



September 10, 1996

Memorandum

Date Additives Evaluation Branch #1, HFS-226 Mats # 876
Special Project Team
From

Perfluoroalkyl substituted phosphate ester acids formed by the reaction of 2,2-bis(gamma,omega-perfluoroC4-20alkylthio)methyl]-1,3-propanediol, polyphosphoric acid and ammonium hydroxide or (b) (4) as an oil water repellent for paper and paperboard. 21 CFR 176.170

To Memorandum for File
Indirect Additives Branch HFS-216

FOOD ADDITIVE PETITION No.6B4513 Ciba-Geigy Corporation
Greensboro, NC 27419

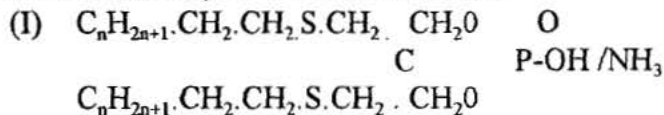


Names of additive:

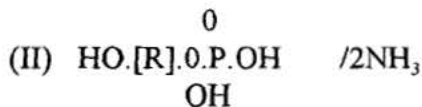
Perfluoroalkyl substituted phosphate ester acids, ammonium salts formed by the reaction of 2,2-bis[(gamma,omega-perfluoroC4-20alkylthio)methyl]-1,3-propanediol, polyphosphoric acid and ammonium hydroxide or trade name (b) (4)

It is composed of at least 4 Perfluoroalkyl substituted phosphate ester acids, ammonium salts formed by the reaction of 2,2-bis[(gamma,omega-perfluoroC4-20 alkyl thio)methyl]-1,3-propane diol, polyphosphoric acid and ammonium hydroxide and these are:

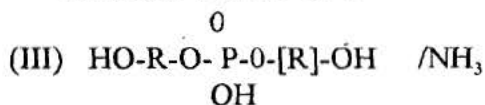
1: 5,5-bis [(gamma,omega-perfluoroC4-20 alkylthio)methyl]- 2-hydroxy-2-oxo-1,3,2-dioxaphosphorane, ammonium salt; CAS No. 148240-85-1



2: 2,2-bis[(gamma,omega-perfluoroC4-20alkylthio)methyl]-3-hydroxy propyl phosphate, di ammonium salt; CAS No. 148240-87-3



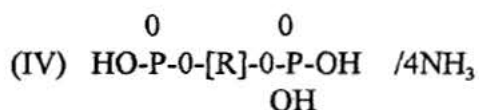
3: Di-[2,2-bis[(gamma,omega-perfluoroC4-20alkylthio)methyl]]-3-hydroxy propyl phosphate, ammonium salt CAS No. 148240-89-5



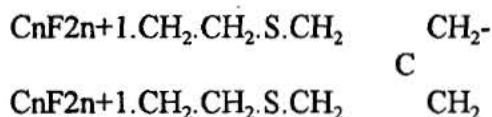
4: 2,2-bis[(gamma,omega-perfluoroC 4-20 alkylthio)methyl]-1,3-di(dihydrogenphosphate)-propane, tetra-ammonium salt

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where -[R]- is:



Rf distribution is suggested as follows:

C_6F_{13}	3-38%	mol. wt. 877
C_8F_{17}	30-53%	mol. wt. 1077
$\text{C}_{10}\text{F}_{21}$	15-35%	mol. wt. 1277
$\text{C}_{12}\text{F}_{25}$	7-17%	

Constituent contaminants:

Perfluoroalkyl bisulfide	4.5%
2,2-bis (γ,ω -perfluoro C_{4-20} alkylthio)methyl]-1,3-propanediol	4%
Tri- R_f -diolphosphate	1%
MPK	0.05%
Glyme CAS # 110-71-4	0.05%

Use level:

At 0.44% by weight of finished paper.

Related petition:

3B4353; 3B4360

Dietary Exposure:

The Chemistry Review Branch (CRB), HFS-247 memo of August 30, 1996 suggested the dietary exposure of the additive as:

dietary concentration = 0.04 ppm; with an EDI of 0.12 mg/p/d.

On a cumulative basis it will be 0.13 mg/p/d.

Toxicity data:

None submitted refers to data submitted in FAP# 3B4353.

AEB #1 memos (Dr. Isabel Chen) of September 7, November 5, 1993, March 15, 1994 (2 memos), and November 14, 1994 contain a review of toxicity data.

It consisted of acute oral LD_{50} for (b) (4) mutagenicity assays (AEB memo of January 27, 1994) on (b) (4) and dermal and eye irritation data on (b) (4)

(b) (4) The proposed used was formalized as SPT, via AEB#1 memo of March 16, 1995.

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A literature search [RETEC] only showed data for Glyme CAS No. 110-71-4.

A published article, by Bryan D. Hardin et al, entitled "Relative potency of four ethylene glycol ethers for induction of paw malformations in the CD-1 mouse", and appearing in *Teratology* 35: 321-328, 1987 indicated Glyme to be a potent teratogen in mouse. Glyme or EGME, or ethylene glycol monomethyl ether when administered at 304 mg/kg on gestation day 11 produced defects among 87% of mice to their forepaws and hindpaws. In other word's Glyme is a **teratogen**.

Evaluation and conclusion:

The additive is a complex mixture of some 4 chemicals.

The purity chemical specifications show some 10% of constituent contaminant impurities, and among them Glyme is present at 0.05% level, a known **teratogen**.

Earlier approval for the additive was via FAP# 3B4353 at a dietary exposure of 0.008 ppm.. The suggested cumulative dietary exposure for the additive continues to remain virtually nil.

While CRB memo has not suggested a dietary exposure for Glyme. When calculated presumably, based on 100% calculation and present at 0.05% of the additive, it would be only a few **parts per trillion** level, much **lower than 0.5 ppb** value for Threshold of Regulation.

In view of such low levels of exposure the proposed use of the additive could be allowed on the basis of "virtually nil exposure". It is suitable for regulation.


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Cc: HFS-216, HFS-226 (Misra, Johnson), HFS-227 (Edwards), HFS-247
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