

Glyphosate/Tox

2-21-86

45

REFERENCE DOSES (RfDs) FOR ORAL EXPOSURE

RELEASABLE

Chemical: Glyphosate

CAS #: 1071-83-6

Caswell #: 661A

Carcinogenicity: Inadequate animal data for classification

Systemic Toxicity: See below.

Endpoint	Experimental Doses	UF	MF	RfD
3-Generation Rat Reproduction Study Bio/dynamics #77-2063	10 mg/kg/day (NOEL)	100		0.1 mg/kg/day
Increased incidence of renal tubular dilation in F3b offspring.	30 mg/kg/day (LEL)			

Endpoint and Experimental Doses:

Street, R.W., et al., 1981. A Three-Generation Reproduction Study in Rats with Glyphosphate. Bio/dynamics, Inc. Study #MSL-1724

Street, R.W., et al., 1982. Addendum to Pathology Report for a Three-Generation Reproduction Study with Rats. Bio/dynamics, Inc. Study #MSL-1724

Four groups of 12 males and 24 females were dietary concentrations of glyphosate that were adjusted so as to maintain treatment doses of 0, 3, 10 and 30 mg/kg/day. Treatment was for three generations, with two matings per generation. No effect of treatment on fertility was noted, nor were any systemic effects in adult rats apparent. An increase in the incidence of unilateral renal tubular dilation was noted in male pups from the F3b mating of the high dose (30 mg/kg/day) group.

Preparation Date: 2/21/86

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Uncertainty Factors (UFs): The standard factor of 100 for extrapolation of animal data to human risk was used.

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Modifying Factors (MFs): NONE.

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Additional Comments: NONE.

Data Considered for Establishing the RfD

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| 1) Chronic feeding- rat | Systemic NOEL = 31 mg/kg/day (HDT)
(adequate data) |
| 2) Chronic feeding- dog | Systemic NOEL = 20 mg/kg/day (MDT)
Systemic LEL = 100 mg/kg/day (HDT)
Decreased absolute and relative pituitary weights.
(excellent study) |
| 3) Reproduction- rat | Systemic NOEL = 30 mg/kg/day (HDT)
Reproductive NOEL = 10 mg/kg/day (MDT)
Renal tubular dilation in pups.
(adequate data) |
| 4) Teratology- rat | Maternal NOEL = 1000 mg/kg/day (MDT)
Developmental NOEL = 1000 mg/kg/day (MDT)
(Ossification delay) (adequate data) |
| 5) Teratology- rabbit | Maternal NOEL = 175 mg/kg/day (MDT)
Developmental NOEL = 350 mg/kg/day (HDT)
(adequate data) |

Data Gap(s)

Chronic feeding- dog
Oncogenicity- rat

Other Data Considered

Oncogenicity- mouse low incidence of kidney tumors observed, however, providing insufficient evidence of oncogenicity. Group D not classified (per Science Advisory Panel)

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Confidence in the RfD:

Study: High

Data Base: High

RfD: High

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Documentation of RfD and Review:

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Agency RfD Review:

First Review: 3/11/86

Second Review:

Verification Date: 3/11/86

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