

REXROLL

SEP - 5 1984

MEMORANDUM

SUBJECT: Picloram Registration Standard, Phase II Status Memo

TO: Deborah Otchere, Review Manager
Special Review Branch
Registration Division (TS-767)

THRU: Amy Rispin, Director
Science Integration Staff (TS-769) ^{15/}

All disciplinary chapters for the Phase II Picloram Registration Standard have been completed with the exception of the Residue Chemistry Chapter. The Non-Target Insect and Phytotoxicity Chapters were prepared by the Ecological Effects Branch (EEB), Hazard Evaluation Division. All other chapters were produced by the registrant, reviewed and revised by HED. The purpose of this memo is to summarize our phase II activities and to indicate issues or facts which are relevant to the Picloram Registration Standard and to highlight those areas which may pose special problems.

Background and Risk Concerns

Picloram, 4 amino-3,5,6-trichloro-picolinic acid, is a herbicide registered for brush and broadleaf weed control in and around agricultural premises, grain rangelands, rights-of-way, industrial sites, forrests, nonagricultural and wasteland and aquatic areas. A range of picloram products are currently registered including one manufacturing-use product containing picloram as the potassium salt and end-use products containing the potassium salt of picloram, the triisopropanolamine salt, the isooctyl ester, and the triethylamine salt. Picloram is highly phytotoxic, moderately toxic to cold water fish and certain combinations of picloram and 2,4-D may produce sensitizing reactions in humans. Water contamination is a major concern in the exposure of nontarget organisms to picloram since this chemical has been detected in ground water apparently as a result of movement through soil or through contamination of wells and in surface waters from runoff from treated areas.

Toxicology Concerns

The Toxicology Chapter for phase II is complete. However, they are unable to determine the residues of concern (e.g., parent, metabolites, HCB) in plants, meat and milk products, pending a review by RCB. The Toxicology Branch concluded the following:

- Where acute studies on technical chemicals other than the acid form of picloram are missing and considered data gaps these data should be provided to determine proper labeling of the chemicals (refer to table B data requirements).
- For chronic feeding studies, the acid form of picloram is considered equivalent to salts and ester forms. Although there is no current evidence that picloram is posing risks of unreasonable adverse health effects, additional long-term studies have been identified as being necessary to support this conclusion and to support present and future tolerances (refer to table B data requirements).
- Since human sensitization studies have shown that the triisopropanolamine salt combination of 2,4-D and picloram are capable of producing sensitizing reactions, those formulated products should include a warning of that potential hazard.
- It was found that some studies on long-term effects performed by Industrial Bio-Test (IBT) Laboratories were invalid due to improper laboratory practices. In addition, a long-term study in rats sponsored by the National Cancer Institute is considered of questionable value due to laboratory procedures. The results of this rat study suggest that picloram may induce benign liver tumors. Even if this study were accepted as positive, given the high doses needed to produce the effect, and the very low potential for human exposure from current uses, existing uses would not pose a significant risk of increased cancer in the population. The registrant is conducting a new rat study to clarify the ambiguous results of this NCI study.
- The excretion and elimination of picloram has been studied in the dog and rat. However, metabolic products and pathways were not delineated. Thus, a general metabolism study in an appropriate species is required.

Ecological Effects Concerns

The Ecological Effects Chapter including non-target insects and phytotoxicity is complete.

- The chemical is highly phytotoxic, easily absorbed by roots and foliage. In soils not subject to leaching, it is very persistent with phytotoxicity being detected in some cases well over one year after application.

- Based upon information provided EEB by RD, damage to nontarget plants is occurring. However, they are unable to determine if this is the result of applicator error, misuse, drift, leaching, runoff, or persistence. Therefore, EEB is unable to determine if a nontarget plant hazard exists, or if the use restriction is providing the degree of safety originally desired by the Agency.
- Data are required on technical picloram for Nontarget Area Phytotoxicity (refer to data table). In addition, EEB suggests that RD contact the appropriate State Agencies in order to gather detailed information on those picloram incidents involving plant damage and/or ground water contamination.
- EEB had only one original nontarget insect study available for review. EEB had several nontarget insect reviews completed by the registrant in their files. However, in the absence of the original studies, EEB made no attempt to ascertain the validity of the reviews or the material received.
- No data were available to determine the effects of the isooctyl ester and the triisopropanolamine, potassium, and triethylamine salts of picloram on nontarget insects.
- Picloram appears to be moderately toxic to cold water fish (trout) and slightly toxic to warm water fish (catfish, bluegill). However, chronic studies on lake trout suggest that low concentrations of picloram will adversely affect the rate of yolk sac absorption and growth of fry.
- Appears to be practically non-toxic to birds.
- Additional toxicity tests are required on technical picloram in order to complete a hazard evaluation including a field monitoring study to determine concentrations of picloram in runoff water and sediment, leachate, groundwater, and in water and sediment of receiving aquifers (refer to data tables).
- EEB recommends labeling requirements for outdoor use including ditch bank use (refer to EEB chapter).

Environmental Fate and Exposure Concerns

The Environmental Fate and Exposure Chapter for phase II is complete. The Exposure Assessment Branch concluded the following:

- Photodegradation and aerobic soil degradation are the main processes for dissipation of picloram in the environment.
- Following normal agricultural, forestry, and industrial applications, long-term accumulation of picloram in the soil does not occur.
- The half-life of picloram under many field conditions is a few months, but it may exceed one year or more especially in dry climates.
- It has a moderate mobility in soil. Its relatively high water solubility and low soil absorption indicate that it has the potential to leach in soil.
- Laboratory studies indicate that picloram does not accumulate in fish tissue.
- Refer to the data tables for the additional generic data requirements.
- Water contamination is a major concern in the exposure of non-target organisms to picloram since this chemical has been detected in ground water apparently as a result of movement through soil or through contamination of wells and in surface waters from runoff from treated areas.
- Additional label restrictions will be needed to prevent well and groundwater contamination (refer to data tables).
- Monitoring studies will be needed to detect picloram residues in groundwater (refer to data tables).

Residue Chemistry Issues

The Residue Chemistry Chapter of the Registration Standard was written by the Registrant and is currently under review by the Residue Chemistry Branch (RCB). RCB reported that they would complete their review during the first week of September, 1984.

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