Di-2-ethyhexyl

$2/1X + (.0187 \times 95) = 42$
$2/1 + 1.7765 = 42$
$3.7765X = 42$
$X = 11.12$ mg/l (or ≈ 10 mg/l)

Thus, the recommended water quality criteria for four phthalate esters are:

dimethyl, 160 mg/l
diethyl, 60 mg/l
dibutyl, 5 mg/l
di-2-ethyhexyl, 10 mg/l
(see Table 11).

It seems clear that exposure from the water route presents no real risk to the population in regard to the phthalate esters. Reported levels of phthalate esters in U.S. surface waters have only been in the ppb range; at approximately 1 to 2 µg/l (see Ingestion from Water section).

Other routes of exposure such as inhalation (industrial sites manufacturing the esters), dermal exposure, consumption of certain fatty or fatty-like foods and certain fish will be the major contributors to the body-load of phthalate esters. Phthalate ester residues in foods such as margarine, cheese and milk may, on some occasions, reach 50 ppm. Also a special group at risk will be patients to whom chronic transfusions of blood and blood products are administered.

Although it is recognized that routes of exposure other than water contribute more to the body burden of phthalate esters, this information will not be considered in forming ambient water quality criteria until additional analysis can be made. Therefore, the criteria presented assumed a risk estimate based only on ambient water exposure.

The need for more accurate residue content of foods, fish and water is still very apparent and, as more data become available, a reevaluation should be made as to the possible hazard to the population by the ingestion of phthalate esters.

Polychlorinated Biphenyls

Criteria Summary

Freshwater Aquatic Life. For polychlorinated biphenyls the criterion to protect freshwater aquatic life as derived using the Guidelines is 0.0015 µg/l as a 24-hour average and the concentration should not exceed 6.2 µg/l at any time.

Saltwater Aquatic Life. For polychlorinated biphenyls the criterion to protect saltwater aquatic life as derived using the Guidelines is 0.024 µg/l as a 24-hour average and the concentration should not exceed 0.20 µg/l at any time.

Human Health. For the maximum protection of human health from the potential carcinogenic effects of exposure to chloroform through ingestion of water and contaminated aquatic organisms, the ambient water concentration is zero. Concentrations of chloroform estimated to result in additional lifetime cancer risks ranging from no additional risk to an additional risk of 1 in 100,000 are presented in the Criterion Formulation section of this document. The Agency is considering setting criteria at an interim target risk level in the range of 10^{-6}, 10^{-6}, or 10^{-7}, with corresponding criteria of 0.2 ng/l, 0.02 ng/l and 0.002 ng/l respectively.

Basis for the Criteria

Freshwater Aquatic Life. The maximum concentration of polychlorinated biphenyls is the Final Acute Value of 6.2 µg/l and the 24-hour average concentration is the Final Chronic Value of 0.0015 µg/l. No important adverse effects on freshwater aquatic organisms have been reported to be caused by concentrations lower than the 24-hour average concentration.

For polychlorinated biphenyls the criterion to protect freshwater aquatic life as derived using the Guidelines is 0.0015 µg/l as a 24-hour average and the concentrations should not exceed 6.2 µg/l at any time.

Summary of Available Data

Final Fish Acute Value + 7.7 µg/l
Final Invertebrate Acute Value = 6.2 µg/l
Final Acute Value = 6.2 µg/l
Final Fish Chronic Value = 0.20 µg/l
Final Invertebrate Chronic Value = 0.73 µg/l
Final Plant Value = 0.10 µg/l
Residue Limited Toxicant
Concentration = 0.0015 µg/l
Final Chronic Value = 0.0015 µg/l
0.44 x Final Acute Value = 2.7 µg/l

Saltwater Aquatic Life. The maximum concentration of polychlorinated biphenyls is the Final Acute Value of 0.20 µg/l and the 24-hour average concentration is the Final Chronic Value of 0.024 µg/l. No important adverse effects on saltwater aquatic organisms have been reported to be caused by concentrations lower than the 24-hour average concentration.

For polychlorinated biphenyls the criterion to protect saltwater aquatic life as derived using the Guidelines is 0.024 µg/l as a 24-hour average and the concentration should not exceed 0.20 µg/l at any time.

Summary of Available Data. The concentrations below have been rounded to two significant figures.

Final Fish Acute Value = not available
Final Invertebrate Acute Value = 0.20 µg/l
Final Acute Value = 0.20 µg/l
Final Fish Chronic Value = 0.049 µg/l
Final Invertebrate Chronic Value = not available
Final Plant Value = 0.1 µg/l
Residue Limited Toxicant
Concentration = 0.024 µg/l
Final Chronic Value = 0.024 µg/l
0.44 x Final Acute Value = 0.087 µg/l

Human Health. An assessment of carcinogenic risk will be made by extrapolation from animal data using a linear (non-threshold) model. The model used takes into account the bioaccumulation of PCBs in fish and shellfish. It is assumed that an average of 2 liters/day of water are consumed along with 18.7 g of fish taken from that water source. Exposures from other food sources, air or occupational exposure are not included in the risk assessment.

Among the studies reviewed by this document, only one appears suitable for use in the cancer risk assessment. None of the mouse studies involved feeding for most or all of a lifetime and are therefore unsuitable. Of the rat studies, the only one involving long term exposure and adequate numbers of animals is the study in Sherman rats by Kimbrough, et al. (1975)[1].

This study has some drawbacks in that it lacks any evidence of a dose-response (due to the use of only one dose level), it tests only one sex of the species, and only one commercial mixture of PCBs was tested. Yet the experimental design is a good one in many ways: the treatment was given over a good proportion of the lifespan, there was an appropriate route (food) and distribution of exposure (uniform dose over time), the authors provided good documentation of the actual intake dose, a sufficiently large number of experimental and control animals were used to detect a statistically significant increase in tumors and there was a thorough and well documented description of the pathology (hepatocellular carcinoma). The NCI study (1978)[2] was the only other study involving a long term exposure and was suggestive of a carcinogenic effect; however, the lack of an adequate number of animals renders it unsuitable as a study upon which to base an estimate of carcinogenic risk.

Under the Consent Decree in *NRDC vs. Train*, criteria are to state "recommended maximum permissible concentrations (including where

[1] Kimbrough, R. D., et al. 1975. Induction of liver tumors in Sherman strain female rats by polychlorinated biphenyl Aroclor 1260. Jour. Natl. Cancer Inst. 55: 1453.

[2] National Cancer Institute. 1978. Bioassay of Aroclor 1254 for possible carcinogenicity. Carcinogenesis Technical Report Series No. 38, DHEW Publ. No. (NIH) 78-838, 62 pp.