

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 9, 2006
- 2) Name of notifier: **SK Chemicals (PNC# 402 and 453)**
- 3) Address: 600 Jungia-1dong Changan-ku Suwon-si Kyungki-do 440-745 South Korea
- 4) Description of the proposed action:

Requested action:

It is proposed that the use of copolymers made from the reaction of terephthalic acid with a mixture of diols containing 65 to 20 mol percent ethylene glycol and 35 to 80 mol percent of 1,4-cyclohexanedimethanol [redacted] in articles or components of articles for food contact applications be allowed.

Need for action:

The [redacted] range and intended use fall within that which is already covered under FCN 179, as films or articles or components of films or articles, in either a non-oriented or oriented finished form, intended for contact with foods (aqueous, acidic, low-alcohol (up to 13% by volume), fatty under Conditions of Use C through G in Table 2 as described in 21 CFR 176.170 (c). Additionally, this product may also be used in foods containing up to 25% by volume alcohol under Conditions of use E through G.

Location of use:

The Food Contact Substance would be manufactured in South Korea. The FCS, will be used by SK Chemical customers and incorporated into molded articles to be used as food contact materials at food-packaging production sites located throughout the United States. The FCS is expected to be widely distributed, in a substitutional use pattern corresponding to FCN 179, 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 within the United States with the FCS ultimately being deposited in municipal solid waste landfills, recycled (where possible) or combusted as a result of the disposal of

the articles made from the resin.

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

CAS Name:

Ethylene-1,4-cyclohexylenedimethylene terephthalate copolymers

CAS Registry Number:

25038-91-9

Physical description:

[redacted] has the appearance and handling characteristics of other resins. It is colorless, odorless and has a similar chemistry to widely used commercial polyester resins. It is non-flammable and stable to light and heat.

Impurities:

This information is contained on page 5 of 19 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 South Korea. 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 [redacted] will result from its use because this substance is completely incorporated into articles or components of articles at industrial sites particular to the end-use application and essentially all of it is expected to remain with these articles throughout their lifetime.

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

i) Landfills:

No significant amount of the FCS is expected to leach from these materials into landfills. This is based on the substitutional use with the FCS as described by FCN 179. 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 [redacted] is composed of carbon, hydrogen, and oxygen, 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 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 FCS 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 [redacted] 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 [redacted] 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 proposed [redacted] [redacted] resin is intended for the same use as other commercial grades of polyester resins already in use made by resin producers such as:

[redacted]

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:

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

12) List of Preparer : Naeem Mady
 Agent on behalf of SK Chemicals
 540 White Plains Rd
 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 9, 2006

A red rectangular box intended for a signature, with a small red square at the top left corner. A handwritten '0' is visible below the box.