4D02A ''Software'' specially designed or modified to support ''technology'' controlled by 4E01 or 4E02.

Requirements

Validated License Required: QSTVWYZ.
Unit: $ value.
Reason For Control: NS, MT, NP, FP (see Notes).
GTDR: Yes, except MT, FP, and for ''software'' for computers that require a validated license, see Notes.
GTDU: No.

Notes: 1. MT controls apply to ''software'' specially designed or modified to support technology for the ''development,'' ''production'' or ''use'' of equipment controlled for MT by 4A01, 4A02 and 4A03.
2. FP and NP controls apply to all destinations, except:
a. Countries listed in § 776.10(d) of this subchapter (Computer Tier 1),
b. Countries listed in § 776.10(e) of this subchapter (Computer Tier 2), for —software— for computers with a CTP equal to or less than 10,000 MTOPS; and
c. Countries listed in § 776.10(f) of this subchapter (Computer Tier 3), for computers with a CTP equal to or less than 2,000 MTOPS to all end-users/uses or a CTP equal to or less than 7,000 MTOPS to end-users/uses that are not military end-users and end-uses and are not nuclear, chemical, biological, and missile end-users and end-uses defined in part 778 of this subchapter.
3. FP controls apply to all destinations except Australia, Japan, New Zealand and members of NATO, for ''software'' specially designed or modified for the ''development'', ''production'', or ''use'' of computers for computerized fingerprint equipment.

4D94F ''Software'' specially designed for the ''development'', ''production'', or ''use'' of ''digital computers'', ''assemblies'' and related equipment therefor controlled by 4A94F.

Requirements

Validated License Required: SZ, Iran, Sudan, Syria.
Unit: $ value.
Reason For Control: FP.
GTDR: No.
GTDU: No.

4E01A Technology, according the General Technology Note, for the ''development'', ''production'' or ''use'' of equipment controlled by 4A01, 4A02, 4A03, or 4A04, or ''software'' controlled by 4D01, 4D02, or 4D03.

Requirements

Validated License Required: QSTVWYZ.
Reason for Control: NS, MT, NP, FP (see Notes).
GTDR: Yes, except MT, FP, and ''technology'' required for computers with a CTP greater than 2,000 MTOPs.
GTDU: No.

Notes: 1. MT controls apply to certain items controlled by 4A01, 4A02, 4A03, 4D01, or 4D02. See *Reason for Control* paragraphs in these entries to determine which items are subject to MT controls.
2. FP and NP controls apply to all destinations.
3. FP controls apply, for all destinations *except* Australia, Japan, New Zealand, and members of NATO, to technology for the ''development'', ''production'', or ''use'' of computers controlled by 4A03 for computerized fingerprint equipment.

4E94F Technology for the ''development'', ''production'', or ''use'' of ''digital computers'', ''assemblies'' and related equipment therefor controlled by 4A94F.

Requirements

Validated License Required: SZ, Iran, Sudan, and Syria.
Reason for Control: FP.
GTDR: No.
GTDU: No.

Dated: January 4, 1996.

Sue E. Eckert,

Assistant Secretary for Export Administration.

[FR Doc. 96–293 Filed 1–22–96; 2:52 pm]

BILLING CODE 3510–DT–P

TENNESSEE VALLEY AUTHORITY

18 CFR Part 1301

Privacy Act Regulations; Implementation

AGENCY: Tennessee Valley Authority.

ACTION: Final rule.

SUMMARY: The Tennessee Valley Authority (TVA) is amending its regulations implementing the Privacy Act of 1974 (the Act), 5 U.S.C. 552a. The amendment modifies existing TVA regulations (18 CFR 1301.24) exempting the system of records known as OIG Investigative Records—TVA (TVA–31) from certain provisions of the Act and corresponding agency regulations.

EFFECTIVE DATE: January 25, 1996.

FOR FURTHER INFORMATION CONTACT: Wilma H. McCauley, TVA, 1101 Market St. (CST 13B), Chattanooga, TN 37402–2801, telephone number: (423) 751–2523.

SUPPLEMENTARY INFORMATION: On October 28, 1993, (58 FR 57972–57974) TVA gave notice as required by the Privacy Act of its intention to amend the system of records known as OIG Investigative Records—TVA (TVA–31) from certain provisions of the Act and corresponding agency regulations. No comments were received. TVA is therefore updating its regulations at 18 CFR part 1301 to reflect this amendment.

List of Subjects in 18 CFR Part 1301

Administrative practice and procedure, Freedom of Information, Privacy Act, Sunshine Act.

For the reasons set forth in the preamble, TVA is amending 18 CFR, chapter XIII, part 1301, as follows:

PART 1301—PROCEDURES

1. The authority citation for part 1301 continues to read as follows:

Authority: 16 U.S.C. 831–831dd, 5 U.S.C. 552a.

2. Section 1301.24(d) is revised to read as follows:

§ 1301.24 Specific exemptions.

* * * * *

(d) The TVA system OIG Investigative Records is exempt from subsections (c)(3), (d), (e)(1), (e)(4), (G), (H), and (I) and (f) of 5 U.S.C. 552a (section 3 of the Privacy Act) and corresponding sections of these rules pursuant to 5 U.S.C. 552a(k)(2). The TVA system OIG Investigative Records is exempt from subsections (c)(3), (d), (e)(1), (e)(2), (e)(3), (e)(4)(G), (H), and (I), (e)(5), (e)(8), and (g) pursuant to 5 U.S.C. 552a(j)(2). This system is exempt because application of these provisions might alert investigation subjects to the existence or scope of investigations, lead to suppression, alteration, fabrication, or destruction of evidence, disclose investigative techniques or procedures, reduce the cooperativeness or safety of witnesses, or otherwise impair investigations.

* * * * *

William S. Moore,

Senior Manager, Administrative Services.

[FR Doc. 96–1191 Filed 1–24–96; 8:45 am]

BILLING CODE 8120–08–W

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 175

[Docket No. 94F–0381]

Indirect Food Additives: Adhesives and Components of Coatings

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the

food additive regulations to provide for the safe use of glyceryl polyoxypropylene triol;α,α′,α″-1,2,3-propanetriyltris[ω-hydroxypoly(oxypropylene)], minimum average molecular weight 250, as a reactant in the preparation of polyester and polyurethane resins used as components of adhesives for food-contact articles. This action is in response to a petition filed by the Dow Chemical Co.

DATES: Effective January 25, 1996; written objections and requests for a hearing by February 26, 1996.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of November 23, 1994 (59 FR 60363), FDA announced that a food additive petition (FAP 4B4435) had been filed by the Dow Chemical Co., 1803 Bldg., Midland, MI 48674–1803. The petition proposed to amend the food additive regulations in § 175.105 *Adhesives* (21 CFR 175.105) to provide for the safe use of glyceryl polyoxypropylene triol;α,α′,α″-1,2,3-propanetriyltris[ω-hydroxypoly(oxypropylene)], minimum average molecular weight 250, as a reactant in the preparation of polyester and polyurethane resins used as components of adhesives for food-contact articles.

The chemical, glyceryl polyoxypropylene triol;α,α′,α″-1,2,3-propanetriyltris[ω-hydroxypoly(oxypropylene)] is currently listed in 21 CFR 175.105 under the synonym, glyceryl polyoxypropylene triol. Therefore, for consistency, the subject additive is being listed by its synonym in this final rule.

In its evaluation of the safety of this additive, FDA has reviewed the safety of the additive itself and the chemical impurities that may be present in the additive resulting from its manufacturing process. Although the additive itself has not been shown to cause cancer, it has been found to contain minute amounts of unreacted propylene oxide, a carcinogenic impurity, resulting from the manufacture of the additive. Residual amounts of reactants and manufacturing aids, such as propylene oxide, are commonly found as contaminants in chemical products, including food additives.

I. Determination of Safety

Under section 409(c)(3)(A) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)(3)(A), the so-called ''general safety clause'' of the statute, a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. FDA's food additive regulations (21 CFR 170.3(i)) define safe as ''a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use.''

The food additives anticancer or Delaney clause (section 409(c)(3)(A) of the act) further provides that no food additive shall be deemed safe if it is found to induce cancer when ingested by man or animal. Importantly, however, the Delaney clause applies to the additive itself and not to the impurities in the additive. That is, where an additive itself has not been shown to cause cancer, but contains a carcinogenic impurity, the additive is properly evaluated under the general safety clause using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the proposed use of the additive, *Scott* v. *FDA*, 728 F.2d 322 (6th Cir. 1984).

II. Safety of Petitioned Use of the Additive

FDA estimates that the petitioned use of the additive, glyceryl polyoxypropylene triol (also known as glyceryl polyoxypropylene triol;α,α′,α″-1,2,3-propanetriyltris[ω-hydroxypoly(oxypropylene)], minimum average molecular weight 250, will result in exposure to the additive of no greater than 7 parts per billion in the daily diet (Ref. 1).

FDA does not ordinarily consider chronic toxicological testing to be necessary to determine the safety of an additive whose use will result in such low exposure levels (Ref. 2), and the agency has not required such testing here. However, the agency has reviewed the available toxicological data from acute toxicity studies on the additive. No adverse effects were reported in these studies.

FDA has evaluated the safety of this additive under the general safety clause, considering all available data and using risk assessment procedures to estimate the upper-bound limit of risk presented by the carcinogenic chemical that may be present as an impurity in the additive, propylene oxide. This risk evaluation of propylene oxide has two aspects: (1) Assessment of the worst-case exposure to the impurity from the proposed use of the additive; and (2) extrapolation of the risk observed in the animal bioassays to the conditions of probable exposure to humans.

A. Propylene Oxide

FDA has estimated the hypothetical worst-case exposure to propylene oxide from the petitioned use of the additive in the manufacture of adhesives to be 7 parts per quadrillion of the daily diet or 21 picogram (pg)/person/day (Ref. 1). The agency used data from a carcinogenesis bioassay on propylene oxide, conducted for the Institute of Hygiene, University of Mainz, Germany, to estimate the upper-bound lifetime human risk from exposure to this chemical stemming from the proposed use of the additive (Ref. 3). The results of the bioassay on propylene oxide demonstrated that the material was carcinogenic for female rats under the conditions of the study. The test material caused carcinomas and papillomas in the squamous epithelium of the forestomach.

Based on the estimated worst-case exposure of 21 pg/person/day, FDA estimates that the upper-bound limit of individual lifetime risk arising from likely exposure to propylene oxide resulting from the use of the subject additive is in the range of 3.2×10^{-12} (or 3.2 in 1 trillion) to 1.5×10^{-11} (or 1.5 in 100 billion) (Ref. 4). The range in FDA's estimate results from the agency's evaluation of complex tumor data in an oral toxicity study using rats. Because of the numerous conservative assumptions used in calculating the exposure estimate, the actual lifetime averaged individual exposure to propylene oxide is expected to be substantially less than the worst-case exposure, and therefore, the calculated upper-bound limit of risk would be less. Thus, the agency concludes that there is a reasonable certainty that no harm from exposure to propylene oxide would result from the proposed use of the additive.

B. Need for Specifications

The agency has also considered whether specification are necessary to control the amount of propylene oxide as an impurity in the additive. The agency finds that specifications are not necessary for the following reasons: (1) Because of the low level at which propylene oxide may be expected to remain as an impurity following production of the additive, the agency would not expect the impurity to become a component of food at other than extremely small levels; and (2) the

upper-bound limits of lifetime risk from exposure to the impurity, even under worst-case assumptions, is very low, in the range of less than 3.2 in 1 trillion to 1.5 in 100 billion.

III. Conclusion

FDA has evaluated data in the petition and other relevant material and concludes that the proposed use of the additive in adhesives is safe. Based on this information, the agency has also concluded that the additive will have the intended technical effect. Therefore, § 175.105 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

IV. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA 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 finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

V. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum from the Chemistry Review Branch (HFS–247), Center for Food Safety and Applied Nutrition (CFSAN), FDA, to the Indirect Additives Branch (HFS–216), CFSAN, FDA, concerning FAP 4B4435—Dow Chemical Co.—exposure to the food additive and its component, propylene oxide, dated March 1, 1995.

2. Kokoski, C. J., ''Regulatory Food Additive Toxicology,'' in *Chemical Safety Regulation and Compliance*, edited by F. Homburger and J. K. Marquis, S. Karger, New York, NY, pp. 24–33, 1985.

3. Dunkelberg, H., ''Carcinogenicity of Ethylene Oxide and 1,2-Propylene Oxide Upon Intragastric Administration to Rats,'' *British Journal of Cancer*, 46: 924, 1982.

4. Memorandum, ''Report of the Quantitative Risk Assessment Committee,'' CFSAN, FDA, dated April 20, 1995.

VI. Objections

Any person who will be adversely affected by this regulation may at any time on or before February 26, 1996, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. 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. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 175

Adhesives, Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 175 is amended as follows:

PART 175—INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS

1. The authority citation for 21 CFR part 175 continues to read as follows:

Authority: Secs. 201, 402, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 379e).

2. Section 175.105 is amended in paragraph (c)(5) in the table by alphabetically adding a new entry under the headings ''Substances'' and ''Limitations'' to read as follows:

§ 175.105 Adhesives.

* * * * *

(c) * * *

(5) * * *

Substances	Limitations
* * * * * * *	
Glycerol polyoxypropylene triol, minimum average molecular weight 250 (CAS Reg. No. 25791–96–2).	For use only in the preparation of polyester and polyurethane resins in adhesives.
* * * * * * *	

Dated: January 17, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–1143 Filed 1–24–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 178

[Docket No. 93F–0243]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of 4,5,6,7-tetrachloro-2-[2-(4,5,6,7-tetrachloro-2,3-dihydro-1,3-dioxo-1H-inden-2-yl)-8-quinolinyl]-1H-isoindole-1,3(2H)-dione (C. I. Pigment Yellow 138), as a colorant for all food-contact polymers. This action is in response to a petition filed by BASF Corp.