DEPARTMENT OF HEALTH & HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Public Health Service

Memorandum

Date • August 30, 1996

From Chemist, Special Project Team
Chemistry Review Branch, HFS-247

AD

Subject FAP 6B4513 (MATS# 876, M2.0 & 2.1): Perfluoroalkyl substituted phosphate ester acid salts as oil and water repellant for paper and paperboard. Ciba-Geigy Corporation submissions dated 5-21-96 and 6-17-96.

To Memorandum to the file

Ciba-Geigy Corporation (Ciba) has submitted this petition to amend 21 CFR 176.170 (Components of paper and paperboard in contact with aqueous and fatty foods) to expand the regulated uses of the ammonium salts of perfluoroalkyl substituted phosphate esters formed from the reaction of 2,2-bis[(γ,ω-perfluoroC_{4-20}alkylthio)methyl]-1,3-propanediol, polyphosphoric acid and ammonium hydroxide as an oil repellant for use in contact with fatty foods under Conditions of Use C through G as described in Table 2 of §176.170(c). Ciba refers to the additive as "perfluoroalkyl substituted phosphate ester acid salts" or (b) (4) [redacted] The additive is currently regulated for use in contact with non-alcoholic foods under Condition of Use H as a result of FAP 3B4353.

Ciba had requested Conditions of Use A through H in FAP 3B4353, but in our review (S. Carberry to R. White, 8-28-93 memorandum) we noted that the migration data supported only Condition of Use H. The current petition consists of new migration data to include Conditions of Use C through G.

Identity and Manufacture

The identity and manufacturing data are the same as those reviewed for FAP 3B4353. We have reviewed the information and found it to be complete (FAP 3B4353 memoranda dated 9-28-93, 12-1-93, 10-28-94, and 2-13-95) and our reviews are incorporated by reference (copies attached).

Intended Technical Effect and Use Level

Ciba proposes to use the additive at a level not to exceed 0.44% perfluoroalkyl actives by weight of the finished paper in contact with fatty foods under Conditions of Use C through G. Data establishing the intended technical effect were reviewed for FAP 3B4353 (9-28-93 memorandum).

Migration Studies

Migration studies were performed (Study FDA94004, dated 8-19-94) on paper samples formulated with the additive to determine the extractability of (b) (4) [redacted] into food-

simulating solvents.

(b) (4) [redacted] was applied as an external size to #41 waterleaf paper with 2.4% oxidized starch to deposit 0.3% fluorine by weight of the paper. Paper with only 2.4% oxidized starch was used as blanks.

The extraction study was carried out with heptane as the food simulant. Ciba has previously explained that food oil or Myglyol 812 caused interferences in the fluorine analyses. We have previously accepted the use of heptane as a simulant in this case, recognizing that it frequently exaggerates migration relative to other fatty-food simulants (9-28-93 memorandum). The extractions were carried out for 2 hours at 150°F followed by 120°F for 10 days, with analyses performed after 2, 24, 48, and 240 hours. The analytical procedure, flameless molecular absorption spectrometry, is the same method reviewed previously.

For each sample, a 1" × 2" paper was placed in a 2 oz. jar and exactly 50 mL of heptane was added, submersing the paper within. With both sides in contact with the heptane, the ratio of solvent to surface area is 12.5 mL/in^2 (8.5 g/in^2). The jars were placed into a preheated 150°F oven for 2 hours and then moved into a preheated 120°F oven for 10 days. At the end of 2, 24, 48, and 240 hours, jars were removed from the oven and the paper removed from the extraction solvent. LODYNE P-208E content was measured directly in the extracts based on the fluorine content.

Complete analytical methodology, including details of the instrument parameters, calibration, and validation, is provided on pp. 000013 - 000014. Calibration (Table 1, p. 000015 and Graph 1, p. 000018) shows good linearity. Validation was performed by spiking the 240 hour blank extracts, in triplicate, with approximately ½×, 1×, 1½×, and 2× the detected levels. Recoveries ranged from 85 - 110%. The analyses are adequately validated. The analytical results are summarized in Table 3, p. 000017. We find no significant difference between the 2 hour and 240 hour analyses. The 240 hour analyses show an average level of 0.52 ppm (b) (4) [redacted] in the extracts, which corresponds to a level of 0.52 ppm in food.

Exposure

The petitioner has calculated an estimated daily intake (EDI) of 0.12 mg/p/d, based on a food-type distribution factor (f_T) of 0.4 and a consumption factor (CF) of 0.2 for fatty food in contact with polymer-coated paper as described in our "Recommendations for Chemistry Data for Indirect Food Additive Petitions," June, 1995. We concur with their calculations. The weighted average concentration in food would be:

$$\langle M \rangle = f_{fatty}(M_{heptane}) = 0.4(0.5\ ppm) = 0.2\ ppm$$

The resulting dietary concentration would therefore be:

$$Dietary\ Concentration = CF \times \langle M \rangle = 0.2 \times 0.2\ ppm = 0.04\ ppm$$

Assuming a daily diet of 3000 grams of food per person per day (g/p/d), the EDI would be:

$$EDI = 3000\ g\ food/p/d \times (0.04 \times 10^{-6}\ \frac{g\ Lodyne}{g\ food} = 0.12 \times 10^{-3}\ g\ Lodyne/p/d$$

or 0.12 mg/p/d.

The cumulative exposure to the additive may be obtained by adding the exposure from aqueous and acidic foods calculated for FAP 3B5343 (11 μg/p/d, data contained in 9-28-93 memorandum) to the current value, giving 0.13 mg/p/d.

Regulation

Ciba has proposed language for a regulation (p. 000021) that describes the additive and the proposed use separate from the currently regulated use. We propose that the regulations be amended by adding to the current regulation:

> . . . and in contact only with food of Types III, IVA, V, VIIA, and IX described in Table 1 of paragraph (c) of this section under conditions of use C through G as described in Table 2 of paragraph (c) of this section.

Conclusion

We have no questions.

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