

ATTACHMENT #12

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: July 31, 2003
- 2) Name of notifier: **GE Plastics**
- 3) Address: 1 Plastics Ave, Pittsfield, MA 01201
- 4) Description of the proposed action:

Requested action:

It is proposed that the use of Siloxanes and Silicones, di-methyl, 3-(4-hydroxy-3-methoxyphenyl)propyl group-terminated, polymers with bisphenol A, carbonic dichloride and 4-(1-methyl-1-phenylethyl)phenol or siloxane-modified polycarbonate as a plastic material in articles or components of articles for single and repeat use food contact applications, such as food trays and containers, be allowed.

Need for action:

The resin would be used in the manufacturing of molded articles. This product is a modified polycarbonate resin with improved physical properties compared to a traditional polycarbonate resin.

Location of use:

This product would be manufactured in the United States. The resin, by GE Plastics' customers, will be 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 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:

CAS Name:

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Siloxanes and Silicones, di-methyl, 3-(4-hydroxy-3-methoxyphenyl)propyl group-terminated, polymers with bisphenol A, carbonic dichloride and 4-(1-methyl-1-phenylethyl)phenol

CAS Registry Number:
202483-49-6

Physical description:

This product has the appearance and handling characteristics of a free-flowing neat polymer resin. It is colorless, odorless and has a similar chemistry to widely used commercial polycarbonate resins. It is non-flammable and stable to light and heat.

Impurities:

This information is contained on page 5 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 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 of the Siloxane-modified Polycarbonate will result from its use because this substance is completely incorporated into molded 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 on molded plaques comprised of the Siloxane-modified Polycarbonate that were 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 Siloxane-modified Polycarbonate is composed of carbon, hydrogen, silicon 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. In addition, Si oxides would be collected as ash and disposed of.

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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 Siloxane-modified Polycarbonate 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 Siloxane-modified Polycarbonate, 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 Siloxane-modified Polycarbonate 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 Siloxane-modified Polycarbonate resin is intended for the same use as other commercial grades of polycarbonate resins already in use made by resin producers such as:

GE Plastics
Bayer
Dow Chemicals
RTP Company

10) Mitigation measures:

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

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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 : Huqiu Zhang, Ph.D.
 Manager, Global Food Contact Programs
 GE Specialty Chemicals
 1 Noryl Avenue
 Selkirk, NY 12158

13) Certification:

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

July 31, 2003



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