

ATTACHMENT #4

Part IV — Environmental Impact of Food Contact Substance (21 CFR part 25)

B. Environmental Assessment

This environmental assessment has been prepared in accordance with 21 CFR 25.31a, using the abbreviated format described in (b)(1).

- 1) **Date:** February 9, 2004
- 2) **Name of notifier:** Ciba Specialty Chemicals Corporation
- 3) **Address:** 540 White Plains Road
Tarrytown, NY 10591

4) Description of the proposed action:

Requested action:

It is proposed that the use of Hexanedioic acid, polymer with azacyclotridecane-2-one and .alpha.-hydro.-omega.-hydroxypoly(oxy-1,2-ethanediyl) as a permanent polymeric antistatic agent for use in polymers for food contact applications.

Need for action:

The Hexanedioic acid, polymer with azacyclotridecane-2-one and .alpha.-hydro.-omega.-hydroxypoly(oxy-1,2-ethanediyl) would be used in film or molded articles. This product, commercially marketed as _____, is a polyamide/polyether block copolymer used as a permanent, non-migratory antistatic agent for use in film and molded articles.

Location of use:

This product would be manufactured in France. The material will be incorporated into articles to be used as food contact materials at food-packaging production sites located throughout the United States. The FCS is expected to be distributed widely across the country in patterns corresponding to national population density.

Location of disposal:

Disposal of the food contact substance (FCS) is expected to occur nationwide with the FCS ultimately being deposited in municipal solid waste landfills or combusted as a result of the disposal of the molded article.

5) Identification of the chemical substances that are the subject of the proposed action:

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CAS Name:

Hexanedioic acid, polymer with azacyclotridecane-2-one and .alpha.-hydro.-omega.-hydroxypoly(oxy-1,2-ethanediyl)

CAS Registry Number:

70290-02-7

Physical description:

A granulated, dust-free polymer with a white to slightly yellow color.

Impurities:

This information is contained in Part II, Section B 3. *Impurities* of the FCN. Only very low amounts of these chemicals will be expected to enter the environment as a result of this action.

6) Introduction of substances into the environment:**a) Introduction of substances into the environment as a result of manufacture:**

This product will be manufactured in France. No extraordinary circumstances apply to the manufacture of the FCS.

b) Introduction of substances into the environment as a result of use:

Little or no introduction of the Hexanedioic acid, polymer with azacyclotridecane-2-one and .alpha.-hydro.-omega.-hydroxypoly(oxy-1,2-ethanediyl) will result from its use because this substance is completely incorporated into the finished article and essentially all of it is expected to remain with these molded articles throughout their lifetime.

c) Introduction of substances into the environment as a result of disposal:**i) Landfills:**

Based on the migration studies of the Hexanedioic acid, polymer with azacyclotridecane-2-one and .alpha.-hydro.-omega.-hydroxypoly(oxy-1,2-ethanediyl) in molded polymer plaques, performed to demonstrate its safety, only very low levels of the FCS are expected to leach from these materials in landfills. Moreover, even if a very small amount of the FCS migrates from the food packaging in landfills, we expect extremely low quantities to actually enter the environment; this finding is based on the Environmental Protection Agency's (EPA's) regulations governing municipal solid waste landfills. In addition, introducing these substances into the environment will not threaten a violation of the Environmental Protection Agency's (EPA) regulations in 40 CFR part 258 that pertain to landfills.

ii) Combustion:

The FCS is composed of carbon, hydrogen, nitrogen, and oxygen, elements

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commonly found in municipal solid waste. The complete combustion of this FCS in a properly functioning incinerator will produce only carbon dioxide and water. Because the market volume of the FCS is a small fraction of the municipal solid waste generated and disposed in the United States, adding the FCS to waste that is combusted will not alter significantly the emissions from municipal waste combustors. Because of the nature of the combustion products and their low levels compared to the amounts currently generated by municipal waste combustors, we do not expect that the combustion products from incineration of the molded articles containing the will cause a violation of applicable emissions laws and regulations.

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 disposal of, because only small quantities of substances, if any, will be introduced into the environment from its use and disposal. Therefore, the use and disposal of the FCS are not expected to threaten a violation of applicable laws and regulations, e.g., EPA's regulations in 40 CFR parts 60 and 258.

8) Environmental effects of released substances:

No information need be provided on the environmental effects of the substances released into the environment as a result of use and/or disposal of Hexanedioic acid, polymer with azacyclotridecane-2-one and .alpha.-hydro.-omega.-hydroxypoly(oxy-1,2-ethanediyl) because only small quantities, if any, of the substances will be introduced into the environment as a result of the use and disposal of this product. Therefore, the use and disposal of the FCS is not expected to threaten a violation of applicable laws and regulations, e.g., EPA's regulations in 40 CFR parts 60 and 258.

9) Use of resources and energy

This item does not ordinarily require documentation because the proposed Hexanedioic acid, polymer with azacyclotridecane-2-one and .alpha.-hydro.-omega.-hydroxypoly(oxy-1,2-ethanediyl) antistatic agent is intended for the same use as other commercially available antistatic agents, such as:

Uniqema Atmer® products
Croda Crodastat® products
Azko Nobel Armostat® products

10) Mitigation measures:

We identify no adverse environmental effects, based upon our review of adequate and

11) Alternatives to the proposed action:

We identify no adverse environmental effects, based upon our review of adequate and complete data and information.

12) List of Preparer : Patty Kinne
Head, Regulatory Services
Plastics Additives Segment
Ciba Specialty Chemicals Corporation

13) Certification:

The undersigned certifies that the information presented is true, accurate and complete to the best of the knowledge of Ciba Specialty Chemicals Corporation.

February 9, 2004

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Patty Kinne
Head, Regulatory Services