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Agency

Office of Health and
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Research and Development

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Project Summary

Health and Environmental Effects Profiles: Fiscal Year 1984

In 1984 a total of 96 Health and Environmental Effects Profiles were prepared by the Environmental Criteria and Assessment Office, Cincinnati, OH, for the Office of Solid Waste, Washington, D.C. These profiles are utilized to support listings of hazardous constituents of a wide range of waste streams under Section 3001 of the Resource Conservation and Recovery Act (RCRA). Both published literature and information obtained from Agency program office files were evaluated as they pertained to potential human health, aquatic life and environmental effects of hazardous waste constituents.

This Project Summary was developed by EPA's Environmental Criteria and Assessment Office, Cincinnati, OH, to announce key findings of the research project that is fully documented in 96 separate reports (see Project Report ordering information at back).

The Environmental Criteria and Assessment Office, Cincinnati, OH of the Office of Health and Environmental Assessment, Office of Research and Development prepared 96 Health and Environmental Effects Profiles (HEEPs) for the Office of Solid Waste in fiscal year 1984. These profiles provide a comprehensive review of all available information on the toxicological effects of specific chemicals or compounds, or chemical groups. Computerized literature searches were performed on a variety of scientific data bases, all pertinent Agency files examined and hand searches of more recent literature performed. All information was compiled and evaluated pertaining to potential human health, aquatic life and environmental effects of hazardous waste constituents.

The introductory material for each HEEP provides information on the molecular structure, CAS and NIOSH/RTECS numbers, physical and chemical properties, and production and use data for each chemical. Environmental fate and transport processes in air, water and soil are also examined and related to potential and actual exposure of human and other biological systems to each toxic substance. The pharmacokinetic profile (absorption, distribution, metabolism, and excretion data) of each chemical is also discussed.

Subsequent sections of each HEEP discuss the health and environmental effects of exposure to the chemical(s). Experimental end points critically examined in each HEEP include carcinogenicity, mutagenicity, teratogenicity and other reproductive effects, and chronic and subchronic toxicity. Other effects relevant to risk estimation may also be noted. Acute and chronic effects in aquatic environments (e.,g., effects on plankton, macroinvertebrates and fish) may be discussed if data are avaiable.

Acute, subchronic (i.e., exposure for an interval that does not constitute a significant portion of the lifespan) and chronic exposure data for any route of exposure are identified. In general, data that yield a more developed dose-response curve are more likely to be included in the HEEP literature summary. Although human epidemiological studies may also be described in the HEEP, most of the studies described utilize animal models.

The final chapter of each HEEP presents a health risk assessment. Existing standards for aquatic environments and for human exposure are cited. Quantitative estimates are presented, provided sufficient data were available. For systemic toxicants (that is,

systemic refers to an effect other than carcinogenicity or mutagenicity induced by a toxic chemical), Acceptable Daily Intakes (ADIs) for chronic exposure are determined. An ADI is defined as the amount of a chemical to which humans can be exposed on a daily basis over an extended period of time (usually a lifetime) without suffering a deleterious effect. In the case of suspected carcinogens, ADIs are not estimated in this document series. Instead, a carcinogenic potency factor, or q_1^*, is provided. These potency estimates are derived for both oral and inhalation exposures where possible. In addition, unit risk estimates for air and drinking water are presented based on inhalation and oral data, respectively.

Calculation of the ADI is based on a No-Observed-Adverse-Effect Level (NOAEL) or a No-Observed-Effect Level (NOEL) for chronic exposure. The NOAEL or NOEL is determined from an appropriate human or animal study. The chosen NOAEL (or NOEL) is divided by an uncertainty factor(s), which reduces the NOAEL by a factor of ten for each of several confounding factors. These factors include the protection of especially sensitive individuals in the population, extrapolation of animal data to human exposure, extrapolation of subchronic data to chronic exposure, and extrapolation of a Lowest-Observed-Adverse-Effect Level (LOAEL) to a NOAEL. When existing studies are not sufficient for risk assessment, the best of the available studies are summarized, deficiencies in study design are noted, and areas requiring additional research are identified. In some cases Confidential Business Information (CBI) files have been summarized as they pertain to risk assessment.

Chemicals under study may also be evaluated for carcinogenic potential based upon carcinogenesis studies of males and females of one or more species of animals. Chemicals are considered carcinogenic in animals if data from animal studies demonstrate a clear dose-response relationship between exposure and tumorigenesis, or if highly suggestive evidence of tumorigenesis in animals is supported by positive results in human exposure studies and/or mutagenesis assays.

The cancer unit risk, q_1^*, is usually derived from a linearized multistage model with 95% upper confidence limits providing a low-dose estimate of cancer risk. It represents an increment of risk per milligram of chemical per kilogram of body weight per day. The cancer risk is characterized as being an upper limit estimate, that is, the true risk to humans, while not identifiable, is not likely to exceed the upper limit estimate and in fact may be lower.

The carcinogenicity of a chemical or compound may also be classified according to the scheme developed by EPA's Carcinogen Assessment Group based on the weight of evidence of carcinogenicity in human and animal data. This classification consists of five groups:

Group A: Human Carcinogen

This group is used only when there is sufficient evidence from epidemiologic studies to support a causal association between exposure to the agents and cancer.

Group B: Probable Human Carcinogen

This group includes agents for which the weight of evidence of human carcinogenicity based on epidemiologic studies is "limited" and also includes agents for which the weight of evidence of carcinogenicity based on animal studies is "sufficient".

Group C: Possible Human Carcinogen

This group is used for agents with limited evidence of carcinogenicity in animals in the absence of human data.

Group D: Not Classifiable as to Human Carcinogenicity

This group is generally used for agents with inadequate human and animal evidence of carcinogenicity or for which no data are available.

Group E: Evidence of Non-Carcinogenicity for Humans

This group is used for agents that show no evidence for carcinogenicity in at least two adequate animal tests in different species or in both adequate epidemiologic and animals studies. This designation should not be interpreted as a definitive conclusion that the agent will not be a carcinogen under any circumstances.

Each HEEP document concludes with a list of primary and secondary references and a tabular summary of the study or studies used for risk assessment.

The quantitative risk assessment conclusions are presented in Table 1 for carcinogens and Table 2 for noncarcinogens. In the 96 documents, 111 specific chemicals, compounds and isomers are evaluated. Of these 33 are human or animal carcinogens and 78 are either noncarcinogens, or are of unknown carcinogenic potential. Acceptable Daily Intake values are determined for 51 of the 78.

Table 1 *Carcinogens**

Chemical	q_1^* (mg/kg bw/day)$^{-1}$
Acephate	6.6×10^{-3}
Alachlor	1×10^{-1}
Bromacil	6.4×10^{-2}
Bromoethene	1.1×10^{-1}
1,3-Butadiene	ID
Captafol	8.6×10^{-3}
Captan	1.0×10^{-2}
Chlorobenzilate	1.7×10^{-1}
Chlorothalonil	2.9×10^{-3}
Diallate	7.8×10^{-1}
Dibenzofurans, tetra-, penta-, & hexachloro	ID
1,2-Dibromoethane	ID
1,2-Diethylhydrazine	ID
1,1-Dimethylhydrazine	8.7
1,2-Dimethylhydrazine	1.4×10^{3}
Dioxins, tetra-, penta-, & hexachloro-dibenzo-p-	ID
Ethylene thiourea	1.8×10^{-1}
Folpet	5.0×10^{-3}
Hydrazine	ID
Hydrazine sulfate	3.0
Linuron	9.8×10^{-3}
Methylene, 4-4'-(bis) benzeneamine	2.5×10^{-1}
Methylhydrazine	1.1
Oxirane	1.3
2-Phenylphenol	1.9×10^{-3}
Profluralin	2.8×10^{-2}
Propazine	7.8×10^{-2}
Sodium diethyl dithiocarbamate	2.5×10^{-1}
Stirofos	2.4×10^{-2}
Toluidines	
o-isomer	2.4×10^{-1}
m-isomer	ID
p-isomer	1.9×10^{-1}
Trifluraline	2.9×10^{-2}

*As new data are generated, these values are subject to change

ID = Insufficient data

Table 2 *Noncarcinogens**

Chemical	ADI (mg/kg bw/day)
Allidochlor	ID
Ametryn	1×10^{-2}
Atrazine	ID
Benefin	2.5×10^{-1}
1,1-Biphenyl	5×10^{-2}
Brominated diphenyl ethers	
Pentabromo-	4.4×10^{-4}
Octabromo-	6.2×10^{-4}
Decabromo-	1×10^{-2}
Bromobenzenes	
Class	ND
1,4-Dibromo-	1×10^{-2}
1,2,4-Tribromo-	5×10^{-3}
Hexabromo-	2×10^{-3}
Bromoxynil	6×10^{-2}
Bromoxynil octanoate	3×10^{-1}
Busan 77	ID

(Continued)

Table 2 (Continued)

Chemical	ADI (mg/kg bw/day)
Busan 90	ID
Butylate	1×10^{-1}
Butyrolactone, gamma-	ID
Carbaryl	9.6×10^{-2}
Carbofurans	ID
2-Chloro-1,3-butadiene	1.9×10^{-3}
Chloropropenes	
3-Chloropropene	1.6×10^{-3}
1,2,3-Trichloropropene	4.6×10^{-3}
Other isomers	ID
Chlorpyrifos	1×10^{-2}
Chlorpyrifos, methyl	1×10^{-2}
Chrysene	ID
Cyanazine	6×10^{-3}
Cycloate	ID
Dalapon	8.5×10^{-2}
2,4-DB	8×10^{-3}
DCPA	4.8×10^{-2}
Diazinon	9×10^{-4}
Dichlorobutenes	ID
Dichloroprop	2.5×10^{-1}
Dimtehoate	2.0×10^{-2}
Dimethyl terphthalate	8.8
Dinitrophenols	
2,4-isomer	ID
Other isomers	ID
Dinoseb	1×10^{-3}
EPTC	5×10^{-2}
Ethoprop	ID
Fluridone	9×10^{-2}
Isopropalin	5.6×10^{-2}
Mancozeb	2.9×10^{-2}
Maneb	5×10^{-3}
MCPA	1×10^{-3}
MCPB	1×10^{-3}
MCPP	3.4×10^{-3}
Mephosfolan	9×10^{-5}
Merphos	1.8×10^{-3}
Merphos oxide	2.5×10^{-3}
Methylcyclohexane	ID
Methyl ethyl benzenes	ID
Molinate	6.3×10^{-4}
Monochlorobutanes	ID
N,N-Dimethylurea	ID
N-Propyl alcohol	ID
Pebulate	5×10^{-2}
Pendimethalin	5×10^{-3}
Phosphorothioic acid, trimethyl esters	ID
Propachlor	1.3×10^{-2}
2-Propenoic acid	ID
Ronnel	5×10^{-2}
Selected toluenediamines	
2,5-isomer	5.6×10^{-1}
2,6-isomer	1.6×10^{-1}
Other isomers	ID
Simazine	ID
TCMTB	2.5×10^{-2}
Temephos	5.4×10^{-3}

(Continued)

Table 2. (Continued)

Chemical	ADI (mg/kg bw/day)
Terbufos	1×10^{-4}
Terephthalic acid	ID
Triallate	1.5×10^{-2}
Trichloropropanes	ID
Trinitrophenols	ID
Vernolate	5×10^{-2}
4-Vinyl-1-cyclohexene	ID
Zineb	5×10^{-2}

*As new data are generated, these values are subject to change

ID = Insufficient data
ND = Not determined

This Project Summary was prepared by staff of the Environmental Criteria and Assessment Office, USEPA, Cincinnati, OH 45268. This Project Summary covers 96 separate reports, entitled "Health & Environmental Effects Profile for–,"

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