

US EPA ARCHIVE DOCUMENT

Tox. Chem. No. Lindane -- 527

10/11/1985

Acceptable Daily Intake -  
EPA/ OPP / HED / Tox.

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Material :

Doc. No. for Updated ADI

004566

~~ADDI~~ PADI 0.00030 mg/kg/day

Safety Factor = 1000

Dated : 2/4/81, 10/13/82 ; and 7/11/85

Updated : 9/29/85

Study : 90-Day Rat Feeding (Guideline)

NOEL : 0.3 mg/kg

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Lab. : Research and Consulting Co.

Study No. : 005220

Study Date : 2/3/83

Doc. No. : 002993

O.K'ed 10/11/85  
R. L. Beyer  
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Comments:

Since (1) a data gap exists for a 2 year rat feeding study and (2) the NOEL for the 90-day rat feeding study is 0.3 mg/kg, which is more sensitive than the NOEL for the 2 year dog feeding study of 1.25 mg/kg, the 90-day rat feeding study with a safety factor of 1000 was selected in determining a PADI.

Q\* (liver tumors in mice) ~~not used~~

1/7/85

Lindane : PADI from a 90-Day Rat Feeding Study

As of 7/29/85, an ADI for Lindane (CFR 180.133) could not be located. A data gap exist for a 2-year rat feeding study. In an effort to support the published tolerances, a PADI was established from a 90-day rat feeding study. Since (1) a data gap exists for a 2-year rat feeding study and (2) the NOEL for the 90-day rat feeding study is 0.3 mg/kg, which is more sensitive than the NOEL for the 2-year dog feeding study of 1.25 mg/kg, the 90-day rat feeding study with a safety factor of 1000 was selected in determining a PADI.

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Data Considered for Establishing an ADI, a PADI  
or PLD

1. 90-Day Feeding - rat (NOEL = 0.2 ~~mg/kg~~ or 4 ppm;  
guideline) <sup>used</sup> <sub>7</sub> NOEL = 0.3 mg/kg based on diet analysis
2. 2-year Feeding - dog (NOEL = 1.25 mg/kg or 50 ppm  
minimum)
3. Teratology - rat (maternal NOEL = 5 mg/kg; minimum)
4. Teratology - rabbit (maternal NOEL = 5 mg/kg; minimum)
5. Reproduction - (Reproductive NOEL = 5 mg/kg; minimum)

### Data Gap

1. 2-year Rat Feeding Study

### Other Considerations

1. 26-month Oncogenicity - mice (liver tumors)
2. 80-week Oncogenicity - mice (liver tumors)

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