Environmental Assessment
LANXESS Deutschland GmbH FOOD CONTACT NOTIFICATION

1. Date: September 26, 2006

2. Name of Applicant/Petitioner: LANXESS Deutschland GmbH

3. Address: All communications on this matter are to be sent in care of Counsel for Notifier:
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4. Description of Proposed Action:

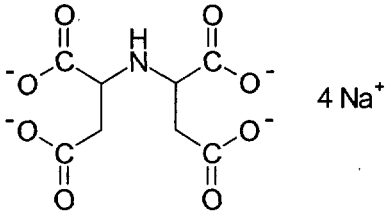
The action requested in this Notification is the establishment of a clearance of the food-contact substance (FCS) that is referred to as [redacted], for use as a stabilizer for bleach used in the manufacture of food-contact paper and paperboard at the wet end of the process. With the clearance of this Food-Contact Notification (FCN), paper and paperboard produced with the FCS will be used in contact with all food types without limitation on conditions of use.

The subject additive offers several technical properties that make it useful in a variety of food-contact applications. In particular, it removes metal ion impurities from process water in which peroxides are used as bleaching agents (in place of chlorine-based bleaches). Hydrogen peroxide decomposition is catalyzed by certain metal ions, which must be removed for effective bleaching.

The Notifier does not intend to produce finished food-contact paper and paperboard with the subject FCS. Rather the stabilizer will be sold to manufacturers engaged in the production of food-contact paper and paperboard. The paper and paperboard will be widely distributed across the country. Therefore, it is anticipated that disposal of the subject stabilizer will occur nationwide, with the material being discharged into wastewater treatment systems.

5. Identification of Substances that are the subject of the Proposed Action:

A description of the FCS stabilizer appears elsewhere in this Notification. The FCS that is the subject of this notification is [redacted], iminodisuccinic acid, tetrasodium salt [Na-IDS, Chemical Abstracts Service (CAS) name D,L-aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt, CAS Registry Number (CASRN) 144538-83-0]. Na-IDS has the following structure:



The additive is marketed under the trade name [redacted], a solution containing 33% – 35% Na-IDS.

The concentrations of the impurities in the solution and the calculations of expected final concentration in receiving waters are described in the Confidential Attachment to this Assessment.

6. Introduction of Substances into the Environment:

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

Under 21 C.F.R. § 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 substances. 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 a result of the manufacture of the FCS stabilizer. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

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

[redacted] is added to the wet end of the papermaking process at a maximum level of 0.5% by weight of dry pulp. Therefore, Na-IDS itself is present at 0.18% by weight of dry pulp. Given the negative log Pow, -3.9305, and LANXESS's own experiments, as

discussed in Attachment 8 to the FCN, Na-IDS is non-substantive to the paper, and more than 98% should remain in the white water. Since the consistency of pulp in the wet end is about 0.5%, the concentration of Na-IDS in this water should be 8.5 parts per million (mg/l).

$$(0.0017\ g_{Na\text{-}IDS}/g_{pulp})(0.005\ g_{pulp}/g_{water}) = 8.5 \times 10^{-6}\ g_{Na\text{-}IDS}/g_{water} = 8.5\ mg/l$$

There are other sources of water in the paper or paperboard plant that will be combined with the waste stream from the wet end of the process and this will result in further dilution in the plant waste treatment facility. Degradation will occur in the treatment facility and FDA recognizes an additional ten-fold dilution factor on discharge to navigable waters. Given the amount of material calculated to be present in the white water from the wet end of the plant and conservatively not including additional degradation and dilution during treatment, but including FDA's dilution factor at discharge, the concentration of Na-IDS would be 0.85 mg/l in the receiving water.

7. Fate of Emitted Components in the Environment:

In a study designed to assess "ready biodegradability," performed in accordance with Commission Directive 92/69/EEC and essentially identical to OECD Guideline 301 E , 79% of the test material had degraded in 28 days (Bayer AG report 628 N/97 O, 4/4/97, **Appendix 1**). In a second study, designed to assess "inherent biodegradability," performed in accordance with OECD Guideline 302 B, 99% had degraded in 28 days (Bayer AG report 940 N/00 Z, 3/8/00, **Appendix 2**). In a third study, designed to assess "anaerobic biodegradability," performed in accordance with the ECETOC Technical Report No. 28, 39% of Na-IDS degraded after incubation with sludge under anaerobic conditions in the dark for 56 days (Summary of Bayer AG report 769 N/98 AT, 2/9/99, **Appendix 3**).

Under aerobic conditions, the probable degradation products would be sodium, sulfate and nitrate ions, carbon dioxide and water. Anaerobic decomposition would ultimately yield sodium and sulfide ions, methane, carbon dioxide, water, and ammonia.

Under conditions operative in paper plant waste holding facilities, the Na-IDS should readily degrade.

LANXESS determined the adsorption coefficient *Koc* on soil and on sewage sludge using OECD TG121. Under these test conditions log *Koc* was <-3, indicating that Na-IDS

should not be bound to soil or sludge to any significant extent (Bayer AG report N00/0054/08 LEV, January 17, 2002).

8. Environmental Effects of Released Substances:

LANXESS has performed studies on [redacted] to determine its toxicity. The studies represent the toxicity of all of the components of the product as it will be used. The test results, expressed as Na-IDS, are summarized below:

Test	Endpoint	Concentration
Acute toxicity to rats	LD_{50} oral	> 2000 mg/kg
Dermal toxicity to rats	LD_{50} (24 h)	> 2000 mg/kg
Toxicity to zebra fish*	LC_0 (96h)	≥ 82.6 mg/l
Toxicity to daphnia*	EC_0 (48 h)	≥ 84 mg/l
Toxicity to bacteria (OECD 209)	EC_{50} (0.5 h)	≥ 10,000 mg/l
Algae growth (inhibition)*	NOEC (72 h)	≥ 91.5 mg/l
Toxicity to zebra fish*	NOEC (14 day)	≥ 12 mg/l
Daphnia Magnia Reproduction*	NOEC (21 d)	11.7 mg/l

* Summary reports provided in **Appendix 4**

All of these endpoints are substantially higher than the concentration of the material that will be present in the receiving water. The material is not mutagenic (Ames test) or clastogenic (mouse micronucleus test).

9. Use of Resources and Energy

The use of the FCS stabilizer will not require additional energy resources for treatment and disposal of waste solution, as the components readily degrade. The raw materials used in the production of the stabilizer are commercially-manufactured materials that are produced for use in a variety of chemical reactions and production processes. Energy used specifically for the production of the FCS stabilizer is not significant.

10. Mitigation Measures

As discussed above, no significant adverse environmental impacts are expected to result from the use and disposal of the FCS stabilizer. Thus, the use of the subject stabilizer

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 necessitate alternative actions to that proposed in this Food Contact Notification. The alternative of not approving the action proposed herein would simply result in the continued use of current stabilizers, such as ethylenediamine tetraacetic acid (EDTA)[1] or diethylenetriamine pentaacetic acid (DTPA), that are not readily biodegradable.

12. Green Chemistry Challenge Award

It is worth noting that [redacted] was the winner of the Sixth Annual Presidential Green Chemistry Challenge Award 2001 established by the EPA in 1991. [redacted] is friendly to the environment.[2]

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1 *See* the European Commission's risk assessment of EDTA at http://ecb.jrc.it/?A=EX&B=/Risk-Assessment/.

2 *http://www.epa.gov/greenchemistry/pubs/pgcc/winners/gspa01.html.*

13. List of Preparers

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13. Certification

The undersigned official certifies that the information provided herein is true, accurate, and complete to the best of his knowledge.

Date: September 26, 2006

Catherine R. Nielsen

Counsel for LANXESS Deutschland GmbH

Enclosures:
Appendix 1: Bayer AG report 628 N/97 O, 4/4/97
Appendix 2: Bayer AG report 940 N/00 Z, 3/8/00
Appendix 3: Bayer AG report 769 N/98 AT, 2/9/99
Appendix 4: Toxicity to zebra fish, daphnia, and algae growth (inhibition)