



The Chemical Company

**Attachment XV**

**Environmental Assessment for  $\beta$ -Alanine, N-(2-aminoethyl)-, monosodium salt, polymer with 1,4-butanediol, 1,6-diisocyanatohexane, 1,3-diisocyanatomethylbenzene and hexanedioic acid**

**1. Date:** March 5th, 2008

**2. Name of submitter:** BASF SE

**3. Address:**

All communications on this matter are to be sent to

BASF SE

Dr. Ruth Zschiesche,

Manager of Plastic Safety and Regulatory Affairs

KT/KS – E 100,

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 the polyurethane coating and adhesive consisting of  $\beta$ -Alanine, N-(2-aminoethyl)-, monosodium salt, polymer with 1,4-butanediol, 1,6-diisocyanatohexane, 1,3-diisocyanatomethylbenzene and hexanedioic acid (CAS 141073-56-5) for all food types.

BASF SE, Germany, has developed a coating and adhesive for plastic films,

000347

paper and paper board, analogous to FDA 21 CFR §175.105, §175.300 and §175.320, which are used for packaging and holding all kind of foodstuff as single use application. The contact material might be printed or not. The surface is either coated completely with the FCS or the FCS is used only for seam sealing.

**b. Need for action:**

The action is needed to provide for an improved food contact material for coating and adhesive application. The FCS can be used to seal at lower temperature as usually, between 60 – 140°C, depending on the food contact material. The PU dispersion is organo-tin-free and needs no additional emulsifier because of the monomer Sodium-N-(2-aminoethyl)-β-alaninate, which works as an incorporated stabilizer to get colloidal stability. It is water based and therefore has no potential for emitting solvents as volatile organic compounds.

**c. Locations of use:**

The Notifier does not intend to produce finished food packaging from the FCS. Rather, the FCS will be sold to manufacturers engaged in the production of food packaging material. Food-contact articles produced with the copolymer will be utilized in patterns corresponding to the national population density and will be widely distributed across the country.

**d. Locations of Disposal**

It is anticipated that disposal will occur nationwide, with about 76% of the materials being deposited in land disposal sites, and about 24% combusted (Characterization of Municipal Solid Waste in the United States 1997 Update, EPA 530-R-98-007, U.S. Environmental Protection Agency (.5305W), Washington DC, 20460, May 1998.)

The types of environments present at and adjacent to these disposal locations are the same as for the disposal of any other food-contact material in current use. Consequently, there are no special circumstances regarding the environment surrounding either the use or disposal of food-contact materials

000348

prepared from the FCS.

**5. Identification of the substance that is the subject of the proposed action:**

Generic information regarding the chemical identity of Polyurethane coating or adhesive is 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:  $\beta$ -Alanine, N-(2-aminoethyl)-, monosodium salt, polymer with 1,4-butanediol, 1,6-diisocyanatohexane, 1,3-diisocyanatomethylbenzene and hexanedioic acid

Trade name: Luphen® D alternativ Epotal® D

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

141073-56-5

**c. Physical description:** Polyurethane coating and adhesive

**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

000349

circumstances in this case indicative of any adverse environmental impact as the result of the manufacture the FCS. 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 the FCS into the environment will result from its use in the manufacturing of the food-packaging material. In these applications, the FCS is expected to be used on food-contact articles mostly covered by a second layer. Any waste materials generated in this process, *e.g.*, plant scraps, are expected to be disposed of as part of the packaging manufacturer's overall non hazardous solid waste in accordance with established procedures.

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

**i. Landfilling:**

Food-packaging material manufactured from the FCS is not intended to be recycled. It will be disposed of in patterns corresponding to population density with 76% disposed of in landfills. Based on the migration calculations on food-packaging materials containing the FCS, 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 pertains 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 24% disposed of by incineration. The FCS consists of carbon, hydrogen, nitrogen, and

000350

oxygen. Thus, no toxic combustion products are expected as a result of the proper incineration of the copolymer.

## **7. Fate of substances released into the environment:**

### **(a) Air**

No significant effect on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the FCS. The FCS is of high molecular weight and does not volatilize. Additionally the FCS is water based and does not contain any organic solvent as potential VOC.

Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact articles manufactured with the FCS. This expectation is confirmed by the results of extraction studies described elsewhere in the Notification. Thus, the quantity of FCS components in solid waste deposited in landfills will be extremely small. The products of complete combustion of the FCS would be carbon dioxide and water, along with small amounts of nitrogen oxides; the concentrations of these substances in the environment will not be significantly altered by the proper incineration of the FCS in the amounts utilized for food packaging applications.

### **(b) Water**

No significant effects on the concentrations of exposures to any substances in fresh water, estuarine, or marine ecosystems are anticipated due to the proposed use of the FCS. No significant quantities of any substance will be added to these water systems upon the proper incineration of food packaging employing the FCS, nor upon its disposal in landfills due to the extremely low levels of residuals of the FCS.

000351

**(c) Land**

Considering the factors discussed above, no significant effects on the concentrations of and exposures to any substances in terrestrial ecosystems are anticipated as a result of the proposed use of the subject FCS. In particular, the extremely low levels of maximum residuals in the FCS, indicate that virtually no leaching of these substances may be expected to occur under normal environmental conditions when finished food-contact materials are disposed of. Furthermore, the very low production of the FCS for use in food-contact applications precludes any substantial release to the environment of their components. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of the FCS. Considering the foregoing, we respectfully submit that there is no reasonable expectation of a significant impact on the concentration of any substance in the environment due to the proposed use of the FCS in the manufacture of articles intended for use in contact with food.

**8. Environmental Effects of Released Substances**

As discussed previously, the only substances that may be expected to be released to the environment upon the use and disposal of food packaging materials fabricated with the use of the FCS consist of extremely small quantities of residuals and impurities. Thus, no adverse effect on organisms in the environment is expected as a result of the disposal of articles containing the FCS. In addition, the use and disposal of food-contact articles containing the FCS are not expected to threaten a violation of applicable laws and regulations, e.g., the Environmental Protection Agency's regulations in 40 C.F.R. Part 60 that pertain to municipal solid waste combustors, and Part 258 that pertain to landfills.

**9. Use of Resources and Energy**

As is the case with other food packaging materials, the production, use and disposal of the FCS involves the use of natural resources such as petroleum

000352

products, coal, and the like. However, the use of the FCS in the fabrication of food-contact materials is not expected to result in a net increase in the use of energy and resources, since the FCS is intended to be used in packaging which will be used in place of similar coating or adhesive materials now on the market for use in food packaging applications. Coatings and adhesives currently used in the applications in which the FCS is anticipated to be used include those that are permitted under 21 C.F.R. §175.105 ("Adhesives"), § 175.300 ("Resinous and polymeric coatings") and § 175.320 ("Resinous and polymeric coatings for polyolefin films"). The partial replacement of these types of materials by the FCS is not expected to have any adverse impact on the use of energy and resources. Manufacture of the food-contact substance, and its conversion to finished food-contact materials, will consume energy and resources in amounts comparable to the manufacture and use of the other food contact substances. Furthermore, the use proposed in this Notification for the FCS is for a type of articles that is not currently recovered for recycling, e.g. food packing made of plastic films or paper. Food-contact materials produced using the subject food-contact substance are expected to be disposed of according to the same patterns when they are used in place of the current materials. Thus, there will be no impact on current or future recycling programs.

#### **10. Mitigation Measures**

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of food-contact materials fabricated using the FCS. This is primarily due to the minute levels of leaching of potential migrants from finished articles employing the FCS, the insignificant impact on environmental concentrations of combustion products of the FCS, and the close similarity of the FCS to the materials they are intended to replace. Thus, the use of the FCS as proposed is not reasonably expected to result in any new environmental problem requiring mitigation measures of any kind.

#### **11. Alternatives to the Proposed Action**

No potential adverse environmental effects are identified herein that would

**000353**

necessitate alternative actions to those proposed in this Notification. The alternative of not approving the action proposed herein would simply result in the continued use of the materials that the FCS would otherwise replace; such action would have no environmental impact. In view of the fact that the constituents of the FCS are not expected to enter the environment in more than minute quantities upon the use and disposal of finished food-contact articles, and the absence of any significant environmental impact which would result from its use, the establishment of an effective Food Contact Notification to permit the use of the FCS as described herein is environmentally safe in every respect.

**12. List of Preparers**

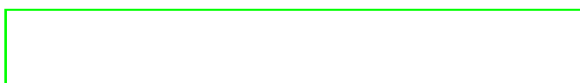
Dr. Ruth Zschiesche  
Manager Product Safety and Regulatory Affairs  
PhD Chemist  
BASF SE

**13. Certification:**

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

14. 3 08

(Date)



(Signature of responsible official)

Dr. Ruth Zschiesche, Manager of Product Safety and Regulatory Affairs

**000354**