Supplement to the Environmental Assessment for Food Additive Petition 9A4155

This document incorporates by reference the petitioner's environmental assessment dated June 30, 1989.

The estimated concentration of the subject additives and their metabolites in effluents from municipal sewage treatment facilities (POTWs) is very low. The petitioner estimated the concentration entering POTWs to be 0.28 ppm, but assumed no human metabolism of the ingested additives. Other information presented by the petitioner shows that the subject additives are hydrolyzed in the human digestive system to fatty acids, glycerides, and polyoxyethylene residues, and that the fatty acids and glycerides are metabolized while the polyoxyethylene residues are expected to be excreted unchanged. Since polyoxyethylene represents the major part of the original molecule of the subject additives, we estimate that the concentrations of polyoxyethylene residues entering POTWs will be about 0.3 ppm or less.

The polyoxyethylene residues are expected to be similar to the corresponding polyethylene glycols (PEGs) that are used in the production of the subject additives. Published literature includes reports that PEGs can be degraded by bacteria. The petitioner refers to a study by Watson and Jones. (copy attached), who investigated the biodegradation of PEGs with molecular weights up to about 4,000 by bacteria isolated from sewage effluents. These bacteria could grow on and degrade PEGs with molecular weights up to about 1,500 but not on PEGs of a molecular weight of about 4,000. Kawai *et al.* (copy attached) found that a synergistic, mixed culture of two strains of bacteria *(Flavobacterium* and *Pseudomonas)* could utilize PEGs from 300 to 20,000 for growth.

We expect that the polyoxyethylene residues would be degraded in a manner similar to their PEG counterparts. Polyoxyethylene residues with molecular weights up to about 1,500 are likely to be degraded in sewage. Larger polyoxyethylene residues may not be degraded in sewage, but are likely to be degraded (at a slower rate) by bacteria in the environment.

We do not have information about the toxicity of polyoxyethylene residues to organisms that might be exposed to waters receiving effluents from POTWs. However, data on similar chemicals were submitted in support of FAP 0B4179. A screening test of brown shrimp exposed to polyethylene glycol (MW 1,500-4,000)/poly(12-hydroxystearic acid) copolymers showed no mortalities at concentrations apparently exceeding the water solubility of these chemicals. This apparent lack of toxicity to an aquatic organism presented in FAP 0B4179 corroborates information about the lack of toxicity of the subject additives to rats and mice presented in the current petition. These toxicity data are consistent with general information about nonionic materials of high molecular weight. The polyoxyethylene residues that are not degraded by sewage bacteria will have high molecular weights and are not expected to be taken up by aquatic organisms. Therefore, it appears unlikely that these residues would have

any systemic toxicity. Moreover, the polyoxyethylene residues are neutral (uncharged) molecules and, therefore, are unlikely to have any surface reactivity, *i.e.* they should not react with biological membranes. Therefore, the additives are not expected to be toxic substances in the environment.

References:

Kawai, F., T. Kimura, M. Fukaya, Y. Tani, K. Ogata, T. Ueno, and H. Fukami (1978) "Bacterial Oxidation of Polyethylene Glycol," *Applied and Environmental Microbiology, 35*, pp. 679-684.

Watson, G. K. and N. Jones (1977) "The Biodegradation of Polyethylene Glycols by Sewage Bacteria," *Water Research, 11*, pp. 95-100.

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