

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

AD



Date: October 6, 1970

Reply to
Attn of: DFCT/FAPEB, BF-117

Subject: FAP 1B2571 (Amended by 8/31/70 letter and data). E.I. Du Pont. Amend 121.2526 to provide for use of diethanolamine salts of mono and bis (1H, 1H, 2H, 2H-perfluoroalkyl) phosphates ("(b) (4)") at a level not to exceed 0.17 pound (0.09 pound of fluorine) per 1,000 square feet of treated paper and paperboard when such paper and paperboard is used in contact with non-alcoholic foods under the conditions of use (B), (C), (D), (E), (F), (G), and (H) described in paragraph (c), table 2 of 121.2526.

TO: A. Rothschild, DRPC, BF-322)

A. Identity

(b) (4)

B. Usage

In response to FAP 5B1747, regulation 121.2526 was amended to permit use of (b) (4) in paper and paperboard under conditions of use E, F, and G at levels of 0.17 lbs/100 sq. ft. of treated paper. The petitioner is now requesting that the conditions of use be extended to include conditions B, C, and H and to maintain the maximum application rate at 0.17 lbs/1000 sq. ft. of treated paper.

C. Intended Effect

The effectiveness of (b) (4) as an oil repellent can be checked by a standardized oil penetration test described on pages 7 and 8. Satisfactory production will provide paper having an oil holdout time greater than 30 minutes under the conditions of the test. Effectiveness of the oil repellent treatment on molded paperboard articles is illustrated by two examples described on pages 17 and 18.

C. Migration

Paperboard samples treated with (b) (4) (0.11 to 0.17 lbs/1000 ft²) were extracted with water and heptane under time-temperature conditions (B), (C), (D), (E), (F), (G), and (H) described in paragraph (c), table 2 - 121.2526 (limited end-tests). Extractives were analyzed for total fluorine using a fluoride ion activity method (Orchem Method 2-10-6) instead of the spectrophotometric procedure (Orchem Method 6-11-34) employed in FAP 5B1747. No validation data were provided.

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Rec'd DRPC

Oct 9, 1970

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The heptane extractability data (exhibit A in the 7/1/70 and 8/31/70 submissions) do not cover the requested high temperature applications (Du Pont representatives were informed of this deficiency in our 9/24/70 conference). The water extractability data (Exhibit B, 7/1/70 submission), however, permit us to estimate maximum migration levels for all the requested use conditions.

The following table summarizes the water extractability data and shows the basis of our estimates for maximum migration levels (ppm) under conditions of use (B), (C), and (D).

For 0.17 pounds/1000 ft²

- B - 0.41 (212° F exposure) + .10 (RT-120° F package life) = 0.51.
- C - 0.06 (> 150° F exposure) + .10 (RT-120° F package life) = 0.16.
- D - 0.13 (2 hrs 150° F) + .10 (RT-120° F package life) = 0.23.

For 0.14 pounds/1000 ft²

- B - 0.27 (212° F exposure) + .10 (RT-120° F package life) = 0.37.
- C - Same as 0.17 pound application.
- D - Same as 0.17 pound application.

The migration levels for the molded paperboard application (characterized under "H" use condition, Exhibit A - 8/31/70 data) are difficult to evaluate because of the inconsistency of the results - e.g. lesser times at same temperature giving higher migrations than longer extraction times. However, the general levels of extraction for this type application are definitely lower - both water and fatty - than the above extractions which involve surface coating type applications. This is readily explainable since in the molded articles the (b) (4) is distributed throughout the paper thickness and is bound to the paper fibers by additional paper adjuvants. Therefore, if the higher extraction levels of the surface applications are toxicologically acceptable then the molded paperboard uses should also be safe at the same levels of treatment.

Conclusions

The maximum migration to aqueous foods is estimated to be of the order of 0.51 ppm (condition B and top level of application 0.17 lbs. (b) (4) 1000 ft² treated paper). Petitioner has agreed to conduct additional extractions using an edible oil (e.g. U.S.P. Cottonseed Oil) instead of heptane.

The petitioner should be informed that the following extractions using an edible oil would cover conditions of use (B), (C), and (D):

- I. One hour at 212° F.
- II. One hour at 160° F.
- III. Twenty-four hours at 120° F.

Results from I plus III = (B).
Results from II " " III = (C).
Results from III " " = (D).

As a safeguard against migration levels which might be too high for acceptance by DT/PEB, the petitioner should be reminded to run the oil extractions on samples containing (b) (4) at levels of 0.14 lbs/1000 ft² as well as at the top level of 0.17 lb/1000 ft². (petitioner indicated in the 9/24/70 conference that the top level application is not necessary for surface sizing applications).

The petitioner should also be informed that the individual extractions can be run and analyzed separately or the extractions can be run consecutively on the same samples with analyses made at the appropriate time periods. In addition, validation data and sample calculations should be provided to substantiate the reliability of the ion activity electrode method (Orchem Method 2-10-6) and the standard addition method (Orchem Method 2-10-10) for the determination of fluoride ion.

DT/PEB may evaluate the aqueous migration data or wait until the results from the oil extractions are reported.

cc: BF-100
BF-112
BF-301
BF-117
BF-148

GHigginbotham:mcs 10/6/70
D/Init: MProchazka 10/5/70
AHoltz 10/5/70

G. Higginbotham

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