Tox. Chem. No. Lindane - 527

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

Material:

PAD1

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

Lab.: Research and Consulting Co.

Study No.: 005220

Study Date: 2/3/83

Doc. No.: 002993

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 rat feeding study at 1.25 mg/kg, the 90-day rat feeding study with a safety factor of 1000 was selected in determining a PAD1.

[Handwritten note: "tumors in mice"]
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 existed 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.
Data considered for establishing an ADI, o PADI, or PEL

1. 90-Day Feeding - rat (NOEL = 0.2 mg/kg or 4 ppm guideline) and NOEL = 0.3 mg/kg based on histopathology
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)