



## Notification for New Use of a Food Contact Substance Crosspure®

### Environmental Assessment

1. **Date** January 10, 2006
2. **Name of Sponsor** BASF AG  
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Germany

3. **Description of the Proposed Plan**

- a) **Requested Action**

BASF is seeking FDA approval for a new food contact substance, Crosspure®.

Crosspure® is intended for repeated use. It is to be used as a processing aid in clarification and stabilization of alcoholic beverages, including beer and wine. Crosspure® is completely removed from the beverages by filtration equipment. The recommended use level is 80-150 g in 100 L wine or beer, depending on the characteristics of the beverage.

The food contact time during filtration depends on the filter type (3.5 hl/m<sup>2</sup>/hour or 5 hl/m<sup>2</sup>/hour) and varies between 3 and 10 minutes.

The expected service lifetime is expected to be 100 cycles. As the normal dosage level is 80-150 g/100 L, the product is expected to contact approximately 10,000 L of beverage over its lifetime.

- b) **Need for Action**

The need for sustainable components in the filtration of alcoholic beverages is driven by market need. Crosspure® is intended to replace an existing material, which is recognized as more hazardous as dry substance and creates more waste because it is not for repeated use. Crosspure® can be used to broaden the profits of the alcoholic beverage industry since it is more economical from both a cost and reuse point. When added to alcoholic beverages, it can also serve as a stabilizer by removing components that cause chill-haze and flavour degradation.

- c) **Locations of Use**

Crosspure® will be used at alcoholic beverage production facilities at various locations around the country.

**d) Locations of Disposal**

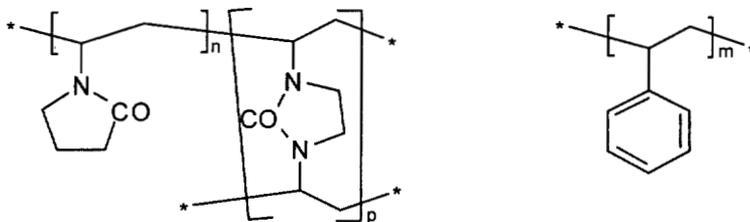
BASF expects that Crosspure® will not be disposed of since it is regenerated and is intended for repeated use. Product loss is expected to be less than 2% per regeneration cycle during the use phase. This loss will enter the environment via the wastewater (see also section 5).

**4. Identification of Substances that are the Subject of the Proposed Action**

Crosspure® is a polymer created from 30% PVPP and 70% Polystyrene.

**Molecular Formula:**  $(C_6H_9NO)_n (CHC_6H_5-CH_2)_m$

**Structural Formula:**



The Safety Data Sheet for Crosspure® is attached.

**5. Introduction of Substances into the Environment**

**a) Introduction of Substances into the Environment as a Result of Manufacture**

No extraordinary circumstances apply to the manufacture of the food-contact substance. The product is produced in one site in Germany in a chemical plant in a closed system. The remaining material after the milling process is reintroduced in the production process or internally incinerated at the production site.

**b) Introduction of Substances into the Environment as a Result of Use and Regeneration**

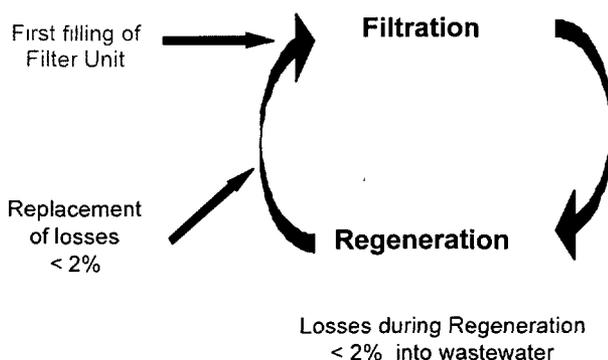
Crosspure® is intended for use as a clarifying agent during the manufacture of alcoholic and non-alcoholic beverages. Crosspure® is insoluble in beverages, and will be removed from the beverage production process by filtration equipment. No degradation is expected during the use of Crosspure® for the beverage filtration. The recommended use levels are in the range of 80-150 g / 100 L, depending on the characteristics of the beverage. Crosspure® is intended for repeated use.

Special filtration and regeneration equipment consisting of a metering device and a filter unit are used to recycle the product.

Crosspure® is suspended in water and is continuously fed into the beverage stream by means of a metering pump. When the filtration process is complete, the Crosspure® filter cake is regenerated by intensive washing in the regeneration unit. This is performed by subsequent steps of washing with sodium hydroxide (2-5%) and water. Based on trials in pilot plants the minute amount of less than 2% material of the original filling amount which adhere to the walls of the equipment will be lost during the cleaning, rinsing, and recycling process into the wastewater (see figure 2 for illustration and see section 6 Fate). This lost amount is replaced before the next use cycle.

The service lifetime is expected to be about 100 cycles. This number is calculated on the assumption that during routine use the losses are in the range of 1%, so that after about 100 cycles, the total amount of the initial filling is replaced. The value of 1% losses is based on preliminary results from a trial in a brewery in Europe, and the fact that via reduction of losses, breweries can improve their earnings. We therefore expect that the handling procedure will be continuously optimised in order to reduce the losses. It is expected that about 10,000 L beverage can be treated by 80–150 g Crosspure®.

Figure 2



**c) Introduction of Substances into the Environment as a Result of Disposal**

Based on the recycling process there is no intention to dispose of Crosspure® directly. This is also the competitive economic and ecologic advantage of the product versus the available alternative. Only the losses as a result of the use are introduced into the wastewater (see also section 5 b).

## 6. Fate of Substances Released into the Environment

Crosspure® is insoluble in water. Releases in the environment are only via the wastewater, which is normally treated in a wastewater plant. For example, according to publicly available sources, the major brewing companies (e.g., Miller and Anheuser Busch) operate their own wastewater treatment plants at each of their production sites.

In a first step due to the insolubility in water, the FCS can be eliminated from water via mechanical treatment.

Based on its physicochemical properties, and consistent with the intended mode of action during the filtration process (adhesion of yeast cells), Crosspure®, if not totally removed via mechanical treatment, will adhere to the biomass sludge in a wastewater treatment plant. The sludge will then be either put into a landfill or incinerated.

In the landfill we expect that the product will very slow decompose, mainly via photodegradation and radical mediated degradation, such as occurs with other polymers (e.g., polystyrene or polyethylene).

For the expected market volume and a worst case scenario calculation on the nitrogen oxide formation during incineration, please see the information in the confidential attachment. In principle, it can be said that the expected possible emission of NO<sub>2</sub> is by a factor of 1,000,000 smaller than the NO<sub>2</sub> released in the US from anthropogenic sources of municipal solid waste.

## 7. Environmental Effects of Released Substances

Several ecotoxicological studies are available for Crosspure®. The studies include toxicity data on fish, invertebrates and algae as well as on inhibitory effects on activated sludge of wastewater treatment plants:

Test organism	Result	Guideline	Remark	Title of Study *)
Fish <i>Danio rerio</i>	LC <sub>50</sub> (96h) > 100 mg/l (nominal)	OECD 203, under GLP	due to the insolubility in water an aqueous dispersion was tested and no concentration control analysis was performed	Acute Toxicity Study on the Zebrafish ( <i>Danio rerio</i> ) in a Static System over 96 hours Proj. No. 17F0467/015040
Invertebrates <i>Daphnia magna</i>	EC <sub>50</sub> (48h) > 100 mg/l (nominal)	OECD 202, under GLP	due to the insolubility in water an aqueous dispersion was tested and no concentration control analysis was performed	Crosspure® F – Determination of the acute effect on the swimming ability of the water flea <i>Daphnia magna</i> STRAUS Proj. No. 01/0467/50/1

<b>Algae</b> <i>Desmodesmus subspicatus</i>	E <sub>b</sub> C <sub>50</sub> (72h) > 100 mg/l (nominal) E <sub>r</sub> C <sub>50</sub> (72h) > 100 mg/l (nominal)	OECD 201, under GLP	due to the insolubility in water an eluate was tested and no concentration control analysis was performed	Crosspure® F – Determination of the inhibitory effect on the cell multiplication of unicellular green algae Proj. No. 01/0467/60/1
<b>Activated sludge</b> (municipal sludge)	EC <sub>20</sub> (180 min) > 1000 mg/l (nominal)	OED 209, under GLP	activated sludge from a laboratory wastewater plant treating with municipalsewage	Determination of the Inhibition of Oxygen Consumption by Activated Sludge in the Activated Sludge Respiration Inhibition Test Proj. No. 01/0467/08/1

\*) All studies are enclosed as attachment.

Based on the available data, the aquatic toxicity of Crosspure® can be assessed as follows:

Based on these studies, the test substance is not acutely harmful to aquatic organisms. The inhibition of the degradation activity of activated sludge is not anticipated when introduced to biological treatment plants in appropriately low concentrations.

The biodegradability and elimination of Crosspure® can be assessed as follows:

The test substance is considered to be not readily biodegradable. No study regarding this endpoint is available. However, polymers in general are known to be not readily or even only poorly biodegradable. Furthermore, due to the insolubility in water the test substance can be eliminated from water via mechanically treatment.

The bioaccumulation potential can be assessed as follows:

Based on the polymeric structure properties and the particle size, the polymer is not biologically available. Therefore, bioaccumulation in organisms is not expected.

## 8. Use of Resources

Crosspure® is intended to be used as a processing aid in clarification and stabilisation of alcoholic beverages, including beer and wine. Crosspure® is completely removed from the beverages by filtration equipment. In addition, Crosspure® is regenerable, thus resulting in a more energy efficient process and less waste. Thus, there is a positive effect on the use of natural resources and energy associated with this product.

**9. Mitigation Measures**

Mitigation measures to the proposed action need not be considered because no potential adverse effects have been identified.

**10. Alternatives to the Proposed Action**

Alternatives to the proposed action need not be considered because no potential adverse effects have been identified.

**11. List of Preparers**

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**12. Certification**

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

10.01.2006



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(Signature of Preparer)

Dr. Gerhard Gans  
Head of Quality Management and Regulatory Affairs

**13. Attachments**

4 ecotoxicological studies