**Chapter 2 – Draft Propazine Effects Characterization**

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# Introduction

In target pests (e.g., various weed species), propazine has a mechanism of action of inhibiting photosynthesis in photosystem II (PSII). Triazine herbicides such as propazine bind with a protein complex of the Photosystem II in chloroplast photosynthetic membranes (Schulz et al., 1990). The result is an inhibition in the transfer of electrons through the light reactions of photosynthesis that in turn inhibits the formation and release of oxygen, production of adenosine triphosphate, and the fixation of carbon dioxide into sugars.

Propazine is practically non-toxic to birds and mammals and to terrestrial invertebrates on an acute exposure basis. In most terrestrial animal species, sublethal effects are the predominant concern and are discussed further below. No data on the toxicity of the degradates of propazine are available. Based on the mechanism of action, *i.e.*, disruption of photosynthesis, propazine is toxic to most photoautotroph organisms including unicellular algae and flowering plants.

Propazine is practically non-toxic to freshwater fish and invertebrates, estuarine/marine fish and invertebrates, and highly toxic to freshwater aquatic invertebrates on an acute exposure basis. Similar to terrestrial animals, sublethal effects are the predominant concern. There are no data available for the toxicity of propazine degradates to aquatic organisms. However, in both terrestrial and aquatic taxa, previous assessments have considered degradates to be no more toxic than parent propazine and present in lower concentrations.

The following sections discuss toxicity data available for propazine divided into major taxonomic groups of fish and aquatic amphibians, aquatic invertebrates, aquatic plants, birds, reptiles, terrestrial-phase amphibians, mammals, terrestrial invertebrates and terrestrial plants. Based on these data, mortality and sublethal effects (*i.e.,* growth and reproduction) endpoints are determined and are used to evaluate direct effects to a listed species or effects to plants or animals that a species uses for prey, pollination, habitat, and/or dispersal (PPHD). A presentation of these data for all taxa are provided in Table 2‑1 in Section 2.

In establishing the sublethal thresholds and endpoints used in the analysis, EPA used the most sensitive sublethal endpoint based on growth or reproduction or any sublethal endpoints that are strongly linked to survival, growth or reproduction. In determining whether toxicity endpoints are strongly linked to apical endpoints, EPA staff used best professional judgement, also considering factors such as data quality and relevance to effects on survival and reproduction. Specific consideration was given to any endpoints associated with sensory or behavioral effects. It was determined that no other endpoints in these categories were more sensitive and relevant than the sublethal endpoint established for each taxon. The sublethal endpoint used for each taxon therefore represents a growth or reproductive endpoint directly. Information on additional endpoints is found in **APPENDIX 2-2**.

If sufficient data are available, the toxicity data for each taxon are generally presented as summary data arrays developed using the Data Array Builder v.1.0; described in **ATTACHMENT 2-1**. Sufficient effects data were not available for each taxon for propazine to utilize the data arrays. Reported endpoints in ECOTOX are presented in **APPENDIX 2-2**. Reviews of open literature studies reviewed for the effects characterization are presented in **APPENDIX 2-3**. Citations for registrant submitted studies are presented in **APPENDIX 2-4**.

# Endpoints used in Effects Determinations

Toxicity data available for propazine was reviewed and divided into major taxonomic groups including fish and aquatic amphibians, aquatic invertebrates, aquatic plants, birds, reptiles, terrestrial-phase amphibians, mammals, terrestrial invertebrates and terrestrial plants. For each of these groups, endpoints are determined for each taxon for mortality (animals only) and sublethal effects (*e.g.* growth or reproduction). These endpoints are used to establish thresholds, which are then used in conjunction with exposure data to make effects determinations based on the taxon with which they are associated. These data are described more fully in each relevant toxicity section below. Table 2‑1 through2-6 summarizes the toxicity endpoints used in the effects determinations for all taxa. The available toxicity data for each taxon is discussed more in this chapter, as well as previous risk assessments for propazine.

Table 2‑1. Terrestrial mortality endpoints used to evaluate impacts to species and impacts to PPHD.

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Type of Threshold** | **Taxon** | **Test Species** | **Type of endpoint** | **Value** | **Units** | **Slope** | **Weight of test animal (g)** | **Comments** | **Reference** |
| DOSE BASED MORTALITY | Mammals | Norway rat | LD50 | 5050 | mg ai/kg-bw | 4.5 | 20 | Default slope and weight; non-definitive value | MRID 43474101 |
| Birds | Bobwhite quail | LD50 | 1640 | mg ai/kg-bw | 4.5 | 120 | Non-definitive (>) value, assumed slope | MRID 44287301 |
| Reptiles | Bobwhite quail | LD50 | 1640 | mg ai/kg-bw | 4.5 | 120 | Non-definitive (>) value, assumed slope | MRID 44287301 |
| Terrestrial Invertebrates | Honeybee | LD50 | 756 | mg ai/kg-bw | 4.5 | NA | Honeybee; non-definitive; assumed slope; calculated with Reverse BeeRex | MRID 00036935 |
| DIETARY BASED MORTALITY | Mammals | No Data | | | | | | | |
| Birds | Zebra finch | LC50 | 2800 | mg ai/kg-diet | 6.56 |  | Zebra finch; slope CI 2.9-10.2 | MRID 49635701 |
| Reptiles | Zebra finch | LC50 | 2800 | mg ai/kg-diet | 6.56 |  | Zebra finch is surrogate | MRID 49635701 |
| Terrestrial Invertebrates | Honeybee | LD50 | 96.7 | ug ai/bee | 4.5 |  | honeybee, non-definitive; assumed slope; contact exposure | MRID 00036935 |

Table 2‑2. Terrestrial sublethal endpoints used to evaluate impacts to species and impacts to PPHD.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Type of Threshold** | **Taxon** | **Test Species** | **NOAEC (or LOAEC if no NOAEC)** | **MATC or LOAEC** | **Units** | **Comments** | **Reference** |
| DOSE BASED SUBLETHAL ENDPOINTS | Mammals | Lab Rat | 5 | 15.8 | mg ai/kg-bw | Reduced male and female body weights; Default weight; LOAEC 50 | MRID 00041409 |
| Birds | Bobwhite Quail | 35 | 65 | mg ai/kg-bw | Converted from avian repro endpoints | MRID 43576901 |
| Reptiles | Bobwhite Quail | 13 | 28 | mg ai/kg-bw | Converted from avian repro endpoints | MRID 43576901 |
| DIETARY BASED SUBLETHAL ENDPOINTS | Mammals | Lab Rat | 100 | 447 | mg ai/kg-diet | Reduced male and female body weights; LOAEC 2000 ppm | MRID 00041409 |
| Birds | Bobwhite Quail | 243 | 262 | mg ai/kg-diet | Bobwhite; LOAEC 492 (5% hatchling weight); default weight; MATC is LOAEC from other studies | MRID 48036201  MRID 49957101 |
| Reptiles | Bobwhite Quail | 243 | 262 | mg ai/kg-diet | Bird used as a surrogate | MRID 48036201  MRID 49957101 |
| SUBLETHAL/Mortality | Terrestrial Invertebrates | Honeybee | 756 | 756 | mg ai/kg-bw | honeybee; Mortality (6.5%) | MRID 00036935 |
| Terrestrial Invertebrates | Honeybee | 96.7 | 96.7 | µg ai/bee | honeybee; Mortality (6.5%) | MRID 00036935 |

Table 2‑3. Aquatic mortality endpoints used to evaluate impacts to species and impacts to PPHD.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Taxon** | **Test Species** | **Type of endpoint** | **Value**  **(ug ai/L)** | **Slope** | **Duration of study (days)** | **Comments** | **Reference** |
| FW FISH | Rainbow trout | LC50 | 5000 | 2.77 | 4 | Only definitive endpoint; slope CI 1.70-3.85 | MRID 47452301 |
| E/M FISH | Sheepshead Minnow | LC50 | 4300 | 4.5 | 4 | Observed NOAEC 2010; nondefinitive value; default slope | MRID 48036204 |
| AQ AMPHIBIANS | -- | LC50 | 5000 | 2.77 | 4 | Fish surrogate; definitive endpoint; slope CI 1.70-3.85 | MRID 47452301 |
| FW INVERTEBRATES | Daphnid | LC50 | 5320 | 4.5 | 4 | Nondefinitive value; default slope | MRID 44287305 |
| E/M INVERTEBRATES | Mysid | LC50 | 4200 | 2.0 | 4 | NOAEC 586; slope CI 1.0-3.0 | MRID 44184801 |
| MOLLUSKS | -- | LC50 | 4200 | 2.0 | 4 | Mysid surrogate | MRID 44184801 |

Table 2‑4. Aquatic sublethal endpoints used to evaluate impacts to species and impacts to PPHD.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Taxon** | **Test Species** | **NOAEC** | **MATC or LOAEC** | **Units** | **Duration of study (days)** | **Comments** | **Reference** |
| FW FISH | Fathead minnow | 772 | 938 | ug ai/L | 33 | ~5% decrease in length; LOAEC 1140 | MRID 48036205 |
| E/M FISH | Sheepshead minnow | 1340 | 1866 | ug ai/L | 32 | Time to hatch 41% effect at LOAEC 2590 | MRID 44184802 |
| AQ AMPHIBIANS | Tropical clawed frog | 99 | 99 | ug ai/L | 28 | Developmental effects; growth (reduction in developmental stage reached, 25% reduction in hind limb length); value represents LOAEC; NOAEC not reported | ECOTOX # 178499; Saka et al. 2018; |
| FW INVERTEBRATES | Daphnid | 47 | 65.4 | ug ai/L | 21 | MATC used as input; LOAEC = 91; 18% decrease in weight | MRID 44327602 |
| E/M INVERTEBRATES | Mysid | 135 | 189.5 | ug ai/L | 28 | MATC used as input; LOAEC = 266; 26% decrease in young per female | MRID 44184803 |
| MOLLUSKS | -- | 135 | 189.5 | ug ai/L | 28 | Mysid surrogate | MRID 44184803 |

Table 2‑5. Aquatic plant endpoints used to evaluate impacts to species and impacts to PPHD.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **EPA Category** | **Species** | **NOAEC** | **MATC or LOAEC** | **IC50** | **Units** | **Comments** | **Reference** |
| NON-VASCULAR | Freshwater diatom  (*Navicula pelliculosa*) | 6.5 | 9.19 | 25 | ug ai/L | LOAEC 13; 120hr exposure; 25% inhibition in yield at LOAEC | MRID 44287310 |
| VASCULAR | *Lemna gibba* | 22 | 34.5 | 100 | ug ai/L | 9% inhibition at NOAEC; LOAEC 54, with 30% reduced frond abundance; note that 14d value is presented | MRID 44287309 |

Table 2‑6. Terrestrial plant endpoints used to evaluate impacts to species and impacts to PPHD.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **EPA Category** | **Species** | **NOAEC** | **MATC or LOAEC** | **IC25** | **Units** | **Comments** | **Reference** |
| MONOCOT | Oat | 0.01 | 0.013 | 0.0104 | lb ai/A | Reduced biomass; IC25 based on HC05 species from the seedling emergence SSD; LOAEC 0.018 | MRID 44184804 |
| DICOT | Lettuce | 0.038 | 0.054 | 0.0104 | lb ai/A | Reduced biomass; IC25 based on HC05 species from the seedling emergence SSD | MRID 44184804 |

# Office of Water Aquatic Life Criteria

The U.S. EPA’s Office of Water (OW) may develop [ambient water quality criteria](https://www.epa.gov/wqc/national-recommended-water-quality-criteria-aquatic-life-criteria-table) for chemicals, including pesticides, that can be adopted by states and tribes to establish water quality standards under the Clean Water Act. At this time, OW has not published ambient water quality criteria for propazine.

# Effects Characterization for Fish and Aquatic-phase Amphibians

## Introduction to Fish and Aquatic-phase Amphibian Toxicity

Acute and chronic studies for fish have been submitted by the registrant. It should be noted that EPA does not typically request toxicity studies for amphibians from pesticide registrants, but rather uses data on freshwater fish to represent potential effects to amphibians in the aquatic phase. In cases when information is lacking for amphibians, the fish endpoints will be referenced as a surrogate.

Although the LC50s for fish are near or above the solubility limit of propazine (i.e. 8600 µg ai/L), sublethal effects (such as loss of equilibrium) were observed in all the acute studies.

## Effects on Mortality of Fish and Aquatic-phase Amphibians

An acute exposure study with the rainbow trout (MRID 47452301) is available for propazine, which provides the only frank endpoint. The 96-h LC50 was 5000 µg ai/L. This value will be used to derive the acute mortality threshold for freshwater fish. The observed NOAEC value, based on sub-lethal effects, was 228 µg ai/L. Sublethal effects included fish laying on bottom of test chamber and discoloration at 4510 µg ai/L.

Other studies, such as the sheepshead minnow, report LC50s as near to or greater than the solubility limit of propazine. The threshold for freshwater fish will serve as a surrogate for other fish species. Since no data for aquatic-phase amphibians is available, the threshold for freshwater fish will serve as a surrogate.

## Effects on Growth and Reproduction of Fish and Aquatic-phase Amphibians

In an early life-stage study (ELS) with fathead minnow (*Pimephales promelas*), propazine induced a statistically significant reduction in total length (roughly 5%) at 1140 µg ai/L with a NOAEL of 772 µg ai/L. The MATC of 938 µg ai/L will be used as the sublethal threshold for freshwater fish (MRID 44287307; Supplemental). Weight was also affected. The study was classified as supplemental because pH and hardness exceeded recommended levels, potentially affecting solubility; however, this study is still considered scientifically valid and the endpoint is considered reliable for representing effects of propazine on growth of fish.

For the chronic toxicity testing with estuarine/marine fish, a study is available with sheepshead minnow (*Cyprinodon variegatus*). In an early life-stage study, propazine affected embryo survival and hatching success at 2599 µg ai/L (41%). The NOAEC of 1340 µg ai/L results in a maximum acceptable toxicant concentration (MATC; geometric mean of LOAEC and NOAEC) of 1866 µg ai/L which will be used as the sublethal threshold for estuarine/marine fish (MRID 44184802).

*Silurana* (*Xenopus*) *tropicalis* (tropical clawed frog), an amphibian, was studied in Saka *et al*. 2018 (ref. # 178499). Although nondefinitive, the 96h mortality endpoint was reported as higher than that used for freshwater fish, >5200 µg ai/L. Sublethal endpoints reported include a NOAEL for growth of 99 µg ai/L, but noted decreased development in hindlimb length and thyroid weight at the same concentration at 26 to 28 days.

## Other Sublethal Effects to Fish and Aquatic-phase Amphibians

No acceptable data relevant to propazine.

# Effects Characterization for Aquatic Invertebrates

## Introduction to Aquatic Invertebrate Toxicity

The effects of propazine on aquatic invertebrates are limited to registrant submitted studies due to the lack of identified open literature studies. In this effects characterization, when sufficient data are available for propazine, different endpoints are identified for freshwater and estuarine/marine invertebrates.

## Effects on Mortality of Aquatic Invertebrates

Acute toxicity data for propazine are available for daphnids (*Daphnia magna*). A submitted acute study for daphnids provided a 48-hr EC50 value of >5320 µg ai/L (observed NOAEC 5320 µg ai/L) for the TGAI (technical grade active ingredient). This value will be used to derive the acute mortality threshold for freshwater invertebrates (MRID 44287305). The study is classified as Supplemental because of concerns about the solubility limit. A study on the mysid (*Americamysis bahia*) resulted in an LC50 value 4200 µg ai/L with an observed no-effect value of 586 µg ai/L based on mortality and erratic swimming (MRID 44184801; Acceptable). This value will be used to derive the acute mortality threshold for estuarine/marine invertebrates, including mollusks.

## Effects on Growth and Reproduction of Aquatic Invertebrates

Submitted data show reductions in growth (length and weight (18%)) in daphnids (*Daphnia magna*) following exposure to propazine at 91 µg ai/L (LOAEC). The NOAEC is 47 µg ai/L; the MATC of 65.4 µg ai/L will be used as the sublethal threshold of propazine to freshwater invertebrates (MRID 44327602; Acceptable).

A registrant-submitted chronic toxicity study using the mysid (*Americamysis bahia*) was reviewed. The data indicate that propazine produced significant effects to growth and reproduction as low as 266 µg ai/L, where there was a roughly 25% decrease in young per female. The NOAEC is 135 µg ai/L; the MATC of 189.5 µg ai/L will be used as the sublethal threshold for propazine to estuarine/marine invertebrates (MRID 44184803); the study was classified as supplemental due to deviations in study design.

## Other Sublethal Effects to Aquatic Invertebrates

No other data on effects to aquatic invertebrates have been identified.

# Effects Characterization for Aquatic Plants

## Introduction to Aquatic Plant Toxicity

Most of the available toxicity studies with aquatic plants focus on growth and population effects. All but one of the available toxicity endpoints for aquatic plants involve non-vascular species. All of the threshold values for aquatic plants are based on effects to yield. Threshold values in this assessment are based on endpoints expressed in environmentally relevant concentrations in terms of the amount of the propazine (*e.g*., µg/L).

Because of the variability in study designs and proximal endpoint values, a species sensitivity distribution (SSD) with the available plant data was not conducted. Discussion of endpoints are provided for non-vascular aquatic plants and vascular aquatic plants separately.

Discussion of endpoints are provided for effects on aquatic plants and aquatic plant communities. These serve as a surrogate for effects on an individual of a listed species and the effects on the PPHD of a listed species, respectively.

## Effects on Growth of Non-Vascular Aquatic Plants

Several aquatic plant toxicity studies are required to establish the toxicity of propazine to non-target aquatic nonvascular plants. Data are available for four species: freshwater green alga (*Pseudokirchneriella subcapitata*), marine diatom (*Skeletonema costatum*), cyanobacteria (*Anabaena flos-aquae*), and a freshwater diatom (*Navicula pelliculosa*). The lowest 7-day IC50 for the freshwater nonvascular plant (*Navicula pelliculosa*) is 25 µg ai/L (NOAEC = 6.5 µg ai/L; LOAEC 13 µg ai/L), based on cell density (MRID 44287310; Acceptable). However, all endpoints are similar across test species.

One study available in the open literature identified a 24h NOAEC of 6.5 µg ai/L for green algae (Faust *et al.* 2001). Although this endpoint comports well with the non-vascular aquatic plant endpoint in the available propazine toxicity data, it is a 24h time-step, rather than 96h. Quite often, in population studies such as nonvascular aquatic plants, recovery at the 96h time-step results in a different endpoint than seen at 24h. However, it remains unknown what would be the case for this study.

## Effects on Growth of Vascular Aquatic Plants

Single-species aquatic plant toxicity studies are used as one of the measures of effect to evaluate whether propazine may affect primary production and diversity in aquatic ecosystems. Few aquatic vascular plant toxicity studies have been submitted to the EPA and/or published in the open literature.

Freshwater vascular plants are as sensitive to propazine as freshwater non-vascular plants, with the most sensitive vascular plant (*Lemna gibba*) IC50 value of 100 µg ai/L (14 day), based on frond density, with a NOAEC of 22 µg ai/L (MRID 44087309; Acceptable).

# Effects Characterization for Birds

## Introduction to Bird Toxicity

There are no open literature studies on birds identified in ECOTOX for propazine. Registrant-submitted studies involving birds, include acute oral, sub-acute dietary, chronic reproduction with technical grade propazine.

The available data does not allow for calculation of a species sensitivity distribution; thresholds are based on the most sensitive lethal and sublethal effects identified among registrant-submitted studies.

## Effects on Mortality of Birds

The submitted acute data for propazine include an acute oral LD50 value of >1,640 mg ai/kg-bw. This value will be used to derive the acute mortality threshold for birds. There were no mortalities observed in the study. The observed NOAEL was determined to be 244 mg ai/kg-bw, based on weight loss (MRID 44287301).

The passerine dietary study (MRID 49635701; zebra finch (*Taeniopygia guttata*)) derived an LC50 of 2800 mg a.i./kg-diet with a probit slope of 6.6 (95% confidence interval 2.92-10). Confidence in the reported slope is low. The data that were submitted show that the 8-day subacute dietary LC50's were >4,930 and >5,140 mg ai/kg-diet for bobwhite quail and mallard, respectively; no mortalities were reported (MRIDs 44287302 and MRID 44287303; both Acceptable).

## Effects on Growth and Reproduction of Birds

Three avian reproduction studies are available for propazine, only one of which results in a frank endpoint (bobwhite quail). Given the magnitude of effects (242 mg ai/kg-diet; weight) at the LOAEC in two studies, the frank endpoint is surrounded by some uncertainty. Therefore, to account for this uncertainty, the NOAEC value was used as the no-effect threshold for chronic effects to birds, but the LOAEC (262 mg ai/kg-diet) from the first bobwhite study was used in lieu of an MATC.

In a study with mallard duck (*Anas platyrhynchos*; MRID 48036202; Supplemental), significant reductions (p<0.05) in eggs laid, eggs set, viable embryos, live embryos, number hatched, number hatched to eggs set, hatchling survivors, hatchling survivors to eggs set, survivor weights, adult food consumption and female weight gain parameters at the 500 and 1007 mg ai/kg diet levels. The greatest sensitivity was revealed for the ratio of number hatched to eggs laid, which was significantly reduced (p<0.05; 15 to 35%) at all treated levels. As a result, a NOAEC could not be determined in this study (<262 mg ai/kg diet). Additionally, the reviewer’s analysis detected significant reductions (p<0.05) in live embryos to viable embryos and hatchling weights at the 1007 mg ai/kg diet level.

In a study with bobwhite quail (*Colinus virginianus*; MRID 48036201), adult female body weight gain was significantly reduced (p<0.01; 34 to 43%) at all treatment levels. As a result, a NOAEC could not be determined in this study (<262 mg ai/kg diet). The reviewer’s analysis additionally detected significant (p<0.05) reductions in male weight gain (67 and 107% of control) at the 500 and 1007 mg ai/kg diet levels. There were no treatment-related effects on any reproductive or offspring parameter at the 262 and 500 mg ai/kg-diet levels. At the 1007 mg ai/kg diet level, there was a statistically significant treatment-related reduction (p=0.040) in mean hatchling body weight compared to the control (7.2 g versus 7.6 g for the control).

A third avian reproduction study, on bobwhite quail, did result in a NOAEC (MRID 49957101; Acceptable). No significant treatment-related mortalities, signs of toxicity, or effects on weight gain and reproduction were observed during the study. Incidental mortalities included 3, 1, 2, 1, and 0 mortalities in the control, 60.7, 132, 243, and 492 mg ai/kg diet groups, respectively. No treatment-related findings were observed based on the gross necropsy results. Hatchling weight was significantly reduced in the 492 mg ai/kg diet treatment level relative to the control. The NOAEC was 243 mg ai/kg diet based on a 5% reduction in hatchling weight relative to the control with an MATC of 345.8 mg ai/kg-diet, with a LOAEC of 492 mg ai/kg-diet. This, the third reproduction study, stands out from all the other available avian studies in that it does not report the adult weight loss seen in other available acute, subacute and reproduction studies. Additionally, while this study provides a no-effect endpoint, there is uncertainty in selecting this endpoint, as it represents only one of the two required species for avian reproduction.

## Other sublethal effects to Birds

No other data are available regarding sublethal effects to avian species.

## Drinking water studies

No studies involving avian exposure via drinking water were identified in registrant studies or the ECOTOX database.

## Dermal studies

No studies involving avian dermal exposure were identified in registrant studies or the ECOTOX database.

## Inhalation studies

No studies involving avian exposure via inhalation were identified in registrant studies or the ECOTOX database.

# Effect Characterization to Reptiles

Because no additional data are available on reptilian toxicity to propazine, the available toxicity data for birds are used as a surrogate for reptiles.

# Effect Characterization to Terrestrial-phase Amphibians

Because no additional data are available on terrestrial-phase amphibians to propazine, the available toxicity data for birds are used as a surrogate for amphibians.

# Effects Characterization for Mammals

## Introduction to Mammal Toxicity

The effects of propazine on mammals have been studied relatively extensively by the Health Effects Division (HED). Studies were excluded if they were considered invalid or not associated with an environmentally relevant exposure route. Because acute toxicity data were only available for two species, thereby preventing calculation of a species sensitivity distribution, thresholds are based simply on the most sensitive lethal and sublethal effects identified among the available registrant-submitted studies and open literature in the ECOTOX database.

## Effects on Mortality of Mammals

Propazine, rat toxicity values are obtained from the Agency's Health Effects Division (HED) documents. The results indicate that propazine is categorized as practically non-toxic to small mammals on an acute oral basis (LD50 >5,050 mg/kg-bw; MRID 43474101). This value is used to derive the threshold for acute mortality.

Table 10‑1. Acute Toxicity Profile - Propazine technical

| **Guideline No.** | **Study Type** | **MRID(s)** | **Results** |
| --- | --- | --- | --- |
| 870.1100 | Acute Oral | 43474101 | LD50 > 5050 mg/kg |
| 870.1200 | Acute Dermal | 43474102 | LD50 > 5050 mg/kg |
| 870.1300 | Acute Inhalation | 43474103 | LC50 > 1.22 mg/L |

## Effects on Growth and Reproduction of Mammals

Reproductive and developmental mammalian toxicity studies provide adequate toxicity data on chronic developmental and reproductive effects of propazine (Table 10‑2; USEPA 2007). In a 3-generation reproduction study with rats exposed to propazine, the NOAEL was 5 mg/kg-bw/day, based on decreased body weights in males and females; the LOAEC was 50 mg ai/kg-bw/day and the MATC was 15.8 mg ai/kg-diet; the magnitude of effect on weight was not included by the reviewer. This value represents the sublethal effect threshold for mammals (MRID 00041409). Other developmental endpoints are available for propazine; however, none are as sensitive as the reproduction study.

Table 10‑2. Summary of the Most Sensitive Reproductive and Developmental Mammalian Endpoints for Propazine.

| **Guideline No./ Study Type** | **MRID No. (year)/ Classification /Doses** | **Results** |
| --- | --- | --- |
| 870.3200  21/28-Day dermal toxicity (rat) | 44127401  0, 10, 100 or 1000 mg/kg/day | systemic NOAEL = 100 mg/kg/day  systemic LOAEL = 1000 based on decreased body weight gain |
| 870.3700a  Prenatal developmental in Rat | 00150242  0, 10, 100 or 500 mg/kg/day | Maternal NOAEL = 10 mg/kg/day  LOAEL = 100 mg/kg/day based on decreased body weight and food consumption.  Developmental NOAEL = 10 mg/kg/day  LOAEL = 100 mg/kg/day based on decreased ossification. |
| 870.3700b  Prenatal developmental in Rabbit | 44153401  0, 2, 10 or 50 mg/kg/day | Maternal NOAEL = 10 mg/kg/day  LOAEL = 50 mg/kg/day based on decreased body weight gain, decreased food consumption, and decreased defecation.  Developmental NOAEL > 50 mg/kg/day (hdt)  LOAEL: not identified. |
| 870.3800  Reproduction and fertility effects  (Rat) | 00041409  0, 3, 100, or 1000 ppm  (0, 0.15, 5, or 50 mg/kg/day) | Parental/Systemic NOAEL = 5.0 mg/kg/day (M&F)  LOAEL = 50 mg/kg/day based on decreased body weight.(M&F)  Offspring NOAEL > 50 mg/kg/day  LOAEL: not identified) |
| 870.4200  Carcinogenicity  (rat) | 00041408  Acceptable-guideline  0, 3, 100, or 1000 ppm  M: 0, 0.1, 5.2, or 51 mg/kg/day  F: 0, 0.2, 6.4, or 68 mg/kg/day | NOAEL = 5.2 mg/kg/day (M); 6.4 mg/kg/day (F)  LOAEL = 51 mg/kg/day (M) based on decreased body weight; 68 mg/kg/day (F), based on decreased body weight.  Carcinogenicity -treatment-related increase in mammary gland tumors (adenocarcinomas and adenomas) |
| 870.4300  Carcinogenicity  (mouse) | 00044335  Acceptable-guideline  0, 3, 1000 or 3000 ppm  (0, 0.45, 150 or 450 mg/kg/day) | NOAEL = 450 mg/kg/day (M); 150 mg/kg/day (F)  LOAEL = 450 mg/kg/day based on myocardial degeneration (F).    No evidence of carcinogenicity. |
| Gene Mutation: Chinese Hamster Cells | 00163222  Acceptable-guideline  100-1000 µg/ml in the in the presence and absence of mammalian metabolic activation | Propazine produced a dose-related positive response without metabolic activation. A lesser and non-dose-related response was observed in presence of metabolic activation. |
| Structural Chromosomal Aberration:  Chinese Hamster Cells | 00150622  Acceptable-guideline  1250, 2500 or 5000 mg/kg | Negative |
| DNA Damage: Primary Rat Hepatocytes | 00150623  0, 0.5, 2.5, 12.5, or 62.5 µg/ml | Negative |
| Chromosomal Aberration: Mouse Spermatogonial Cells | 46171701  0, 500, 1000, or 2000 mg/kg | Negative |
| 870.6200a  Acute neurotoxicity screening battery | Not available. | N/A |
| 870.6200b  Subchronic neurotoxicity screening battery | Not available. | N/A |
| 870.7485  Metabolism and pharmacokinetics  (rat) | 43689801  Acceptable-guideline | Propazine (2-chloro-4,6-bis(isopropylamino)-1,3,5-*s*-triazine, unlabeled 98.2% a.i. or as [ring-UL-14C]-Propazine, 99.6% a.i.) was administered to Sprague Dawley rats (5/sex/dose group) as a single gavage dose of 1.0 or 100 mg/kg labeled Propazine or as 14-daily doses of unlabeled 1.0 mg/kg Propazine followed by a single 1.0 mg/kg labeled dose. Corn oil was the vehicle for all treatments. Absorption from the gastrointestinal tract was rapid and similar for all study groups and no apparent sex-related differences were found. Based on recoveries from urine/cage wash and tissues, absorption was ³73%. Within 48 hours of treatment, 82-95% of the administered dose was recovered from excreta, predominately the urine. No specific target organs were identified. Labeled Propazine was recovered only in the feces of male and female rats in the single high-dose group and female rats in the single low-dose group. As presented, it cannot be determined if this represents unabsorbed material or material that underwent enterohepatic circulation. Less than 0.1% of the administered dose was detected as CO2 during a pilot study.  Thirteen metabolites were recovered; three of which were identified. The predominant, G 28273, accounted for 20-30% of the administered dose while the other two contributed <5%. Of 10 unidentified metabolites detected, the combined contribution of six was <15% of the administered dose. Unidentified Metabolite 5 was predominant and contributed 18-24% of the administered dose for all study groups with unidentified Metabolites 4 and 8 next abundant. Although unidentified Metabolite 1 was found at <3% of the administered dose for most treatment groups, it accounted for 11% of the dose from male rats in the single high-dose group. Based on the results and literature review of other 2-chloro-*s*-triazines, the study author proposed that Phase I metabolism proceeded by dealkylation at the 4 and 6 amin positions to ultimately form G 28273 while Phase II metabolism involved glutathione conjugation. Although glucuronidation could not be ruled out, the author suggested that unidentified Metabolites 4 and 5 were glutathione conjugates. |
| Dermal Absorption - rat | Not available | Not available |

## Other Sublethal Effects to Mammals

A study on the Norway rat reports a NOAEL of 26.7 mg ai/kg-bw (LOAEL = 53.0 mg ai/kg-bw) for uterus weights (Laws *et al*. 2003 (ref # 78785)); other endpoints reported in the study are all greater than this value.

## Drinking water studies

No studies involving mammalian exposure via drinking water were identified in the ECOTOX database or in review of registrant submitted studies.

## Dermal exposure studies

Dermal LD50s for propazine are >5050 mg ai/kg-bw (MRID 43474102).

### Inhalation studies

The acute inhalation endpoint (MRID 43474103) for propazine as LC50 >1.2 mg ai/L.

## Studies in Units of Mass/Area for Mammals

There were no such studies available for propazine.

# Effects Characterization for Terrestrial Invertebrates

## Introduction to Terrestrial Invertebrate Toxicity

The use of propazine may result in exposure to non-target terrestrial invertebrates, such as the honeybee. Bee data are not available in ECOTOX. The results of acute contact toxicity testing of propazine on the adult honey bee (*Apis mellifera*) show that by 48 hours in the contact test (MRID 00036935; Supplemental), 6.5% mortality was observed in the 96.7 µg a.i./bee treatment group; therefore, the LD50 value for the contact test is >96.7 µg a.i./bee. As a result, propazine is categorized as practically non-toxic to honeybees on an acute contact basis.

# Effects Characterization for Terrestrial Plants

## Introduction to Terrestrial Plant Toxicity

Plant toxicity data from both registrant-submitted studies and studies in the scientific literature have been reviewed for this assessment. Registrant-submitted studies are conducted under conditions and with species defined in OCSPP test guidelines. Sub-lethal endpoints such as plant height and biomass are evaluated for both monocots and dicots, and effects are evaluated at both seedling emergence and vegetative life stages. Mortality and emergence are evaluated as necessary.

Discussion of endpoints are provided for effects on terrestrial plants and terrestrial plant communities. These serve as a surrogate for effects on an individual of a listed species and the effects on the pollination, prey, habitat, or dispersal of a listed species, respectively. Based on the results of the submitted terrestrial plant toxicity tests, effects are evident at the seedling emergence stage of plant development; however, effects are also evident at the vegetative vigor stage of development. All tested plants, except for corn, exhibited adverse effects following exposure to propazine. The registrant submitted data represents the most sensitive endpoints for effects to listed species and effects to the PPHD of a listed species.

Based on the results of the submitted terrestrial plant toxicity tests, effects are evident at the seedling emergence stage of plant development; however, effects are also evident at the vegetative vigor stage of development. All tested plants, except for corn, exhibited adverse effects following exposure to propazine.

## Effects Data for Terrestrial Plants

For Tier II seedling emergence, the most sensitive dicot is lettuce and the most sensitive monocot is onion. IC25 values, on an equivalent application rate basis, for lettuce and onion, which are based on a reduction in dry weight, are 0.016 and 0.049 lb a.i./A, respectively; NOAEC value for lettuce is 0.01 lb a.i./A. For onion, the NOAEC was 0.018 lb a.i./A).Table 12‑1summarizes the terrestrial plant seedling emergence toxicity data used to derive risk quotients in this assessment.

For Tier II vegetative vigor studies, the most sensitive dicot is cucumber with an IC25 and NOAEC of 0.097 and 0.075 lb a.i./A respectively. The most sensitive monocot was wheat (IC25 = 0.048 lb a.i./A) and with a NOAEC of 0.038 lb a.i./A.

Table 12‑1. Nontarget Terrestrial Plant Seedling Emergence and Vegetative Vigor Toxicity Endpoints (Tier II) for Propazine.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Species** | **Seedling Emergence** | | | | **Vegetative Vigor** | | | |
| **Endpoint** | **NOAEC**  **(lbs a.i./A)** | **LOAEC**  **(lbs a.i./A)** | **MATC**  **(lbs a.i./A)** | **Endpoint** | **NOAEC**  **(lbs a.i./A)** | **LOAEC**  **(lbs a.i./A)** | **MATC**  **(lbs a.i./A)** |
| Corn (*Zea mays*) | None | 2.4 | >2.4 | >2.4 | None | 2.5 | >2.5 | >2.5 |
| Oat (*Avena sativa*) | Biomass | 0.01 | 0.018 | 0.013 | Biomass | 0.0022 | 0.0047 | 0.003 |
| Onion (*Allium cepa*) | Biomass | **0.0181** | **0.036** | 0.025 | Biomass | 0.15 | 0.31 | 0.216 |
| Ryegrass (*Lolium perenne*) | Biomass | 0.16 | 0.3 | 0.219 | Biomass | 0.15 | 0.31 | 0.216 |
| Wheat (*Triticum aestivum*) | Biomass | 0.018 | 0.036 | 0.025 | Biomass | **0.038** | **0.077** | 0.054 |
| Cabbage (*Brassica oleracea*) | Height | 0.02 | 0.038 | 0.028 | Biomass | 0.02 | 0.038 | 0.028 |
| Cucumber (*Cucumis sativus*) | Biomass | 0.077 | 0.16 | 0.111 | Biomass | **0.075** | **0.15** | 0.106 |
| Lettuce (*Lactuca sativa*) | Biomass | **0.01** | **0.018** | 0.013 | Biomass | 0.075 | 0.15 | 0.106 |
| Radish (*Raphanus sativus*) | Biomass | 0.077 | 0.16 | 0.111 | Biomass | 0.15 | 0.31 | 0.216 |
| Soybean (*Glycine max*) | Biomass | 0.59 | 1.2 | 0.841 | Biomass | 0.33 | 0.68 | 0.474 |
| Tomato (*Solanum lycopersicum*) | Biomass | 0.16 | 0.30 | 0.219 | Biomass | 0.1312 | NA | NA |

1Bold indicates most sensitive.

2 IC15 used in lieu of a NOAEC so there is no LOAEC.

Data from several identified ECOTOX studies do not result in more sensitive no-effect values for plants. Although in general the studies identify NOAECs ranging from 0.25 to 3 lbs a.i./A, clear LOAEC values were not defined, so there is uncertainty associated with using these values. No regression based (*e.g.*, ICx) values for terrestrial plants were identified in ECOTOX.

## 12.3 Effects Data for Terrestrial Plant Communities

Twenty-five percent inhibition concentration (IC25) values for terrestrial plants are used to derive the threshold for effects to the PPHD of an individual of a listed species. Studies with effects on measures of growth (i.e., height, weight, and biomass) for both monocots and dicots were conducted with propazine and had 21-d exposure durations that were used to derive Species Sensitivity Distributions (SSD). These parameters were selected to maximize comparability of results. Studies used to derive the SSDs are from registrant studies alone. SSDs were developed separately for both seedling emergence and vegetative life stages.

Toxicity estimates for propazine range from 0.016 to greater than 2.4 lb a.i./A and span three orders of magnitude (**APPENDIX 2-6**), indicating a range of sensitivity to atrazine among terrestrial plants. Based on the results of the submitted terrestrial plant toxicity tests, it appears that, though variable, both stages of plant development tested have similar sensitivity to propazine.

Table 12‑2. Nontarget Terrestrial Plant Seedling Emergence and Vegetative Vigor Toxicity Endpoints for Propazine.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Species** | **Seedling Emergence** | | **Vegetative Vigor** | |
| **MRID 42634603** | | **MRID 42634604** | |
| **Endpoint** | **EC25**  **(lb a.i./A)** | **Endpoint** | **EC25**  **(lb a.i./A)** |
| **Monocots** | | | | |
| Corn (*Zea mays*) | No Effect | >2.4 | No Effect | >2.5 |
| Oat (*Avena sativa*) | Biomass | 0.101 | Biomass | 0.122 |
| Onion (*Allium cepa*) | Biomass | **0.0487** | Biomass | 0.229 |
| Ryegrass (*Lolium perenne*) | Biomass | 0.818 | Biomass | 0.211 |
| Wheat (*Triticum aestivum*) | Biomass | 0.108 | Biomass | **0.0481** |
| **Dicots** | | | | |
| Cabbage (*Brassica oleracea*) | Height | 0.0347 | Biomass | 0.127 |
| Cucumber (*Cucumis sativus*) | Biomass | 0.172 | Biomass | **0.097** |
| Lettuce (*Lactuca sativa*) | Biomass | **0.0160** | Biomass | 0.114 |
| Radish (*Raphanus sativus*) | Biomass | 0.199 | Biomass | 0.219 |
| Soybean (*Glycine max*) | Biomass | 0.979 | Biomass | 0.66 |
| Tomato (*Solanum lycopersicum*) | Biomass | 0.370 | Biomass | 0.151 |

For the species sensitivity distributions (SSD), six distributions were tested, and a variety of methods were used. The Gumbel distribution and method maximum likelihood (ML) was selected to represent HC05 value (p=95) for vegetative vigor endpoints and the triangular distribution and linearization (GR) method were selected to represent the HC05 value for seedling emergence endpoints. Figure 12‑1 and Figure 12‑2 provide a graphical summary of the results. The threshold for species that rely upon terrestrial plants for PPHD is 0.0104 lb a.i./A based on the HC05 from the SSD for seedling emergence vegetative vigor. The HC05 is 0.058 for vegetative vigor.

A close up of a map

Description automatically generated

Figure 12‑1. Species sensitivity distribution for seedling emergence data. HC05 is 0.0104.

**A close up of a map

Description automatically generated**

Figure 12‑2 Species sensitivity distribution for vegetative vigor data. HC05 is 0.058.

# Incident Reports

The Incident Data System (IDS) database was queried for ecological incidents associated with propazine that have been reported to the Agency as of July 20, 2020. When available, the information reported includes date and location of an incident, type and magnitude of effects observed in various species, use(s) of pesticides known or suspected of contributing to the incident, and results of any chemical residue analysis or other analyses conducted during incident investigation. In IDS incidents are categorized according to the certainty that the incident resulted from pesticide exposure. Additionally, incidents determined to be minor incidents are capture as Aggregate Incidents. No ecologically relevant aggregate incidents are reported in the database for propazine.

At the time of the query there were no reported major incidents for propazine in IDS database. The absence of reported incidents should not be construed as the absence of incidents. Incident reports for non-target organisms typically provide information only on mortality events and plant damage. Sublethal effects in organisms such as abnormal behavior, reduced growth and/or impaired reproduction are rarely reported, except for phytotoxic effects in terrestrial plants.

Table 13‑1. Overview of reported incidents by taxa

|  |  |  |
| --- | --- | --- |
| **Terrestrial or Aquatic** | **Taxa** | **Incident Data Available? (Yes/No)** |
| **Terrestrial** | Plants | No |
|  | Mammals | No |
|  | Birds | No |
|  | Reptiles | No |
|  | Amphibians | No |
|  | Terrestrial Invertebrates | No |
| **Aquatic** | Amphibians | No |
|  | Freshwater Fish | No |
|  | Estuarine/Marine Fish | No |
|  | Aquatic Invertebrates | No |
|  | Mollusks | No |
|  | Aquatic Plants | No |

# Alternative Toxicity endpoints

In addition to the thresholds provided in Table 2‑1above, alternative toxicity endpoints were also developed to use in the weight of evidence analysis for a species where appropriate (see *Revised Methods Document*). The alternative toxicity endpoints provide consideration of endpoints that may reflect variation in the available data (such as using the HC50 values from the SSD instead of an HC05 value or considering other endpoints within the data set for a particular taxon). Alternatively, if a taxon did not include enough data to select a specific alternative toxicity endpoint, a 10x factor was applied to the original threshold. The alternative endpoints allow for consideration of the possibility a listed species is toxicologically less sensitive than the tested species in the alternative weight of evidence analysis, which is captured for the analysis of any species that reaches that point of the analysis. Alternative endpoints are listed in Table 14‑1and brief additional comments are provided to clarify the alternative endpoint selection, as appropriate. Endpoints are analyzed for a subset of available units.

Table 14‑1. Alternative toxicity endpoints used in weight of evidence analysis.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Alternative toxicity endpoints - Mortality | | Type of endpoint (HC50, etc.) | Value | Slope | Weight of test animal (g) | Comments |
| Units | Taxa |
| mg ai/kg-bw | Mammals | LD50 | 99999 | 4.5 | 20 | No change, non-definitive |
| mg ai/kg-bw | Birds | LD50 | 99999 | 4.5 | 120 | No change, non-definitive |
| mg ai/kg-bw | Reptiles/Terrestrial Amphibian | LD50 | 99999 | 4.5 | 120 | No change, non-definitive |
| mg ai/kg-bw | Terrestrial inverts | LD50 | 99999 | 4.5 |  | No change, non-definitive |
| ug ai/L | FW FISH | LC50 | 50,000 | 4.5 |  | 10x applied |
| ug ai/L | E/M FISH | LC50 | 99999 | 4.5 |  | No change, non-definitive |
| ug ai/L | AQ AMPHIBIANS | LC50 | 50,000 | 4.5 |  | FW fish value |
| ug ai/L | FW INVERTEBRATES | LC50 | 99999 | 4.5 |  | 10x applied |
| ug ai/L | E/M INVERTEBRATES | LC50 | 42,000 | 4.5 |  | 10x applied |
| ug ai/L | Mollusks | LC50 | 42,000 | 4.5 |  | Mysid value |
| **Alternative toxicity endpoints - Sublethal** | | Type of endpoint (HC50, etc.) | MATC or LOAEC | Description of effect | Duration of study (days) | Comments |
| Units | Taxa |
| mg ai/kg-diet | Mammals | MATC | 4470 |  |  | 10x applied |
| mg ai/kg-diet | Birds | MATC | 2620 |  |  | 10x applied |
| mg ai/kg-diet | Reptiles/Terrestrial Amphibian | MATC | 2620 |  |  | Avian surrogate |
| mg ai/kg-diet | Terrestrial inverts | LOAEC | 99999 |  |  | No data available in these units; alternative endpoint anticipated to be high based on mg/kg bw endpoint |
| ug ai/L | FW FISH | MATC | 9380 |  |  | 10x applied |
| ug ai/L | E/M FISH | MATC | 18660 |  |  | 10x applied |
| ug ai/L | AQ AMPHIBIANS | MATC | 990 |  |  | 10x applied |
| ug ai/L | FW INVERTEBRATES | MATC | 654 |  |  | 10x applied |
| ug ai/L | E/M INVERTEBRATES | MATC | 1895 |  |  | 10x applied |
| ug ai/L | Mollusks | MATC | 1895 |  |  | Mysid surrogate |
| TERRESTRIAL PLANTS | | Type of endpoint (HC50, etc.) | MATC or LOAEC | IC25 | Description of effect | Comments |
| lb ai/A | SUBLETHAL- Monocots | MATC | 0.13 | 0.1818 |  | 10x applied; HC50 species of SSD |
| lb ai/A | SUBLETHAL- Dicots | MATC | 0.54 | 0.1818 |  | 10x applied; HC50 species of SSD |
| AQUATIC PLANTS (TGAI) | | Type of endpoint (HC50, etc.) | MATC or LOAEC | IC50 | Description of effect | Comments |
| lb ai/A | Non-vascular | MATC | 91.9 | 250 |  | 10x applied |
| ug ai/L | Vascular | MATC | 345 | 1000 |  | 10x applied |

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