Pydrin; CASRN 51630-58-1

Human health assessment information on a chemical substance is included in the IRIS database only after a comprehensive review of toxicity data, as outlined in the IRIS assessment development process. Sections I (Health Hazard Assessments for Noncarcinogenic Effects) and II (Carcinogenicity Assessment for Lifetime Exposure) present the conclusions that were reached during the assessment development process. Supporting information and explanations of the methods used to derive the values given in IRIS are provided in the guidance documents located on the IRIS website.

STATUS OF DATA FOR Pydrin

File First On-Line 03/31/1987

Category (section)	Assessment Available?	Last Revised
Oral RfD (I.A.)	yes	03/31/1987
Inhalation RfC (I.B.)	not evaluated	
Carcinogenicity Assessment (II.)	not evaluated	

I. Chronic Health Hazard Assessments for Noncarcinogenic Effects

I.A. Reference Dose for Chronic Oral Exposure (RfD)

Substance Name — Pydrin CASRN — 51630-58-1 Last Revised — 03/31/1987

The oral Reference Dose (RfD) is based on the assumption that thresholds exist for certain toxic effects such as cellular necrosis. It is expressed in units of mg/kg-day. In general, the RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. Please refer to the Background Document for an elaboration of these concepts. RfDs can also be derived for the noncarcinogenic health effects of substances that are also carcinogens. Therefore, it is essential to refer to other sources of

information concerning the carcinogenicity of this substance. If the U.S. EPA has evaluated this substance for potential human carcinogenicity, a summary of that evaluation will be contained in Section II of this file.

I.A.1. Oral RfD Summary

Critical Effect	Experimental Doses*	UF	MF	RfD
Neurological dysfunction	NOEL: 50 ppm (diet) (2.5 mg/kg/day)	100	1	2.5E-2 mg/kg/day
13-Week Rat Feeding Study	LEL: 150 ppm (diet) (7.5 mg/kg/day)			
Shell Development Co, 1984				

^{*}Conversion Factors and Assumptions — Doses in mg/kg bw/day calculated from food consumption data.

I.A.2. Principal and Supporting Studies (Oral RfD)

Shell Development Company. 1984. MRID No. 00151030. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Fenvalerate (84% A-alpha isomer) was administered in the diet at levels of 0, 50, 150, 300 and 500 ppm to groups of 30 Sprague-Dawley rats/sex for a period of 13 weeks. All rats in the 500 ppm group, several in the 300 ppm group, and one rat in the 150 ppm group exhibited neurological dysfunction characterized by one or more of the following: 1) "jerky leg movement" (shaking of forepaws in a fanning motion) was present, 2) flexion of the hind limb was prolonged or exaggerated and during ambulation the limb was momentarily suspended and held posteriorly, 3) gait was unsteady or uncoordinated, 4) there was hypersensitivity to sound and/or convulsions prior to death. Body weight gain was decreased in males and females in the 500-ppm group and in males in the 300-ppm group. Food consumption was decreased, although relative food consumption was increased in rats in the 500-ppm group. Males in the 500-ppm group exhibited slight hypertrophy of the parenchymal cells of the pars intermedia of the pituitary gland. Males and females in the 500-ppm group exhibited slight hypertrophy of the parenchymal cells of the parsible to the particles of the particles alivary gland and a few of these rats also had hypertrophy of

the submaxillary salivary glands. A few rats in the 300-ppm group had hypertrophy of the parenchymal cells of the parotid salivary gland.

I.A.3. Uncertainty and Modifying Factors (Oral RfD)

UF — An uncertainty factor of 100 was used to account for inter- and intraspecies differences. The UF of 1000 generally used on subchronic toxicological endpoints was not considered necessary in this case, since comparing the NOELs from the chronic and subchronic studies shows that chronic exposure does not lower the NOEL for this chemical.

MF — None

I.A.4. Additional Studies/Comments (Oral RfD)

The rationale for using the rat subchronic feeding study rather than the rat chronic feeding study is as follows: Initially, an ADI was set based on the results of the chronic study. The test material, pydrin, was composed of 4 stereoisomers: A-alpha, B-alpha, A-beta and B-beta in equal proportions. However, only the A-alpha isomer possesed significant insecticidal activity. Therefore, the sponsor developed a new pydrin technical (ASANA) consisting primarily of the A-alpha isomer. Rather than rerun all the studies, a decision was made to run a 13-week study with the new pydrin technical for comparing the relative toxicities of the two different technicals. As a result, the new technical was found to be 5 times more toxic using neurological dysfunction as an endpoint. (This involved comparing the NOEL of 250 ppm in the 2-year rat study with the racemic fenvalerate technical to the NOEL of 50 ppm in the 13-week rat study with the enriched fenvalerate technical.) Neurological dysfunction is the most sensitive indicator of pydrin toxicity in rats, and is apparent in the early phase of repeated-dose studies. Therefore, the NOEL observed in the 13-week study could adequately reflect the NOEL that would be expected if a chronic study had been run based on the most sensitive parameter (neurological dysfunction). Therefore, it was decided to use a 100-fold uncertainty factor with the NOEL observed in the 13week study in order to determine the RfD.

Subchronic feeding studies were conducted in the rat with both the racemic and A-alpha enriched fenvalerate technicals. For the study with racemic fenvalerate technical, the NOEL was 125 ppm. For the study conducted with the A-alpha enriched fenvalerate technical, the NOEL was 50 ppm.

Data Considered for Establishing the RfD: [All studies were conducted with racemic fenvalerate technical, with the exception of 1) the 13-Week rat feeding study and 2) the 1-year dog feeding study (currently being written)]

1) 13-Week Feeding - rat: Principal study - see previous description; core grade minimum

- 2) 6-Month Feeding dog: Systemic NOEL=250 ppm (6.25 mg/kg/day) (emesis, headshaking, biting of the extremities, normocytic anemia, increased serum cholesterol levels, possible CNS and peripheral nerve dysfunction, hepatic microgranule matosis); core grade guideline (Shell Chemical Co., 1981a)
- 3) 2-Year Feeding/Oncogenic rat: Systemic NOEL=250 ppm (12.5 mg/kg/day) (HDT); core grade guideline (Shell Chemical Co., 1978a)
- 4) 3-Generation Reproduction rat: NOEL=250 ppm (l2.5 mg/kg/day) (HDT); core grade minimum (Shell Oil Co., 1978)
- 5) Teratology mouse: Teratogenic NOEL=50 mg/kg/day (HDT); no core grade (Shell Chemical Co., 1976)
- 6) Teratology rabbit: Teratogenic NOEL=50 mg/kg/day (HDT); no core grade (Shell Chemical Co., 1975)

Other Data Reviewed:

- 1) 2-Year Feeding/Oncogenic mouse: Systemic NOEL (males)=10 ppm (1.5 mg/kg/day); NOEL (females)=50 ppm (7.5 mg/kg/day); LEL (males)=50 ppm (7.5 mg/kg/day) (multifocal granulomata in lymph nodes, liver and spleen); LEL (females)=250 (37.5 mg/kg/day) (decreased body weight gain, multifocal granulomata in lymph nodes, liver and spleen); core grade guideline (Shell Chemical Co., 1978b)
- 2) 18-Month Feeding/Oncogenic mouse: Systemic NOEL=250 ppm (37.5 mg/kg/day) (HDT); no core grade (Shell Chemical Co., 1977)
- 3) 20-Month Feeding/Oncogenic mouse: Systemic NOEL=30 ppm (4.5 mg/kg/day); LEL=100 ppm (15 mg/kg/day) (decreased erythrocyte count, increase in MCV, granulomatous changes in liver and lymph nodes); core grade guideline (Shell Chemical Co., 1981b)
- 4) 2-Year Feeding/Oncogenic rat: Systemic NOEL=none; LEL=1000 ppm (50 mg/kg/day) (only dose level) (decreased body weight gain in males and females; reversible hind leg weakness in males); core grade supplementary (Shell Chemical Co., 1979)
- 5) 2-Year Feeding/Oncogenic rat: NOEL not proposed; dose levels 50, 150, 500 and 1500 ppm (2.5, 7.5, 25 and 75 mg/kg/day, respectively) [decreased body weight gain at 150 ppm (males) 500 and 1500 ppm (females), increased neutrophil count in males at 1500 ppm, giant-cell infiltration in lymph nodes and adrenals at 500 and 1500 ppm and giant-cell infiltration of spleen

at 1500 ppm, increased proliferation of reticuloendothelial cells in mesenteric lymph nodes at 500 and 1500 ppm]; core grade supplementary (Shell Chemical Co., 1981c)

Data Gap(s): 1-Year Dog Feeding Study (This study has been completed and the report is presently being written. According to a scientist at Shell, the NOEL will be 200 ppm, the HDT) - conversation with D. Peterson, 9/9/86

I.A.5. Confidence in the Oral RfD

Study — High Database — High RfD — High

The principal study is of good quality and is given a high confidence rating. Additional studies are generally of good quality; therefore, the database is given a high confidence rating. High confidence in the RfD follows.

I.A.6. EPA Documentation and Review of the Oral RfD

Pesticide Registration Files

Agency Work Group Review — 09/16/1986, 03/18/1987

Verification Date — 03/18/1987

Screening-Level Literature Review Findings — A screening-level review conducted by an EPA contractor of the more recent toxicology literature pertinent to the RfD for vinyl bromide conducted in August 2003 did not identify any critical new studies. IRIS users who know of important new studies may provide that information to the IRIS Hotline at hotline.iris@epa.gov or 202-566-1676.

I.A.7. EPA Contacts (Oral RfD)

Please contact the IRIS Hotline for all questions concerning this assessment or IRIS, in general, at (202)566-1676 (phone), (202)566-1749 (FAX) or hotline.iris@epa.gov (internet address).

I.B. Reference Concentration for Chronic Inhalation Exposure (RfC)

Substance Name — Pydrin CASRN — 51630-58-1

Not available at this time.

II. Carcinogenicity Assessment for Lifetime Exposure

Substance Name — Pydrin CASRN — 51630-58-1

This substance/agent has not undergone a complete evaluation and determination under US EPA's IRIS program for evidence of human carcinogenic potential.

III. [reserved]

IV. [reserved]

V. [reserved]

VI. Bibliography

Substance Name — Pydrin CASRN — 51630-58-1

VI.A. Oral RfD References

Shell Chemical Company. 1975. MRID No. 00071664. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Shell Chemical Company. 1976. MRID No. 00064329. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Shell Chemical Company. 1977. MRID No. 00071949. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Shell Chemical Company. 1978a. MRID No. 00082007, 0082244. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Shell Chemical Company. 1978b. MRID No. 00079876. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Shell Chemical Company. 1979. MRID No. 00079877. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Shell Chemical Company. 1981a. MRID No. 00093652; HED Doc. No. 004041. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Shell Chemical Company. 1981b. MRID No. 00093662; HED Doc. No. 004041. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Shell Chemical Company. 1981c. MRID No. 00093652; HED Doc. No. 004041. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Shell Development Company. 1984. MRID No. 00151030; HED Doc. No. 004681, 00005341. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Shell Oil Company. 1978. MRID No. 00085501. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

VI.B. Inhalation RfD References

None

VI.C. Carcinogenicity Assessment References

None

VII. Revision History

Substance Name — Pydrin CASRN — 51630-58-1

Date	Section	Description
10/28/2003	I.A.6	Screening-Level Literature Review Findings message has been added.

VIII. Synonyms

Substance Name — Pydrin CASRN — 51630-58-1 Last Revised — 03/31/1987

- 51630-58-1
- BELMARK
- BENZENEACETIC ACID, 4-CHLORO-alpha-(1-METHYLETHYL)-,CYANO(3-PHENOXYPHENYL) METHYL ESTER
- alpha-CYANO-3-PHENOXYBENZYL-2-(4-CHLOROPHENYL)-3-METHYLBUTYRATE
- CYANO(3-PHENOXYPHENYL)METHYL 4-CHLORO-alpha-(1-METHYLETHYL)BENZENEACETATE
- ECTRIN
- FENVALERATE
- PHENVALERATE
- Pydrin
- PYDRIN, alpha-CYANO-3-PHENOXYBENZYL-2-(4-CHLOROPHENYL)ISOVALERATE
- S 5602
- SANMARTON
- SD 43775
- SUMICIDIN
- SUMIFLY

- SUMIPOWER
- WL 43775