



The Chemical Company

Attachment XV  
4 pages

**Environmental Assessment for 4,4'-Biphenol-4,4'-dichlorodiphenyl sulfone copolymer**

1. **Date:** February 5<sup>th</sup>, 2007
2. **Name of submitter:** BASF Aktiengesellschaft
3. **Address:** All communications on this matter are to be sent to  
BASF Aktiengesellschaft  
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D-67056 Ludwigshafen,  
Germany

**4. Description of the proposed action:**

**a. Proposed action:**

The action requested in this notification is to allow the safe use of 4,4'-Biphenol-4,4'-dichlorodiphenyl sulfone copolymer as food-contact article for all food types. BASF Aktiengesellschaft, Germany and its subsidiary BASF Corporation, USA have developed a 4,4'-Biphenol-4,4'-dichlorodiphenyl sulfone copolymer as an amorphous high temperature thermoplastic polymer. It is suitable for all kind of applications where high thermal and chemical stability is needed. It can be processed by standard thermoplastic processes like injection molding, blow molding, stretch blow molding and others. It is intended for single use application for all kind of foods at freezing conditions as well as high temperature conditions (21 CFR 176.170(c), Table 1 Types of raw and processed food I-IX ,Conditions of use A-J, including microwave ovens).

**b. Need for action:**

Biphenol-4,4'-dichlorodiphenyl sulfone copolymer is suitable for all kind of applications where high thermal and chemical stability is needed. It is repeatedly sterilizable with steam up to 134°C and resistant against many cleaning and disinfecting agents. In addition it is very impact resistant and therefore suitable also for thin-walled bottles. Its high heat deflection temperature of more than 180°C allows also applications where a high stiffness at high temperatures is needed. Not limiting selection of applications is:

The FCS is used for packaging for ready-cooked food, for example baby food, which might be heated in microwaves. It can also be used as parts of machinery in the food processing industries, dairy equipment, microwave dishes, catering containers, plates, cutlery or fittings for drinking water installation.

In catering containers the food is typically regenerated and displayed at temperatures up to 95°C and remains in contact with the FCS up to 3 hours.

Microwaves dishes are regularly used to quickly regenerate ready-cooked food.

Here the temperatures can reach locally up to 175°C. At this temperatures the contact time is normally up to 15 min.

**c. Locations of use:**

Biphenol-4,4'-dichlorodiphenyl sulfone copolymer will be incorporated into food-packaging materials at production plants located throughout the United States or in other production plants of BASF. Food-packaging materials are expected to be used by consumers in patterns corresponding to the national population density and to be widely distributed across the country.

**d. Locations of disposal:**

Disposal of food-packaging materials is expected to occur nationwide with the materials ultimately being deposited widely across the country in municipal solid waste landfills or combusted.

**5. Identification of substances that are the subject of the proposed action:**

Generic information regarding the chemical identity of the Biphenol-4,4'-dichlorodiphenyl sulfone copolymers provided below. A complete description of the physical and chemical properties is confidential and are not for public disclosure. This information is provided in Chapter II-a of this Notification.

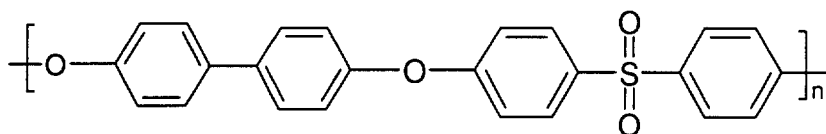
**a. Complete nomenclature**

Chemical Abstracts Service name: [1,1'-Biphenyl]-4,4'-diol, polymer with 1,1'-sulfonylbis[4-chlorobenzene]  
respectively: Poly(oxy[1,1'-biphenyl]-4,4'-diyoxy-1,4-phenylenesulfonyl-1,4-phenylene  
IUPAC name: Biphenol-4,4'-dichlorodiphenyl sulfone copolymer  
Trade name: Ultrason® P

**b. Chemical Abstracts Service (CAS) registration number:**

25608-64-4 respectively: 25839-81-0

**c. Structural (graphic) formula**



4,4'-Biphenol-4,4'-dichlorodiphenyl sulfone copolymer

**d. Physical description:** uncolored pellets

**6. Introduction of substances into the environment:**

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

Under 21 CFR § 25.40(a), an environmental assessment ordinarily should focus

on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated articles. Moreover, information available to the notifier does not suggest that there are any extraordinary circumstances in this case indicative of any adverse environmental impact as the result of the manufacture of Biphenol-4,4'-dichlorodiphenyl sulfone copolymer. Consequently, information on the manufacturing site and compliance with relevant emission requirements is not provided here.

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

Little or no introduction of Biphenol-4,4'-dichlorodiphenyl sulfone copolymer into the environment will result from its use in the manufacturing of the food-packaging material or in the packaging of food because this substance is almost completely incorporated into food-packaging materials and essentially all of it is expected to remain with this packaging throughout use of the product.

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

**i. Landfilling:**

Food-packaging material manufactured from the subject FCS is not intended to be recycled. It will be disposed of in patterns corresponding to population density with 79.8% disposed of in landfills. Based on the migration calculations on food-packaging materials containing of Biphenol-4,4'-dichlorodiphenyl sulfone copolymer, which were performed to demonstrate human safety of this substance, only very low levels of substances are expected to leach from these materials in landfills. In addition, even if very small quantities of these substances are present in landfill leachate, the introduction of these substances into the environment will not threaten a violation of the Environmental Protection Agency's regulations in 40 CFR Part 258 that pertain to landfills.

**ii. Combustion:**

Food-packaging material manufactured from the subject FCS is not intended to be recycled. It will be disposed of in patterns corresponding to population density with 20.2% disposed of by incineration. Biphenol-4,4'-dichlorodiphenyl sulfone copolymer is composed of carbon, hydrogen, oxygen, elements commonly found in municipal solid waste, and sulfur. The complete combustion of this substance will produce carbon dioxide, water, and sulfur dioxide. Because the market volume of the food contact substance is a small fraction of the municipal solid waste generated and disposed in the United States, adding this substance to waste that is combusted will not alter significantly the emissions from municipal waste combustors. The market volume and related calculations are provided in a confidential section of the Environmental Assessment.

**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/or disposal of Biphenol-4,4'-dichlorodiphenyl sulfone, because, as discussed under Format Item 6, only small quantities, if any, of substances will be introduced into the environment as a result of use and/or disposal of Biphenol-4,4'-dichlorodiphenyl sulfone. Therefore, the use and disposal of the food additive are not expected to threaten a violation of applicable laws and regulations, e.g.,

the Environmental Protection Agency'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 Biphenol-4,4'-dichlorodiphenyl sulfone, because, as discussed under Format Item 6, only small quantities, if any, of substances will be introduced into the environment as a result of use and/or disposal of Biphenol-4,4'-dichlorodiphenyl sulfone. Therefore, the use and disposal of the food additive are not expected to threaten a violation of applicable laws and regulations, e.g., the Environmental Protection Agency's regulations in 40 CFR parts 60 and 258.

**9. Use of Resources: See confidential part of the Environmental assessment**

The FCS is not intended to be recycled. Therefore it has potential for significant impact on resource use. The competition material which is replaced by the FCS is glass. Currently, if a glass baby food jar breaks during filling or storage, all of the baby food in that batch must be disposed of to ensure safety. The use of the FCS will reduce breakage and eliminate the waste.

More details see confidential part of the Environmental Assessment

**10. Mitigation measures:**

No significantly adverse impacts have been identified for the proposed action, and therefore no mitigation measures are necessary.

**11. Alternatives to the proposed action:**

No significantly adverse impacts have been identified for the proposed action.

**12. List of preparers:**

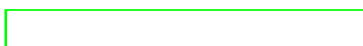
Dr. Martin Klatt  
Head of Product Safety and Regulator Affairs  
PhD Chemist  
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Dr. Ruth Zschiesche  
Manager Product Safety and Regulatory Affairs  
PhD Chemist  
BASF Aktiengesellschaft

**13. Certification:** The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of BASF Aktiengesellschaft.

26.03.2007

(Date)



(Signature of responsible official)

Dr. Martin Klatt, Head of Product Safety and Regulatory Affairs