EN

Section H - Environmental Assessment

H.1 - Environmental Assessment Report

This environmental assessment report has been prepared in accordance with 21 CFR 25.31a using the abbreviated format of (b)(1). See item 4a below for justification.

1. Date: May 9, 1996

2. Name of Petitioner: Henkel Corporation
Organic Products Group

3. Address of petitioner: 300 Brookside Avenue
Ambler, PA 19002

4. Description of proposed action:

a. Requested approval and need for action:

This petition proposes that section 178.3400 be amended by adding the proposed food additive, "α-Sulfo-ω-(dodecyloxy) poly(oxyethylene), sodium salt," to the list of approved substances. The proposed food additive is used as a surface active agent at a maximum level of 2% by weight of monomers in the emulsion polymerization of acrylic and modified acrylic polymers and copolymers and vinyl acetate copolymers listed in 176.170. These copolymers are subsequently used at about 11% in binders for latex coatings applied to paper and paperboard which complies with 176.170.

As discussed in Section D, the maximum concentration of the proposed food additive in the coating was about 2% which resulted in a concentration of 263 mg of proposed food additive/kg of coated paper or 0.0263% of the finished food-packaging material. This is less than the 5 percent-by-weight of finished food-packaging material criteria which qualifies the proposed food additive for the abbreviated environmental format.

b. Locations where the proposed food additive will be produced:

Henkel Corporation,

c. Locations where the proposed food additive will be used and disposed of:

Paper coating facilities are dispersed throughout the United States, so the use of the proposed food additive is similarly dispersed. Coated paper food-packaging articles which have been disposed of by consumers are either recycled, land filled or incinerated.

d. Types of environments present at or adjacent to those locations:

It is expected that the types of environments are as diverse as the locations themselves.

5. Identification of the chemical substances that are the subject of the proposed action:

   a. Chemical nomenclature:

      α-Sulfo-ω-(dodecyloxy)poly(oxyethylene), sodium salt.

   b. The CASRNs for this product are included in section A.

   c. Structural Formula:

      $R(OC_2H_4)_xOSO_3^- Na^+$

      Where R = $C_{12}H_{25}$, primarily; some $C_{14}H_{29}$ is present in the typical commercial product as are small quantities of $C_{10}H_{21}$ and $C_{16}H_{33}$ and where x = 2-30.

   d. Molecular Weight:

      Theoretical average molecular weight calculated from the above structural formula:

      When x = 2, molecular weight = 376
      When x = 30, molecular weight = 1608

6. Introduction of substances into the environment:

   a. For the site of production:

   The proposed food additive is produced by the sulfation of using followed by neutralization with to form the sodium salt. Prior to neutralization, the major by-product is which is removed from the system, diluted with water and sold. After neutralization, the by-products are water and small amounts of and which are retained as impurities. can decompose in water to form and . Any unreacted would be decomposed by the water of solution associated with the , and the resulting transient acids would be neutralized to and .

Regulatory Overview

<u>Substances Expected to be Emitted and Applicable Laws</u>

and are designated as hazardous substances under the Federal Water Pollution Control Act (FWPCA), (Clean Water Act as amended (CWA)), but are excluded when they are discharged in compliance with a permit under section 402 of the Act. It

is unlikely that sulfuric acid or sodium hydroxide would be expected emissions. When the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund) was adopted, these substances were incorporated into it as hazardous substances. Their respective Reportable Quantities (RQs) are 1000, 5000, 1000 and 1000 pounds. Hydrochloric acid is also regulated by the Clean Air Act (CAA) and is subject to the Toxic Chemical Release Reporting requirements of Section 313 of the Emergency Planning and Community Right-To-Know Act of 1980 (EPCRA) (Title III of the Superfund Amendments and Reauthorization Act of 1986 a.k.a. SARA)(40 CFR 372). However, EPA has proposed to remove this requirement. Should these substances be shipped off site in their original form as wastes, they may be regulated by the Resource, Conservation and Recovery Act (RCRA) as unlisted hazardous wastes with the characteristic of corrosivity based on their pH. However, sodium hydroxide and CSA should not be shipped off site because they should all be consumed.

The proposed food additive *per se* is considered a glycol ether under the definition of the CAA. However, it is anticipated that it will eventually be deleted from this category as it has been removed from the SARA glycol ether definition, and it was determined that there should not be a CERCLA RQ for the glycol ether category. Also, the proposed food additive may contain trace amounts of and as impurities which are associated with the production of the intermediate and may be carried through to the final proposed food additive. These substances are regulated by CERCLA with the following RQ values in pounds: and If any are present, the concentration would be at very low ppm levels. As a worst case scenario, if there were , the RQ of the proposed food additive would be 1-10 million pounds which would have to be exceeded before the reporting requirement was triggered. These three impurities are contained on the list of substances subject to SARA Section 313 reporting. However, their concentration in the proposed food additive is expected to be well below the *de minimis* concentration of 0.1% which would trigger the SARA 313 reporting requirement. They are also regulated by the CAA and comparable state laws, but again, their concentrations are expected to be so low as to be of negligible concern. In addition California includes them on its "Proposition 65" lists.

Workplace Occupational Exposures

and and are corrosive liquids. Potential workplace routes of exposures would probably be via skin, eyes and respiration of vapors or mists. Oral exposure would be unusual.

The headspace of the container in which the

intermediate is shipped and/or stored provides some potential for exposure, via the inhalation route, to any possible trace amounts of and . However, it is unlikely that these trace impurities would enter the air at levels exceeding their OSHA PELs.

The facility controls most potential exposure by the use of closed systems and other engineering controls. It complies with the Occupational Safety and Health Acts (OSHA) Toxic and Hazardous Substances Hazard Communication Standard (29 CFR 1910.1200) which requires training the workers in the use of the protective equipment recommended in the suppliers MSDSs to avoid exposure and if exposure does occur, in the use of proper first aid measures to minimize damage from the exposure.

It should be noted that products like the proposed food additive have been manufactured at the facility for many years, and the workers there are familiar with the handling of the raw materials. Furthermore, the hazards associated with the final product are significantly less than those of the raw materials. The final products are comparable to typical surfactants found in many household and cosmetic products.

Controls Exercised and Compliance with Applicable Laws

The regulation of this additive for use in food-contact applications will have minimal effect upon compliance with emission requirements at the manufacturing site. This proposed food additive is only one of many sulfated products made at the facility. It will increase current total sulfate production by less than 6%. The equipment and processes needed to control emissions for currently produced products are the same as will be used for the proposed food additive. If all other production remained constant, the increase in quantity discharged as a result of this use would be no more than a few pounds. Because discharges at the facility are typically well below the permitted levels, any increase in discharge would still be well within the allowable limits.

All of the water associated with the manufacturing process is sent to an on-site holding/equalizing tank before it is discharged to a publicly owned treatment works. All effluent into this system must comply with Federal, state and local waste-water laws which give maximum levels of COD, BOD, pH, etc. BOD, COD and pH would be the parameters impacted by this proposed food additive. Since the facility must be in compliance with the applicable laws, there can be no increase in the discharges above the permitted levels. Therefore, the manufacture of this substance will not change the compliance of the facility with the applicable water regulations.

Air emissions are not expected to be affected because of the low volatility of the proposed food additive. Good general ventilation will be provided to keep fume concentrations below the Acceptable Exposure Limits for occupational exposure recommended by the supplier of the . Fume scrubbers and mist eliminators will be used as required to limit air emissions from the facility so that the facility will continue to comply with all Federal, state and local air regulations.

There are no intentional or anticipated discharges to land.

I certify that the facility complies with all applicable current emission requirements, laws and/or permits.

b. For the site of production of the food-packaging material:

Estimate of the Maximum Yearly Market Volume

An estimate of the maximum yearly market volume of the proposed food additive for use as a surfactant in the emulsion polymerization of acrylic and modified acrylic polymer and copolymer and vinyl acetate copolymers is found in section B.2 of this petition. The proposed food additive will not react or otherwise degrade during its use in emulsion polymerization. Approximately 0.5% may be lost at the site of polymer/copolymer production. Therefore, 99.5% of this market volume will remain as a component of the acrylic and modified acrylic polymer and copolymer or vinyl acetate copolymer used as a binder in the latex coating applied to the food-contact article.

It is not expected that the proposed food additive will enter the environment at the site of production of the food-packaging material considering the low volatility of the additive and its physical incorporation into the finished food-contact article.

The only foreseeable loss of the proposed food additive would be via spills. Spills at the site where the copolymers are manufactured would be of more concern than at the site where they are applied to the food packaging material because the proposed food additive is more concentrated at the former site than at the latter site. Spills are recovered using an absorbent media, packaged, labeled, transported and disposed or reclaimed in conformance with applicable laws and regulations. Land filling of liquids is to be avoided. In the event the proposed food additive is flushed to a sewer, it is biodegradable as demonstrated by the following data. See Appendix H.15 for ecologial test reports.

At the present time, the 2 mole and 30 mole proposed food additive equivalents are made in Germany. Accordingly, they have to meet German standards. The **Primary Degradation** of the 2 EO-sulfate was measured in the OECD-Screening Test using a

chemically related substance ($C_{12/14}$ fatty alcohol + 3 EO-sulfate) and resulted in 99% MBAS-removal. **Ultimate Biodegradability** evaluates the biodegradability of a substance via oxygen consumption and is performed in OECD tests for "ready biodegradability" using the Closed Bottle Test/OECD-test guideline 301D. To be "ready biodegradable", the BOD_{28}/COD ratio must be ≥ 60%. The chemically related substance had a BOD_{28}/COD ratio of 77-79%. The completeness of the ultimate degradation was evaluated in the **Metabolite Test**, a test for detecting recalcitrant biodegradation intermediates. A Disolved Organic Carbon (DOC) removal result of 102% showed the accumulation of the smallest possible metabolite, a C_1-metabolite, was excluded. The excellent ultimate biodegradability of the substance in the Closed Bottle Test was confirmed under more environmentally related conditions in the **Sewage Plant Simulation Test**, (OECD 303A) with 89±6% DOC removal. **Anaerobic Degradation** was evaluated in the stringent ECETOC-Screening test (ISO 11734). Good anaerobic biodegradability was proven by a fouling gas production of 74.1 ± 17.6%.

Evaluation of the 30 mole ethoxylate provided comparable results. **Primary Degradation** in the OECD Screening Test: 98% MBAS removal and 97% BiAS removal. **Ultimate Biodegradability** was determined using the DOC-Die Away Test (OECD 301A). To meet the OECD criteria for "ready biodegradability", ≥ 70% DOC removal is required. The 30 mole ethoxylate had a result of 96 - 97% DOC removal.

A spill into water also presents ecotoxicity concerns. The 2 mole ethoxylate exhibits an aquatic toxicity slightly better compared to surfactants in the usual detergents. All of the following data are based on 100% active substance. See Appendix H for test reports.

Fish Toxicity, acute: Test with "Golden Orfe" (*Leuciscus idus*), 48 hours, OECD 203, DIN 38412/15

LC_{50} 7.9 mg active substance/L

Daphnia Toxicity, acute, *Daphnia magna*, 48 hours, OECD 202/1 DIN 38412/11,

EC_{50} 79 mg active substance/L

Daphnia Toxicity, chronic, 21 days, Daphnia Life Cycle (*Daphnia magna*), OECD 202/2

NOEC: 0.7 mg active substance/L
FOEC: 2.2 mg active substance/L

Algae Test: Growth inhibition test with *Scenedesmus subspicatus*

EC_{50} 1.8 mg active substance/L

Bacterial Toxicity, acute: Growth inhibition test with *Pseudomonas putida*,OECD 209

EC_0 360 mg active substance/L
EC_{10} 500 mg active substance/L

Bacterial Toxicity, chronic: Growth inhibition test with *Pseudomonas putida*, 18 hrs, DIN 38412/8

EC_0 72 mg active substance/L
EC_{10} 220 mg active substance/L

Data for the 30 mole ethoxylate are as follows:

Fish Toxicity, acute: Test with "Golden Orfe" (*Leuciscus idus*), 48 hours, OECD 203, DIN 38412/15

LC_{50} 18 mg active substance/L

Daphnia Toxicity, acute, *Daphnia magna*, 48 hours, OECD 202/1 DIN 38412/11,

EC_{50} 60 mg active substance/L

c. During disposal:

Very little if any of the proposed indirect food additive is anticipated to enter the environment directly from disposal because it will remain bound into the polymeric component of the packaging. The quantity of packaging produced is unlikely to be affected by the use of the proposed additive.

If over a period of time, some of the product does gradually leach from the polymeric coating, it is expected that it will readily degrade based on the biodegradation information provided above.

7-8. Environmental fate and environmental effects:

Documentation of environmental fate and effects is not normally required for these items. As noted in item 6, essentially 100 percent of the proposed food additive will remain with the finished food-contact article, and as noted in item 4, this amounts to less than 5 percent-by-weight of the proposed indirect food additive in the finished food-packaging material.

9. Use of resources and energy:

Documentation is not normally required for this item. This

product is intended for the same type of use as other additives currently in use, such as other entries in 21 CFR 178.3400. For example, it may replace some of the currently permitted use of alkylphenol ethoxylates. The additive will not change the potential uses of the packaging.

10-11. Mitigation measures and alternatives to the proposed action:

Documentation is not normally required for these items.

12. List of preparers:

W. Monroe Atkinson	Consultant of Henkel Corporation, Ch.E., experienced in regulatory affairs matters including health, safety and environmental issues.
Geogi Rauscher	Manager, Regulatory Affairs, Henkel Corporation, M.S. Chemistry, experienced in regulatory affairs matters including health, safety and environmental issues. (deceased April 12, 1996)

13. Certification:

The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of the firm or agency responsible for the preparation of the environmental assessment.

(Date) May 9, 1996

(Signature of responsible official) Inez J. Kowalski

(Title) Senior Analyst, Regulatory Affairs

14. References: Only references, as noted in the text, to standard Federal government regulations such as 29 CFR 1910.1200 and 40 CFR 372.

15. Appendices: Ecological Evaluation summary report which was the source of the information listed in H.6.b. above.