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CHLORDIMEFORM RISK ASSESSMENT
February 1988

The risk estimates are for the upper 95% level for a B2 oncogen classification. Estimates were based on a life expectancy of 70 years and 35 years working lifetime. A potency factor (Q_1^*) for chlordimeform of .94 (see page 6) was used to calculate the risk estimates above. .94 represents the geometric mean of male and female Q_1^* 's for chlordimeform only.

The risk estimates for mixers/loaders based on the CDFA study were considered unrealistic because of the small sample size and extreme care taken by workers under observation.

Risk estimates for mixer/loaders based on the Ciba/Nor-Am urine data are consistent with those risk estimates based on the Agency's surrogate dermal data base, (10^{-3}).

No comments were received on the Agency's risk estimates to workers contained in the draft Registration Standard.

2. Dietary Risk

Since many plants and mammals are capable of metabolizing chlordimeform, dietary exposure, unlike worker exposure in which direct exposure is limited to chlordimeform, might represent a mixture of the parent compound and metabolites. There are no data available showing the proportion of chlordimeform and its metabolites which are in various food substances. Therefore, the Agency concluded that it would be reasonable at this time to estimate potency for dietary exposures by using the geometric mean of the Q_1^* 's for chlordimeform and the two metabolites tested for oncogenicity, N-formyl-4-chloro-o-toluidine and 4-chloro-o-toluidine. Using these potency estimates, a dietary cancer potency (Q_1^*) of $1.3 \text{ (mg/kg/day)}^{-1}$ was calculated.

Since the only registered use for chlordimeform is on cotton, potential dietary exposure is primarily from residues in cottonseed oil and in milk, meat and eggs from animals fed cotton seed products. Exposure levels for milk, the primary source of dietary exposure (see page II-19), are expected to be highest in the region with the highest chlordimeform use per person - the Delta (AL, AR, LA, MS, TN). Exposure for this region was estimated to be 7.0×10^{-8} mg/kg/day. This estimate is based on available data (compiled by the Agency from several sources including the USDA and the U.S. Department of Commerce) on the number of dairy cows in the Delta, the amount of chlordimeform treated feed fed to these dairy cows per year, the amount of chlordimeform in treated feed, the resulting residues in milk and the population of the region.

Using the Q_1^* and exposure estimate above, risk was calculated to be about 10^{-7} for people living in the Delta. This value will

be somewhat higher for local areas within the Delta, somewhat lower in other cotton-growing regions, and substantially lower in other parts of the country because, as previously stated, dietary exposure is significantly influenced by the amount of chlordimeform use per person in a specific region.

No comments were received on the Agency's dietary risk estimates contained in the draft Registration Standard.