
[OPTS-42068; TSH-FRL 2849-1]

Carbofuran Intermediates: Response to the Interagency Testing Committee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice is EPA's response to the Interagency Testing Committee's (ITC) recommendation of methyl-2-nitrophenyl ether (CAS No. 13414-54-5), 7-nitro-2,2-dimethyl-2,3-dihydrobenzofuran (CAS No. 13414-55-6), and 7-amino-2,2-dimethyl-2,3-dihydrobenzofuran (CAS No. 68298-46-4), collectively known as the carbofuran intermediates (CIs), for priority consideration for chemical fate and environmental effects testing. EPA is not initiating rulemaking at this time under section 4(a) of the Toxic Substances Control Act (TSCA) to require any testing of the CIs because EPA does not believe that there is a basis to find that these substances may present an

unreasonable risk of injury to the environment nor that there is or may be substantial environmental release.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-543, 401 M St., SW., Washington, DC 20460. Toll Free: (800-424-9065). In Washington, DC (554-1404). Outside the U.S.A.: (Operator-202-554-1404).

SUPPLEMENTARY INFORMATION: EPA is not initiating rulemaking at this time under section 4(a) of TSCA to require chemical fate or environmental effects testing of the CIs as recommended by the ITC in its Eleventh Report.

I. Background

Section 4(e) of the TSCA (Pub. L. 94-469, 90 Stat. 2010 *et seq.*; 15 U.S.C. 2603 *et seq.*) established the ITC to recommend to EPA a list of chemicals to receive priority consideration for testing under section 4(a) of TSCA.

The ITC recommended, but did not designate for response within 12 months, methallyl-2-nitrophenyl ether (MNE, CAS No. 13414-54-5), 7-nitro-2,2-dimethyl-2,3-dihydrobenzofuran (NDD, CAS No. 13414-55-6) and 7-amino-2,2-dimethyl-2,3-dihydrobenzofuran (ADD, CAS No. 68248-46-4), collectively known as the carbofuran intermediates (CIs), for priority testing consideration in its Eleventh Report, published in the Federal Register of December 3, 1982 (47 FR 54626). This notice constitutes EPA's response to the ITC's recommendation of the CIs.

The ITC recommended chemical fate testing for the CIs with emphasis on environmental monitoring. The ITC's rationale for chemical fate testing was that there was insufficient information to characterize the nature of dispersion, concentration, and persistence of CIs in the environment.

The ITC also recommended environmental effects tests for the CIs including acute toxicity to fish and aquatic invertebrates. The ITC's rationale for environmental effects testing was that concentrations of CIs in wastewater effluent released to the aquatic environment were believed to approach the concentrations of CIs reported to cause acute effects in goldfish and possibly exceed levels for more sensitive species.

Under section 4(a)(1) of TSCA, the Administrator shall, by rule, require testing of a chemical substance to develop appropriate test data if the agency finds that—
(A) the manufacture, distribution in commerce, processing, use, or disposal of a

chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment.

(ii) there are insufficient data and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data; or

(B)(i) a chemical substance or mixture is or will be produced in substantial quantities, and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (II) there is or may be significant or substantial human exposure to such substance or mixture,

(ii) there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data.

EPA uses a weight-of-evidence approach in which both exposure and toxicity information are considered in making a section 4(a)(1)(A)(i) finding that the chemical may present an unreasonable risk. For the section 4(a)(1)(B)(i) finding, EPA considers only production, exposure, and release information to determine whether there is substantial production, and significant or substantial exposure, or substantial release. Thus, EPA can require testing for an effect under section 4(a)(1)(A) only if there is a suspicion of a hazard. Under 4(a)(1)(B), EPA can require testing whether or not there are data suggesting adverse effects if the relevant production and exposure or release criteria are met.

For the findings under both section 4(a)(1)(A)(ii) and 4(a)(1)(B)(ii), EPA examines toxicity and fate studies to determine whether existing information is adequate to reasonably determine or predict the effects of human exposure to, or environmental release of, the chemical. In making the third finding, that testing is necessary, EPA considers whether ongoing testing will satisfy the information needs for the chemical and whether testing that the Agency might require would be capable of developing the necessary information. EPA's process for determining when these findings can be made is described in detail in EPA's first and second proposed test rules as published in the Federal Register of July 18, 1980 (45 FR 48516) and June 5, 1981 (46 FR 30300). The section 4(a)(1)(A) finding is

discussed in 45 FR 48528, and the section 4(a)(1)(B) finding is discussed in 46 FR 30302.

In evaluating the ITC's testing recommendations for the CIs, EPA considered all available relevant information including the following: information presented in the ITC's report recommending testing consideration; production volume, use, exposure, and release information reported by the manufacturer of CIs under the TSCA section 8(a) Preliminary Assessment Information Rule (40 CFR Part 712—Chemical Information Rules, Subpart B—Manufacturers Reporting—Preliminary Assessment Information); and published and unpublished data available to the Agency.

II. Review of Available Data

A. Environmental Release

The carbofuran intermediates are produced solely by FMC Corporation in Baltimore, Maryland. Production was about 10 to 50 million pounds for each CI in 1977 (Ref. 1). The manufacturer has submitted to EPA production volumes for 1982 as confidential business information (Ref. 2).

FMC reports that the CIs are used consumptively as intermediates in closed systems during the production of the insecticide-nematicide carbofuran (Ref. 3). The manufacturer pretreats the effluent through a carbon bed adsorption system and a settling basin with pH adjustments. Since January, 1984, the manufacturer's pretreated effluent has been further treated by a local publicly owned treatment works (POTW). Approximately 10 to 20 thousand pounds of each of the CIs is expected to enter the POTW in 1985 (Ref. 4).

EPA has calculated worst-case predicted environmental concentrations (PECs) for the CIs in the discharge environment of 1.75 parts per billion (ppb) for MNE, 1.97 ppb for NDD and 0.85 ppb for ADD. These figures were derived from recent release data supplied to EPA by the manufacturer. Because we have no data on the fate of the CIs in the POTW or the environment, calculation of the PECs was based on the assumption that none of the CIs are removed during treatment by the POTW or from the discharge environment by physical or biological processes (Refs. 4 and 5). In addition, the dilution estimate for the discharge environment was conservatively based on an average 7 day per 10-year, low flow rate (7Q10) and included tidal flushing for the receiving brackish water. Sludge waste from the POTW

likely to contain the Cls is either rated or placed in a Resource Conservation and Recovery Act (RCRA)-regulated landfill where the Cls are expected to biodegrade (Ref. 6).

B. Chemical Fate

1. *Water solubility and octanol/water partition coefficient.* EPA has calculated water solubilities of 1,100 mg/L for MNE, 120 mg/L for NDD, and 2,300 for ADD and logs of the octanol/water partition coefficient (log P) of 2.75 for MNE, 3.33 for NDD, and 2.36 for ADD (Ref. 5). These calculated properties indicate that under equilibrium conditions the Cls will remain mainly in the water compartment.

2. *Soil mobility.* The adsorption properties of the Cls have not been reported in the available literature. However, using equations developed by Kenaga (Ref. 7) and Kenaga and Goring (Ref. 8), values for the adsorption coefficients (K_{oc}) have been estimated from the calculated log P values (Ref. 5). These estimated adsorption coefficients of 746 for MNE, 1,540 for NDD and 458 for ADD indicate that the Cls will adsorb moderately to organic matter in soil and sediment and therefore can be considered moderately mobile. There is experimental data to indicate that toxic amines chemically bind to soil particles (Refs. 9 and 10). Because ADD is an aromatic amine, it may bind chemically to organics in soil and therefore be less mobile than the other two Cls.

3. *Persistence.* EPA is not aware of any information on the environmental persistence of the Cls in the available literature. However, data on a compound structurally related to the Cls indicate that the Cls are likely to biodegrade in soil (Ref. 11).

Environmental Effects

1. *Acute toxicity.* The manufacturer reported measured 96hr LC_{50} values for goldfish of 6.5 ppm for MNE, 30 ppm for NDD and 56 to 140 ppm for ADD (Ref. 12).

2. *Other toxicity data.* EPA knows of no data on the chronic effects of Cls on fish, or on the acute or chronic effects of Cls on aquatic and benthic invertebrates.

III. Decision Not To Initiate Rulemaking

EPA has decided not to initiate rulemaking at this time to require chemical fate or environmental effects testing of the Cls. The ITC

recommended environmental effects testing because concentrations of Cls in water affluent released to the aquatic environment were believed to approach the concentrations of Cls

reported to cause acute effects in goldfish and possibly exceed effected levels for more sensitive species. The ITC recommended chemical fate testing because there was insufficient information to characterize the nature of dispersion, concentration and persistence of Cls in the environment.

EPA has estimated the environmental risk posed by the Cls by comparing goldfish LC_{50} s (Unit II.C) to the PECs (Unit II.A). In general, if the LC_{50} for a chemical exceeds its environmental concentration by three orders of magnitude the Agency considers the substance to be of low concern. The factor of three orders of magnitude between the LC_{50} s and PEC takes into account interspecies, acute-to-chronic, field-to-lab, and lab-to-lab variability. Since the LC_{50} s for the Cls exceed the PECs for the Cls by three orders of magnitude, EPA finds no indication of potential unreasonable risk. Furthermore, EPA believes that factors used in calculating the predicted environmental concentrations, such as assuming a 7Q10 low flow rate for dilution and that no biodegradation or adsorption occurs to remove Cls in the POTW or environment, are very conservative and provide an additional margin of confidence that the Cls present no unreasonable risk to the environment.

In summary, the ITC recommended chemical fate and environmental effects testing of the Cls because they believed the environmental exposure exceeded effects levels in goldfish and possibly more sensitive species. However, EPA concludes from available data that information in Unit II.A through C of this notice does not support a TSCA section 4(a)(1)(A) finding that the Cls may present an unreasonable risk of injury to fish and invertebrates in the environment. EPA also concludes on the basis of information presented in Unit II.A of this notice, some of which was not available to the ITC, that there is not sufficient environmental release to support TSCA section 4(a)(1)(B) findings for chemical fate and environmental effects testing of Cls. Therefore, the Agency is not requiring testing for the Cls at this time.

IV. Public Record

EPA has established a public record for this decision not to test under Section 4 of TSCA (docket number OPTS-42068). The record includes the following information:

A. Supporting Documentation

(1) Federal Register notice containing the ITC Report recommending methallyl-2-nitrophenyl ether, 7-nitro-2, 2-

dimethyl-2,3-dihydrobenzofuran, and 7-amino-2, 2-dimethyl-2, 3-dihydrobenzofuran to the priority list.

(2) Communications consisting of:

(a) Written public and intra-agency or interagency memoranda and comments.

(b) Summaries of telephone conversations.

(c) Summaries of meetings.

(3) Reports—published and unpublished factual materials, including contractors' reports.

B. REFERENCES

(1) USEPA. U.S. Environmental Protection Agency. Nonconfidential TSCA Inventory for Carbofuran Intermediates from Producers of Chemicals in Commerce for 1977. 1981.

(2) USEPA. U.S. Environmental Protection Agency. Letter from D. Palmer of FMC Corporation to S. Newburg-Rinn, Office of Toxic Substances, USEPA with attached data for TSCA section 8(a) Preliminary Assessment Information Rule. (40 CFR part 712—Chemical Information Rules, Subpart B—Manufacturers REporting—Preliminary Assessment Information.) February 15, 1983.

(3) USEPA. U.S. Environmental Protection Agency Hazard Information Review, Report for the Interagency Testing Committee prepared by Enviro Control Inc. Rockville, Maryland. September 17, 1981.

(4) USEPA. U.S. Environmental Protection Agency. Letter from R. Roseberry of FMC Corporation to M. McCommas, Office of Toxic Substances, USEPA. January 10, 1985.

(5) USEPA. U.S. Environmental Protection Agency. Memo: Estimated Environmental Concentration and Chemical Fate of the Carbofuran Intermediates, from R. Kinerson, Design and Development Branch, Office of Toxic Substances to M. McCommas, Test Rules Development Branch, Office of Toxic Substances. USEPA. February 16, 1984.

(6) USEPA. U.S. Environmental Protection Agency. Personal Communication between H.K. Latourette of FMC Corporation and M. McCommas, Office of Toxic Substances, USEPA. December 28, 1982.

(7) Kenaga, E.E. "Predicted bioconcentration and soil sorption coefficients of pesticides and other chemicals." *Ecotoxicol. Environ. Saf.* 4:26-38. 1980.

(8) Kenaga, E.E. and Goring C.A.I. "Relationship between water solubility, soil sorption, octanol-water partitioning, and concentration of chemicals in biota." *ASTM Spec. Tech. Publ. STP. 707-78-115.* 1980.

(9) Parris, G.E. "Covalent binding of aromatic amines to humate, 1—Reactions with carbonyl and quinones." *Env. Sci. Technology* 14:1099-1106. 1980.

(10) Bollag, J.M., Minard, R.D., and Liu, S.V. "Crosslinkage between anilines and phenolic humus constituents." *Env. Sci. Technol.* 17:72-80. 1983.

(11) Clay, V.E., Fahmy, A.H.M., Martin, J.P. and T.R. Fukuto. "Degradation of 2,3-dihydro-2,2-dimethyl-7-benzofuranyl in Cosad Sandy Loam." *J. Agr. Food Chem.* 28(8):1122-1129. 1980.

(12) USEPA. U.S. Environmental Protection Agency. Letter from R. Roseberry of FMC

Corporation to M. McCommas, Office of Toxic Substances, USEPA, March 21, 1948.

This record includes basic information considered by the Agency in developing this notice. Confidential business information (CBI), while part of the record, is not available for public review. A public version of the record from which CBI has been deleted is available for inspection in the OPTS Reading Room, Rm. E-107, 401 M St., SW., Washington, DC, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays. The Agency will supplement the record periodically with additional relevant information received.

Dated: July 15, 1985.

Authority: 15 U.S.C. 2603.

J.A. Moore.

Assistant Administrator for Pesticides and Toxic Substances.

[FR Doc. 85-17343 Filed 7-19-85; 8:45 am]

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