

6.0 Potential Public Health Impacts of Renovate®

6.1 Brief Overview of Triclopyr Toxicity

An overview of the toxicology information indicates that triclopyr is not considered to be a carcinogen, mutagen or to cause adverse reproductive effects or birth defects. Triclopyr is considered to have a low degree of systemic toxicity based on findings from acute and subchronic toxicology studies (WDOE, 2001).

6.1.1 Acute Toxicity

There are four FIFRA acute Toxicity Categories, numbers I through IV (USEPA, 2003). Category I designates pesticides being the most toxic or irritating, while Category IV represents the least toxic or irritating chemicals. Pesticides in Categories II and III fall in between the two extremes. The acute oral, acute dermal, and acute inhalation toxicity of triclopyr are in Categories III, IV and IV, respectively. The skin irritation study in rabbits placed triclopyr in Category IV, indicating that it is non-irritating to the skin. The main adverse health effect appears to be associated with eye contact with concentrated triclopyr, which can result in severe eye irritation and damage. Results of undiluted triclopyr in acute eye irritation studies place the chemical in Toxicity Category I as causing irreversible eye damage (WDOE, 2001).

The results of a rat acute oral toxicity study determined that the LD₅₀ (dose causing lethality in 50% of the test animals) was approximately 2,000 mg/kg. The acute dermal LD₅₀ was > 5,000 mg/kg based on a study in rabbits. A rat acute inhalation toxicity study resulted in a 4-hour LC₅₀ (concentration causing lethality in 50% of the test animals) of >2.6 mg/L (WDOE, 2001).

SePRO recently conducted acute toxicity studies on the granular form of triclopyr (conducted by Product Safety Laboratories). These studies were completed in January, 2006. The results of these studies are generally similar to the previous acute toxicity study results summarized in WDOE (2001). An acute oral toxicity study in rats showed that the single dose acute oral LD₅₀ of the test substance is greater than 5,000 mg/kg of body weight in male and female rats. An acute dermal toxicity study in rats showed that the single dose acute dermal LD₅₀ of the test substance is greater than 5,000 mg/kg of body weight in male and female rats.

As part of the toxicity testing of triclopyr, inhalation studies were conducted even though the very low vapor pressure of triclopyr (1.26×10^{-6} mmHg at 25°C) makes it unlikely that the chemical vapor will be a health problem (Chakrabarti, 1988). An acute inhalation study based on the flake form of triclopyr showed the exposure acute inhalation LC₅₀ for triclopyr is greater than 2.04 mg/L in male and female rats. Previous acute inhalation studies with triclopyr TEA resulted in an LC₅₀ of >2.6 mg/L. The report by Product Safety Laboratories states that triclopyr meets the requirements for Toxicity Category IV for inhalation toxicity. Based on the results of the rat acute inhalation study and the large size of the spray droplets, it is considered unlikely that applicator workers or bystanders will be overexposed to triclopyr during aquatic herbicidal (WDOE, 2001).

A dermal sensitization study in guinea pigs indicated that triclopyr is not a contact sensitizer, since no skin response was noted at any of the doses tested. A primary skin irritation study conducted with rabbits showed that triclopyr is classified as non-irritating to the skin. A primary eye irritation study conducted with rabbits classified triclopyr as moderately irritating to the eye.

6.1.2 Subchronic and Chronic Toxicity

Results of a rat triclopyr 13-week dietary feeding study consisting of doses of 0, 5, 20, 50, 200 or 300 mg/kg-day demonstrated that animals in the 2 high dose groups displayed signs of decreased food consumption and body weight gain. None of the animals demonstrated any signs of systemic toxicity. No toxic effects were

observed in a 1-year dog dietary study at doses of 5 mg/kg-day. In a 21-day rat subchronic triclopyr dermal study with doses up to 342 mg/kg-day, there were no signs of toxicity or deaths during the 21-day test period. However, there was a dose-response degree of dermal irritation (WDOE, 2001).

The chronic or lifetime exposure effects from triclopyr have been evaluated in the mouse and rat. The findings from the investigations all show that triclopyr does not demonstrate any carcinogenic potential. In 1995, USEPA classified triclopyr as a Group D chemical (not classifiable as to human carcinogenicity). A 2-year rat triclopyr dietary study at doses up to 36 mg/kg-day showed that the high dose groups had increased kidney weights, but no signs of systemic toxicity. A mouse triclopyr lifetime feeding study at doses up to 1,250 mg/kg-day showed that the high dose groups had a significant decrease in body weights, but no signs of systemic toxicity. Various reproduction and teratology toxicology studies have not shown any evidence that triclopyr is associated with reproductive dysfunction or teratological effects (WDOE, 2001).

6.1.3 Metabolism

Metabolism and distribution tests have shown that triclopyr is rapidly absorbed from the gut and primarily excreted in the urine as the parent compound. Tests in rats showed that approximately 94% of the dose was excreted in the urine with an average half-life of 10 hours. The parent compound was excreted mainly unchanged. Triclopyr is poorly absorbed through the skin. Results of rabbit acute and subchronic investigations and a human dermal penetration study revealed that the chemical does not readily absorb through the skin (WDOE, 2001).

6.2 New York State Drinking Water Standard

There are no specific drinking water standards available for triclopyr. Section 702.15 of 6 NYCRR (Derivation of Guidance Values) states that a “general organic guidance value” of 50 ug/L may be used for an individual organic substance. In the Reregistration Eligibility Decision (RED; USEPA, 1998) for triclopyr, USEPA has developed a Reference Dose (RfD) for triclopyr of 0.05 mg/kg-day. An RfD is defined as an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. It can be derived from a NOAEL, LOAEL, or benchmark dose, with uncertainty factors generally applied to reflect limitations of the data used (USEPA, 2005). RfDs are used in risk assessments to assess risks and define acceptable limits of chemical exposure. The RfD may be used to develop a screening level acceptable concentration of triclopyr in drinking water. Using the RfD of 0.05 mg/kg-day and assuming that a 60-kg adult female drinks 2 L of water per day results in an acceptable concentration of triclopyr in drinking water of 1,500 ug/L.

$$\text{Concentration}(ug / L) = \frac{0.05mg / kg - day \times 60kg \times 1000ug / mg}{2L / day} = 1500ug / L$$

Even assuming a 20% source contribution factor (which is often used by USEPA in setting drinking water standards), the resultant concentration is 300 ug/L. This concentration is higher than 50 ug/L, so the 50 ug/L general organic guidance value should be adequately protective for drinking water.

While it is very unlikely that triclopyr would impact a drinking water source, potential risk to humans via drinking water due to application of Renovate® 3 is minimal because:

- Triclopyr use in waters of New York used for drinking water purposes is highly regulated and expected to result in intermittent exposures to those using such waters;

- Renovate® 3 labeling requires minimum setback distances in order to make applications in proximity to functioning potable water intakes (see: Table 4: Minimum Setback Distances from Functioning Potable Water Intakes in Appendix D); and
- Functioning potable water intakes must be turned off until the triclopyr level in the intake water is determined to be 50 ppb or less by laboratory analysis or immunoassay.

6.2.1 Risk from Recreation Exposure

A more likely exposure scenario would be someone swimming in a pond or lake that has been treated with triclopyr. The Washington State Department of Ecology (Triclopyr Questions and Answers; WDOI, undated) conducted a swimmer exposure assessment. The most conservative scenario considered was a six-year old who swims for three hours and inadvertently swallows 150 ml of water from a lake treated with the maximum allowable rate of triclopyr. The estimated amount the child would absorb in this scenario was still more than 100 times less than the daily dose animals were fed over their lifetime with no observable adverse effects. These results indicate that triclopyr application would not harm humans who may be exposed while swimming in a lake.

The Renovate® 3 product USEPA labeling does not bear any restrictions on use of water in the treatment area for recreational purposes, including swimming and fishing. However, the New York State Special Local Need (SLN) labeling has a “do not swim in the water treated with Renovate® 3 for three (3) hours after treatment” statement. Considering this temporary use restriction, as well as the documentation that triclopyr residues in water degrade rapidly via photolysis, the risks from exposure to triclopyr via recreational uses should be negligible based on the following:

- That triclopyr is slightly toxic via acute oral and dermal route of exposure and is not a dermal sensitizer; and
- That triclopyr use in waters of New York used for recreational purposes is highly regulated and expected to result in intermittent exposures to those using such waters.

6.2.2 Summary of Human Health Risk Concerns

When the USEPA established the tolerance for combined residues of triclopyr and its metabolites it conducted a comprehensive risk assessment using modeling and risk assessment techniques to estimate maximum exposure potential from all sources (total aggregate exposure) including food, drinking water, and residential uses. This risk assessment concluded that there is a reasonable certainty that no harm will result to the general population and to infants and children from aggregate exposure to triclopyr and TCP (Antunes-Kenyon and Kennedy, 2004).