.3295 to remove these limitations on the food type and temperature of use, and to slightly increase the maximum level at which the additive may be employed, from 0.3% to 0.35%. Most of the pertinent information with respect to the manufacture of NC-4, its use in polypropylene food-contact

materials, and the disposal of these materials was previously submitted in the Environmental Assessment for Food Additive Petition No. 7B4042, which was filed in 1987 by the current Petitioner, Mitsui Toatsu Chemicals, Inc., and which led to the promulgation of a responsive regulation permitting the additive for its existing cleared uses. For the convenience of the Environmental Impact review staff, the relevant information set forth in FAP 7B4042 is repeated herein and revised and/or updated as appropriate.

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

The substance that is the subject of this Petition is identified fully below.

Chemical Name	Bis(p-ethylbenzylidene) sorbitol
CAS Number	79072-96-1
Molecular Weight	414
Empirical Formula	C <sub>24</sub> H <sub>30</sub> O <sub>6</sub>
Physical Description	Fine white powder, melting point 212-217°C
Impurities	None of significance
Chemical structure	



6. Introduction of Substances Into the Environment

The action requested in this Petition is promulgation of a food additive regulation permitting somewhat expanded use of a currently cleared product, bis(p-ethylbenzylidene) sorbitol, as a clarifying agent in polypropylene food contact materials. The maximum level of use for the additive proposed herein is 0.35% by weight of the polymer. Therefore, the additive will be present in packaging materials at concentrations of far less than 5% by weight. Accordingly, Petitioner is using the abbreviated format for functional components of finished food-contact articles as provided by 21 C.F.R. § 25.31a(b)(1).

Petitioner considers the details of its manufacturing process and figures for the production of the additive to be valuable trade secrets. Consequently, in accordance with 21 C.F.R. § 25.30(b), this information is being provided in Appendix V, entitled Confidential Environmental Information, rather than as a part of the Environmental Assessment. The information in Appendix V is provided solely to assist in the Environmental Assessment and should be protected from disclosure to the public in accordance with FDA's Public Information Regulations.

To summarize the information presented in Appendix V, NC-4 is produced by the condensation of sorbitol with two moles of p-ethylbenzaldehyde. Waste streams generated from the manufacture of NC-4 include airborne organic solvent residues, liquid organic solvent wastes, and waterborne organic catalyst salts. Solvent vapors are recovered by absorption in water and are recycled to the reactor. Waste water containing solvent and catalyst wastes is treated with bio-activated sludge and released to the sea.

The Mitsui Toatsu plant is operated in full compliance with all applicable emissions requirements. Compliance with these requirements will not be affected by approval of this Petition. A certificate of compliance with applicable emissions requirements, and citation to these laws, is attached under Item 15, Appendices.

Disposal by the ultimate consumer of food packaging materials containing polypropylene clarified with NC-4 will be by conventional rubbish disposal and, hence, by open dump, sanitary landfill or incineration. As noted in Item 4 above, it is expected that disposal will occur nationwide in patterns corresponding to the national population density, with about 80% of the materials ultimately being deposited in land dispos-

al sites or, to a small extent, being recycled, and with about 20% being incinerated.

The subject clarifying agent is prepared from only carbon, oxygen, and hydrogen containing materials. No toxic combustion products are expected as a result of the incineration of this substance in a properly functioning incinerator.

When polypropylene food packaging materials containing NC-4 are added to open dumps and sanitary landfills, no significant amount of leaching of the substance from these materials into the environment is anticipated. This conclusion is based on the results of extraction studies which showed extremely low levels of migration of the clarifying agent from polypropylene subjected to highly exaggerative exposure conditions, from an environmental condition standpoint. In particular, a full report of studies in which migration of NC-4 to food-simulating solvents was measured under FDA's Condition of Use "B" is provided in Appendix V of FAP 7B4042; these studies, and the results obtained, are discussed below.<sup>1/</sup>

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<sup>1/</sup> Possible leaching of NC-4 under landfill conditions is conservatively estimated using the extraction data set forth in the previous Petition instead of the data provided in this Petition because, while the original studies were highly exaggerative of actual environmental conditions, the studies provided herewith are even more exaggerative since they were carried out at higher temperatures. Consequently, the data provided in the original Petition provide the closer estimate of potential leaching of NC-4, albeit still an overestimate.

The extraction studies involved immersing polypropylene (homopolymer and copolymer) test plaques in distilled water at 212°F for 90 minutes. The test sheets were 0.6 mm in thickness and 50 mm wide by 70 mm long. Five sheets were used per extraction container. At the end of the extraction period, the extracts were analyzed for NC-4, using a liquid chromatographic procedure. (A complete description of the test samples, extraction and analytical procedures, and full results of the analyses, are provided in Appendix V of FAP 7B4042.)

To summarize the data previously provided, an average of 0.39 milligram of NC-4 per extraction cell was found to migrate into water. The percentage of the clarifier contained in the test samples that is represented by this value may be calculated as follows. The total volume of the test specimens (5 sheets x 5 cm x 7 cm x 0.06 cm) was 10.5 cm<sup>3</sup>. The concentration of NC-4 in the test sheets was approximately 0.7%. At a density of about 0.9 g/cm<sup>3</sup> for the polypropylene, each set of sheets weighed 9.45 g. Thus, the quantity of NC-4 in each set of 5 sheets was about 0.066 g, or 66 mg.

An average migration level of 0.39 mg from 5 sheets represents approximately 0.6 percent of the total amount of clarifying agent in the test sheets. This fraction may be multiplied by the total estimated market volume for NC-4 to

determine the maximum quantity of the clarifier that may possibly enter land disposal-site leachate per year. This calculation is shown in Appendix V, Confidential Environmental Information. Since the extraction studies were carried out under conditions (immersion in water at 212°F for 90 minutes) far more severe than any conditions that may be found in landfill sites, actual leaching of the additive is expected to be well below the value calculated in Appendix V. Based on the foregoing, the concentration of NC-4 in land-disposal site leachate is expected to be extremely low.

7. Fate of Emitted Substances in the Environment

In accordance with the provisions of § 25.31a(b)(1) for additives that are present as functional components of finished food packaging materials at not greater than 5% by weight, the fate of emitted substances is not addressed in this assessment.

**8. Environmental Effects of Released Substances**

In accordance with the provisions of § 25.31a(b)(1) for additives that are present as functional components of finished food packaging materials at not greater than 5% by weight, the question of environmental effects is not addressed in this assessment.

9. Use of Resources and Energy

In accordance with the provisions of § 25.31a(b)(1), documentation of the use of resources and energy is not required since (1) the proposed food additive is intended for the same use as other clarifying agents for polypropylene already in use, and (2) the proposed action will not materially change the potential uses of the packaging materials in which the additive is used. An example of another substance intended to be replaced by NC-4 is aluminum p-tert-butyl benzoate.

10. Migration Measures

In accordance with the provisions of § 25.31a(b)(1) for additives that are present as functional components of finished food packaging materials at not greater than 5% by weight, the question of mitigation measures is not addressed in this assessment.

11.      Alternatives to the Proposed Action

In accordance with the provisions of § 25.31a(b)(1) for additives that are present as functional components of finished food packaging materials at not greater than 5% by weight, alternatives to the proposed action are not addressed in this assessment.

12. List of Preparers

- a. Yojiro Onoya, Technical Representative, Mitsui Toatsu Chemicals, Inc., 140 East 45th Street, New York, New York 10017.
- b. Junta Komamura, Assistant Marketing Manager, Mitsui Toatsu Chemicals, Inc., 140 E. 45th Street, New York, New York 10017.
- c. Holly H. Foley, B.S, Staff Scientist, Keller and Heckman, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001.

13. Certification

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

Date: June 10, 1992

  
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Jerome H. Heckman

Counsel for Mitsui Toatsu  
Chemicals, Inc.

**14. References**

All data referred to in this Environmental Assessment are provided elsewhere in this Petition, or are presented in FAP 7B4042, which is incorporated herein by reference.

15. Appendices

A letter certifying compliance of Petitioner's plant located in Japan with all applicable emissions requirements is attached.



MITSUI TOATSU CHEMICALS,  
INCORPORATED

25, KASUMIGASEKI 3 CHOME  
CHIYODAKU, TOKYO, JAPAN

P.O. ADDRESS  
P.O. BOX 83, KASUMIGASEKI BLDG.  
TOKYO 100, JAPAN

TELEPHONE:(TOKYO)3592  
CABLE:MITSUITOATSU TOKYO  
TELEX:0222-3622(2223622 MTCHEM J)

April 6, 1992

Certificate

I hereby certify that we, Mitsui Toatsu Chem. Inc., are producing our NC-4 in compliance with the following Japanese laws which regulate all Japanese chemical plants.

1. Fire Service Law
2. Industrial Safety and Health Law
3. Water pollution Control Law

*Takashi Kobayashi*  
Takashi Kobayashi  
Production Manager of NC-4

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