

(**Federal Register** of June 1, 2000, Vol. 65, No 106, p. 35069–35090, Table 10; Guidance on Pesticide Import Tolerances and Residue Data for Imported Food). Furthermore, USDA's import statistics show that not more than 38% of beer consumed in the USA is imported and/or contains imported hops, which translates into a diet contribution from imported hops of not more than 0.0007%. For the purposes of this risk assessment, it was also demonstrated in brewing studies using hops treated with folpet at maximum label rates (range of residues: 25 to 65 ppm) and exaggerated hopping rates (0.002% or up to 2 g per liter wort) that no folpet residues could be measured in the finished beer (LOD = 0.003 ppm). Hopping rates in beer production are usually less than 0.001% in brew water (wort). Even considering that trace amounts of folpet would enter the brewing process, it will be rapidly hydrolyzed and completely degraded by the end of the beer brewing.

In view of this information and assumptions, the resulting dietary risk contribution via imported hops is negligible, even if 100% of the imported hops would be treated with folpet at maximum label rates.

ii. *Drinking water.* The potential for folpet to leach into groundwater or contaminate surface water is very limited considering that folpet is currently only registered for the use on avocados in two counties in Florida. Based on the available information, the predicted residues in drinking water do not indicate an unacceptable contribution to acute or chronic dietary exposure at this time. Since the proposed petition does not add any new uses or exposures to it, contribution of any folpet residues in drinking water to the total dietary intake is negligible.

2. *Non-dietary exposure.* Not applicable.

D. Cumulative Effects

There is a common mechanism of toxicity that folpet shares with captan with regard to its carcinogenicity in the mouse. Folpet and captan share the common metabolite, thiophosgene, which contributes to the irritancy of the duodenum in mice along with the parent compounds, leading (at dose levels above the established threshold and for administration with sufficient time) to adenomas. Thiophosgene reacts not only with thiol groups, as does folpet and captan, but also with a variety of other functional groups. This instability results in its rapid loss. The cumulative effect of captan and folpet oral exposure is of theoretical interest only, as the threshold for irritancy in the

mouse duodenum is above 60 mg/kg/day (captan) or 50 mg/kg/day (folpet). If the mouse test system reflected human susceptibility, a 70 kg individual would need to consume more than 3.5 grams folpet plus captan in order to approach the NOEL of 50 mg/kg/day. Given the expected residue levels of folpet and those of captan, this is not possible.

E. Safety Determination

1. *U.S. population.* Using the exposure assumptions described above, MANA concludes that the total dietary exposure to folpet is acceptable. According to import information statistics from the USDA and under the conservative (worst-case) dietary exposure assumption described above, not more than 0.0022% of the U.S. population diet is constituted of hops, which means not more than 0.0007% can potentially be contributed to imported hops. Based on these insignificant dietary contributions, MANA considers the potential folpet residue contribution negligible, concluding that the most sensitive population group of concern are still females (15–50 years) with an aPAD of 25% and a cPAD of <1%. There is generally no concern for exposures below 100% of the PAD since it represents the level at or below which no appreciable risks to human health is posed. The upper bound calculated dietary cancer risk was 9.8×10^{-8} , based on a Q^* of 0.00186 mg/kg/day⁻¹, which is far less than EPA's level of concern of 1×10^{-6} .

Thus, there is reasonable certainty that no harm will result to the U.S. population in general or to any of its subgroups of concern from aggregate exposure to folpet residues in or on imported hops.

2. *Infants and children.* Data from rat and rabbit development toxicity studies and rat multigeneration reproduction studies are generally used to assess the potential for increased sensitivity of infants and children. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development. Reproduction studies provide information relating to reproductive and other effects on adults and offspring from pre-natal and post-natal exposure to the pesticide.

FFDCA Section 408 provides that the Agency may apply an additional safety factor for infants and children to account for pre- and post-natal toxicity or incompleteness of the database. However, the toxicology database for folpet regarding potential pre- and post-natal effects in offspring is complete

according to existing Agency data requirements and does not indicate any particular developmental or reproductive concerns.

EPA assigned an FQPA safety factor of 3x in the 1999 Reregistration Eligibility Decision (RED). This was based on the apparent hydrocephaly seen in New Zealand rabbits. Subsequently, additional data were provided to the Agency that showed folpet does not induce hydrocephaly. The Agency agreed with the assessment contained in the submitted document and rescinded its request for a new rabbit study. The Agency has not, as of yet, removed the FQPA 3x safety factor. A FQPA safety factor of 1x would be also consistent with that of captan. The appropriate acute Reference Dose (aRfD) for folpet, calculated with a FQPA safety factor of 1x, would be 0.01 mg/kg/day. This aRfD should be used in future assessments concerning the potential risks to infants and children. However, for the purpose of this assessment, MANA used the existing aRfD of 0.03 mg/kg/day, as it was done in the 1999 RED.

MANA concludes that there is a reasonable certainty that no harm will result to infants and children from the anticipated dietary exposure to residues of folpet and considering that the proposed import tolerance does not affect foods and beverages legally consumed by children and infants.

F. International Tolerances

Germany has established an MRL (maximum residue limit) of 120 ppm for residues of folpet in dried hops. No CODEX MRL for hops exists.

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ENVIRONMENTAL PROTECTION AGENCY

[FRL–7437–1]

Proposed CERCLA Section 122(h)(1) Administrative Agreement for Recovery of Response Costs for the City Chemical Corporation Site, Hudson County, Jersey City, NJ

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; request for public comment.

SUMMARY: In accordance with section 122(i) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (“CERCLA”), 42 U.S.C. 9622(i), notice is hereby given by the U.S. Environmental Protection Agency (“EPA”), Region II, of a