Attachment 25

Environmental Assessment for the use of TAA EGK as a Food Contact Substance

May 30, 2003

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Requested Action

The Food Contact Substance, TAA EGK, is intended for use as a catalyst in the manufacture of Bleached Kraft Pulp. The FCS is likely to be used in paper pulp that may be used in paper towels and paper used to wrap foods. The intended paper products are most likely to have a single use. In laboratory models where an excess of catalyst was used the estimated concentration of FCS was about 1.6 ug/g of pulp. The actual use level will be less because the use level of the lab test used about 33% more catalyst than is expected to be used in commercial products and because the amount of pulp processed with the FCS used in the final paper will also be less than 100% of the paper. The use level of 1.6 ug/g can be considered a maximum use level.

Need for Action

The FCS functions as an oxidation catalyst in the manufacture of kraft paper pulp. Through the use of the catalyst the fibers that make up the finished paper have improved reactivity with commonly used cationic papermaking additives and the finished paper has improved wet strength. Disposable paper towels produced on a pilot tissue machine and containing kraft pulp made using the FCS had 20 – 25% higher wet burst strength than comparably produced towels containing untreated kraft pulp. The final commercial process has not been determined but in lab models a catalyst level of 200 ppm was evaluated. The performance data given in this FCN are based on this level. It is expected that the actual use level will be about 1/3 less, or about 140 ppm.

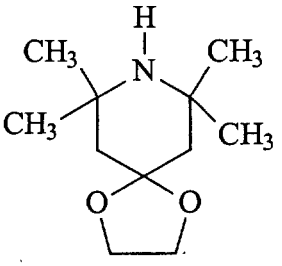
Locations of use/disposal

The use location of the FCS is at our customer's paper pulp manufacturing location in It is estimated that 95-99.5% of the FCS and it's by-products will be discharged in various waste stream during the preparation of the paper pulp. The rate of discharge will be less than 15 ppm and processed in an on-site wastewater

treatment facility. The customer's treatment facility has a primary settlement pond and an aerated wastewater treatment lagoon. The lagoon's efficiency of removal is typically 90% and has been as high as 93%. Known by-products include triacetoneamine, triacetonamine nitroxide, and triacetoneamine ethyleneglycol ketal nitroxide. It is not known how much of each species will be present as some of the by-products are not detectable in the laboratory model performed so far.

Identification of the FCS

CAS Name: 1,4-Dioxa-8-azaspiro[4,5]decane, 7,7,9,9-tetramethyl-
CAS Number: 36793-27-8
Molecular formula: $C_{11}H_{21}NO_2$
Molecular weight: 199.29 g/mol
Molecular structure:



Physical description: Colorless to light yellow liquid with an amine odor

Introduction of the FCS into the Environment

Through manufacture: The yield of the FCS is over 90% and unreacted starting materials and solvents are reused when possible. The final product purity is 100%.

Through use: As noted above, it is expected that >90% of all of the FCS that is not retained on the pulp will be removed via wastewater treatment. The 24 hr EC_{50} to Daphnia was found to be about 152 mg/L, the 48 hr EC_{50} to daphnia was shown to be about 136 mg/L and the 96 hr LC_{50} to carp was about 100 mg/L . This indicates a relatively low level of ecotoxicological concern despite poor biodegradability as shown in a Sturm Test.

It is estimated that the annual production volume of FCS used at our customer's location is about 50 MT. Given the expected removal efficiency of >90% no more than 5,000 kg will be present in the wastewater over the course of a year. The best information currently available about environmental exposure comes from laboratory modeling where the use levels of FCS are higher than will be done during commercial use and the efficiency of removal is poor. Under these conditions about 200 ppm of FCS was added to the model stream. The amount of FCS detected in the wastewater was about 95% of that added or about 195 ppm is in the wastestream. If we accept that the commercial

wastewater treatment process removes at least 90% of the catalyst then the estimated amount of catalyst and by-product not removed during treatment is about 19 ppm. The test level of FCS is about 1/3 greater than is expected to be used in commercial manufacture meaning that a conservative "real world" estimate of the concentration of the FCS in environmental waters is about 13 ppm before any environmental effects occur such as absorption, hydrolysis, etc.

Environmental Fate of Released FCS

The FCS is completely soluble in water and fat, is poorly biodegradable and does not appear to be susceptible to hydrolysis. However, it appears to rapidly sorb to soil with an adsorption coefficient, K_{oc} of >2,500. The soil absorption method used was an HPLC method using reference materials so the organic carbon content, f_{oc}, was not determined. However, if the value of f_{oc} of 0.006 is used a Soil/Water Distribution Coefficient can be calculated to be about 15. From this value it can be concluded that about 15 times more of the FCN will be found on soil than in water. This suggests that the environmental exposure will be less than 1 ppm.

Environmental Effects of Released FCS

The concentration of the FCS, as estimated above, falls below all of the toxicity thresholds noted in the reports attached to this FCN. These include the 24 hr EC_{50} to Daphnia that was found to be about 152 ppm, the 48 hr EC_{50} to daphnia that was shown to be about 136 ppm and the 96 hr LC_{50} to carp that was about 100 ppm.

Use of Resources and Energy

Using pulps made with the FCS present in the paper manufacturing process will enable more efficient use of chemicals added and should reduce the use and discharge of these chemicals. Using pulps made with the PMN substance present in the paper manufacturing process will enable some papers to be produced at a lower basis weight. This will reduce the amount of virgin pulp fiber that must be produced and will reduce the weight of paper entering the solid waste stream.

Mitigation Measures

Mitigation measures to the proposed action need not be considered because no potential adverse effects have been identified.

Alternative to the Proposed Action

Alternatives to the proposed action need not be considered because no potential adverse effects have been identified.

List of Preparers

This Environmental Assessment was prepared by:

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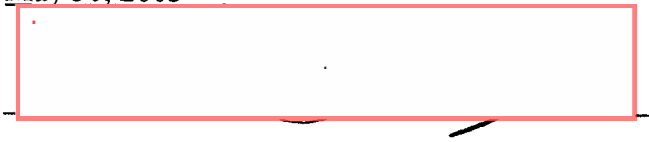
Nine years of Product Safety and Regulatory Affairs experience. This experience includes the assessment of data regarding mammalian and ecotoxicology, exposure assessments, and life cycle assessments.

Certification

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

May 30, 2003



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