

**ATTACHMENT 7****ENVIRONMENTAL ASSESSMENT  
INNOSPEC LIMITED FOOD CONTACT NOTIFICATION  
PNC 577**

- 1. Date:** December 24, 2007
- 2. Name of Applicant/Petitioner:** Innospec Limited
- 3. Address:** All communications in this matter are to be sent in care of Counsel for Notifier:  
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**4. Description of Proposed Action:**

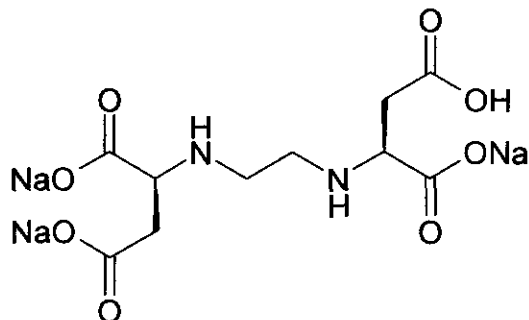
The action requested in this Notification is the establishment of a clearance of the food contact substance (FCS) that is referred to as [S,S]-ethylenediaminedisuccinic acid trisodium salt, for use as a chelating agent in the process water slurry used in the manufacture of food-contact paper and paperboard 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 the conditions of use.

The subject chelating agent offers several technical properties that make it useful in a variety of food-contact applications. In particular, it removes metal ion impurities from the 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 chelating agent 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 the disposal of the subject chelating agent 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 appears elsewhere in this Notification. The FCS that is the subject of this notification is [S,S]-ethylenediaminedisuccinic acid, trisodium salt [S,S]-EDDS trisodium salt, Chemical Abstracts Service (CAS) name L-Aspartic acid, N,N'-1,2-ethylenediylbis, trisodium salt, CAS Registry Number (CASRN) 178949-82-1]. S,S-EDDS trisodium salt has the following structure:



Tri-sodium [S,S]-EDDS

The chelating agent is marketed under the trade name ENVIOMET™ C140, which contains 38% w/w Na<sub>3</sub>[S,S]-EDDS in water.

The concentrations of the impurities in the solution and the calculation of expected final concentration of the food contact substance 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 chelating agent. 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:

S,S-EDDS, trisodium salt is added to the wet end of the paper- and paperboard-making process at a maximum level of 0.30 wt-% to finished paper. Given the negative log Pow, < -4.7, S,S-EDDS trisodium salt is non-substantive to the paper and paperboard, and no more than 2% should remain in the process slurry water. Since the consistency of pulp in the wet end is about 0.6%, the concentration of S,S-EDDS trisodium salt in this water should be 18 parts per million (mg/l).

$$3\text{kg/t FCS to pulp} = 3\text{g/kg pulp or } 0.003\text{g/g pulp}$$

0.6% pulp in process water = 6g pulp/l  
Therefore 0.018g FCS/l wet end water in headbox = 18mg/l or 18ppm.

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 of the waste stream 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 S,S-EDDS, trisodium salt is calculated to be 3.5 ppm in the receiving water. See Section II of the Confidential Attachment.

#### **7. Fate of Emitted Components in the Environment:**

Innospec is submitting six studies which address the fate of S,S-EDDS, trisodium salt in the environment. These studies are summarized below and are designated as Attachments 1 through 5, which are contained on the CD that is attached to this Environmental Assessment.

1. Reference No: ECM ETS 465/03  
  
Title: Biodegradation study of E-4589.01 activated sludge simulation test  
  
Methods: Test substance at 40.5% active (E-4589.01)  
  
OECD Guidelines for Testing of Chemicals, Guideline 303A: Simulation Test – Aerobic Sewage Treatment: Coupled Units Test  
  
Directive 79/831/EEC, Part C: Methods for the Determination of Ecotoxicity: Biodegradation Activated Sludge Simulation Tests  
  
Conclusion: % DOC removal: mean: 96  
sd: 3.3  
95% confidence intervals: 94-97
  
2. Reference No: ECM ETS 465/05  
  
Title: Adsorption/desorption of E-4589.01 to activated sludge with <sup>14</sup>C analysis  
  
Methods: Test substance >90% radiochemical purity (E-4589.01)

Conclusion: Sorption coefficient (Kd) values with sludge from the blank unit of CAS-test ECM ETS 465/03:

| test material concentration | adsorption | desorption |
|-----------------------------|------------|------------|
| 0.1 mg/l                    | 30         | 421        |
| 1.0 mg/l                    | 37         | 334        |

Kd values with inactivated sludge from the test unit of CAS-test ECM ETS 466/03:

| test material concentration | adsorption | desorption |
|-----------------------------|------------|------------|
| 0.1 mg/l                    | 71         | 1034       |
| 1.0 mg/l                    | 90         | 1298       |

The adsorption of the test substance to activated sludge solids is low.

3. Reference No: NOTOX Project 079199

Title: Soil Adsorption/Desorption of E-4589.02 on 3 Soils (Screening Version)

Methods: Test substance approximately 94% SS-EDDS (E-4589.02)

The determination of the soil adsorption/desorption on 3 soils (screening version) was based on OECD Guideline No. 106 (Screening version) "Adsorption/Desorption: (1981).

For the screening test adsorption/desorption of E-4589.02, three different soils were used:

Soil I: strong silty sand (pH 4.0, 6.0% clay, 1.4% organic matter)

Soil II: strong sandy loam (pH 7.5, 13.6% clay, 1.8% organic matter)

Soil III: weak sandy loam (pH 6.6, 12.1% clay, 1.1% organic matter)

Conclusion: The amount of adsorption (A) was determined to be 98%, 83% and 89% for soil I, II, and III, respectively.

The amount of desorption (D) was determined to be <4%, <3% and <4% for soil I, II and III, respectively.

The amount of adsorbed material which was not desorbed (R) was determined to be >96%, >97% and >96% for soil I, II and III, respectively.

The corresponding K' values were calculated to be  $2.6 \times 10^2$ , 28 and 44 for soil I, II and III, respectively.

The corresponding K'oc values were calculated to be  $1.9 \times 10^4$ ,  $1.6 \times 10^3$  and  $4.0 \times 10^3$  for soil I, II and III, respectively.

The test was performed at room temperature.

4. Reference No: ECM ETS 465/01
- Title: Biodegradation Study of E-4589.01 Modified Sturm Test
- Methods: Test substance at 40.5% active (E-4589.01)
- OECD Guidelines for Testing Chemicals, Guideline 301F: Ready Biodegradability: Modified Sturm Test.
- Directive 84/449/EEC, Part C: Methods for the Determination of Ecotoxicity: Biotic Degradation: Modified Sturm Test.
- Conclusion: The following results are obtained for the ready biodegradability after 34 days:
- |   |      |
|---|------|
| Test substance E-4589.01 10 mg/l              |      |
| biodegradation (% of ThCO <sub>2</sub> )      | : 88 |
| % DOC-removal                                 | : 94 |
| Test substance E-4589.01 20 mg/l              |      |
| biodegradation (% of ThCO <sub>2</sub> )      | : 90 |
| % DOC-removal                                 | : 93 |
| Reference substance online 20 mg/l            |      |
| biodegradation (% of ThCO <sub>2</sub> )      | : 92 |
| % DOC-removal                                 | : 98 |
| Reference substance diethylene glycol 20 mg/l |      |

biodegradation (% of ThCO<sub>2</sub>) : 64  
% DOC-removal : 67

5. Reference No: ECM ETS 519/01; BCO project 93-09041
- Title: Determination of [S,S]-EDDS in samples from a 7 days pre-test on photostability.
- Methods: Test substance E-4589.01

Algal growth medium samples were dosed with 30 mg/l E-4589.01. E-4589.01 contains 34.2% Na-[S,S]-EDDS with a sodium concentration of 8.1%. Samples were withdrawn from the 2 test solutions (one algae-free and one containing algae) at days 0, 1, 2, 4 and 7. Immediately after sampling 3% formaldehyde (37% v/v) was added. The samples were analyzed against the primary [S,S]-EDDS standard (E-4593.01, acid form).

- Conclusion: No substantial degradation occurred between days 0 and 7.

The presence of algae had no influence on the [S,S]-EDDS test concentration during the test period. On average  $90 \pm 7\%$  of the EDDS was retrieved in the test solutions containing algae and  $91 \pm 3\%$  in algae-free test medium.

No substantial difference in analytical recovery was noticed for both test systems.

5. Reference No: ECM ETS 519/01; BCO project 93-09041
- Title: Determination of [S,S]-EDDS in samples from the TNO Pre-test on photostability
- Methods: Test substance E-4589.01

Twenty samples were dosed with E-4589.01 at different concentrations. E-4589.01 contains 34.2% Na-[S,S]-EDDS with a sodium concentration of 8.1%. Eighteen samples were withdrawn from the algae-free test solutions at days 0, 1, 2 and 4. The two algae containing samples were sampled after 4 hours. Immediately after sampling 3% formaldehyde (37% v/v) was added. The samples were analyzed against the primary [S,S]-EDDS standard (E-4593.01, acid form).

**Conclusion:** The results show a general decrease in [S,S]-EDDS response of 5 to 9% during the first day. No substantial degradation occurred between days 1 and 4.

There is no evidence from this limited number of data that [S,S]-EDDS decomposed in the light.

The analytical recovery in presence of algae, measured on one single sample, was 86% and completely in agreement with the algae-free samples.

Under the conditions operative in paper and paperboard plant waste holding facilities, S,S-EDDS trisodium salt should degrade readily. Further, the adsorption of the test substance to activated sludge solids should be low.

### 8. Environmental Effects of Released Substances:

Studies have been conducted on S,S-EDDS trisodium salt to determine its toxicological effects. The results of these studies are summarized below. The studies represent the toxicity of all the components of the product as it was tested.

| STUDY   | RESULTS  |
|---|--|
| Acute Oral Rats (E-3657.01)   | Acute lethal oral dose >2.7 g/kg   |
| Acute Oral Rats (E-4589.02)   | LD50>2000  |
| Acute Dermal Rabbits (E-3657.01)                                    | LD50>2640  |
| Acute Dermal Rats (E-4589.02)                                       | LD50>2000  |
| Acute Inhalation Rats (E-3657.01)                                   | LC50 (4-hour) > 1.49 mg/l  |
| Primary Eye Irritation Rabbits (E-4589.02)                          | -No staining of cornea/conjunctivae<br>-No corrosion<br>-Primary irritation score of 0.56<br>-Classified as non-irritant |
| Irritant Effects Rabbit Eye (E-3657.01)                             | Considered to be non-irritant  |
| Irritant Effects Rabbit Skin (E-3657.01)                            | Primary Irritation Index = 0   |
| Contact Hypersensitivity in Albino Guinea Pigs (E-4589.02)          | Not a sensitizer   |
| Dermal Sensitization Guinea Pigs (E-4589.02)                        | Dermal reactions of 0 in all except one animal   |
| Acute Toxicity to the worm species Eisenia fetida (10000286)*       | NOEC (of active) = 10 mg/kg of dry soil  |
| Semi-Static Acute Toxicity with Brachydanio rerio (E-4589.01)*      | NOEC value for survival and condition > 1,000 mg ai/l  |
| Semi-Static Early Life Stage Test on Brachydanio rerio (E-4589.06)* | -The highest concentration tested without a significant effect on growth (measured as dry weight) was 180 mg ai/l.       |

|  |   |
|--|---|
|  | -The lowest NOEC for mortality and growth was 56 mg ai/l.   |
| Static Acute Toxicity on <i>Daphnia magna</i> (E-4589.01)*           | NOEC values for mobility and condition are > 1000 mg ai/l and 320 mg ai/l respectively.   |
| Semi-Static Reproduction Test with <i>Daphnia magna</i> (E-4589.01)* | -Reproduction: 21 d EC50 = 80 mg ai; 21 d NOEC5.25 = 32 mg ai; 21 d FOEC5.25 = 100 mg ai.<br>-Survival: 21 d LC50 > 100 mg ai; 21 d NOEC = 32 mg ai; 21 d FOEC = 100 mg ai.<br>-Condition and Size: 21 d NOEC = 32 mg ai; 21 d FOEC = 100 mg ai |

\* These studies are designated as Attachments 6 through 10 and are provided on the enclosed CD.

All of these endpoints are substantially higher than the concentration of the FCS that will be present in the receiving water.

**9. Use of Resources and Energy:**

The use of the FCS chelating agent will not require additional energy resources for treatment and disposal of waste solution, as the components will readily degrade. The raw materials used in the production of the chelating agent 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 chelating agent. Thus, the use of the subject chelating agent 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 chelating agents, such as ethylenediaminetetracetic acid (EDTA) or diethylenetriamine pentaacetic acid (DTPA), which are not readily biodegradable.

**12. Green Technology Award**



ENVIOMET (Trade named Octaquest at the time, but the name has since been changed to ENVIOMET) was the winner of the United Kingdom Green Technology Award for 2003. The competition was run by the Crystal Faraday Partnership, which brings together the Institution of Chemical Engineers, the Royal Society of Chemistry and the Chemical Industries Association. Unlike typical chelants, such as EDTA and the phosphonates, ENVIOMET biodegrades harmlessly before entering any river or other water course.

### 13. List of Preparers:

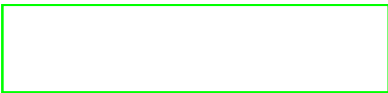
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Nick Dixon, Ph.D., Product & Technical Manager, Innospec Limited, Innospec Manufacturing Park, Oil Sites Road, Ellesmere Port, Cheshire CH65 4EY, United Kingdom

### 14. Certification:

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

Date: December 24, 2007

  
Walter G. Talarek  
Counsel for Innospec Limited

Enclosures on CD:

Appendix 1: Study No WB-01-024; Biodegradation study of E-4589.01 activated sludge simulation test

Appendix 2: WG-03-002; Adsorption/desorption of E-4589.01 to activated sludge with <sup>14</sup>C analysis

Appendix 3: NOTOX Project 079199; Soil Adsorption/Desorption of E-4589.02 on 3 Soils (Screening Version)

Appendix 4: Study NO WB-04-048; Biodegradation Study of E-4589.01 Modified Sturm Test

Appendix 5: BCO Project 93-09041; Determination of [S,S]-EDDS in samples from a 7 days pre-test on photostability.

Appendix 5: BCO project 93-09041; Determination of [S,S]-EDDS in samples from the TNO Pre-test on photostability

Appendix 6: Summary Reports of Eco-Toxicity Studies

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