DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

AD

Date: September 4, 2002

From: Division of Food Contact Substance Notification Review, Chemistry Review Group 1

Subject: FCN 255- Ciba Specialty Chemicals Corporation.
A perfluoroalkyl substituted carboxylic acid ((b) (4)) as an oil repellent sizing agent (internal and external) for paper and paperboard. Submissions dated 5/6/02 and 6/28/02.

To: Division of Food Contact Substance Notification Review, Regulatory Group 2
Attention: H. Macon

FCN 255 was submitted by Ciba Specialty Chemicals Corporation (Ciba) for the use of their perfluoroalkyl substituted carboxylic acid, marketed under the tradename (b) (4) as a component of paper and paperboard[1].

(b) (4)

The chemistry information (b (b) (4) was reviewed by an external contractor, ICF Consulting, in a final notification data evaluation report (NDER) dated 8/27/02 (receipt date 8/28/02). The NDER is included as an Attachment 2 to this memorandum. This memorandum summarizes the pertinent information in the NDER and addresses any outstanding chemistry issues.

Identity and Proposed Use

The food-contact substance (FCS) is identified as follows:

CAS name: 3-cyclohexene-1-carboxylic acid, 6-[(di-2-propenylamino)carbonyl]-, sodium salt, (1R,6R), reaction products with pentafluoroiodoethane-tetrafluoroethylene telomer, ammonium salts

CAS RN: 392286-82-7

Tradename: (b) (4) formulated product)

As described in the NDER (pp. 3-4), the manufacturing process (b) (4)

1 Ciba submitted FCN 59 (effective) for a similar perfluoroalkyl substituted carboxylic acid. The chemistry review is contained in a memorandum dated 8/1/00 (R. Costantino to E. Machuga).

2 Ac(b) (4)

(b) (4) [redacted]

The FCS is intended for use as an oil repellent sizing agent for food-contact paper and paperboard. Paper manufactured with the FCS may be used in contact with all food types under conditions of use B through H as described in Tables 1 and 2, respectively, of 21 CFR 176.170(c). The FCS may be applied by either internal (wet-end) or external (surface) addition to paper and paperboard. The FCS will be used in an amount not to exceed 0.55 wt.-% of actives by weight (0.33 wt.-% fluoride) of finished paper and paperboard, where the paper or paperboard has a sheet basis weight of approximately 300 lbs per 3000 square feet (equivalent to approximately 315 mg/in^2).

Migration Study and Exposure

As discussed in the 8/27/02 NDER (pp. 7-8), two (b) (4) [redacted]-treated samples were prepared to simulate both external and internal application. The first sample was prepared by surface application, in combination with commercial ethylated starch, on hardwood/softwood blended kraft pulp. The second sample was prepared by wet-end addition with bleached softwood pulp using a dual polymer retention system. The application rate was 0.34% fluoride (0.57% actives) in both samples.

Both samples were cut to size (1-sided surface area of 93.5 in^2) and extracted with 10% ethanol and corn oil as food simulants (280 mL) under conditions of use B (100°C/2 h, then 40°C for 238 h). The solvent volume-to-surface area ratio was 3 mL/in^2. The extracts (2, 24, 96 and 240 h) were analyzed for the FCS by gas chromatography using electron capture detection (gc-ecd). Calibration standards (0.1, 0.3 and 0.5 µg/mL) were prepared by serial dilution of stock solutions of the FCS in 10% ethanol or corn oil. The notifier quantified extraction levels using the peak with a retention time of 1.5 minutes, reported to be a co-eluted peak of all homologs of the FCS. The FCS was not detected in the extracts at 0.1 µg/mL, corresponding to 0.5 µg/in^2 or 50 µg/kg food.

As discussed in the 8/27/02 NDER (p. 8), the dietary concentration (DC) for the proposed use of the FCS was determined to be <2.5 µg/kg, corresponding to an estimated daily intake (EDI) of <7.5 µg/p/d. This exposure estimate was determined using the non-detect levels in the solvents (<50 µg/kg) and a consumption factor (CF) of 0.05 representative of specialty papers.

Comments

The only remaining issues are to determine the regulatory status and derive exposure estimates, as needed, for certain impurities (i.e., residual starting materials and reaction

byproducts) and other components added to produce (b) (4)

Referring to Attachment 2 of the NDER, (b) (4) contains a total of (b) components, including water (see Table 1, below). Components (b) include the FCS (component ( ) and various impurities, (b) (4)

Table 1- Composition of LODYNE 2010

Component	Identity	Class	Level (wt.-%)
(b) (4)			
5	Similar in structure to FCS, but with only 1 Rf group	Byproduct	(b) (4)
6	Similar in structure to FCS, but with hydroxylation of double bond	Byproduct	
7	FCS	FCS	

(b) (4)

(b) (4)

(b) (4)

[redacted]

FCS and Related Substances

As noted above, the DC for the FCS was determined to be <2.5 µg/kg (EDI <7.5 µg/p/d). We believe that this DC would be inclusive of the FCS (component 7) as well as component 6. This conclusion is based on observation that component 6 is structurally similar to the FCS and, thus, would be expected to migrate to food at the same rate as the *FCS which is actually a series of homologs* (b) (4) [redacted] Moreover, data contained in the FCN indicate that component 6 co-elutes with the homologs of the FCS (component 7).

Exposure estimates for components 2, 3, 4 and 5, which are also structurally similar to the FCS, may be calculated by assuming that they migrate at the same rate. Thus, the DC for component 2 may be calculated by multiplying the residual level in the FCS (0.8/15.7 or 5 wt.-%) by the DC for the FCS (<2.5 µg/kg) to give a DC of <0.1 µg/kg (EDI <0.3 µg/p/d). Proceeding in a similar manner for the other components gives the following DCs and EDIs: component 3, <0.015 µg/kg; <0.045 µg/p/d; component 4, <0.1 µg/kg, <0.3 µg/p/d; and component 5, <0.18 µg/kg, <0.5 µg/p/d.

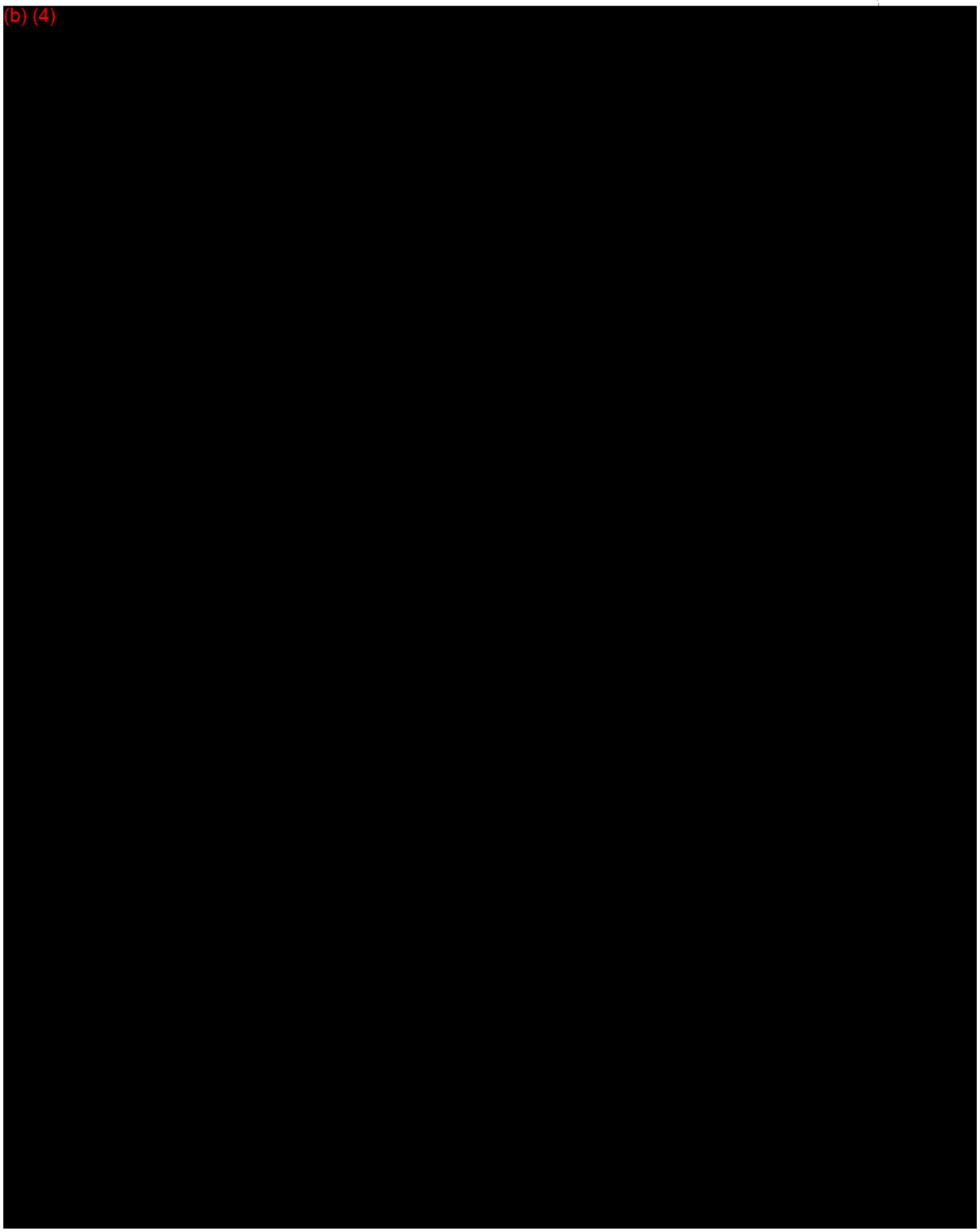
(b) (4)

[redacted]

(b) (4)

[redacted]

(b) (4)



use and, thereby, not be expected to be present in the diet in other than insignificant amounts.

Additional Components

(b) (4)

[redacted]

Conclusion

The language used in the acknowledgement letter dated 7/11/02 is adequate. We have no questions on this notification.

[redacted]

Allan B. Bailey

HFS-205 (Kuznesof), 245 (Begley), Chemistry Reading File
HFS-275:ABBailey:418-3007:abb:08/29/02 (FCN0255_C_memo.doc)
Final:abb

Attachments