

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:** November 10, 2005
- 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 2-Propenoic acid, homopolymer, sodium salt (with a weight average molecular weight of 2300 to 5700 Daltons and a weight average molecular weight to number average molecular weight ratio of not more than 6.3), marketed commercially as , be allowed.

Need for action:

The food contact substance (FCS) will be used to control the mineral scale formed during the evaporation of beet or cane sugar juice liquor, at an addition rate not to exceed 3.6 mg/kg (ppm) of active sodium polyacrylate to the sugar juice liquor, in compliance with 21 CFR 173.73 (with the exception of subparagraphs (a)(1) and (a)(2)).

Location of use:

This product would be manufactured in the United States. The polymer used by Ciba Specialty Chemicals Corporation customers, will be used in the processing of beet and cane sugar at production sites located throughout the United States. The resultant sugar and sugar by-products are 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) would be part of the waste material that is typically generated by the sugar processing industry. It 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 sugar processing waste.

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

000230



ATTACHMENT #4

CAS Name:

2-Propenoic acid, homopolymer, sodium salt

CAS Registry Number:

9003-04-7

Physical description:

The neat FCS is colorless, odorless granulated powder and has a similar chemistry to comparable commercial sodium polyacrylate polymers. It is non-flammable and stable to light and heat.

Impurities:

This information is contained on page 5 of the FDA form 3480 for FCN 000554. 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 the United States. 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 into the environment of the 2-Propenoic acid, homopolymer, sodium salt (sodium polyacrylate) will result from its use in sugar processing. Many of the materials left over from the production of sugar are recycled and reused. The water that is removed through cane sugar refining and sugar beet processing still contains sugar, and it is pumped back into the system to be recycled in order to extract the maximum amount of sugar.

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

Due to the nature of sugar processing, only extremely low levels of the FCS are expected to be present in landfills. Moreover, even if a very small amount of the FCS are present 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 2-Propenoic acid, homopolymer, sodium salt (sodium polyacrylate) is composed of carbon, hydrogen, sodium, and oxygen, which are elements 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 minute fraction of the municipal solid waste generated and disposed in the

000231

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 2-Propenoic acid, homopolymer, sodium salt (sodium polyacrylate) 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 2-Propenoic acid, homopolymer, sodium salt (sodium polyacrylate), 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 substances released into the environment as a result of use and/or disposal of 2-Propenoic acid, homopolymer, sodium salt (sodium polyacrylate) because only small quantities, if any, of 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 2-Propenoic acid, homopolymer, sodium salt (sodium polyacrylate) is intended for the same use as other commercial grades of sodium polyacrylates already in use made by manufacturers such as:

Cytec Industries Inc.
Houghton Chemical Corp.
Arkema Inc.

10) Mitigation measures:

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

11) Alternatives to the proposed action:



ATTACHMENT #4

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

12) List of Preparer : Neal Earhart, Ph.D.
Head, Regulatory Services – Plastic Additives
Ciba Expert Services
Ciba Specialty Chemicals Corporation
540 White Plains Road
Tarrytown, NY 10591

13) Certification:

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

November 10, 2005
