Drive 75DF

Active Ingredient Quinclorac

<u>TOXICOLOGICAL RISK ASSESSMENT</u>: Neither quinclorac nor the DriveÆ formulated product was very toxic in acute oral, dermal or inhalation exposure studies in laboratory animals, nor were very irritating to the eyes or skin (tested on rabbits). Whereas the formulated product was not a skin sensitizer, the active ingredient had skin sensitizing properties (tested on guinea pigs).

Quinclorac caused some toxicity in chronic feeding studies. In a chronic feeding/oncogenicity study in mice, quinclorac caused a decreased body weight gain at 150 milligrams per kilogram body weight per day (mg/kg/day); the no-observed-effect level (NOEL) was 38 mg/kg/day. In rats chronically fed quinclorac, female animals showed a decrease in body weight gain at 757 mg/kg/day, whereas males showed evidence of an increase in benign pancreatic tumors at a dose of 487 mg/kg/day. The respective NOELs were 478 and 385 mg/kg/day. In dogs, decreases in red blood cells and hemoglobin, reduced body weight gain and food consumption, and increased liver and kidney weights were reported at 469 and 513 mg/kg/day in females and males, respectively; the respective NOELs were 140 and 142 mg/kg/day. The USEPA, Office of Pesticide Programs established a reference dose (RfD) of 0.4 mg/kg/day based on a NOEL of 38 mg/kg/day in the chronic feeding/oncogenicity study in mice and an uncertainty factor of 100. This RfD has not yet been adopted by the USEPA's Integrated Risk Information System (IRIS).

Quinclorac caused some developmental toxicity in the offspring of pregnant rabbits, but not pregnant rats, fed this chemical during organogenesis at doses that also caused maternal toxicity. In rabbits, increased resorptions and post-implantation loss, decrease in number of live fetuses and reduced fetal body weight were reported at a maternal dose of 600 mg/kg/day; the NOEL was 200 mg/kg/day. Maternal toxicity (decreased body weight gain and food consumption) occurred at 200 mg/kg/day; the NOEL was 70 mg/kg/day. In rats, maternal toxicity consisting of increased mortality, decreased food consumption and increased water consumption occurred at a dose of 438 mg/kg/day; the NOEL was 146 mg/kg/day. No developmental toxicity was observed at doses of 438 mg/kg/day (the highest dose tested). In a two-generation reproduction study in rats, a decrease in pup body weights and viability and developmental delays (eye opening) were reported at a dose of 600 mg/kg/day; the NOEL was 200 mg/kg/day. Parental toxicity consisting of reduced body weight gain during the pre-mating periods for both sexes and reduced maternal body weight during lactation occurred at a dose of 600 mg/kg/day; the parental NOEL was 200 mg/kg/day.

Quinclorac did not cause oncogenic effects in mice, but was associated with "an equivocal increase of acinar cell adenomas of the pancreas" (a benign tumor) in male rats. This chemical was negative in a number of genotoxicity studies. The USEPA classified quinclorac as "Group D -- not classifiable as to human carcinogenicity."

An occupational and residential/non-residential risk assessment for dermal and inhalation exposures to quinclorac used on turf was submitted. For determining margins of exposure (MOEs), the registrant compared estimated short-term exposures to a NOEL of 200 mg/kg/day from the oral developmental toxicity study in rabbits (for the inhalation route of exposure) and a NOEL of 1,000 mg/kg/day from the 21-day dermal study in rabbits (for the dermal route of exposure). For intermediate-term exposures, a NOEL of 75 mg/kg/day from the 90-day oral mouse study (for ingestion exposures) and the NOEL of 1,000 mg/kg/day from the rabbit dermal study (for dermal exposures) was used. For commercial handlers, the MOEs were estimated to be about 1000-fold and greater for combined exposures. These estimates assumed that workers wore gloves, a single layer of clothing and no respirator as per label requirements. Generally, the USEPA considers MOEs of 100-fold or greater to provide adequate worker protection. For post-application activities, including lawn mowing and recreational activities on turf, including children playing, the MOEs were estimated to be about 1,300 and above.

A review of the environmental fate data for quinclorac indicates that this chemical has the ability to leach through certain soil types and contaminate groundwater; the adsorption coefficients (Koc) in sand and clay were reported to be 13 and 54, respectively. These values suggest that quinclorac has a very high mobility through some soils. In addition, the application rate for DriveÆ is not low (340.2 grams quinclorac per acre, a maximum of twice a year). Accordingly, the label for the DriveÆ product states under "Environmental Hazards" that "This chemical has properties and characteristics associated with chemicals detected in groundwater. The use of this chemical where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination."

There are no chemical-specific federal or State drinking water/groundwater standards for quinclorac. Based on its chemical structure, this compound falls under the 50 microgram per liter (g/L) New York State drinking water standard for "unspecified organic contaminants" (10 NYCRR Part 5, Public Water Systems).

The available information indicates that the expected direct exposure from the labeled use of DriveÆ 75 DF Herbicide should not pose a significant risk to workers or to the general public. However, there are concerns for the leaching potential of quinclorac and its ability to contaminate groundwater/drinking water in vulnerable areas of the State.

ECOLOGICAL EFFECTS RISK ASSESSMENT: DriveÆ 75 DF Herbicide is labeled for the control of many broadleaf and grass weeds on residential and nonresidential turf. It is applied postemergence to actively growing weeds at 1.0 pound per acre, 0.367 ounce per 1000 square feet, as a broadcast spray or spot treatment. No more than 2.0 pounds per acre, 1.5 pounds active ingredient, may be applied per year. DriveÆ may not be applied aerially or through irrigation systems. Quinclorac is generally considered to achieve its herbicidal activity through mimicry of the plant hormone auxin.

Technical quinclorac has a water solubility of 64.0 mg/L. Its vapor pressure is low at

0.75x10-7 mmHg, volatilization will not contribute significantly to its dissipation. With an octanol/water partition coefficient, KOW, of 0.266 at pH 7.0, quinclorac should not bioaccumulate. Its 36 ml/g mean soil organic carbon partitioning coefficient, KOC, indicates that quinclorac may be very mobile in soil.

Quinclorac is stable to hydrolysis at pH 5.0, 7.0, and 9.0. It is stable to aqueous photolysis in sterile water, but does undergo photolysis in the presence of sensitizers such as humic acids, tryptophan, tyrosine, riboflavin et al., that occur in natural waters. Very little photodegradation occurred during the submitted 30-day guideline study conducted with sterile laboratory water. Non-guideline studies and literature reviews submitted to the USEPA Environmental Fate and Groundwater Branch, however, yielded half-lives, T1/2, of 24-65 hours in H2O2 solutions, 5-10 days in non-sterilized rice paddy and river waters, and 22-38 days in buffered solutions containing soil humic acid and/or rose bengal. Quinclorac has a mean soil surface photolysis T1/2 of 141 days.

Aerobic soil metabolism T1/2 values were reported as 168 days for a clay soil, 391 days for loamy sand, and "> 1 year" for two silt loam soils. Extrapolated aerobic half-lives for the two silt loam soils are 1140 to 9125 days. Aerobic aquatic metabolism T1/2s in clay soil/water and loam soil/water systems were calculated to be 393 and 1229 days, respectively. Quinclorac is stable to anaerobic aquatic metabolism, T1/2 values from two studies utilizing two soils each ranged from 1250 to 2520 days.

Data Evaluation Records (DERs) for six terrestrial field dissipation studies were submitted with the quinclorac data package. Five of the six turf studies conducted in 1988-89 in California, Georgia, Missouri, New Jersey, and Oregon, were classified as unacceptable in 1990 when the DERs were produced. The value of the these studies was limited due to identified deficiencies; no route of dissipation provided, contamination of control plots, interception by turf not accounted for and variable recovery of fortified samples. The reported 0-6 inch soil layer dissipation T1/2 values ranged from 18-166 days. Dissipation half-lives given for these studies only represent the loss of parent material from the top six inches of the soil profile. This loss does not represent degradation of the active ingredient but primarily translocation most likely via leaching and/or runoff. The laboratory degradation studies, in this case, probably more accurately predict environmental residence times.

The sixth field dissipation study, an acceptable wheat and sorghum study, was conducted in Kansas in 1997. In this study spring and winter quinclorac applications dissipated from upper soil layers with a T1/2s of 10 and 40 days, respectively. Parent quinclorac was identified in the 42-48 inch deep soil layer 180 days post application at 0.017ppm, representing roughly 1.4% of the applied material. At 21 days post application one metabolite was found at the 6-12 inch depth at 0.02 ppm (1.6% of applied), at 180 days another metabolite was identified at the 12-18 inch depth at 0.019 ppm (roughly 1.4% of applied).

Screening level exposure modeling was conducted for terrestrial and aquatic non-target organisms using highly conservative values and assumptions. All toxicity and fate parameters were taken from the data package submitted by the applicant. Terrestrial feeding exposures were modeled using Hoerger and Kenaga "immediate post application, upper limit vegetation residue levels." Aquatic runoff modeling assumptions included: no product interception by target vegetation, 100% of the runoff water reached the model pond, and no active ingredient degradation between applications.

Model results indicate that no direct toxic effects to fish or wildlife resources are anticipated through labeled use of DriveÆ 75 DF Herbicide. The only toxicity threshold exceeded was the mouse chronic NOEC at the highest vegetation residue level. Given the highly conservative screening nature of the modeling conducted for this assessment, actual field vegetation residue levels are not likely to exceed the mammalian chronic toxicity threshold as predicted by MAMTOX.

ENVIRONMENTAL FATE RISK ASSESSMENT: DriveÆ 75 DF Herbicide (75% quinclorac) is labeled for postemergence control of broadleaf and grass weeds in residential and nonresidential turf grasses. This product is foliarly applied and cannot be applied aerially or through chemigation equipment. The DriveÆ 75 DF product labeling limits application to 1.5 lb quinclorac/acre/year. The inerts do not appear to be solvent carriers.

USEPA reviews of quinclorac were generated for products labeled for aquatic and terrestrial food crop use patterns with a maximum application rate of up to 0.75 lb quinclorac/acre/year, half of the proposed DriveÆ 75 DF Herbicide turf rate. The DERs were produced over a period of several years as studies were repeated. Information for the Department's risk assessment was primarily taken from a September 17, 1992 Environmental Fate & Ground Water Branch (EFGWB) memorandum associated with a rice crop use pattern and an Environmental Fate and Effects Division (EFED) risk assessment (04/27/99) accompanying the registration of Paramount Herbicide (EPA Reg. No. 7969-113), which is labeled for sorghum and wheat.

Hydrolysis: Quinclorac is stable at pHs 5, 7, and 9.

Aqueous Photolysis: Quinclorac is stable to photolysis in sterile water. A non-acceptable study indicated that quinclorac degraded photolytically in the presence of non-sterile water with half-lives of 5.3 and 15.7 days.

Soil Photolysis: Relatively stable half-lives of 122-162 days were found. The EFGWB memo indicates that photodegradation is probably not a major route of degradation under terrestrial field conditions.

Aerobic Soil Metabolism: Quinclorac is very stable. The half-life in loamy sand was 391 days, while the half-life in clay soil was 168 days. One major degradate, 2-OH-514 H, was detected at 14.9%.

Aerobic Aquatic Metabolism: Quinclorac is very stable under aerobic aquatic conditions with a half-life of >1 year in flooded silty clay and silty clay loam soils during the 30-day study.

Anaerobic Aquatic Metabolism: Quinclorac is very stable. In the EFGWB memo, a half- life of >365 days was cited.

Leaching and Adsorption/Desorption: Quinclorac was very mobile in five soils ranging in texture from sand to silty clay. In general, absorption increased with increasing soil organic matter content, CEC, and clay content. Koc values ranged from 13 for the sandy loam to 54 for the clay loam soil.

Leaching and Adsorption/Desorption of the Primary Degradate BH-514-1: The degradate was mobile to very mobile in five soils ranging in texture from sand to silty clay. In general, adsorption increased with increasing soil organic matter content, CEC, and clay content. Koc values ranged from 860 for the sandy loam to 2080 for the silty clay soil.

Field Dissipation: Dissipation half-lives were reported to be 18, 36, 44, 50 and 166 days in five different field studies at an application rate of 2.0 lb quinclorac per acre. None of the these studies were found to be acceptable since the authors did not speculate on the route of quinclorac degradation. In general, quinclorac was not detected below the 12 inch soil depth. The EFGWB notes that, given the low Kd values reported for quinclorac, it is feasible that leaching below 12 inches occurred.

USEPA's Comments (04/27/99): Note that the following EFED comments pertain to an annual quinclorac application rate one-half of the maximum labeled rate for DriveÆ.

"Quinclorac laboratory fate data suggest that the compound is stable to hydrolysis, soil photolysis, and microbially mediated metabolism. Information regarding the lengthy intervals required between quinclorac use and the planting of sensitive crops further suggests environmental stability. The compound is of relatively high aqueous solubility and has a low affinity for soil organic carbon, factors suggesting that quinclorac is mobile in the environment. Movement of quinclorac residues by surface runoff may be a significant mode of dissipation under terrestrial use conditions, especially if excess precipitation occurs immediately following a quinclorac application."

"EFED has identified two quinclorac metabolites present in both the aerobic soil metabolism studies and terrestrial field dissipation studies (BH514-2-OH and BH514-Me ester). Data are needed to confirm the mobility of these metabolites in soil. Therefore EFED requests that guideline (163-1) leaching adsorption/desorption studies be performed on these two metabolites."

"Finally, the environmental persistence of quinclorac, its potential to enter groundwater as modeled by SCI-GROW and indicated in terrestrial field studies, and the potential for groundwater impacts to non-target crops via contaminated groundwater all suggest the need for a small-scale prospective groundwater contamination study for the compound under the expected conditions of use in wheat and sorghum."

The DriveÆ 75 DF Herbicide product labeling bears the following text under the "Environmental Hazards" heading: "This chemical has properties and characteristics associated with chemicals detected in groundwater. The use of this chemical where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination."

The Department's groundwater model (LEACHM) was run on Riverhead soil using a parent Koc of 13 for sandy loam and a degradate Koc of 860, a half-life of 391 days and an application rate of 1.5 lb quinclorac/acre/year (maximum use rate) with 14.9% degrading to the degradate, the model projects breakthrough in the first year, and cyclical peaks of about 200 parts per billion (ppb) for the parent with one peak at 400 ppb. For the degradate, the model predicts an accumulation of about 100 ppb during the 10-year modeling period.

Running LEACHM on Howard soil using a parent Koc of 54 for clay loam soil and a degradate Koc of 2080, a half-life of 168 days and an application rate of 1.5 lb quinclorac/acre/year, the model projects breakthrough in the second year, and slowly accumulating peaks of about 100 ppb for the parent with one peak at about 150 ppb. For the degradate, the model predicts an accumulation of up to 0.3 ppb during the 10-year modeling period.

CONCLUSION: Laboratory fate data indicate that quinclorac is stable to hydrolysis, photolysis in sterile water, as well as aerobic and anaerobic metabolism. Terrestrial field dissipation data indicate that leaching is a route of dissipation, especially if excess precipitation occurs immediately following application. The product labeling bears a groundwater contamination advisory. SCI-GROW and LEACHM modeling predict impacts to groundwater/drinking water. The USEPA had enough concerns, based on half of the application rate on the proposed label, to require guideline leaching/desorption studies on two metabolites and to request a small-scale prospective groundwater contamination study.

When used as labeled, DriveÆ 75 DF Herbicide has the potential to adversely impact ground and surface water resources in New York State. Therefore, the Department hereby denies the application to register DriveÆ 75 DF Herbicide (EPA Reg. No. 7969-130) in New York State.

BASF Corporation may reapply to register the subject product. Such an application must be accompanied by a new application fee and meet the requirements listed in Appendix 1.A. of "New York State Pesticide Product Registration Procedures" (August 1996). Prior to submitting an application for any product containing quinclorac, the environmental fate characteristics should be completely defined (metabolities) and a small-scale prospective groundwater contamination study should be completed.

Please contact me at (518) 402-8788, if you have any questions regarding this action.

Sincerely,

Maureen P. Serafini
Director
Bureau of Pesticides Management

cc: N. Kim/D. Luttinger, NYS Dept. of Health
R. Zimmerman/R. Mungari, NYS Dept. of Ag. & Markets
G. Good/W. Smith, Cornell PMEP