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Environmental Assessment
LANXESS Deutschland GmbH FOOD CONTACT NOTIFICATION

1. Date: April 19, 2007

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), polyaspartic acid, sodium salt. The FCS is intended for use as follows:

1. As a dispersant for fillers (e.g., clay, calcium carbonate, etc.) at levels not to exceed 0.5% by weight of the fiber in the wet end of the manufacture of paper and paperboard intended for use in contact with food.
2. As an anti-scale additive during the processing/evaporation of raw beet and cane sugar juice at levels up to 5 parts per million (ppm) by weight in the final sugar.

The subject additive offers several technical properties that make it useful in a variety of food-contact applications. In particular, it acts as a dispersant for fillers in paper and paperboard manufacture and as an anti-scale additive in sugar processing. When used in the processing of sugar, it is typically used at a maximum level of 17.66 mg/kg beets as the liquid product, or 7.06 mg/kg beets as the active ingredient. (*See* sugar processing diagram attached as Appendix 6.) From an environmental impact perspective, the FCS represents a readily biodegradable alternative to other polymers, such as polyacrylates, that are commonly used in the manufacture of paper and paperboard and in sugar production.

The Notifier does not intend to produce finished food-contact paper and paperboard or to process sugar with the subject FCS. Rather, the material will be sold to manufacturers

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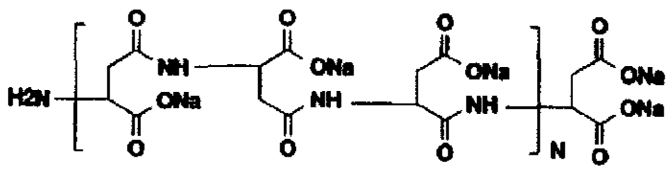
engaged in the production of food-contact paper and paperboard or to sugar processors. The paper and paperboard and sugar will be widely distributed across the country. However, the FCS is not expected to be present significantly in the products (sugar and paper and paperboard). Disposal of the subject FCS will occur nationwide as a consequence of its intended uses.

5. Identification of Substances that are the Subject of the Proposed Action

A description of the FCS appears elsewhere in this Notification. The FCS that is the subject of this notification is Polyaspartic acid, sodium salt [Chemical Abstracts Service (CAS) name 2-Butenedioic acid (Z)-, ammonium salt, homopolymer, hydrolyzed, sodium salts, CAS Registry Number (CASRN) 181828-06-8]. Polyaspartic acid, sodium salt has the following structure:



The additive is marketed under the trade name [redacted], a solution containing approximately 40% polyaspartic acid, sodium salt.

The concentrations of the confidential impurities in the solution and the calculations of expected final concentration in receiving waters are described in the confidential attachment.

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. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

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b. Introduction of Substances into the Environment as a Result of Use/Disposal – Paper and Paperboard Manufacture

The FCS is added to the wet end of the papermaking process at a maximum level of 0.5% polyaspartic acid, sodium salt by weight of dry pulp. Given the negative log Pow, -2.4, and LANXESS's own experiments, polyaspartic acid, sodium salt 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 polyaspartic acid, sodium salt in this water should be 25.0 parts per million (mg/l).

$$(0.005\ g_{\text{polyaspartic acid, sodium salt}}/g_{\text{pulp}})(0.005\ g_{\text{pulp}}/g_{\text{water}}) = 2.5 \times 10^{-5}\ g_{\text{polyaspartic acid, sodium salt}}/g_{\text{water}} = 25\ \text{mg/l}$$

Other sources of water in the paper or paperboard plant will be combined with the waste stream from the wet end of the process, resulting 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 polyaspartic acid, sodium salt would be 2.5 mg/l in the receiving water.

The other components of the FCS may also remain in the process water, given their water solubility. Expected concentrations of these components in receiving waters are discussed in the confidential attachment.

c. Introduction of Substances into the Environment as a Result of Use/Disposal – Sugar Processing

Little release of this product is expected from its use as an anti-scale agent in the evaporation step in sugar processing, because much of the water in that process is evaporated and not released. A small amount (<5 ppm a.i.) may remain in the sugar. The remaining material is expected to be present in the molasses recovered from the crystallization process.

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After evaporation, the concentration of the FCS polymer in the thick juice is a maximum of approximately 25.2 mg/kg, as shown in the attached sugar process flow chart. The thick juice goes through a crystallization step to produce the sugar and molasses. A maximum concentration of up to 5 ppm of the active ingredient may remain in the dry sugar.

It is possible to calculate the concentration of polyaspartic acid that might be in the molasses. As shown in the attached flow diagram, the maximum addition rate for the FCS polymer is 7.06 mg/kg beets. For the sake of conservatism, because the polymer is not expected to remain with the finished sugar at a significant level, we will assume that all of the polymer added will be present in the molasses. Typical molasses yields are 3-4 tons per 100 tons of sugar cane, or 4-6 tons per 100 tons of sugar beet.[1] We will use the sugar beet value, as the FCS usage rate is given in terms of sugar beets. We also will assume an average of 5 tons of molasses per 100 tons of sugar beet.

On this basis, if all of the FCS polymer added to assist in evaporation remains in the molasses, this will correspond to a maximum content of 141 mg/kg.[2] Thus, introduction of the FCS polymer to the environment will occur primarily as a result of its presence at this maximum level as a residue in the molasses.

The fate of the FCS as a component of molasses will depend upon the ultimate use or disposal of the molasses. If some portion of the molasses is disposed of as waste, this would be expected to occur by means of incineration or sanitary landfill. No significant release of the FCS into the environment would result from this disposal based on the controls placed on such facilities. In particular, no significant environmental release from landfills would be expected based on the Environmental Protection Agency's (EPA) regulations governing municipal solid waste landfills, i.e., 40 CFR Part 258. Moreover, due to the low amount of material involved (see confidential attachment for market projections) in comparison to the total municipal solid waste currently combusted (estimated to be 33 million tons in 2003), the incineration of a portion of the molasses produced that contains the FCS as a residue would not be expected to cause municipal waste combustors to threaten a violation of applicable

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[1] "The Origins of Molasses." Tate & Lyle Molasses Germany. Article available on-line at http://www.melasse.de/originsofmolasses.html.

[2] (7.06 mg/kg beets) x (100 tons beets/5 tons molasses) = 141 mg/kg.

emissions laws and regulations, i.e., EPA's regulations in 40 CFR Parts 60 and local government air emission regulations.

Disposal is expected to represent only a minor form of disposition for molasses that contains residues of the FCS. As with molasses generally, the molasses formed in the production of sugar using the FCS is expected to be used primarily as a component of animal feed and in the fermentation production of ethanol, as shown in the attached flow diagram. In discussing these applications, it is important to note that the concentration of FCS residues in an end product where molasses is used as an ingredient would be expected to diminish over time because the polymer biodegrades, as discussed further in Section 7 below.

With regard to the use of molasses in animal feed, the worst-case concentration of FCS residues in the feed will be determined by the concentration at which the molasses is incorporated into the feed. A molasses concentration of 13% to 18% has been reported for silage given to cows.[3] A molasses concentration of 10% has been reported in feeds for dairy cattle, pigs, horses, and lambs; 20% in beef cattle; and 2.5% to 4% in poultry.[4] On this basis, a conservative estimate of a typical molasses content in feed would be 10%. If the molasses contains FCS residues at 141 mg/kg, then the resulting concentration of the FCS residues in the feed will be 14.1 mg/kg. However, due to the ready biodegradability of the polymer (see Section 7 below), it is expected that the concentration of FCS residues in feed will have diminished to well below this maximum concentration of 14.1 mg/kg as of the time it is consumed in the feed.

The use of molasses containing FCS residues as an ingredient in animal feed is not expected to result in the FCS being released to the environment. Rather, the FCS will be consumed as a residue in the feed. If the FCS is present in the finished product, so that the animals are exposed to the intact polymer in the feed, it is fully expected that any residue of the polymer that remains in the feed at the time it is consumed will be fully broken down in the animal's digestive tract. This expectation is due to the polymer's close structural

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3 . "Molasses and Milk Protein Quality." Tate & Lyle Molasses Germany. Article available on-line at http://www.melasse.de/molassesandmilkpr.html.

4 L.E. Harris. *Guide for Estimating Toxic Residues in Animal Feeds or Diets.* 1975, cited in: http://www.epa.gov/opptsfrs/publications/OPPTS_Harmonized/860_Residue_Chemistry_Test_Guidelines/Series/860-1480.pdf

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similarity to natural polypeptides and reflects its demonstrated ready degradability. Moreover, based on the toxicological profile of the FCS, as discussed in Section 8 below, the presence of the polymer at the anticipated levels in animal feed would not present any toxicological concern.

With further regard to the possible presence of FCS residues in the molasses, we note that aspartic acid is naturally found primarily in sugar cane and molasses.[5] Thus, the possible presence of polyaspartic acid at low levels in molasses is not expected to have any impact on the safety and suitability of the molasses as a component of animal feed.

The second commercial use for the molasses is in the production of ethanol. If the molasses containing FCS residues is fermented to produce ethanol, this use is not expected to result in an introduction of the FCS polymer to the environment. This is because the fermentation process would be expected to fully degrade the polymer, in keeping with the biodegradability data described in Section 7 below.

In sum, the FCS is not expected to enter the environment as a result of its use in sugar processing, either as a release from the sugar processing facility or as a result of the major commercial uses of molasses. Nonetheless, the data summarized in Sections 7 and 8 below indicate that the possible release of the polymer at the processing facility or upon subsequent use or disposal of the molasses would not be expected to have any adverse environmental impact.

The other components of the FCS may also remain in the molasses, along with the polymer itself. Expected concentrations of these components in the molasses are discussed in the confidential attachment. These compounds are not expected to have any adverse impact on the use of the molasses in the applications described here, due to the low concentrations of these species in the molasses and their inherent low degree of toxicity.

7. Fate of Emitted Components in the Environment

In a study designed to assess "ready biodegradability," performed in accordance with modified OECD Guideline 301 E , 74% of the test material had degraded in 28 days (Bayer AG report 40 A/01 O, Appendix 1). In a second study to assess "inherent biodegradability"

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[5] See, *Medline Plus Medical Encyclopedia*, a service of the U.S. National Library of Medicine and the National Institutes of Health. Available on-line at http://www.nlm.nih.gov/medlineplus/ency/article/002234.htm.

001637

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performed in accordance with OECD Guideline 302 B, 77% of the test material had degraded in 28 days and 81% had degraded in 56 days (Bayer AG report 939 A/00 Z). In a third study designed to assess "anaerobic biodegradability," which was performed in accordance with the ISO 11734 Test, 30% of polyaspartic acid, sodium salt degraded under anaerobic conditions after 56 days (Bayer AG report 779 A/98 AT, Appendix 2).

In addition, the FCS was evaluated for biodegradability in the modified Sturm test (OECD 301 B), in which degradation of the test compound is measured in terms of generated CO_2. As indicated by the graph attached to this Environmental Assessment (see Appendix 7), degradation of the FCS polymer closely tracked that of the control compound, glucose. By comparison, degradation of a standard polyacrylate was considerably lower than that of the FCS.

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

Under conditions operative in paper or sugar plant waste holding facilities, the polyaspartic acid should readily degrade.

LANXESS determined the octanol water partition coefficient *Kow* using EG Guideline 92/69. Under these test conditions log *Kow* was <-2.4, indicating that polyaspartic acid should not be bound to soil or sludge to any significant extent (Bayer AG report N99/0025/03 LEV, September 20, 1999, Appendix 4).

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 polyaspartic acid, sodium salt, are summarized below:

001638

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)	≥ 3160 mg/l
Toxicity to daphnia*	EC_0 (48 h)	≥ 2500 mg/l

[redacted]

Toxicity to bacteria (OECD 209)	EC_{50} (0.5 h)	≥ 15,000 mg/l
Algae growth (biomass)*	EC_{50} (72 h)	≥ 528 mg/l
Toxicity to marine diatoms*	NOEC (72 h)	≥1108 mg/l
Toxicity to marine copepod*	NOEC (48 h)	≥1000 mg/l
Toxicity to marine fish*	NOEC (96 h)	≥1000 mg/l

* Reports provided in Appendix 5

These studies demonstrate that the FCS is of a low order of toxicity to aquatic organisms.

In addition, the FCS was evaluated in a battery of *in vitro* genotoxicity assays, including a reverse mutation assay (Ames test) in *Salmonella typhimurium* tester strains TA1535, TA100, TA1537, TA98 and TA102; a chromosomal aberration assay in Chinese hamster V79 cells; and a forward mutation assay at the HPRT locus in Chinese hamster V79 cells. No evidence of genotoxic activity was observed in any of these assays.

In terms of oral toxicity testing in mammals, the acute oral is LD_{50} >2000 mg/kg. In addition, a subacute study was carried out in which groups of male and female Wistar rats received the FCS by daily gavage for a period of four weeks, followed by a recovery period of two weeks. Dose levels were 0, 40, 200, and 1000 mg/kg b.w./day. Apart from microscopic effects on the urinary bladder that have been found to be species (rat) specific, there were no adverse effects in this study. Thus, the available data indicate that residues of the FCS that may remain in molasses will not present a toxicological concern upon the use of the molasses as a component of animal feed.

9. Use of Resources and Energy

The use of the FCS 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 FCS 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 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. Thus, the use of the subject additive is not

001639

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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 dispersants and anti-scale additives.

12. 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 her knowledge.

Date: April 19, 2007

Catherine R. Nielsen
Counsel for LANXESS Deutschland GmbH

Enclosures:	Appendix 1:[6]	Bayer AG report 1140 A/01 O, January 31, 2002
	Appendix 2:	Bayer AG report 939 A/00 Z, March 23, 2000
	Appendix 3:	Bayer AG report 779 A/98 AT, September 1, 1999
	Appendix 4:	Bayer AG report N99/0025/03 LEV, September 20, 1999
	Appendix 5:	Toxicity to zebra fish, daphnia, algae growth and marine species
	Appendix 6:	Sugar Processing diagram
	Appendix 7:	Modified Sturm test degradation curve

001640

[6] Appendices 1-5 were submitted with the original EA on January 22, 2007 and are not also enclosed with this filing.

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