

CHR HANSEN

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March 21, 2000

Revised: April 4, 2000

AKM/ATo

Environmental Assessment for a substance intended to be used as a component of a food contact surface intended for repeated use. Revised.

FCN No.: 52

NOTIFIER: Chr. Hansen A/S

SUBSTANCE AND USE: A high density agarose resin that is cross-linked and alkylated with epichlorohydrin followed by chemical binding of the ligand (benzylamine)

1. **Date:** March 21, 2000 - Revised April 4, 2000
2. **Name of sponsor:** Chr. Hansen A/S
3. **Address:** 10-12, Boege Alle, Hoersholm, DK-2970, Denmark
4. **Description of the proposed action:** A premarket notification for a food- contact substance of a food contact surface for repeated use.

The substance is a high density agarose resin that is cross-linked and alkylated with epichlorohydrin followed by chemical binding of the ligand (benzylamine).

The substance is used as the adsorbent in a chromatographic process intended for isolation and purification of food enzymes. The substance, in form of resin beads, is contained in a column into which the enzyme liquid is pumped through. The resin is reused more than 500 times. A typical chromatographic unit contains 700 - 1000 liter of resin (density 1.3-1.6 g/ml).

The food contact substance will not enter the U.S. market directly. The substance comes into contact with an enzyme product but will not be incorporated into the finished enzyme product. Thereafter the enzyme product is exported into the U.S.

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**5. Environmental consequences of the proposed action:**

a. *Production of the food-contact substance:* No extraordinary circumstances apply to the manufacture of the food- contact substance.

b. *Use and disposal of the food contact substance:* This action involves a food contact substance that is a component of a food contact surface for repeated use. The principal route of potential environmental introduction of the food contact substance results from its disposal after use. However, the potential for significant introduction of substances resulting from disposal is very low because of the long service life, more than one year, of food contact surface for repeated use and because of the limited market volume of the substance. The estimated market volume of the food contact substance is zero in the U.S. The use of the food contact material takes place in Europe and the estimated market volume for Europe is about 1,300 - 1,600 kg per year. Therefore, the proposed action will not have a significant environmental effect.

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

7. List of preparers: The EA has been prepared by Anne Kristine McNair, Regulatory Officer, Chemical Engineer. Anne Kristine McNair has 18 years of experience in the fields of regulatory affairs, environmental assessments, risk assessments. She has worked as consultant on environmental, health and safety matters and has since 1995 been employed with Chr. Hansen A/S as a regulatory officer.

8. Certification: The undersigned official certifies that the information presented is true, accurate, and complete to the best knowledge of Chr. Hansen A/S.

4-4-2000
Date (revised)

A rectangular box with a red border, used to redact the signature of the responsible official.

Signature of responsible official

Anne Kristine McNair

Name and title of responsible official, printed or typed