21 CFR Part 178

[Docket No. 80F-0194]

Direct Food Additives; Di-n-Alkyl (C_{8}-C_{18}) Dimethylammonium Chloride, n-Alkyl (C_{12}-C_{16}) Benzyldimethylammonium Chloride and Ethyl Alcohol

AGENCY: Food and Drug Administration

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) amends the food additive regulations to provide for the safe use of di-*n*-alkyl(C_{8}-C_{18})dimethylammonium chloride, *n*-alkyl(C_{12}-C_{16})benzyldimethylammonium chloride and ethyl alcohol as components of sanitizing solutions. The agency is taking this action in response to a petition filed by Lonza, Inc.

DATES: Effective June 12, 1981; objections by July 13, 1981.

ADDRESS: Written objections to the Dockets Management Branch (formerly the Hearing Clerk's office) (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James B. Lamb, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St., SW., Washington, D.C. 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of June 27, 1980 (45 FR 43473), FDA announced that a food additive petition (FAP 0H3502) had been filed by Lonza, Inc., Fair Lawn, NJ 07410, proposing that § 178.1010 (21 CFR 178.1010) of the food additive regulations be amended to provide for the safe use of di-*n*-alkyl(C_{8}-C_{18})dimethylammonium chloride compounds, *n*-alkyl(C_{12}-C_{16})benzyldimethylammonium chloride compounds and ethyl alcohol as components of a sanitizing solution to be used on food-contact surfaces.

Having evaluated the data in the petition and other relevant material, FDA concludes that the proposed food additive use is safe and that § 178.1010 of the regulations should be amended as set forth below.

The agency has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's findings of no significant impact and the evidence supporting that document may be seen in the Dockets Management Branch (formerly the Hearing Clerk's office) (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10 (formerly 21 CFR 5.1; see 46 FR 20652, May 11, 1981)), Part 178 is amended in § 178.1010 by adding new paragraphs (b)(22) and (c)(17) to read as follows:

§ 178.1010 Sanitizing solutions.

* * * * *

(b) * * *

(22) An aqueous solution containing (1) di-*n*-alkyl(C_{8}-C_{18}) dimethylammonium chloride compounds having average molecular weights of 332-361, (2) *n*-alkyl(C_{12}-C_{16}) benzyldimethylammonium chloride compounds having average molecular weights of 351-380 and consisting principally of alkyl groups with 12 to 16 carbon atoms with or without not over 1 percent each of groups with 8 and 10 carbon atoms, and (3) ethyl alcohol. The ratio of compound (1) to compound (2) is 60 to 40.

* * * * *

(c) * * *

(17) Solutions identified in paragraph (b)(22) of this section shall provide, when ready to use, at least 150 parts per million and not more than 400 parts per million of active quaternary compound.

Any person who will be adversely affected by the foregoing regulation may at any time on or before July 13, 1981 submit to the Dockets Management Branch (formerly the Hearing Clerk's office) (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held; failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Four copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this regulation. Received objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. This regulation shall become effective June 12, 1981.

(Secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348))

Dated: June 1, 1981

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs

[FR Doc. 81-17215 Filed 6-11-81; 8:45 am]

BILLING CODE 4110-03-M

13 DEC 1982

I. D. Russell Co.
2463 Harrison Street
Kansas City, MO 64141

Attention: I. D. Russell
DRM, MRM

Subject: Russell/Quat Two
EPA Registration No. 346-41
Your Application Dated October 26, 1982

The amendment referred to above, submitted in connection with registration under FIFRA, is acceptable provided that you:

1. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:

a. We have noted your product name change and have adjusted our records accordingly:

OLD PRODUCT NAME: Russell/Quat Two
NEW PRODUCT NAME: Russell/Dual Chain

b. We have no objections to revising the use directions to obtain even ounce measurements.

c. The Statement:

"All treated equipment that will contact feed or drinking water must be rinsed with potable water before reuse," must be retained on the label.

The Federal Register reference only refers to indirect food additives used as a sanitizer on food contact surfaces and its impact on the human environment. This regulation doesn't apply to feed, poultry and livestock applications. Therefore the above statement cannot be deleted from the label.

d. Move the statements:

Precautionary statements

Hazards to Humans and Domestic Animals to appear directly above the statements:

DANGER

Keep out of reach of children. Corrosive, causes eye damage and skin irritation. Do not get in eyes....

2. Submit five (5) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 Enclosure for a further description of final printed labeling.

Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the labeling is enclosed for your records.

Sincerely yours,

James H. Lee
for

John H. Lee
Product Manager (31)
Disinfectants Branch
Registration Division (TS-767C)

Enclosure

DIS:JohnLee:DCR-03591:1546C:hjc:Raven:479-2013:11/8/82