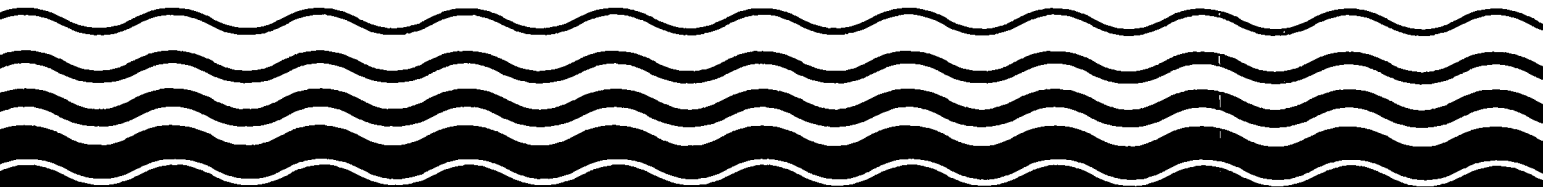




# Information Document on Aquatic Life Toxicity for:

## Di-2-Ethylhexyl Phthalate (DEHP)





**Environmental Protection Agency**  
**40 CFR Part 131, 401.15, 423; Appendix A**

**Agency:** Environmental Protection Agency  
[OW-FRL-----]

**Action:** Notice of Availability of an Information Document on Aquatic Life Toxicity for Di-2-Ethylhexyl Phthalate (DEHP)

**Summary:** The U. S. Environmental Protection Agency (EPA) is announcing the availability of an information document on aquatic life toxicity for Di-2-Ethylhexyl Phthalate (DEHP). Ambient water quality criteria documents are developed pursuant to Section 304(a)(1) of the Clean Water Act. The current guidelines for ambient water quality criteria for the protection of aquatic life specify the data needed for development of a national criteria. Sufficient acute and chronic toxicity data for DEHP were not available to derive a national criteria. For this reason, EPA is announcing the availability of an information document which presents only lowest observed effect levels (LOEL's) for DEHP.

The group of chemicals commonly referred to as phthalates are esters of phthalic acid. Phthalates are used in the manufacture of plastics where they increase the flexibility, extensibility and workability of plastic. Di-2-Ethylhexyl Phthalate is the Phthalate compound that is produced in the largest volume.

**ADDRESSES:**

A copy of the comments/responses and supporting documents (cited in the Reference section of this document) are available for review at EPA's Water Docket; 401 M Street, S.W.; Washington, D.C. 20460. For access to Docket materials, call (202) 260-3027 between 9:00 a.m. and 3:30 p.m. for an appointment.

Requests for copies of the supporting documents should be sent to:

U.S. Environmental Protection Agency  
National Center for Environmental Publications  
and Information  
11029 Kenwood Road  
Cincinnati, OH 45242  
(513) 489-8190  
Internet address: Waterpubs@EPAMail.EPA.gov

**FOR FURTHER INFORMATION CONTACT:**

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U.S. Environmental Protection Agency  
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## **SUPPLEMENTARY INFORMATION:**

### **Background**

EPA publishes and periodically updates ambient water quality criteria pursuant to Section 304(a)(1) of the Clean Water Act, (33)U.S.C. 1314(a)(1). These criteria are intended to reflect the latest scientific knowledge on the identifiable effects of pollutants on public health and welfare, aquatic life and recreation. Beginning in 1973, EPA has periodically issued ambient water quality criteria.

In July 1976, EPA published "Quality Criteria for Water - 1976", which provided a freshwater aquatic life criteria for phthalate esters. A criterion value of 3 ug/L was established based on available acute and chronic data.

Four years later, EPA published a notice of availability of "Ambient Water Quality Criteria for Phthalate Esters" in the Federal Register, (45 FR 79318, November 28, 1980), (Ref. 2). This document established a Lowest Observed Effect Level (LOEL) of 3 ug/L for aquatic life, based on acute and chronic data. In addition this document greatly expanded the data base considered for this chemical.

A draft aquatic life criteria document for DEHP was made available for public comment on May 14, 1990, (55 FR 1986). This draft proposed establishing a chronic criteria of 360 ug/L and an acute criteria of 400 ug/L for both freshwater and saltwater. EPA is announcing the availability of an information document on aquatic life toxicity for Di-2-Ethylhexyl Phthalate for the protection of freshwater and

saltwater aquatic organisms. This final document was derived after consideration of all comments received and following analysis of additional data received after the draft document was published in 1990.

### **Summary of Information Document on Aquatic Life Toxicity for Di-2-Ethylhexyl Phthalate**

The procedures described in the "Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses", (hereafter referred to as the Guidelines) do not allow for the derivation of national criteria for Di-2-Ethylhexyl Phthalate (DEHP), based on the available test information.

Limited data indicate that acute toxicity occurs to freshwater aquatic life at a concentration as low as 2,000 ug/L, which is above the reported solubility limit for DEHP. Based on water solubility values which ranged from 270 ug/L to 400 ug/L, the mean concentration of 334 ug/L was calculated as the best estimate of water solubility for DEHP for this document. Chronic toxicity occurs to one freshwater species at a concentration as low as 160 ug/L, and would occur at lower concentrations among untested species that are more sensitive.

DEHP toxicity data for saltwater aquatic life is limited. However, if the chronic sensitivity of saltwater aquatic life to DEHP is similar to that of freshwater aquatic life, adverse effects on individual species might be expected at  $\leq 160$  ug/L.

Data on the acute toxicity of DEHP are available for fourteen species of freshwater animals and four saltwater organisms. In nearly

species of freshwater animals and four saltwater organisms. In nearly all acute tests, the highest concentrations tested were not acutely toxic. Therefore, only "greater-than" the tested concentrations could be reported in this document. A final acute value for freshwater or saltwater organisms cannot be calculated because not enough definitive acute values exist to meet the minimum data base requirements according to the guidelines.

No final value, as defined in the Guidelines, can be calculated for either freshwater or saltwater plants. There is no Food & Drug Administration(FDA) action level or an available maximum dietary intake value derived from a chronic feeding study or a long-term field study with wildlife.

A final acute value cannot be calculated for DEHP, and only two acute-chronic ratios are available as greater-than values; therefore, no final chronic value for DEHP can be calculated using the final acute-chronic ratio procedure according to the Guidelines.

**Response to Public Comments on the Information Document on Aquatic Life Toxicity for Di-2-Ethylhexyl Phthalate**

Comments to the draft criteria document were made by the following: Chemical Manufacturers Association (CMA), American Water Works Association (AWWA), Monsanto Company, State of Ohio Environmental Protection Agency, Dow Chemical USA, Detroit Water and Sewerage Department, State of Maryland Department of the Environment, Utility Act Group.

The following are responses to comments by several organizations on the draft document for Di-2-Ethylhexyl Phthalate (DEHP), which was published in the Federal Register on May 14, 1990, (55 FR 11986, Docket No. OW-FRL-3762-9). The draft, dated 9/24/87, was revised by ERL-Duluth and ERL-Narragansett, based on these comments and additional literature information. EPA has chosen not to issue numerical national criteria for DEHP instead of the criteria initially proposed in the Federal Register draft, most of the comments are no longer issued. However, EPA has responded to each comment for the record.

The following comments represent a summary of the most important comments received. The complete response to public comment document can be obtained by contacting the Office of Water Resource Center at the previously noted address.

**Commentor** - EPA should withdraw the numerical Criteria Maximum Concentration (CMC) for DEHP and replace it with a narrative criterion of "free from floating material". The EPA should not



publish the final aquatic life criteria values that are strictly based on solubility for DEHP. EPA should not use the solubility limit as a surrogate for a CMC. The approach of using solubility results is unnecessarily stringent criteria. The EPA should not set water quality criteria in situations where no toxicity has been observed. CMA recommends that EPA formally withdraw the 1980 phthalate esters criteria document with notice in the Federal Register to avoid confusion and misunderstanding that result from continued use of this document.

**Response** - EPA agrees that the CMC for DEHP, as stated in the 9/24/87 draft document, should not be used. EPA acknowledges the fact that a numerical CMC cannot be calculated for Di-2-- Ethylhexyl Phthalate because not enough of the available acute toxicity test information provides definitive toxicity endpoints (i.e., LC50s) for calculating a Final Acute Value for either freshwater or saltwater organisms, according to the "Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses", hereafter referred to as the Guidelines. Several studies shows that DEHP is not toxic at the tested concentrations. This results in "greater than" LC50's for most tests with freshwater organisms and for all tests with saltwater organisms. Most often, concentrations greatly exceed the water solubility limit of 334 ug/L; EPA's best estimate based on the current literature. Therefore, EPA will not issue a freshwater or saltwater CMC for DEHP based on the available acute test information. The

information presented in this document will supersede previous national aquatic life water quality criteria for DEHP (U.S. EPA, 1976 1980 (Ref. 1 and 3 respectively).

**Commentor** - The Criteria Continuous Concentration (CCC) for DEHP should be recalculated using data previously submitted to EPA by the CMA Phthalate Esters Panel as part of a voluntary testing program under Section 4 of TSCA. The CCC for DEHP should be established at 200 ug/L based on available chronic toxicity data although it is less rigorous than the EPA Guidelines approach. The current chronic guidance value for all phthalate esters should be publicly withdrawn immediately. EPA should calculate separate CMC's and CCC's for freshwater and saltwater organisms.

**Response** - EPA acknowledges that not enough chronic toxicity tests are available to provide definitive endpoints for calculating the chronic values for DEHP. This lack of information combined with the lack of definitive acute information also does not allow for calculation of a Final Chronic Value, according to the Guidelines. Therefore, EPA will not issue a freshwater or saltwater CCC for DEHP based on the available chronic test information. However, one chronic toxicity test indicates that DEHP is toxic to Daphnia magna (a freshwater cladoceran) at concentrations below DEHP's water solubility limit of 334 ug/L. Data provided by CMA show that DEHP concentrations as low as 160 and 290 ug/L are chronically toxic to this species. These results conflict with those from other studies which indicate that DEHP is only toxic to this same

species at concentrations above solubility (358 to 5,394 ug/L). Because of the large uncertainty associated with this range of results combined with limited definitive chronic data for DEHP, there is concern that this group of aquatic species could be affected unacceptably if populations are exposed for long periods of time to DEHP at concentrations  $\geq$  160 ug/L.

EPA is not recommending any CCC for DEHP, CMA's recommendation of using 200 ug/L as the CCC for this chemical is no longer an issue. However, this value cannot be recommended as a "level of concern" because CMA's own data show that concentrations  $\geq$  160 ug/L are chronically toxic. In addition, it is possible that untested concentrations that are lower than 160 ug/L could be toxic to cladocerans since the chronic value calculated from CMA's study is 110 ug/L, and effect concentrations could occur at still lower concentrations among untested freshwater species that are more sensitive than cladocerans.

Toxicity data for DEHP and saltwater aquatic life is very limited. However, if their chronic sensitivity to DEHP is similar to that of freshwater aquatic life, adverse effects on individual species might be expected at  $\leq$  160 ug/L. An ecosystem process, ammonia flux, has been shown to be reduced at 15.5 ug/L during summer months.

**Commentor** - Since human health and aquatic life criteria address different uses of a water body, EPA should view these criteria independently. Two separate criteria should be based on sound

scientific studies which are available for public review and comment.

**Response** - Information for deriving water quality criteria for the protection of human health and aquatic life are gathered independently of each other and are currently used separately for preparing individual criteria documents for human health and aquatic life protection. The 1987 draft document only included information on DEHP and aquatic life. In addition, the 1985 Guidelines do not involve human health concerns except for FDA action levels for fish oil or the edible portion of fish or shellfish. DEHP does not have a FDA action level at this time; therefore, aquatic life criteria cannot be influenced by residue that are used in connection with the protection of human health.

**Commentor** - The draft document assumes that DEHP is equal in toxicity to freshwater and saltwater organisms. A minimum data set for saltwater species should be derived with which to calculate saltwater criteria. Water quality factors such as pH, hardness, alkalinity and temperature can play a major role in the toxicity of a constituent. Ideally, the water quality factors likely to impact the toxicity of a constituent should be determined and factored into the development of the Criteria Continuous Concentration (CCC) and the Criteria Maximum Concentration (CMC) numbers. If this is not performed, the states should be allowed flexibility to set water quality criteria based on both positive and negative influence from other water quality factors.

**Response** - EPA agrees that there is not enough data to meet the minimum data base for deriving criteria for saltwater organisms and will not issue a saltwater criteria for DEHP. EPA agrees that water quality factors can play a major role in the toxicity of a chemical and already uses this type of information for deriving criteria, if it is available. Although more information is needed to discern correlations between the above stated factors and the toxicity of DEHP, the limited current information on this chemical does not indicate that such correlations exist.

At the present time, states are allowed the flexibility to derive criteria with any data that are acceptable to the Guidelines and, in addition, are allowed to modify national criteria to site-specific criteria to better reflect local conditions including instances where the above factors may impact toxicity.

**Commentor** - The latest comprehensive literature searches for information for the DEHP document was conducted four years ago. This information document, therefore, may already be out of date. More timely literature searches should be conducted for this an criteria documents.

**Response** - EPA agrees that the literature search for this document is out of date and a new search was conducted in September of 1992. New information from this search has been added to the revised document.

**Commentor** - Many different water solubilities for DEHP are given in the published literature. How did EPA arrive at 400 ug/L as the water solubility for DEHP?

**Response** - Many values for DEHP water solubility are indicated in various published studies. However, only the values derived from studies specifically designed to measure water solubility were considered useable in the 1987 draft (270, 300, 340, 360 and 400 ug/L), and the highest value of 400 ug/L was chosen to provide the most liberal estimate of the amount of DEHP that would be possible in aqueous solution. However, EPA has now revised the estimate to be 334 ug/L by using the mean concentration from the five values listed above.

**Commentor** - The bioconcentration discussion in the document lacks information on the metabolism of DEHP by fish and reported BCF's are for total <sup>14</sup>C analyses, not DEHP.

**Response** - Information now included in the revised draft document for DEHP shows that DEHP can be metabolized by fish (Barron et al., 1989). The Bioconcentration Factors (BCF's) Environmental Protection Agency: AWOC for DEHP - Page 8 of 8 reported in Table 5 of this draft are based on measurements of <sup>14</sup>C in water and tissue and most likely include concentrations of both DEHP and stable metabolites. Consequently, these factors are probably overestimating the bioaccumulation potential of DEHP in the organisms shown in table 5 of the 1987 draft document. However, since the concentrations of actual DEHP relative to the concentrations of it's metabolites are not known for the

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organisms listed, the bioconcentration factor are EPA's best estimate of DEHP bioaccumulation. EPA also agrees that more information is needed to better estimate DEHP bioaccumulation in aquatic organisms. Since there is no FDA action limit or an available maximum dietary intake value derived from a chronic feeding study or a long-term field study with wildlife, a Final Residue Value (FRV) for DEHP cannot be calculated and, therefore, criteria based on a FRV cannot be derived at this time.

Dated: *September 13 1995.*

*Tudor T. Davies.*

Tudor T. Davies, Director

Office of Science and Technology

## References

1. U.S. EPA; "Quality Criteria for Water-1976"; EPA-440/9-76 023; NTIS # PB 263-943. National Technical Information Service. Springfield, VA. pp.191-192.
2. Federal Register notice November 28, 1980; 45 FR 79339.
3. U. S. EPA; "Ambient Water Quality Criteria for Phthalate Esters" October 1980, EPA-440/5-80-067.
4. U. S. EPA Draft "Ambient Water Quality Criteria for Di-2 Ethylhexyl Phthalate; September 24, 1987; 440/5-87-013
5. Stephen, C.E., D.I. Mount, D.J. Hansen, J.H. Gentile, G.A Chapman and W.A. Brungs. 1985 ; 822R85100. "Guidelines for Deriving National Water Quality Criteria for the Protection of Aquatic organisms and Their Uses". PB85-227049. National Technical Information Service Springfield, Va.
6. Barron, M.G., I.R. Schultz and W.L. Hayton. 1989. Presystemic brachial metabolism limits di-2-ethylhexyl phthalate accumulation in fish. Toxicol. Appl. Pharmacol 98:48-57.