



Memorandum

Date November 5, 1993

From ADDITIVES EVALUATION BRANCH #1 (HFS-226)

Subject The Safe Use of Perfluoroalkyl Substituted Phosphate Ester
Acids, Ammonium Salts Formed by the Reaction of 2,2-bis[(r,W-
perfluoro C₄₋₂₀ alkylthio) methyl]-1,3-propane diol,
Polyphosphoric Acid and Ammonium Hydroxide as an Oil and Water
Repellent for Paper and Paperboard
To Re: Chemistry Review Branch (HFS-247) memo dated 9/28/93

INDIRECT ADDITIVES BRANCH (HFS-216)
ATTENTION: R. White

THROUGH: KIRK BIDDLE, PH.D. [REDACTED]
CHIEF, ADDITIVES EVALUATION BRANCH #1 (HFS-226)

FAP 3B4353

CIBA-GEIGY CORPORATION
SEVEN SKYLINE DRIVE
HAWTHORNE, NEW YORK 10532

Ciba-Geigy Corporation has submitted this petition proposing that 21 CFR 176.170 (a)(5) of the food additive regulations be amended with respect to the safe use of perfluoroalkyl substituted phosphate ester acids, ammonium salts formed by the reaction of 2,2-bis[(r,W-perfluoro C₄₋₂₀ alkylthio) methyl]-1,3-propane diol, polyphosphoric acid and ammonium hydroxide, as an oil and water repellent for paper and paperboard under the conditions of use A through H as defined in Table 2 of 176.170 (c). The paper and paperboard will be in contact with aqueous and fatty foods, and the trade name of the subject additive is Lodyne (b)(4) [REDACTED]

Dietary Exposure:

The dietary exposure to the subject additive was calculated by the Chemistry Review Branch (CRB HFS-247, Carberry memo 9/28/93). According to the CRB, the migration data of the subject additive submitted by the petitioner only can support the use of (b)(4) [REDACTED] under condition of use H (Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use) as defined on Table 2 of 176.170 (c). Under this condition, the dietary concentration (DC) of the subject additive is 0.008 ppm and the estimated daily intake (EDI) is 24 ug/p/d which is in the "virtually nil" exposure range (<0.05 ppm or <0.15 mg/person/day). Additional migration studies will be needed, if the petitioner wishes to seek approval for the conditions of use A through H, as

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requested. Then the EDI will be reassessed accordingly (CRB Carberry memo 9/28/93).

The EDI's of the impurities which include perfluoroalkyl disulfide, ammonium salt of phosphoric acid, ammonium salt of 2,2-bis[(r,W-perfluoro C₄₋₂₀ alkylthio) methyl]-1,3-propane diol and tri-[2,2-bis[(r,W-perfluoro C₄₋₂₀ alkylthio) methyl]-3-hydroxy propyl phosphate (by-product) are not calculated by the CRB at this time due to the lack of migration data submitted (Carberry memo 9/28/93).

Safety Data:

A preliminary safety review of the subject additive has been reported in a previous memo (Chen, 9/7/93). The relevant safety data include:

1. Single dose oral toxicity of (b) (4) in rats (Project #91-529 A/CG Tox #91-006).

The LD₅₀ of (b) (4) in rats is greater than 5.0 g/kg BW.


2. The AMES Test of (b) (4) and Chromosome Aberration Assay in Chinese Hamster V79 cells in vitro with FAT 75'798/A (19% aqueous (b) (4) will be reviewed by Dr. E. Matthews.

Summary:

1. Under the current submission, the dietary exposure to the subject additive is in the "virtually nil" exposure range. The LD₅₀ of (b) (4) in rats is greater than 5.0 g/kg BW, and the genotoxicity studies have been submitted for review by Dr. E. Matthews.

2. We will comment on any safety issue concerning the impurities when the dietary exposures are calculated by the CRB.

DHEE will continue our evaluation upon receipt of CRB's review and the report of genotoxicity studies reviewed by Dr. E. Matthews.


Isabel S. Chen, Ph.D.

INIT:

cc: HFS-200, HFS-225, HFS-226 (Biddle), HFS-227 (Edwards)
HFS-216, HFS-226:ISChen:254-3919:Doc:I2B4353.1