

[redacted]

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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 25.40.

- 1) **Date:** December 20, 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:

Phosphonic acid, [[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]methyl]-, diethyl ester (CASRN 976-56-7), marketed by Ciba Specialty Chemicals under the trade name [redacted], be allowed.

Need for action:

The food contact substance (FCS) will be used as an antioxidant/stabilizer for all polyester polymers (PET) compliant with 21 CFR 177.1630, at levels not to exceed 1100 ppm, in contact all food types and temperature conditions of use A through H. The FCS is added during the esterification step of the polymerization and is incorporated into the backbone of the PET resin

Location of use:

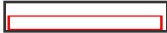
The FCS [redacted] is manufactured at the Ciba Specialty Chemicals production site in [redacted]. The site mailing address is:

[redacted]

The FCS will be used in the manufacture of polyester polymers (PET) compliant with 21 CFR 177.1630 at PET production facilities world-wide.

The PET resin containing [redacted] is expected to be utilized in a wide range of existing PET in-direct food contact applications including: 1) bottles for beverages (e.g. soda, water, milk, juices, and beer), 2) trays and containers for prepared foods for storage and reheating, and 3) films for flexible packaging (e.g. cheese and other dairy, dry snack foods).

Distribution of PET articles that contain the FCS is expected to be distributed across the



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United States in use patterns, comparable to existing PET articles, corresponding to the national population density.

Location of disposal:

The food contact substance (FCS) would be part of the overall PET waste material that is presently being either recycled, deposited in municipal solid waste landfills, or combusted as a result of disposal of PET articles.

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

CAS Name:

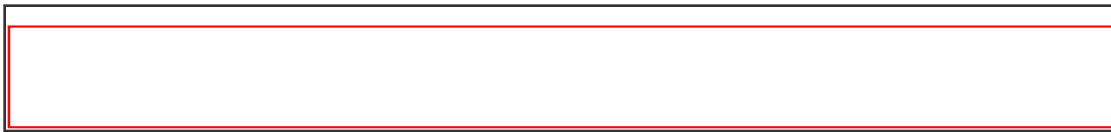
Phosphonic acid, [[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]methyl]-, diethyl ester

CAS Registry Number:

976-56-7

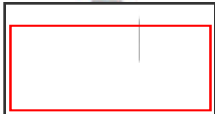
Physical description:

The neat FCS is white to light yellowish powder with a melting point of 116-121°C




PET resin manufactured with the FCS:

It is clearly shown by the molecular weight data (Mn, Mw, PDI, <1000MW species) in FCN 000556, the intrinsic viscosity data as part of FCN 000393, and the thermal data (Tg, Tm) in documentation sent to the FDA by Ciba Specialty Chemicals on December 6, 2005, that there are no measurable physical/chemical differences between a PET resin that contains the FCS in the polymer backbone versus an existing PET resin.



6) Introduction of substances into the environment:

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

The FCS is manufactured at the Ciba Specialty Chemicals production site in . No extraordinary circumstances apply to the manufacturing of the FCS.

PET manufactured *with* the FCS would not introduce any new substances into the environment versus a PET manufactured *without* the FCS.

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

The FCS is incorporated into the backbone of the PET polymer. However, the FCS *is not*

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a *polymer modifier* designed to alter physical or chemical properties (e.g. barrier) of PET to achieve new end-uses. The use of [REDACTED] will result in PET resin with improved thermal stability in order to substitutionally compete with and replace existing PET resin in the marketplace. No new substances would be introduced into the environment as a result of use PET resin with the FCS incorporated into the polymer backbone versus an existing PET resin.

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

Since there are no measurable physical/chemical differences between a PET resin that contains the FCS in the polymer backbone versus an existing PET resin, we expect that there will be no new substances introduced into the environment as a result of disposal, whether the waste material is being recycled, deposited in municipal solid waste landfills, or combusted.

7) Fate of substances released into the environment:

Whether the waste material is being recycled, deposited in municipal solid waste landfills, or combusted, we do not expect any difference in the substances released into the environment from a PET resin that contains the FCS in the polymer backbone versus an existing PET resin.

8) Environmental effects of released substances:

We do not expect any environmental affects because only small quantities, if any, of substances will be introduced into the environment as a result of the use and disposal of the FCS and PET resin which contains the FCS. In addition, any substance released from the disposal of a PET resin which contains the FCS is not expected to be different than from an existing PET resin. Therefore the use and disposal of the FCS and PET resin which contains the FCS is not expected to violate any applicable local/municipal laws or regulations or EPA regulations.

9) Use of resources and energy

The use of the FCS as an antioxidant/stabilizer, which is incorporated into the backbone of PET, will result in a PET that will substitutionally compete with and replace existing PET resin in the marketplace, [REDACTED]. As a result, no additional resources or energy is expected from the use of the FCS in the manufacturing of PET resin.

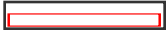
Since there are no measurable physical/chemical differences between a PET which incorporates the FCS into the polymer backbone versus an existing PET, there would not be any additional natural resources or energy requirements needed to process and/or recycle the PET containing the FCS.

10) Mitigation measures:

We identify no adverse environmental effects, based upon our review of the available data and information for the FCS and its proposed use as an antioxidant/stabilizer for all polyester polymers complaint with 21 CFR 177.1630.

11) Alternatives to the proposed action:

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



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complete data and information.

12) List of Preparer : Neal Earhart, Ph.D.
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13) Certification:

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

December 20, 2005
