

40 CFR Part 799

[OPTS-42103A; FRL 3662-9]

RIN 2070-AB07

C.I. Disperse Blue 79:1; Testing Consent Order

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This notice announces that EPA has signed an enforceable Testing Consent Order with eight companies who have agreed to perform certain health and environmental effects tests with C.I. Disperse Blue 79:1 [DB-79:1] (CAS No. 3618-72-2). This action is in response to the TSCA Interagency Testing Committee's (ITC) recommendation of this substance for priority testing. EPA also announces its decision not to initiate rulemaking for C.I. Disperse Blue 79 (DB-79) (CAS No. 3958-55-8) and two of its analogs (CAS Nos. 21429-43-6 and 3618-73-3) for health and environmental effects and chemical fate testing.

EFFECTIVE DATE: November 21, 1989.

FOR FURTHER INFORMATION CONTACT: Michael M. Stahl, Director, Environmental Assistance Division (TS-799), Office of Toxic Substances, Rm. EB-44, 401 M St., SW., Washington, DC 20460, (202) 554-1404, TDD (202) 554-0551.

SUPPLEMENTARY INFORMATION: Under procedures described in 40 CFR part 790, eight manufacturers of DB-79:1, also known as acetamide, N-5-[bis[2-(acetyloxy)ethyl]amino]-2-[(2-bromo-4,6-dinitrophenyl)azo]-4-methoxyphenyl], have entered into a Testing Consent Order with EPA in which they have agreed to perform certain health and environmental effects tests using DB-79:1. This rule amends subpart C of 40 CFR part 799 to add DB-79:1 to the list of chemical substances and mixtures ("chemicals") subject to Testing Consent Orders for which the export notification requirements of 40 CFR part 707 apply.

I. ITC Recommendations

In its Nineteenth Report to EPA, published in the *Federal Register* of November 14, 1986 (51 FR 41417) the ITC recommended that DB-79 (CAS No. 3958-55-8) be tested for (1) chemical fate (water solubility, and aerobic and anaerobic biodegradation); (2) environmental effects (acute and chronic toxicity to algae, aquatic invertebrates, fish, and benthic organisms, and bioconcentration in fish); and (3) health effects (absorption and chemical disposition, and 90-day subchronic toxicity).

In its Twentieth Report to EPA published in the *Federal Register* of May 20, 1987 (52 FR 19020), the ITC also recommended DB-79:1 (CAS No. 3618-72-2), the chloro/methoxy analog of DB-79 (CAS No. 3618-73-3), and the chloro/ethoxy analog (CAS No. 21429-43-6), for the same testing as DB-79.

II. Testing Consent Order Negotiation

In the *Federal Register* of October 12, 1988 (53 FR 34786) and in accordance with the procedures established in 40 CFR 790.28, EPA requested persons interested in participating in or monitoring testing negotiations for DB-79:1 to contact EPA. EPA held public meetings on October 26, 1988, November 29, 1988, and January 24, 1989, to discuss testing appropriate for this chemical. On October 20, 1989 EPA and eight companies signed a Testing Consent Order for DB-79:1. The eight companies agreed to conduct or to provide for the conducting of the following studies: (1) subchronic oral toxicity in the rat, (2) sex-linked recessive lethal (SLRL) test in *Drosophila*, (3) developmental toxicity in the rat and rabbit, (4) metabolism in the rat, and (5) a rainbow trout fish partial life-cycle test. These tests are to be conducted by specific dates and according to the test standards and the Appendices of the Consent Order.

A group of companies who comprise the manufacturing and importing industry for DB-79:1 and DB-79 and its two analogs, have reported to EPA through the Ecological and Toxicological Association of Dyestuffs Manufacturing Industry (ETAD) that less than 1,000 pounds of DB-79 and less than 25,000 pounds of the chloro/methoxy analog were produced in 1985 (Ref. 1). The chloro/ethoxy analog was not manufactured or imported in 1985. The aggregated TSCA section 8(a) inventory update information supports this industry estimate (Ref. 2). Therefore, EPA is not initiating rulemaking proceedings for health, environmental, and chemical fate testing of these

chemicals because there is little or no production.

However, because analogs of DB-79:1 could be used as substitutes for DB-79:1, EPA will monitor future manufacturing of these chemicals through the section 8(a) TSCA Inventory Update Rule, 40 CFR part 710, published in the *Federal Register* of June 12, 1986 (51 FR 21438), and section 5 TSCA premanufacture notification requirements, to determine whether further testing will be needed.

III. Technical Summary

A. Manufacture and Use

The estimated average annual production from 1980 to 1985 is 2 to 3 million pounds for DB-79:1 and related analogs as active colorants (Ref. 3). ETAD has estimated the current domestic sales market (1985) for DB-79:1 to be 1.8 million pounds of active colorant (Ref. 1). The aggregated TSCA section 8(a) inventory update data for 1987 support this industry estimate (Ref. 2).

Disperse Blue-79:1 and related products are used almost exclusively for dyeing or printing polyester fibers.

B. Human Exposure

1. **Occupational exposure.** Dermal and inhalation/ingestion exposure to DB-79:1 can occur during production, processing, and use of DB-79:1. A maximum of 180 workers (10 to 20 workers at 9 sites) are potentially exposed during production, while a maximum of 66 workers are exposed during processing (3 to 6 workers at 11 sites). In addition, from 1 to 3 dye weighers and 1 to 18 machine operators per site are potentially exposed to DB-79:1 during use according to an EPA engineering analysis of occupational exposure (Ref. 5). If the dye weighers are considered for potential worker exposure at 300 to 400 sites (ETAD estimate), then approximately 900 to 1,200 workers are potentially exposed via both inhalation/ingestion and dermal routes. If the machine operators are included, an additional 7,200 workers are potentially exposed via the dermal route. ETAD agrees that EPA's estimates of the number of workers potentially exposed through use are reasonable (Ref. 1).

The results from a preliminary review of a joint study on the occupational exposure of textile dye color on storeroom workers, conducted by the American Textile Manufacturers Institute (ATMI), EPA, and ETAD, support ETAD's position and reports that the average daily level of exposure to dye weighers is 0.09 mg (Ref. 7) and

average daily level of exposure to machine operators is negligible (Ref. 5). The potential remains for more significant single exposures in these cases.

Data available from the National Occupational Exposure Survey (NOES), from 1980 to 1983, reported that 1,450 workers in 25 plants were potentially exposed to DB-79:1 or related compounds. The National Occupational Hazard Survey (NOHS), from 1972 to 1974, reported that 2,305 workers in 107 plants were potentially exposed to DB-79 and related compounds (Ref. 8).

2. *Consumer exposure.* DB-79:1 and related products are fast dyes that are held tightly within the polyester fiber structure and therefore not easily removed (Refs. 5 and 6). Thus, consumer exposure to DB-79:1 and related products is low.

C. Environmental Fate and Exposure

1. *Chemical fate.* The water solubility of DB-79:1 is low (measured between 4.6/1.9 and 6.2/0.5 ug/l); the log octanol/water partition coefficient for DB-79:1 is 4.7/0.1 (Ref. 9). DB-79:1 is not likely to volatilize or photodegrade.

Results of aerobic biodegradation studies using 13 percent liquid, and 26 percent and 52 percent granular formulations of DB-79:1 indicate that at higher concentrations less biodegradation occurs (Ref. 6).

EPA's Environmental Research Laboratory in Cincinnati is completing a study on the adsorption, aerobic, and anaerobic biodegradation of DB-79:1. Early results indicate that DB-79:1 partitions to sludge and is anaerobically biodegraded when added to a model sludge-treatment system in insoluble (particulate) form at its solubility limit (Ref. 10). A recent study from EPA's Environmental Research Laboratory in Athens Georgia reported rapid degradation of DB-79 in anaerobic sediment systems (Ref. 11). The half-life was on the order of minutes.

After reviewing this information, some of which was not available to the ITC, EPA has decided not to include testing for chemical fate as a part of the Consent Order for DB-79:1.

2. *Release and monitoring.* No effluent or ambient monitoring information is available. The majority of releases of DB-79:1 from its manufacturing and use will be to water. Estimated dyestuff pre-treatment losses to water during production are between 0.5 and 1 percent of production (Ref. 5). Estimated dyestuff pre-treatment losses during the use of textile dyestuffs are between 5 and 10 percent. Sludge containing DB-79:1 and products from wastewater

treatment facilities or POTW's may be sent to landfills.

3. *Environmental exposure.* EPA has performed aquatic environmental modeling for DB-79:1 using engineering assessment-based estimated discharge data which suggest that the surface water concentrations of DB-79:1 are relatively low (Ref. 12). The industrial facilities producing DB-79:1 and related compounds were located, and the receiving streams were identified. Releases were estimated to be 1.4 kg per site for 100 days each year, which is the upper bound based on average batch size (Ref. 12). Using a measured log K_{ow} of 4.7, it was estimated that 80 percent of DB-79:1 would be removed by sorption either in the on-site wastewater treatment plant or in a POTW (Ref. 13). Five site-specific surface water concentrations were projected to range from 0.01 to 0.97 ug/l for mean flow conditions, and from 0.04 to 3.9 ug/l for low flow conditions.

4. *Bioconcentration.* The ITC pointed out that no experimental data on the potential for bioconcentration of DB-79:1 by aquatic organisms are available. However, 18 disperse monoazo dyes examined experimentally had log BCF values <1.8 even though the experimental log K_{ow} was 3 in seven out of nine, and the calculated K_{ow} was 3 in one of the remaining nine (Ref. 14). This suggests that the bioconcentration factor for DB-79:1 would be low. The reason proposed for this behavior was that the relatively high molecular weight (450 to 550 g/mole) of these disperse dyes made transport across the fish gill membrane difficult. Additional studies also suggest that high molecular weight and molecular size limit membrane penetration and thus accumulation through the gills (Refs. 16 and 17). After reviewing this information, some of which was not available to the ITC, EPA has decided not to include bioconcentration testing as a part of the Consent Order for DB-79:1.

IV. Testing Program

A. Environmental Effects

No experimental data on the toxic effects of pure DB-79:1 to fresh water fish are available. The 96-hour LC_{50} of a powder formulation of DB-79:1 was reported to be 390 mg/l in bluegill (*Lepomis macrochirus*) (Ref. 6). Converted to LC_{50} values, the 48-hour median tolerance limits of two granular formulations of 26 and 52 percent, and one liquid formulation of 13 percent of DB-79:1 were reported to be 320, 400, and 700 mg/l respectively in rainbow trout (*Salmo gairdneri*) (Ref. 6). The absence of specific descriptions of

formulation compositions used in these studies precludes an accurate evaluation of the toxic potential of the test substances

EPA's predicted LC_{50} 's for fish, daphnid, and algae for DB-79:1 are all above the water solubility limit for DB-79:1, so no acute toxicity is likely at or below DB-79:1's solubility limit (Ref. 18). However, toxicity to fish is possible from long-term exposure at the limits of solubility for DB-79:1. No method is available to determine the effects of long term exposure to benthic invertebrates.

In the absence of useful fish toxicity data and any data on the effects of long-term exposure on fish life stages to disperse dyes, eight companies have agreed to conduct rainbow trout early life-cycle testing of DB-79:1, in accordance with 40 CFR 797.1600 as modified for DB-79:1 (Ref. 4) and contained in the public docket. The final report for this test is due 15 months after the effective date of the Testing Consent Order.

EPA will use the data generated by this test to determine the potential risk to the environment from exposure to DB-79:1 and to determine whether any additional testing of DB-79:1 is necessary.

B. Health Effects

Because of the lack of health effects data and the potential for worker exposure to DB-79:1, EPA and the eight companies have decided to include in the Consent Order subchronic toxicity testing, developmental toxicity testing, mutagenic effects testing (SLRL in *Drosophila*), and metabolism testing. The companies have agreed to conduct the following studies in accordance with the cited test guidelines:

(1) An oral subchronic study in the Sprague-Dawley rat.

(2) Developmental toxicity studies in the Sprague-Dawley rat and rabbit by the oral gavage route.

(3) An oral metabolism test in the Sprague-Dawley rat (Ref. 15), and (4) an SLRL test in *Drosophila*. If the SLRL indicates a hazard of genetic toxicity, EPA will consider the need for further testing.

Testing Plan for DB-79:1

Test	Test Standards in 40 CFR	Report Date ¹
SLRL in <i>Drosophila</i> .	§ 798.5275	12
Subchronic oral toxicity, rat.	§ 798.2650	15
Developmental toxicity, rat.	§ 798.4900	12

Testing Plan for DB-79:1—Continued

Test	Test Standards in 40 CFR	Report Date ¹
Developmental toxicity, reprod. Metabolism, rat.....	§ 799.4000 ETAD Protocol ²	24 24

¹ Months after effective date of this rule.

² ETAD-provided rat oral metabolism protocol (Ref. 15)

The above Table delineates the tests, test standards, and final reporting dates for the health effects tests incorporated in the Testing Consent Order. The test standards with modifications are attached to the Order. EPA will use the data generated by these tests to determine the potential risk to human health from exposure to DB-79:1 and, if any additional testing of DB-79:1 is necessary.

V. Export Notification

The issuance of this Testing Consent Order subjects any person who exports or intends to export DB-79:1 to the export notification requirements of section 12(b) of TSCA. The specific requirements are listed in 40 CFR part 707. Chemicals subject to Consent Orders are listed at 40 CFR 799.5000. This listing serves as notification to persons who export or who intend to export chemical substances or mixtures which are the subject of Testing Consent Orders that 40 CFR part 707 applies.

VI. Rulemaking Record

EPA has established a record for this rule and the Consent Order (docket number OPTS-42103). This record contains the information EPA considered in developing this rule and Consent Order and includes the following:

A. Supporting Documentation

- (1) Testing Consent Order for DB-79:1.
- (2) Federal Register notices pertaining to this rule and the Consent Order consisting of:
 - (a) Notice containing the ITC recommendation of DB-79:1.
 - (b) Rules requiring TSCA section 5(a) and (d) reporting on DB-79:1.
 - (c) Notice soliciting interested parties for Testing Consent Order negotiation on DB-79:1.
- (3) Communications consisting of:
 - (a) Letters.
 - (b) Contact reports of telephone conversations.
 - (c) Meeting summaries.

B. References

- (1) ETAD. Ecological and Toxicological Association of Dyestuffs Manufacturing

Industry. Letter from E.A. Clarke, Executive Secretary to R.H. Brink, Interagency Testing Committee-USEPA (February 12, 1987) on: Disperse Blue 79, with Appendix E Disperse Blue 79 and DB79 analogs; and with enclosure: ETAD's comments on the ITC Testing Recommendations for C.I. Disperse Blue 79 (February 12, 1987).

(2) USEPA. Memo from N. Vogel, Confidential Data Branch, to H. Colbert, Test Rules Development Branch, on: Aggregated production volume figures (December 21, 1988).

(3) USEPA. U.S. Environmental Protection Agency. Technical Support Document for C.I. Disperse Blue 79, prepared by Syracuse Research Corp. for Test Rules Development Branch (1987).

(4) USEPA. OTS Guideline § 797.1600 Fish early life stage toxicity test, with modifications. (1989).

(5) USEPA. Memo from G. Heath, Chemical Engineering Branch, to John Walker, Test Rules Development Branch, on: Disperse Blue 79 with attached report-Engineering report worker exposure, and release analysis for Interagency Testing Committee (ITC) Disperse Blue 79 (May 30, 1986).

(6) ETAD. Letter from E. Clarke, Executive Secretary, to R. Brink, Interagency Testing Committee-USEPA on: Disperse Blue 79; with attachments: Comments by ETAD to Dynamac on the ITC recommendations for testing Disperse Blue 79 and added data (August 11, 1986).

(7) USEPA. Memo from G. Heath, Chemical Engineering Branch, to Mike McCommas, Test Rules Development Branch, on: Supplemental Engineering Report- Disperse Blue 79 (January 28, 1987).

(8) NIOSH. National Institute for Occupational Safety and Health. Computer printout of National Occupational Hazard Survey (1972-1974) and National Occupational Exposure Survey (1960-1982) data bases: C.I. Disperse Blue 79. Cincinnati, OH: Department of Health and Human Services (April 28, 1986).

(9) USEPA. Memo from G.L. Baughman, USEPA-ERL Athens, GA, to E. Bryan, Chief, Exposure Assessment Branch, on: Disperse Blue 79 (August 20, 1987).

(10) USEPA. "Aerobic and Anaerobic Treatment of C.I. Disperse Blue 79." D.A. Gardner, T.J. Holdsworth, Radian Corporation; G.M. Shaul, K.A. Dorval, Risk Reduction Engineering Laboratory-USEPA, Cincinnati, OH; and L.D. Betowski, Environmental Monitoring and Support Laboratory-USEPA, Las Vegas, NV; Contract No. 68-03-3371, Volume 1 and 2 (June 1989).

(11) ETAD. Ecological and Toxicological Association of the Dyestuffs Manufacturing Industry. Letter from E.A. Clarke, Executive Secretary, to Document Processing Center-USEPA (April 8, 1988), with enclosure: E.J. Weber. Fate of textile dyes in the aquatic environment: degradation of Disperse Blue 79 in anaerobic sediment-water systems. Environmental Research Laboratory-USEPA, Athens, GA (1988).

(12) USEPA. Memo from M.H. Thomas, Exposure Assessment Branch, to John

Walker, Test Rules Development Branch, on: Predicted surface water concentrations and drinking water exposure of C.I. Disperse Blue 79 (June 24, 1986).

(13) USEPA. Hand-written table from P. Harrigan, Design and Development Branch, to M. McCommas, Test Rules Development Branch, on: Sewage treatment removal estimates for site specific releases of DB-79:1 (December 11, 1987).

(14) Anliker, R., Clarke, E.A., and Moser, P. "Use of the partition coefficient as an indicator of bioaccumulation tendency of dyestuffs in fish." *Chemosphere* 10:263-274 (1981).

(15) ETAD. Protocol outline for oral metabolism study in rats with disperse blue 79 (DB79), with modifications. (1989).

(16) Opperhuizen, A., Velde, E., Gobas, F., Liem D., Steen, J., and Huntzinger, O. "Relationship between bioconcentration in fish and steric factors of hydrophobic chemicals." *Chemosphere* 14:1871-1896 (1985).

(17) Gobas F., Shiu, W., Mackay, D., and Opperhuizen, A. "Bioaccumulation of PCDD's and OCDF in fish after aqueous and dietary exposure." *Chemosphere* 15:1985-1986 (1986).

(18) Memo from R. Jones, Toxic Effects Branch, to M. McCommas, Test Rules Development Branch, on: Review of Disperse Blue 79 (June 3, 1988).

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 OTS Public Information Office, Rm. NE-C004, 401 M St., SW., Washington, DC from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

VII. Other Regulatory Requirements

Paperwork Reduction Act

OMB has approved the information collection requirements in this Testing Consent Order under the provision of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* and has been assigned OMB control 2070-0033.

Public reporting burden for this collection of information is estimated to average 564 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. The total estimated testing hours for DB-79:1 is 3386.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC

20499; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0033), Washington, DC 20503.

List of Subjects in 40 CFR Part 799

Chemical export, Chemicals, Environmental protection, Hazardous substances, Recordkeeping and

§ 799.5000 Testing consent orders.

reporting requirements, Testing procedures.

Dated: October 20, 1989.
 Victor J. Kimm,
Acting Assistant Administrator for Pesticides and Toxic Substances.

Therefore, 40 CFR part 799 is amended as follows:

PART 799—[AMENDED]

1. The authority citation for part 799 continues to read as follows:

Authority: 15 U.S.C. 2603, 2611, 2625.

2. Section 799.5000 is amended by adding "C.I. Disperse Blue 79:1" to the table in CAS Number order, and the OMB control number to the end of § 799.5000 to read as follows:

CAS Number	Substance or Mixture Name	Testing	FR Citation
3618-72-2.....	C.I. Disperse Blue 79:1 Acetamide,N-[5-[bis[2-(acetyloxy) ethyl]amino]-2-[(2-bromo-4,6-dinitrophenyl)azo]-4-methoxyphenyl]-.....	Health effects Environmental effects	November 21, 1989. -Do-

(Information collection requirements have been approved by the Office of Management and Budget under control number 2070-0033)

[FR Doc. 89-27211 Filed 11-21-89; 8:45am]

BILLING CODE 5690-50-0