UNITED STATES GOVERNMENT

Memorandum

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
CONSUMER PROTECTION AND ENVIRONMENTAL HEALTH SERVICE
Food and Drug Administration

TO : Mr. W. F. Randolph, PCB (SC-13)

DATE: August 4, 1969

(AF 3-562)

FROM : E. I. Kovach, FAPEB, DFCT (SC-470) E. I. Kovach

SUBJECT: FAP #0B2434, Minnesota Mining & Manufacturing Co. Amendment of Sec. 121.2526(a)(5) to provide for additional uses of ammonium bis(N-ethyl-2-perfluoroalkylsulfonamido ethyl) phosphates (L-1953)

The subject chemical's use is presently regulated under 121.2526(a) for use conditions D,E,F, and G as petitioned in FAP #8B2253. The present request is for the extension of the same use for conditions B,C and H in 121.2526(a), with identical specifications and limitations.

Data on the identity, specifications, manufacturing, intended use, efficacy, methodology used in extraction studies, etc., are available in FAP #8B2253, and have previously been evaluated.

The petitioner reports additional extraction studies in the present submission, corresponding to use conditions B,C, and H, and representative of the three proposed types of use. Sheets containing 0.4% L-1953 for surface sizing and 0.75 L-1953 for beater addition, and 1.75% for mineral coating addition in the dry coating were extracted in test cells. Three extraction tests were performed: 1) Water extraction by adding boiling water to the extraction cell and cooling for 30 minutes to 100° F., and analyzing samples after 30, 60 and 90 minutes, 2) Water extraction after 30, 150 and 240 minutes at 212° F., and 3) heptane extraction after 2, 5 and 9 hours at 150° F. The L-1953 samples used were labeled with radiocarbon and the extracts were analyzed by the same radiometric method used in extraction studies reported in FAP #8B2253.

The maximum migration values were found to be 2.2 ppm for water and 4.4/5 = 0.9 ppm for heptane, using the highest extraction values for each solvent. Since the petitioner's calculations are based on 2 ml solvent per square inch of surface, we converted the reported ppm values by dividing by 5 to ppm values in reference to 10 gm food/inch^2.

The corresponding average daily dietary contribution from uses under conditions B, C and H, are calculated in the usual fashion as

$$[(2.2 \text{ ppm} \times 0.9) + (0.9 \text{ ppm} \times 0.1)] \times 0.05 = 0.1 \text{ ppm}$$

Under use conditions D,E,F, and G, we estimated 1 ppm migration to aqueous, 0.3 ppm to fatty foods, and 0.05 ppm to the daily diet (FAP #8B2253, memo by A. Holtz, 2/8/68).

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In both petitions, the petitioner presented detailed calculations for the migration of L-1953 to the daily diet. While in our above calculations we have used our usual calculation procedures and did not rely on the petitioner's figures, in our opinion the figures below illustrate the additional relative contribution of uses B,C and H to the migration level from the presently regulated uses. For uses D,E, F and G, the petitioner estimated a maximum dietary level of 0.08C ppm, while for all use conditions (B,C,D,E,F,G, and H), the corresponding figure is given as 0.098 ppm. Relying on the ratio of these values, the presently petitioned additional uses would cause an increase of ca. 25% over the level from already regulated uses. Using these approximations, the total dietary level of L-1953 may be estimated as:

$$[0.05 \text{ ppm (D,E,F,G)} \times 80] + [0.1/(\text{B,C,H}) \text{ ppm} \times 20] = 0.06 \text{ ppm.}$$

The petitioner does not show, whether a change in use levels (not directly specified in the regulation) is contemplated or not. Levels used in the present extraction studies correspond to those used in the previous extraction studies and use levels shown in #2253.

Conclusions

Pharmacological considerations permitting, the petition is ready for regulation.

cc: SC-1
SC-12
SC-401
SC-470
SC-970

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D/Init: VEMunsey 8/4/69
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