

US EPA ARCHIVE DOCUMENT

RD Risk Assessment - Astex Mattress Cover
EPA File Symbol 71012-R

This assessment uses residue values from bed-sheet study with assumptions listed below to estimate short and intermediate dermal and chronic MOE's plus an estimate of cancer risks for adults and children (six years or older).

Background Information

Astex liners will be impregnated with **550 mg/m²** of permethrin. A bed sheet is placed over liner surface area of queen size bed 3.63 m² (6ft x 6.5ft)
60 kg adult comes in contact with 3 m² of the treated sheet area. (89% of the area of bed)
22 kg child comes in contact with 2.25 m² of the treated area (67% of the area of bed)
adult/child sleeps unclothed

Sampling data on permethrin was used to determine "**rub off**" rate (amount of residue in sheet) samples were taken from sheets covering liners impregnated with permethrin at rate of 200 mg/m² over 15 week period.

10 beds with cotton/polyester blend sheets and 10 beds with cotton sheet samples from the 20 beds were analyzed after: 1 week, 3 weeks, 7 weeks, and 15 weeks results: 10-15% more permethrin measured on cotton sheets for the risk assessment purposes it was assumed that the rub-off rate at 15-days would remain contact for 1 year

To compensate for the difference in the impregnated rate of 550 mg/m³ in the product vs. the rate used in the study a factor of 2.75x was used.

It was assumed that 50% of the residue measured in the sheet was available for dermal transfer (based on studies by Snodgrass in 92 and Asakawa in 96) a 50% dermal absorption was assumed. **(In 1994, HED recommended 50% dermal absorption, no changes from HED since then).**

RD used relevant toxicology endpoints as of 4/24/94, i.e.

Short Term NOEL - 25 mg/kg/day - acute neurotoxicity study in the rat/rabbit

Intermediate Term NOEL - 15.45 mg/kg/day - subchronic neurotoxicity study in the rat.

Chronic NOEL - 5 mg/kg/day - chronic rat and mouse feeding studies

Cancer - Q Star of 1.84×10^{-2} .

Formula for Exposure Calculations

Exp = Daily Residue 2.17 (short term), 1.26 (intermediate term) mg/m²/day; 2.11 (chronic adult), 2.98 (chronic child) ug/kg/day x 2.75 (factor for sheets with 550 mg/m²)
x body contact (3 m² for adults 2.25 for children 6 years +)
x dermal transfer (50% is transferrable) x dermal absorption 50% dermal absorption ÷
body weight
(70 kg (adult) (22 kg (child 6 yrs +)

MOE = NOEL/Exposure

The MOE for short term dermal exposure (Adult) is:

$$\frac{25 \text{ mg/kg/day}}{0.064 \text{ mg/kg/day}} = 390$$

The MOE for intermediate dermal exposure (Adult) is:

$$\frac{15.45 \text{ mg/kg/day}}{0.037 \text{ mg/kg/day}} = 417$$

The MOE for short term dermal exposure (Child 6 yrs. +) is:

$$\frac{25 \text{ mg/kg/day}}{0.152 \text{ mg/kg/day}} = 164$$

The MOE for intermediate dermal exposure (Child 6 yrs. +) is:

$$\frac{15.45 \text{ mg/kg/day}}{0.088 \text{ mg/kg/day}} = 175$$

The MOE for chronic exposure (Adult) is:

$$\frac{5.0 \text{ mg/kg/day}}{2.11 \text{ ug/kg/day}} = 2380$$

The MOE for chronic exposure (Child 6 yrs.+) is:

$$\frac{5.0 \text{ mg/kg/day}}{2.98 \text{ ug/kg/day}} = 1677$$

The MOE's for short and intermediate term exposure for children 2 to 5 yrs. were just barely over 100. In harmony with Canada Health risk assessment we decided against use of mattress covers on bedding for this age group.

Cancer Risk

Risk = Q* x estimated lifetime average daily exposure

$$1.84 \times 10^{-2} \times 0.4056 \times 10^{-3} \text{ mg/kg/day} = 7.46 \times 10^{-6} \text{ (Adults)}$$

$$1.84 \times 10^{-2} \times 0.5734 \times 10^{-3} \text{ mg/kg/day} = 1.05 \times 10^{-5} \text{ (Child 6 yrs.+)}$$

Conclusions and Limitations

1. The assessment from Protec Health did not include anything regarding oral exposure which seems likely for small children. To mitigate we labeled against us on bedding for children 5 yrs. and under.
2. The assessment did not include any estimate of exposure from a pillow case or duvet cover. Therefore we labeled against use on these items.
3. The rub-off rates are conservative and did not take into consideration washing of sheets. Review of the permethrin rub-off study submitted by Protec Health shows residues in laundered sheets (one to five washings) declined to near LOQ levels by week 14.
4. There are no estimates of aggregate short term, intermediate term or chronic exposure/ risk.
5. As a final risk mitigation measure we recommend that an additional sheet be placed between the bottom sheet and mattress cover.
6. The lifetime average daily exposure used in cancer risk assessment was taken from Canada Health. The time period for calculating chronic daily exposure was based on reapplication of a new liner every five (5) months (20 weeks). For purposes of U.S. assessment a reapplication time period of two (2) years was used. The risk exceeds the traditional 10^{-6} threshold. However exposure assumptions used in assessment (rub-off rate, dermal absorption) were conservative and use of additional sheet in between liner and top cover (item 5) should mitigate this risk.