



# Pesticide Fact Sheet

**Name of Chemical:** Zoxamide  
**Reason for Issuance:** New Chemical  
**Date Issued:**

## Description of Chemical

Chemical Name: 3,5-Dichloro-*N*-(3-chloro-1-ethyl-1-methyl-2-oxopropyl)-4-methylbenzamide

Common Name: Zoxamide

Trade Name: Zoxium 80W Agricultural Fungicide

Chemical Class: Oomycete fungicide

EPA Chemical Code: 101702

Chemical Abstracts  
Service (CAS) Number: 156052-68-5

Year of Initial Registration: 2001

Pesticide Type: Fungicide

U.S. Producer: Rohm and Haas Company  
100 Independence Mall West  
Philadelphia, PA 19106-2399

## Use Pattern and Formulations

There are three products containing the fungicide zoxamide; a 98% active ingredient product for formulating use (RH-117281 Technical Agricultural Fungicide), an 80% wettable powder (Zoxium 80W Agricultural Fungicide) and a dry flowable combination product (Gavel 75DF Agricultural Fungicide) containing 8.3% zoxamide and 66.7% mancozeb. Zoxium is used for the control of early and late blight of potatoes and downy mildew on grapes. Due to the

mancozeb, Gavel will also control Bunch Rot and Dead Arm on grapes. The products can be applied aerially or with ground equipment including chemigation. Zoxamide is applied at rates of 0.13 to 0.17 lb. active ingredient (ai)/acre on potatoes and 0.125 to 0.2 lb. ai/acre on grapes. A maximum of 6 applications may be made on potatoes with a seasonal limitation of 1.0 lb. ai/acre/crop. For grapes, a maximum of 8 applications may be made with a seasonal limitation of 1.6 lb ai/acre/crop.

## **Science Findings**

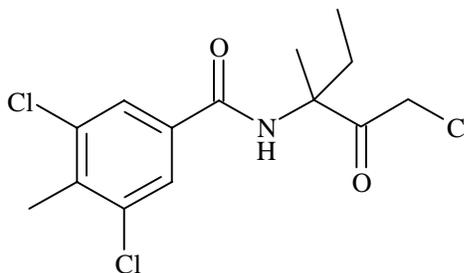
### Summary Science Statement:

EPA has concluded from the review of the supporting data that there are no risks of concern from the use of zoxamide. There was no significant acute toxicity in a battery of acute toxicity studies, however, zoxamide is a strong dermal sensitizer and potential inhalation sensitizer. It was calculated that the risk due to exposure to residues in food and water was below the Agency's level of concern for all population subgroups, including infants and children. Risk from exposure of workers (applicators and other handlers) was also below the Agency's level of concern. There are no residential uses of zoxamide either registered or pending. The Agency also concluded that the use of zoxamide for the labeled uses is unlikely to present a significant threat to non-target organisms or the environment.

### Physical/Chemical Properties:

Color	White Munsell neutral scale
Physical State	Fine powder
Odor	Licorice-like
Stability	Stable at elevated heat and pressure
Oxidation/Reduction	None
Flammability	Not highly flammable
Explosibility	Not considered an explosive substance
Storage Stability	Study in progress
Miscibility	Solid at room temperature
Corrosion Characteristics	Study in progress
pH	6.9 at 24.3° C
Melting Point/Range	159.1-161.0° C
Density	1.38 g/cm <sup>3</sup> at 20° C
Solubility	0.681 mg/L in water, 55.7 g/L in acetone at 25° C
Vapor Pressure	<1.33 x 10 <sup>-5</sup> Pa at 25- 45° C, < 1 x 10 <sup>-7</sup> torr

### Structure:



## Toxicological Characteristics:

## Acute effects.

Zoxamide has low acute toxicity (Toxicity Category IV for acute oral, inhalation toxicity and Category III for acute dermal toxicity and ocular irritation). Zoxamide is considered to be a strong dermal sensitizer, but it is not a skin irritant (Toxicity Category IV).

**Table 1. Acute Toxicity of Zoxamide - Technical (RH-117,281)**

<b>Guideline No.</b>	<b>Study Type</b>	<b>MRID No.</b>	<b>Results</b>	<b>Toxicity Category</b>
81-1	Acute Oral–Rat	44731805	LD <sub>50</sub> > 5000 mg/kg (males and females, combined)	IV
81-1	Acute-Oral–Mouse	44731806	LD <sub>50</sub> > 5000 mg/kg (males and females, combined)	IV
81-2	Acute Dermal–Rat	44731807	LD <sub>50</sub> > 2000 mg/kg (males and females, combined)	III
81-3	Acute Inhalation–Rat	44731808	LC <sub>50</sub> > 5.3 mg/L (males and females, combined)	IV
81-4	Primary Eye Irritation–Rabbit	44731809	Moderate irritant; Corneal opacity on 6/6 rabbits with resolution by day 7. Iritis on 1/6 rabbits at 24 hours with resolution by 48 hours. Conjunctivitis on all rabbits at one hour with resolution by day 7.	III
81-5	Primary Skin Irritation–Rabbit	44731810	Not an irritant	IV
81-6	Dermal Sensitization: Maximization –Guinea pig Buehler's Method –Guinea pig	44731811 44731812	Strong sensitizer. <u>Maximization Test</u> : 100% treated showed erythema. <u>Buehler's Test</u> : 80-90% treated showed erythema, grade 3 out of possible 4, appearing at 3 <sup>rd</sup> induction phase and challenge phase.	NA

Toxicity profile:

**Table 2. Toxicity Profile of Zoxamide Technical**

<b>Guideline No.</b>	<b>Study Type (All Studies Acceptable)</b>	<b>Results</b>
870.3100	90-Day oral toxicity rodents- mouse	NOAEL = <b>1666</b> mg/kg/day LOAEL <b>not established.</b>
870.3150	90-Day oral toxicity in nonrodents- dog	NOAEL = <b>54.5</b> mg/kg/day in females, 322 mg/kg/day in males LOAEL = <b>322</b> mg/kg/day in females and 1139 mg/kg/day in males based on increased liver weights, hepatocellular hypertrophy (males), decrease in albumin and albumin/globulin ratios (males).
870.3200	28-Day dermal toxicity- rat	NOAEL = not established LOAEL < <b>150</b> mg/kg/day based on strong skin sensitization.
870.3700a	Prenatal developmental in rodents- rat	<b>Maternal</b> NOAEL = <b>1000</b> mg/kg/day LOAEL > <b>1000</b> mg/kg/day. <b>Developmental</b> NOAEL = <b>1000</b> mg/kg/day LOAEL > <b>1000</b> mg/kg/day.
870.3700b	Prenatal developmental in nonrodents- rabbit	<b>Maternal</b> NOAEL = <b>1000</b> mg/kg/day LOAEL > <b>1000</b> mg/kg/day. <b>Developmental</b> NOAEL = <b>1000</b> mg/kg/day LOAEL > <b>1000</b> mg/kg/day.
870.3800	Reproduction and fertility effects- rat	<b>Parental/Systemic</b> NOAEL = <b>409</b> mg/kg/day in females, 1474 mg/kg/day in males LOAEL = <b>1624</b> mg/kg/day based on <b>female decreased body weight and body weight gains.</b> <b>Reproductive</b> NOAEL $\geq$ <b>2091</b> mg/kg/day in males, 2239 mg/kg/day in females LOAEL = <b>not established.</b> <b>Offspring</b> NOAEL $\geq$ <b>2091</b> mg/kg/day in males, 2239 mg/kg/day in females LOAEL = <b>not established.</b>
870.4100b	Chronic toxicity dogs	NOAEL = <b>50</b> mg/kg/day in males, 48 mg/kg/day in females LOAEL = <b>255</b> mg/kg/day in males, 277 mg/kg/day in females based on <b>decreased body weights, increased liver and thyroid weights, and increased alkaline phosphatase.</b>
870.4300	Chronic/Carcinogenicity rats	NOAEL = <b>1058</b> mg/kg/day LOAEL = <b>not established.</b> <b>No evidence of carcinogenicity</b>

**Table 2. Toxicity Profile of Zoxamide Technical**

<b>Guideline No.</b>	<b>Study Type (All Studies Acceptable)</b>	<b>Results</b>
870.4300	Carcinogenicity mice	NOAEL = <b>1021</b> mg/kg/day in males, 1289 mg/kg/day in females LOAEL = <b>not established.</b> <b>No evidence of carcinogenicity</b>
870.5265	Gene Mutation	Non-mutagenic when tested up to 5000 ug/plate, in presence and absence of activation, in <i>S. typhimurium</i> .
870.5300	Cytogenetics	Non-mutagenic at the HGPRT locus in CHO cells tested up to 65 ug/ml, in presence and absence of activation.
870.5375	Chromosome aberration	Did not induce structural chromosome aberration up to limit of toxicity (100 ug/ml), but did induce increased levels of numerical aberrations, in presence and absence of activation.
870.5395	Micronucleus	Non-mutagenic in mouse bone marrow micronucleus assay up to 2000 mg/kg.
870.6200a	Acute neurotoxicity screening battery-rat	NOAEL = <b>2000</b> mg/kg/day LOAEL = <b>not established.</b>
870.6200b	Subchronic neurotoxicity screening battery-rat	NOAEL = <b>1509</b> mg/kg/day in males, 1622 mg/kg/day in females LOAEL = <b>not established.</b>
870.7485	Metabolism and pharmacokinetics - rat	120 hours post-dosing, 96-102% recovered from the low and high single-dose groups. Fecal excretion was the primary route of elimination. Parent compound was the principal component excreted, a total of 36 metabolites were detected in the urine and feces.
870.7600	Dermal penetration - rat	Total dermal absorption rate after 10-hour is 8.8% (includes amount on skin after wash).

#### Summary of Toxicology Findings.

The subchronic and chronic studies in the rat did not indicate toxicological endpoints; LOAELs could not be established in the rodent studies. The chronic and subchronic dog studies indicated that the primary target organ for oral exposure to zoxamide is the liver. In both studies, liver and thyroid weights were increased along with liver histopathological changes and increases in alkaline phosphatase in the chronic study. There was no evidence of neurotoxicity in the acute or subchronic neurotoxicity studies or in any other study in the data base.

There was no evidence of developmental or reproductive toxicity for zoxamide. The data demonstrate no increased sensitivity of rats or rabbits to *in utero* or early postnatal exposure to zoxamide.

Zoxamide is not mutagenic in Ames assays, in CHO cells assay at the HGPRT locus, and in the mouse bone marrow micronucleus assay. Zoxamide did not induce structural chromosome aberrations in cultured CHO cells treated up to the limit of toxicity, but did induce increased levels of numerical aberrations. Carcinogenicity studies in rats and mice did not show increased incidence of spontaneous tumor formation. The Agency has classified zoxamide as not likely to be a human carcinogen.

In metabolism studies fecal excretion was the primary route of elimination. A total of 36 metabolites, including the parent compound, were detected in the urine and feces, the parent compound was the principal component excreted. The biliary excretion data support the conclusion that the liver is the predominant organ involved in the metabolism and excretion of zoxamide. Low and high single dose groups showed 96 to 102% parent and metabolites recovered 120 hours post-dosing. Dermal absorption at 10-hours post-application and post-wash was 8.8%.

#### Occupational and Residential Exposure and Risk Characterization.

There is a potential for occupational exposure to zoxamide during mixing, loading, application, and post-application activities. Because no dermal endpoints were identified, the occupational risk assessment was based on inhalation exposure only. Short-term and intermediate-term risks were assessed. Long-term exposures are not expected for handlers of zoxamide for the proposed use patterns.

Margins of exposure (MOEs) for occupational handler inhalation exposure range from 550 for mixing/loading wettable powder for aerial/chemigation application to 420,000 for mixing/loading the dry flowable formulation for airblast sprayer application. All occupational handler MOEs exceed HED's target MOE of 100, and therefore, are not of concern.

Occupational postapplication dermal exposure is possible following treatment of crops with zoxamide. However, because no appropriate dermal endpoints were identified for this exposure potential, a risk assessment is not required. Postapplication inhalation exposure is expected to be negligible; therefore, a risk assessment for this route is also not required.

It is important to note that zoxamide was found to be a strong dermal sensitizer. In addition, a concern was identified for the potential of zoxamide to be an inhalation sensitizer for the following reasons: (1) up to 50% of the wettable powder formulation's dispersed particle size is less than 5  $\mu$ m, and thus inhalable to the alveolar region in humans; and (2) zoxamide's mechanism of action is binding to tubulin, and therefore may bind to other proteins. Because of these findings, the following mitigation measures are imposed: (1) use of chemical-resistant gloves and respirator, (2) Restricted Entry Interval of 48 hours, (3) double notification (oral and

posted warning) to workers, and (4) labels must include technical information on symptoms and use of supportive treatment or medicine that will counteract the skin sensitization.

At present, there are no registered or proposed residential uses of zoxamide. Therefore, a residential risk assessment was not performed.

## Aggregate Exposure and Risk Characterization.

### 1. General Considerations.

The Agency evaluated the available hazard and exposure data for zoxamide and concluded that the FQPA safety factor could be removed (i.e., reduced to 1x) for zoxamide because there is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure; a developmental neurotoxicity study conducted with zoxamide is not required; and the dietary (food and drinking water) exposure assessments will not underestimate the potential exposures for infants and children. Additionally, there are currently no residential uses.

Based on available data, a suitable endpoint for acute dietary risk assessment was not identified since no effects were observed in oral toxicity studies (including developmental studies) which could be attributed to a single-dose exposure. Therefore, an acute dietary risk assessment is not required.

For assessing chronic dietary risk, a chronic reference dose (RfD) of 0.48 mg/kg/day was selected by applying an uncertainty factor (UF) of 100 to the NOAEL (no observable adverse effect level) of 48 mg/kg/day from the chronic toxicity study in the dog. The systemic toxicity LOAEL (lowest observable adverse effect level) for males/females is 255/277 mg/kg/day based on body weight changes, increases in liver and thyroid weights, and increases in alkaline phosphatase. Because the FQPA safety factor was removed (i.e., reduced to 1x), the chronic population adjusted dose (cPAD) also equals 0.48 mg/kg/day.

No systemic toxicity was seen following repeated dermal applications of zoxamide over a four week period in rats. No toxicity was attributed to oral exposure in the developmental rabbit or rat studies. Therefore, a dermal risk assessment is not required.

In the absence of a subchronic inhalation study, the chronic dog study was chosen as an endpoint for inhalation risk assessment. It was recommended that route-to-route extrapolation should be done by converting the inhalation exposure component (g ai/day) using a 100% absorption rate and an application rate to an equivalent oral dose (mg/kg/day) and comparing it to the oral values of 48 mg/kg/day for inhalation exposure over any time period.

### 2. Food.

As mentioned previously, an acute dietary risk assessment is not required. A Tier I chronic

dietary exposure analysis was performed using the Dietary Exposure Evaluation Model (DEEM™). The assumptions of this Tier I analysis were tolerance level residues and 100 percent crop-treated. The resulting dietary food exposures occupy <1% of the chronic PAD for all population subgroups included in the analysis, except for children (1 to 6 years old) which is the highest exposed subgroup. The exposure for children (1 to 6 years old) utilizes 1% of the cPAD. The results of this dietary exposure analysis should be viewed as very conservative (health protective). Refinements such as use of percent crop-treated information and/or anticipated residue values would yield even lower estimates of chronic dietary exposure.

### 3. Water.

The water assessment for zoxamide was designed to assess concentrations of the parent compound and metabolites (zoxamide plus RH-150721, RH-24549, RH-141288, RH-129151, RH-139432, RH-127450, and RH-163353) since the degradates seem to be more mobile than the parent. A cumulative residue approach was employed to provide conservative estimated concentrations in water for zoxamide and its degradation products. This approach was taken because of limited environmental fate data for zoxamide degradation products and its identifiable degradation products. The estimated environmental concentration (EEC) for ground water (from SCI-GROW modeling) is 2.07 µg/L. The EEC for surface water (from PRZM/EXAMZ modeling, 1 in 10 year annual average) is 21.8 µg/L.

#### Aggregate Risk Assessments and Risk Characterization.

Since there are no requested residential use sites for zoxamide, only dietary exposure (food plus drinking water) were considered when assessing aggregate risk for the requested uses of zoxamide.

Acute dietary risk assessment was not required because no acute oral endpoint was identified; therefore, an acute aggregate risk assessment was unnecessary. Short- and intermediate-term aggregate risk assessments were not performed because residential exposure, which is combined with the dietary exposure for aggregate assessments, is not expected.

Chronic risk estimates resulting from aggregate exposure to zoxamide in food and water are below the Agency's level of concern. Surface and ground water EECs were used to compare against back-calculated Drinking Water Levels of Comparison (DWLOCs) for the aggregate assessment. For the chronic scenario, the DWLOCs are 17,000 µg/L for the U.S. population and 4,800 µg/L for the most highly exposed subpopulation (children 1-6 years old). The chronic EECs (highest 21.8 µg/L) are less than the Agency's DWLOCs for zoxamide residues in drinking water as a contribution to chronic aggregate exposure. It is thus concluded with reasonable certainty that residues of zoxamide in drinking water will not contribute significantly to the aggregate chronic human health risk and that the chronic aggregate exposure from zoxamide residues in food and drinking water will not exceed the Agency's level of concern (100% of the chronic PAD) for chronic dietary aggregate exposure by any population subgroup. EPA generally has no concern for exposures below 100% of the chronic PAD, because it is a level at

or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to the health and safety of any population subgroup. This risk assessment is considered high confidence, very conservative, and very protective of human health.

#### Additional Toxicity Data Requirements:

No additional toxicity studies are required, however, additional information is being requested on the nature of residue in grapes, possible refinement of the residue analytical method and storage stability data on zoxamide residues in processed grape commodities. The Agency will also require the registrant to monitor for incidents of dermal and inhalation sensitization.

#### Ecological Effects/Environmental Fate Characteristics:

##### 1. Environmental Fate Summary:

The major routes of dissipation for zoxamide are hydrolysis, photodegradation in water, and microbial mediated degradation. Zoxamide may persist in the environment for days to months and is practically immobile, with a low potential for movement into groundwater. The data show that hydrolysis, especially at pH 9, is an important degradation process of zoxamide. The photodegradation half-life for zoxamide in water was 14 days (corrected for dark control) in pH 4 buffer solution. Photodegradation of zoxamide on soil does not appear to be a major route of dissipation because the half-lives in irradiated and dark control samples were similar, 10.2 and 11.7 days, respectively. Because of its high affinity for soil and sediment, zoxamide has the potential to move off the site of application during rainfall/irrigation by erosion/runoff on soil particles and by drift. Given the degradation rates for metabolism and soil photolysis, and the high  $K_{oc}$  values, zoxamide will probably be adsorbed to sediments and organic material if transported to surface waters.

The estimated drinking water concentrations are based on zoxamide residues for all studies used as input parameters for modeling. Tier II (PRZM-EXAMS) surface water modeling for zoxamide (parent only) using the index reservoir with the percent cropped area (PCA=0.87 for grapes and potatoes) predicts the 1 in 10 year peak (acute) concentration of zoxamide residues on grapes is not likely to exceed 16.9  $\mu\text{g/L}$  and on potatoes is not likely to exceed 4.9  $\mu\text{g/L}$ . The 1 in 10 year annual average concentration (non-cancer chronic) of zoxamide residues on grapes is not likely to exceed 0.9  $\mu\text{g/L}$  and on potatoes is not likely to exceed 0.2  $\mu\text{g/L}$ . The 36 year annual average concentration (cancer chronic) of zoxamide residues on grapes is not likely to exceed 0.5  $\mu\text{g/L}$  and on potatoes is not likely to exceed 0.2  $\mu\text{g/L}$ .

A Tier II drinking water assessment for zoxamide (RH 117281) and its transformation products (zoxamide and its identifiable degradation products including RH-150721, RH-24549, RH-141288, RH-129151, RH-139432, RH-127450, and RH-163353). Tier II surface water modeling using the index reservoir with the percent cropped area (PCA=0.87 for grapes and potatoes) predicts the 1 in 10 year peak (acute) concentration of zoxamide residues on grapes is not likely to exceed 77.7  $\mu\text{g/L}$  and on potatoes is not likely to exceed 20.9  $\mu\text{g/L}$ . The 1 in 10 year

annual average concentration (non-cancer chronic) of zoxamide residues on grapes is not likely to exceed 21.8 µg/L and on potatoes is not likely to exceed 6.2 µg/L. The 36 year annual average concentration (cancer chronic) of zoxamide residues on grapes is not likely to exceed 12.4 µg/L and on potatoes is not likely to exceed 4.1 µg/L

The SCI-GROW predicted concentration of zoxamide in shallow ground water is not expected to exceed 0.061 g/L. The SCI-GROW predicted concentration of zoxamide residues (zoxamide + degradation products) in shallow ground water is not expected to exceed 2.07 g/L.

## 2. Ecological Effects Summary:

### a. Toxicity to Aquatic Animals:

Based on acceptable ecological effects data the Technical Grade Active Ingredient (TGAI) of zoxamide is classified as:

Highly toxic to freshwater fishes ( rainbow trout LC<sub>50</sub> 156 ppb, bluegill sunfish LC<sub>50</sub> >790 ppb) on an acute basis

Practically non-toxic to estuarine/marine fishes (sheepshead minnow LC<sub>50</sub> >860 ppb) on an acute basis

Freshwater rainbow trout chronic NOAEC 3.48 ppb-( post hatchling survival rate affected) and fathead minnow chronic NOAEC 60 ppb-( affected parameters-length, hatchling success, and 28-D survival rate).

Estuarine/marine sheepshead minnow chronic NOAEC 40 ppb-( length affected at 250 ppb and 28-Day survival and hatchling success were affected at >250 ppb)

Highly toxic to freshwater invertebrates (*Daphnia magna* EC<sub>50</sub> >780 ppb) on an acute basis

Highly toxic to estuarine/marine invertebrate (Eastern Oyster LC<sub>50</sub> 715 ppb ) and very highly toxic to saltwater invertebrates (mysid shrimp LC<sub>50</sub> 75 ppb) on an acute basis.

Freshwater invertebrates *Daphnia magna* chronic NOAEC 39 ppb- (survival rate affected) and Freshwater invertebrate midge chronic NOAEC 210 ppb

Estuarine/marine Mysid shrimp- chronic NOAEC 7.2 ppb-(reproduction and growth rate affected)

Based on acceptable ecological effects data the co-formulation (69% mancozeb + 8.26% zoxamide) is classified as:

Moderately toxic to freshwater fishes (rainbow trout LC<sub>50</sub> 1900 ppb) on an acute basis

Moderately toxic freshwater invertebrates (*Daphnia magna* EC<sub>50</sub> 3800 ppb) on an acute basis

### b. Aquatic Organism Risk Characterization

Risk to aquatic organisms are expected to be low, even when the high end use rate for

zoxamide (0.2 lbs ai/A at 8 applications per year) is used. No levels of concern (LOCs) were exceeded and therefore it is concluded that aquatic organisms will be at low risk when multiple applications are used. However, the Agency's level of concern for endangered and threatened freshwater fish and estuarine/marine invertebrates is slightly exceeded for the proposed use of zoxamide on grapes and potatoes. The acute endangered species LOC for aquatic animals is 0.05. The acute risk quotient (RQ) for freshwater fish (rainbow trout) is 0.05 and for estuarine/marine invertebrates (mysid shrimp) the RQ is 1.0. Although the RQs are at or slightly above the LOC, risk to endangered or threatened species would be unlikely since these figures are based on a Tier 1 assessment and further refinement of the exposure analysis would result in significantly lower calculated risks. Additionally, the model used in the calculations is an uncertain but likely conservative predictor of zoxamide concentrations in water.

#### c. Toxicity to Terrestrial Animals

Based on acceptable ecotoxicity effects data the Technical Grade Active Ingredient (TGAI) of zoxamide is classified as:

- Practically non-toxic to avian (Bobwhite Quail) on an acute basis ( $LD_{50} > 2000$  mg/kg)
- Practically non-toxic to avian species (Bobwhite Quail) on a subacute dietary toxicity basis ( $LC_{50} > 5250$  ppm)
- Practically non-toxic to mammals on an acute oral toxicity basis ( $LD_{50} = > 5,000$  mg/kg)
- Practically non-toxic to non-targeted insects on an acute basis ( $LD_{50} = > 100$  ug/bee)
- Practically non-toxic to mammals on a chronic reproductive basis (NOAEL=20,000 ppm)
- Practically non-toxic to avian species on a chronic reproductive basis (NOAEC 1000ppm)
- Practically non-toxic to earthworm species on a chronic reproductive basis (NOAEC 2000 ppm)

Based on acceptable ecological effects data the co-formulation (69% mancozeb + 8.26% zoxamide) is classified as:

- Practically non-toxic to non-targeted insects on an acute basis ( $LD_{50} = > 153$  ug/bee)

#### d. Terrestrial Animal Risk Characterization

Risk to mammals are expected to be low even when the high end use rate for zoxamide (0.2 lbs ai/A at 8 applications per year) is used. No levels of concern (LOCs) were exceeded and therefore it is concluded that mammals will be at low risk when multiple applications are used .

Risk quotients for non-target insects are not estimated, however, acceptable studies (MRID #447319-19 and #449505-04) suggest that zoxamide is practically non-toxic to non-target insects.

The Agency's assessment indicates that no ecological risk concerns are posed to avian species from the use of this fungicide at the acute and chronic levels. No LOCs were exceeded for avian species when using the high end use scenarios for potatoes and grapes.

### 3. Environmental Risk Assessment

Although zoxamide is moderately to very highly toxic to aquatic organisms and zoxamide exhibits persistence in the field, model predictions of surface water concentrations using a high exposure application scenario on grapes and potatoes do not trigger high concern for acute toxicity nor chronic risks. This is likely due to the combination of low initial mass of pesticide used at each application and the low mobility of parent compound in terrestrial and aquatic environments. Even though the types of target crops proposed for zoxamide may put application in proximity to estuarine/marine environments, acute effects in estuarine/marine invertebrates are not likely. Although the Agency's level of concern for endangered and threatened freshwater fish and estuarine/marine invertebrates is exceeded, the model used in the calculations is an uncertain but likely conservative predictor of concentrations in surface waters of estuarine systems. No acute or chronic levels of concern for estuarine/marine fish, freshwater invertebrates, estuarine/marine invertebrates, mammals, or birds were exceeded by and single or multiple application of zoxamide.

### 4. Outstanding Environmental Fate Data Requirements:

There are no outstanding environmental fate data requirements but additional information on the proximity of Federally listed endangered or threatened freshwater fish and estuarine/marine invertebrates to the proposed use sites must be provided.

### **Conditions of Registration:**

- Submission of TLC scans for initial grape extracts
- Data on substitution of derivatizing agent in the residue analytical method
- Incorporation of any changes/information as a result of review of method
- Additional supporting storage stability data for the grape processing study
- Protocol for inhalation sensitization study
- Product stewardship plan
- 1-year storage stability data on end use products
- Full scale production data including 5 batch analysis
- Resistance monitoring data for potatoes
- Efficacy data on the lowest use rate for the end use product Gavel 75DF
- Additional information on the proximity of endangered or threatened freshwater fish and estuarine/marine invertebrates to propose use site for grapes.

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