Attachment 37

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

July 23, 2004

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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 to have a single use. The maximum concentration of FCS in the headbox will be 200 ppm. The concentration of FCS in the dry pulp will be in the range of 2-13.9 mg FCS/kg of dry pulp.

Need for Action

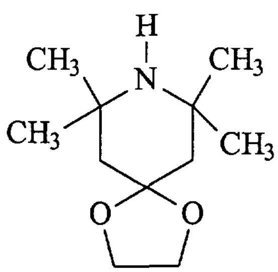
The FCS functions as an oxidation catalyst in the manufacture of kraft paper pulp. Through the use of the catalyst the fibers that make up the finished paper have improved reactivity with commonly used cationic papermaking additives and the finished paper has improved wet strength. Disposable paper towels 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 the maximum catalyst concentration at the headbox will be 200 ppm. 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 [redacted] Canada. 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%. This is based on the analysis of the analysis of influent BOD_5 compared to that of the BOD_5 of the effluent. Data available for the site where the FCS is intended to be used indicates that in the period from 1/1997 until 6/2001 the average influent BOD_5 was about 267 mg/L and the BOD_5 of the effluent was about 29 mg/L. This is an average BOD_5 reduction of 89%. There have been process improvements to the treatment process since this data was collected and it is expected that the BOD_5 reduction has improved to be comparable to other sites of the customer where the BOD_5 reduction is in the 90-93% range noted above.

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%. There are no apparent extraordinary circumstances pertaining to the manufacture of the FCS. There are no releases to the environment expected as part of the manufacturing process.

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.
During the use of the FCS other species are generated. [redacted] Other than the FCS the other species are believed to be transient species with a sufficient lifetime to be analyzed under lab conditions and also to take part in the reaction chemistry described in the FCN. It is not expected that any of the species other than the FCS will be present in wastewater once the pulp bleaching process is complete and the pulp prepared for dewatering.

Given the expected removal efficiency of >90% no more than 1,000 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 waste stream. 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. There are no apparent extraordinary circumstances pertaining to the use of the FCS.

Calculations based on laboratory modeling:

200 ppm added at the head box of which ~95% was recovered in the filtrate after treatment with pulp. This indicates that about 5% of the FCS remained on the pulp and that 195 ppm was in the waste stream to be removed in primary wastewater treatment. The actual expected use level of the FCS in commercial manufacture is about 2/3 of the lab level.

200 x 0.95 (5% absorbed on pulp) = 190 ppm x 0.1 (90% removal in waste treatment) = 19 ppm left in wastewater.

19 ppm x 2/3 (the expected commercial use level) = 12.7 ppm – the anticipated maximum amount of FCS in wastewater. Because of the predicted high affinity of the FCS for absorption onto solids the level is likely to be well below this concentration. This is described below.

Environmental Fate and Effects 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 FCS will be found on soil than in water. This suggests that the aqueous environmental exposure will be less than 1 ppm when introduced into the environment via surface waters. The concentration will be further reduced once it enters the surface waters.

The primary mechanism of removal of the FCS in wastewater treatment is anticipated to be through adsorption onto sludge. In the facility where the FCS is intended to be used the primary settling sludge is disposed of into a sanitary landfill and this is the normal practice at all of the customer's mills. The landfill is lined to restrict the movement of the contents of the landfill. In addition, there is a system to collect leachate which is then transferred back to the wastewater treatment process. There is also a secondary settling area and the sludge there has never been removed from the pond. This further limits exposure of the FCS to the environment.

It is worth noting that since the FCS has not yet been used commercially the actual exposure levels have not been determined. The estimate used are intended to be more challenging that what is likely to be realized in commercial use.

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. This indicates a relatively low level of ecotoxicological concern despite poor biodegradability as shown in a Sturm Test.

Data addressing the acute and chronic effects of the FCS to terrestrial species such as earthworm and larger plants have not been developed. A review of the literature did not readily reveal the existence of data on analog substances. However, because the wastewater sludge will be contained in a lined landfill the terrestrial environmental exposure will be limited.

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 Food Contact 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.

An example of where there may be an environmental benefit through the use of the FCS is in the use of additives intended to improve wet-strength. It has been found that the use of the FCS in addition to wet-strength additives increases the wet-strength over that of when the FCS is not present. This will allow paper makers to prepare higher quality paper without an increased level of other additives or to reduce the levels of the other additives and/or the level. Examples of commonly used additives are resins based on epichlorohydrin. Since the manufacture of this class of additive is based on epichlorohydrin, a chemical with a number of substantial mammalian and ecological hazards, a reduction in the use of these resins will also mean a reduction in the use of epichlorohydrin.

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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Ten 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.

July 23, 2004

Shaun F. Clancy, Ph.D. Director of Product Regulatory Services