UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

**OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION**

**MEMORANDUM**

**Date:** **March 24, 2021**

**SUBJECT:** **Registration Review Draft Risk Assessment for the Antimicrobial Use of Tebuconazole**

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|---|---|
| PC Code: 128997 | DP Barcode: 455145 |
| Decision No.: 557266 | Docket No: EPA-HQ-OPP-2015-0378 |
| Regulatory Action: Registration Review | Case No.: 7004 |
| Risk Assessment Type: DRA | CAS No.: 107534-96-3 |

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This document provides the draft human health and ecological risk assessment conducted in support of the antimicrobial pesticide AI (1-(4-chlorophenyl)-4,4-dimethyl-3-(1H-1,2,4-triazol-1-ylmethyl) pentan-3-ol): tebuconazole.

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# EXECUTIVE SUMMARY

Tebuconazole is a triazole-derived fungicide registered for antimicrobial uses as a preservative for wood, wood composites, plastics (shower curtains, tarpaulins, umbrellas, *etc*.,), glues, adhesives, sealants, and metalworking fluids (MWF). Additionally, there are registration uses of tebuconazole as a conventional pesticide in/on numerous agricultural field and orchard crops, as a post-harvest use on several fruits, on commercial ornamentals and golf course turf, and on residential ornamentals, non-bearing trees, and flowers.

## Human Health Summary

### Dietary Risk

There are no dietary exposures from the antimicrobial uses of tebuconazole, and as such no dietary risk assessment was conducted.

### Residential Handler Risks

Residential handler exposures to materials preserved with tebuconazole (plastics, glues, adhesives, and sealants) are expected to be minimal, due to tebuconazole's low vapor pressure, minimal dermal contact, and the infrequent use of treated articles. Additionally, registered wood and MWF uses are for industrial use only. Therefore, a quantitative risk assessment was not conducted for residential handlers.

### Residential Post-Application Risks

There is potential for short-and intermediate-term dermal and incidental oral exposures when children play on decks and playsets constructed with wood that has been pressure treated with tebuconazole. The margins of exposure (MOEs) are not of concern because they are greater than the corresponding levels of concern (LOCs) of 100 for dermal exposure and 100 for incidental oral exposures.

### Aggregate Risks

The aggregate exposure risk characterization for tebuconazole is included in the Health Effects Division (HED) DRA (US EPA, 2021a). For short-and intermediate-term aggregate exposures, the selected residential post-application scenario comes from the antimicrobial use of tebuconazole and is the dermal and incidental oral exposure from high-contact activities on treated wooden decking and playsets. Combined with the applicable subpopulation dietary exposure, the short-term aggregate MOE of 212 for children 1 to 2 years old does not fall below HED's LOC (LOC = 100) and is not of concern.

Occupational Handler Risks

There is potential for short- and intermediate-term occupational handler exposures when tebuconazole is used to preserve materials such as plastics, paper coatings, glues, adhesives, sealants and MWF. The inhalation MOE for the open powder pour scenario is 1.2 and is of concern because it is less than the LOC of 100. The MOE for the open powder pour scenario is no longer of concern if the application rate is reduced to 4,500 ppm and when considering the use of label-required respiratory protection. The inhalation MOE for the liquid pour scenario is 160 and is not of concern because it is greater than the LOC of 100. The dermal MOE for the liquid pour scenario is 12 and is of concern because it is less than the LOC of 100. The dermal MOE for the liquid pour scenario is no longer of concern if the application rate is reduced to 4,500 ppm. The dermal MOE for the powder pour scenario is 54 and is of concern because it is less than the LOC of 100. The dermal MOE for the powder pour scenario is no longer of concern if the application rate is reduced to 20,000 ppm.

There is potential for short-, intermediate- and long-term dermal and inhalation exposures when using tebuconazole-treated MWF. The MOEs are not of concern because they are greater than the corresponding LOCs of 100 for dermal exposure and 100 for inhalation exposure.

Short-, intermediate- and long-term dermal and inhalation exposures are anticipated to occur during use of tebuconazole to pressure-treat wood. The MOEs are not of concern because they are greater than the corresponding LOCs of 100 for dermal exposure and 100 for inhalation exposure.

Short-, intermediate- and long-term dermal and inhalation exposures are anticipated to occur during use of tebuconazole to dip or spray treat wood (sapstain treatment). The inhalation MOE for the clean-up crew scenario is 38 and is of concern because it is less than the LOC of 100. The inhalation MOE for the clean-up crew scenario is no longer of concern when considering the use of label-required respiratory protection. The remaining inhalation MOEs range from 810 to 1,400 and are not of concern because they are greater than the LOC of 100. The dermal MOE for the clean-up crew scenario is 26 and is of concern because it is less than the LOC of 100. The dermal MOE for the clean-up crew scenario is no longer of concern if the application rate is reduced to 12,500 ppm (1.25% tebuconazole in the treatment solution). The remaining dermal MOEs range from 110 to 630 and are not of concern because they are greater than the LOC of 100.

Occupational Post-Application Risks

Occupational post-application dermal and inhalation exposures are not anticipated for the antimicrobial uses of tebuconazole based on the physical-chemical properties and registered use patterns. Tebuconazole has a low vapor pressure of $1.3 \times 10^{-8}$ torr at 25°C (Table 1), which precludes inhalation exposures to vapors in areas containing tebuconazole-preserved materials. In addition, tebuconazole is not applied using methods such as fogging, which would result in the generation of small droplets that remain airborne for long periods after application.

**Ecological Summary**

Risks to terrestrial taxa (including pollinators) are not expected from the currently registered uses of tebuconazole due to low exposure potential. Of the current uses, metal working fluids (MWF), and pressure treated wood (*i.e.,* docks) uses are expected to result in the highest aquatic exposures because of their direct discharge or leaching into aquatic areas. Other uses, such as material preservation of adhesives, plastics, and textiles, have the potential for environmental exposure, but the MWF, and wood preservative use assessments were determined to be protective of these uses.

For wood preservative uses, based on the leach rate of 3.1% and no degradation of tebuconazole, exposure estimates did not reach the levels of concern for aquatic plants (vascular and non-vascular), freshwater invertebrates (acute and chronic), or freshwater fish (acute); therefore, these risks are not expected. However, chronic exposure to freshwater fish is expected to reach the level of concern when 3 docks with a total surface area of 232.5 $ft^2$ (0.22% of the water body) or more are on a modeled water body. Ecotoxicity data indicates that tebuconazole is similar in toxicity to estuarine/marine fish (chronic) and invertebrates (chronic) when compared to freshwater fish (chronic). Therefore, if docks treated with tebuconazole were on an estuarine/marine waterbody, chronic risk to estuarine/marine fish and invertebrates is expected to be similar to freshwater fish. Based on the persistence and limited mobility of tebuconazole in soil, exposure to benthic organisms is also expected. Therefore, risk is expected from chronic exposure to freshwater fish, estuarine/marine fish, estuarine/marine invertebrates (water column) and freshwater benthic invertebrates when tebuconazole is used as a wood preservative.

For MWF uses, based on 45.3% removal during wastewater treatment and no degradation of tebuconazole, exposure is expected in the aquatic habitat. Aquatic exposure estimates indicate that acute, chronic, and plant Concentrations of Concern (COCs) were exceeded for all assessed aquatic taxa with days of exceedances ranging from 13 to 333 for the high-end scenario and 1 to 119 for the average-end scenario modeled. Given that tebuconazole is similar or higher in toxicity to estuarine/marine organisms when compared to freshwater organisms, if effluent from waste-water treatment plants (WWTP) treating MWF with tebuconazole were to be discharged into estuarine/marine environments, risk would be comparable to freshwater organisms. According to ecotoxicity data for benthic organisms, tebuconazole is more toxic to freshwater benthic invertebrates than to freshwater invertebrates living in the water column. Therefore, based on the toxicity and persistence of tebuconazole and it's potential to bind to sediment, the use of tebuconazole in metal working fluids is also expected to result in risk to freshwater benthic invertebrates. Therefore, risk to aquatic plants (vascular and non-vascular), freshwater fish and invertebrates (acute and chronic), estuarine/marine fish and invertebrates (acute and chronic) and freshwater benthic invertebrates (acute and chronic) is expected when tebuconazole is used in metal working fluids.

# 1 INTRODUCTION

## 1.1 Case Overview

There are 38 registered antimicrobial products containing tebuconazole as an active ingredient (a.i.) (PC Code 128997, CAS No. 107534-96-3).

Tebuconazole is registered as a conventional pesticide with agricultural and non-agricultural use patterns and as an antimicrobial pesticide with uses in above-ground and ground-contact wood and wood-based composites, and as a materials preservative in plastics, glues, adhesives, sealants, and metalworking fluids. This assessment focuses on the antimicrobial uses of tebuconazole. The conventional uses are assessed separately in the Health Effects Division (HED) and Environmental Fate and Effect Division (EFED) draft risk assessments for tebuconazole (USEPA, 2021a and 2021b).

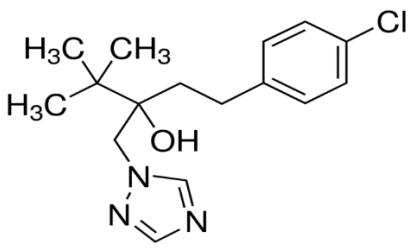
## 1.2 Recent Regulatory Actions

Tebuconazole (PC Code 128997, CAS No. 107534-96-3) was first registered in 1994 for antimicrobial uses, therefore, there is no Reregistration Eligibility Decision (RED) for tebuconazole. The Registration Review docket for tebuconazole (case # 7004) is available at www.regulations.gov in docket number EPA-HQ-OPP-2015-0378. The final work plan (FWP) was issued in June 2016, and the Generic Data Call-In (GDCI-128997-1598) for tebuconazole was issued September 14, 2017.

## 1.3 Ingredient Profile and Chemical Identity

Tebuconazole is persistent in soil (aerobic soil metabolism T ½ =783 days) and has a vapor pressure of 1.3 x 10-8 (torr), and solubility of 36 mg/L. Tebuconazole with a Koc range of 463 to 1251 ml/g, is moderately to slightly mobile. The relevant chemical and physical properties for tebuconazole (PC Code 128997) are listed in Tables 1 and 2.

**Table 1. Tebuconazole Chemical Identity**

| Parameter | Value | Source |
|---|---|---|
| **Selected Physical/Chemical Parameters** | | |
| Chemical Structure |  | |
| Empirical Formula | $C_{16}H_{22}Cl_1N_3O_1$ | https://pubchem.ncbi.nlm.nih.gov/compound/Tebuconazole#section=Names-and-Identifiers |

| Parameter | Value | Source |
|---|---|---|
| IUAPC Name | (RS)-1-p-chlorophenyl-4,4-dimethyl-3-(1H-1,2,4-triazol-1-ylmethyl)pentan-3-ol | https://pubchem.ncbi.nlm.nih.gov/compound/Tebuconazole#section=Names-and-Identifiers |

**Table 2. Chemical Properties of Tebuconazole**

| Parameter | Value | Source (MRID unless specified) |
|---|---|---|
| **Selected Physical/Chemical Parameters** | | |
| Molecular Weight (g/mole) | 307.82 | None |
| Water Solubility Limit at 20°C (mg/L) | 2.6 | 46852904 |
| Vapor Pressure (torr at 20 °C) | $1.3\times10^{-10}$ | 46852904<br>Non-volatile under field conditions |
| Henry's Law Constant at 20°C (atm-$m^3$/mole) | $2.0\times10^{-11}$ | Estimated[1] from vapor pressure and water solubility at 20°C. |
| Log Dissociation Constant (pKa) | 5.0 | FootPrint Pesticide Properties Database@http://sitem.herts.ac.uk/aeru/iupac/Reports/610.htm |
| Octanol-water Partition Coefficient ($K_{ow}$) at 25°C (unitless) | log $K_{OW}$=3.89 at pH 7 | 46852904<br>Not likely to bioconcentrate significantly. |

## 1.4 Use Pattern

As of March 18, 2021, there are 38 products containing antimicrobial-use tebuconazole (PC Code 128997) as an active ingredient (a.i.). Tebuconazole is commonly used in combination with copper and propiconazole for different copper azole formulations. 36 products are end-use products (EPs) with tebuconazole concentrations ranging from 0.1% to 98%. The end-use products are formulated as powders and liquid concentrates for wood protection treatments (dip, spray, flow coat, brush, and pressurized applications), buildings/indoor products, forest products, and for use in a variety of applications as a materials preservative. There are two technical grade active ingredient (TGAI) products with 95.37% to 98% tebuconazole that are used to formulate antimicrobial pesticide products.

According to the labels, tebuconazole can be used to preserve above-ground and ground-contact wood, plastics, glues, adhesives, and metalworking fluids. Tebuconazole may also be applied as an anti-sapstain treatment to wood and wood-composite products including lumber, timbers (logs), landscape ties, fence boards and posts, decks, docks, walkways, and shingles. Application methods include pressure treatment, dipping, and spraying; one product (EPA Reg. No. 88201-1) includes application by brush, trowel, or pump. Two labels (EPA Reg. Nos. 39967-13 and 39967-157) include preservative uses in plastics, glues, adhesives, sealants, and metalworking fluids. The use sites and application rates for each product are outlined in Table 3.

**Table 3. Summary of Registered Antimicrobial Uses for Tebuconazole**

| Use | Application Method | Maximum Application Rate (ppm a.i.) | EPA Reg No.[A] |
|---|---|---|---|
| **Wood Preservation Uses** | | | |
| Wood based composite products (waferboard, fiberboard, particleboard, plywood, oriented-strand board, etc.) | Liquid Pour, Powder Pour | 29400 | 39967-157 |
| Wood products intended for above ground only | Liquid Pour, Powder Pour<br><br>Pressure treatment, Double Vacuum, Dip Immersion, Brush/Roller, Spray, Flow Coat | 12000 | 92617-19 |
| Wood Products intended for above-ground and/or in-ground use | Liquid Pour, Powder Pour<br><br>Pressure treatment, Double Vacuum, Dip Immersion, Flow Coat, Spray, Brush/Roller, Trowel | 49000 | 39967-157 |
| **Material Preservation Uses** | | | |
| Plastics (shower curtains, tarps, umbrellas) [B] | Liquid Pour, Powder Pour | 12000 | 39967-157 |
| Paper coating indoor-non-food contact: Paper board | | 20000 | 39967-157 |
| Glues and adhesives | | 20000 | 39967-13 |
| Sealants | | 10000 | 39967-157 |
| Metal working fluids: Concentrate<br>Ready to use | | 38000<br>1900 | 39967-157 |

A The listed EPA Reg. No. is an example product that represents the maximum application rate.

B Registrant submitted product use data (MRID 51010601) stating that antimicrobial tebuconazole products with this use are not to be used on items which come into contact with food stuff, medical devices, or children's products such as toys or clothing.

### 1.5 Production Volume and Use

Usage information for the antimicrobial uses is not available for tebuconazole. The Kline Biocides Report for 2016 (Kline, 2016) does not include tebuconazole.

## 2 HUMAN HEALTH RISK ASSESSMENT

### 2.1 Data Deficiencies

The toxicology database is considered complete for registration review. No new toxicity data have been received since the original registration evaluation was performed in 1994. No

additional human health studies were requested in the Generic Data Call-In (GDCI) for tebuconazole (GDCI-128997-1598).

## 2.2 Anticipated Exposure Pathways

Occupational handler (dermal and inhalation) exposures to tebuconazole are anticipated when tebuconazole is added to treated articles as a materials preservative, and during wood preservative and metalworking fluid applications. Occupational handler exposures are expected to be short-, intermediate- and long-term in duration.

Residential post-application dermal and incidental oral exposures to tebuconazole are expected from wood pressure-treated with tebuconazole being used in areas such as flooring in outdoor decks and in playground equipment that could result in child contact. Exposures are expected to be short- and intermediate-term in duration.

## 2.3 Hazard Characterization and Dose-Response Assessment

Tebuconazole is a member of the triazole fungicide group; it is currently used to control a wide variety of fungal diseases in fruits and field crops, as well as in residential settings and industrial products. The triazoles act by inhibiting C14-demethylase, an enzyme which plays a role in sterol production in fungi. A mammalian mode of action has not been established for this chemical.

### 2.3.1 Toxicology Studies Available for Analysis

The toxicological database for tebuconazole has been reviewed as part of registration review, and is adequate for hazard characterization, and toxicity endpoint selection. Appendix A includes a summary of the tebuconazole toxicological database. As part of registration review for tebuconazole, a broad survey of the literature was conducted to identify studies that reported toxicity associated with exposure to tebuconazole via human health relevant exposure routes. Tebuconazole was evaluated in this document for antimicrobial uses only. Please see the HED DRA for the complete hazard characterization (US EPA, 2021a):

- Subchronic and chronic oral toxicity in rats and dogs (MRIDs 40700930 and 40700934)
- Subchronic dermal toxicity in rabbits (MRID 40700937)
- Subchronic inhalation toxicity in rats (MRID 40700938)
- Developmental toxicity in rats, mice, and rabbits (MRIDs 40821501, 43776202, 40700945, 43776201)
- Developmental dermal toxicity in rats and mice (MRIDs 41450801, 42010301);
- Reproductive and postnatal toxicity in rats (MRID 40700946),
- Carcinogenicity in rats and mice (TXR#0052724)
- Acute, subchronic, and developmental neurotoxicity in rats (MRIDs 44449301/44545701, 45074301)
- Immunotoxicity in rats (Moser et al, 2001)
- Absorption, distribution, metabolism, excretion (ADME) studies (MRIDs 40995911, 40995912)

- Dermal penetration in rats and monkeys (MRIDs 40995913 and 46534901)

### 2.3.2 Absorption, Distribution, Metabolism, & Elimination (ADME)

After oral administration to rats (MRID 40995911, 40995912), tebuconazole (2 or 20 mg/kg/day) was rapidly and extensively absorbed (approximately 98% of the administered dose), metabolized, and eliminated. At 72 hours post-dosing, >94% of the administered radioactivity was recovered. Approximately 11-33% of the administered dose was eliminated in urine and 61-82% was eliminated in the feces. At sacrifice, total radioactivity in the body, excluding the GI tract, amounted to 0.3 to 0.5% of the administered dose. The data also showed that tebuconazole underwent enterohepatic circulation, and the radioactivity in the feces might be largely attributed to biliary excretion. Elimination via expired air accounted for 0.03% of the administered dose over a 72-hour collection period. A total of 10 metabolites were identified in the excreta, amounting to 51-58% of the administered dose. The parent compound was present in relatively small amounts (0.5-2.2% of the administered dose).

#### 2.3.2.1 Dermal Absorption

Dermal absorption was examined in male rats and male rhesus monkeys (MRIDs 40995913 and 46534901). In the study evaluating male rhesus monkeys, a single dose of 132 µg/cm$^2$ was applied for 8 hours and then washed. Total recovery of radioactivity from cage debris/rinse, urine, and feces was 88.37%. The amount of radioactivity lost to recovery could not be determined because monkeys were not sacrificed at the end of the study, and the contribution of application site skin and distribution in the carcass could not be determined. All bioavailable skin-bound residue was absorbed and excreted within 96 hours. In addition, the metabolism study supports that the 11.6% that was not recovered is likely skin-bound residue that is not bioavailable. The dermal absorption factor of 13% was calculated by determining the mean amount of radioactivity eliminated over a 120-hour period, which is the longest timepoint post-dosing, and was corrected for recovery by dividing by the total percentage recovery.

### 2.3.3 Summary of Toxicological Effects

The toxicological effects of tebuconazole are consistent with those of other triazole-derivative chemicals. In particular, developmental toxicity and hepatocellular tumors are effects common to a number of these pesticides. Tebuconazole also shares common metabolites with other chemicals in this group, including free triazole (1,2,4-triazole) and triazole-conjugated plant metabolites (such as triazole alanine). These common metabolites were the subject of a recent risk assessment document (US EPA, 2011a) updated to incorporate new uses of triazole-derivative fungicides.

After repeated dosing to tebuconazole, the main target organs are the liver, nervous system, and reproductive system; prenatal development was also affected. Decreased body weight was commonly observed in all species after subchronic and chronic oral exposures. Tebuconazole demonstrated neurotoxicity in the acute neurotoxicity study (ACN) in rats (MRID 44449301/44545701) as ataxia, decreased foot splay, and decreased motor activity, but not in the

subchronic neurotoxicity study (MRID 44588001), which tested lower doses. Malformations indicative of disruptions in nervous system development were seen in developmental toxicity studies in two species (mice and rabbits MRIDs 40821501, 43776201, 43776202, 40700945). Neurotoxicity was also observed in offspring in the developmental neurotoxicity study in rats as decreased brain weight (MRID 45074301).

Oral administration of tebuconazole caused developmental toxicity in rabbits (MRIDs 40700945, 43776201) and mice (MRIDs 40821501, 43776201, 43776202), with the most prominent effects observed in the developing nervous system. In the above-mentioned developmental toxicity studies, these effects were manifested as increases in malformations of the neural tube and skull (including exencephaly and acrania, skull bone and vertebral anomalies). In the developmental neurotoxicity study in rats (MRID 45074301), changes were seen in brain weight and body weight. A peer-reviewed developmental neurotoxicity/immunotoxicity literature study (Moser et al., 2001) found impairment in acquisition of a learning task (Morris water maze) in exposed offspring; alterations in some immunological parameters in the same study were not considered adverse by study authors.

In the reproductive toxicity study in rats (MRID 40700946), adverse effects on offspring were manifested only as decreased pup body weight across multiple generations in the absence of maternal effects. Quantitative susceptibility was observed in this two-generation reproductive study and in the previously discussed developmental toxicity studies in mice and rabbits.

It should be noted that tebuconazole has low acute toxicity by the oral and dermal routes of exposure (Toxicity Category III) and is moderately toxic by the inhalation route (Toxicity Category II). It is not a dermal sensitizer or a dermal irritant; however, it is slightly to mildly irritating to the eye (Toxicity Category III). See Appendix Table A1 for more details.

### 2.3.4 Safety Factor for Infants and Children (FQPA Safety Factor)

The HED DRA (US EPA, 2021a) recommends that the Food Quality Protection Act Safety Factor (FQPA SF) of 10X for the protection of infants and children be reduced to 1X for all exposure scenarios based on the following considerations: 1) the toxicity database is complete and dietary and residential exposure analyses are unlikely to underestimate exposure; 2) although there is evidence of developmental toxicity and neurotoxicity in the database, the concern is low because the effects are well-characterized with clearly established no observed adverse effect levels (NOAEL)/lowest-observed adverse-effect level (LOAEL) values; and 3) selected endpoints address the observed effects.

#### 2.3.4.1 Completeness of the Toxicology Database

The toxicity database for tebuconazole is considered complete and adequate for FQPA evaluation. Developmental toxicity studies in rats, rabbits, and mice, a two-generation reproduction study in rats, neurotoxicity studies in rats, an immunotoxicity study in mice, and a developmental neurotoxicity study in rats are available for FQPA consideration. The submitted toxicology studies are of sufficient quality to select endpoints for risk assessment and to determine whether tebuconazole poses a human health hazard.

#### 2.3.4.2 Evidence of Neurotoxicity

Evidence of neurotoxicity was seen in the ACN (MRID 44449301/44545701) and developmental neurotoxicity (MRID 45074301) studies in the rat. However, there is a low degree of concern for the potential neurotoxic effects of tebuconazole since 1) clear NOAELs were identified for the neurotoxic effects; 2) the neurotoxic effects were not the most sensitive endpoint in the toxicity database; and 3) the endpoints chosen for risk assessment are protective of any potential neurotoxicity.

#### 2.3.4.3 Evidence of Sensitivity/Susceptibility in the Developing or Young Animal

There was evidence of quantitative pre-natal susceptibility in the rat two-generation (MRID 40700946) and mice and rabbit developmental toxicity studies (MRIDs 40821501, 43776201, 43776202, 40700945) (see Section 2.3.3). However, the degree of concern is low because 1) clear NOAELs were identified for the effects and 2) the selected endpoints and doses are protective of the observed developmental effects and observed susceptibility.

### 2.3.5 Toxicity Endpoint and Point of Departure Selections

The Agency established points of departure (PODs) and endpoints to perform incidental oral, dermal and inhalation risk assessments for the antimicrobial uses of tebuconazole. The PODs for incidental oral, dermal and inhalation exposure are the same as those used for the conventional uses of tebuconazole (US EPA, 2020a). It should be noted that many of the NOAELs and LOAELs presented in the toxicology profile table (Appendix Table A2) have not been updated to comply with current practices since they did not impact points of departure for risk assessment. Appendix Table A3 contains all current endpoints and points of departure while Table 4 contains only those points of departure chosen for current antimicrobial exposure scenarios.

***Short- and intermediate-term incidental oral (Children 1 to <2 years):*** The two-generation reproduction toxicity study in rats (MRID 40700946) was selected to evaluate incidental oral exposure in children based on decreased pup body weight observed at the offspring LOAEL of 50 mg/kg/day (NOAEL = 15 mg/kg/day). This study is appropriate for the duration of exposure and is protective of all effects seen following subchronic exposure to tebuconazole. The level of concern (LOC) for incidental oral exposures is 100 (10X for interspecies extrapolation, 10X for intraspecies extrapolation, and 1X for FQPA SF).

***Dermal (all durations):*** There were no adverse effects observed in the route-specific dermal toxicity study in rabbits (MRID 40700937) or in the dermal developmental toxicity in rats (MRID 41450801) or mice (MRID 42010301); however, since increased quantitative susceptibility was observed in the two-generation reproduction toxicity study in rats (MRID 40700946), an oral point of departure was selected for dermal risk assessment because the dermal toxicity or the dermal developmental toxicity studies did not evaluate reproductive endpoints. The two-generation reproduction toxicity study in rats was selected to evaluate dermal exposure based on decreased pup body weight observed at the offspring LOAEL of 50 mg/kg/day (NOAEL = 15 mg/kg/day). The LOC for dermal exposures is 100 (10X for interspecies extrapolation, 10X for intraspecies extrapolation, and 1X for FQPA SF).

***Short- and intermediate-term inhalation:*** There were adverse effects observed in the route-specific inhalation toxicity study (MRID 40700938) at 155.8 mg/m$^3$; however, since increased quantitative susceptibility was observed in the database, an oral point of departure (MRIDs 43776201/43776202) was selected for inhalation risk assessment because the inhalation toxicity study did not evaluate developmental and reproductive endpoints. The developmental toxicity study in mice was selected to evaluate inhalation exposures based on an increased incidence of exencephaly, acrania, and skull malformations at the LOAEL of 10 mg/kg/day (NOAEL = 3 mg/kg/day). In addition, developmental effects were observed in the developmental toxicity study in the mouse at a similar dose as the human equivalent dose calculated from the inhalation toxicity study (~3 mg/kg/day), so this study is protective of any effects observed after inhalation exposure. The LOC for inhalation exposures is 100 (10X for interspecies extrapolation, 10X for intraspecies extrapolation, and 1X for FQPA SF). For this endpoint, inhalation exposure is assumed to be equivalent to toxicity by the oral route of exposure.

**Table 4. Summary of Toxicological Doses and Endpoints for Tebuconazole**

| Table 4. Summary of Toxicological Doses and Endpoints for Antimicrobial Uses for Tebuconazole | | | | |
|---|---|---|---|---|
| **Exposure/ Scenario** | **Point of Departure** | **Uncertainty/FQPA Safety Factors** | **RfD, PAD, Level of Concern for Risk Assessment** | **Study and Toxicological Effects** |
| Incidental Oral Short-/Intermediate-Term (1-30 days/1-6 months) | Offspring NOAEL = 15 mg/kg/day | $UF_A$= 10x<br>$UF_H$=10x<br>FQPA SF= 1x | Residential LOC for MOE = 100 | Two-generation reproduction toxicity study – Rat (MRID 40700946)<br>Offspring LOAEL = 50 mg/kg/day based on decreased pup body weight (11-22%; F1 and F2 generations). |
| Dermal (All Durations) | Offspring NOAEL = 15 mg/kg/day<br><br>DAF=13% | $UF_A$= 10x<br>$UF_H$=10x<br>FQPA SF= 1x | Residential LOC for MOE = 100 | Two-generation reproduction toxicity study – Rat (MRID 40700946).<br>Offspring LOAEL = 50 mg/kg/day based on decreased pup body weight (11-22%; F1 and F2 generations). |
| Inhalation Short-/Intermediate-Term (1-30 days/1-6 months) | Developmental NOAEL = 3 mg/kg/day | $UF_A$= 10x<br>$UF_H$=10x<br>FQPA SF = 1x<br><br>Inhalation and oral toxicity are assumed to be equivalent | Residential/Occupational LOC for MOE = 100 | Developmental Toxicity Study – Mice (MRID 43776201/43776202).<br>Developmental LOAEL = 10 mg/kg/day based on increased incidence of skull/neural tube defects including abnormalities of the eyes, head, and skull (exencephaly, open eyes, cleft palate, acrania/partial acrania). |
| Inhalation Long-Term (females) | Developmental NOAEL = 3 mg/kg/day | $UF_A$= 10x<br>$UF_H$=10x<br>FQPA SF= 1x<br><br>Inhalation and oral toxicity are assumed to be equivalent | Residential LOC for MOE = 100 | Developmental Toxicity Study – Mice (MRID 43776201/43776202).<br>Developmental LOAEL = 10 mg/kg/day based on increased incidence of skull/neural tube defects including abnormalities of the eyes, head and skull (exencephaly, open eyes, cleft palate, acrania/partial acrania). |
| Cancer (oral, dermal, inhalation) | Classification: Group C- possible human carcinogen based on statistically significant increase in the incidence of hepatocellular adenoma, carcinoma, and combined adenoma/carcinomas in both sexes of NMRI mice. The chronic risk assessment is considered protective of any cancer effects; therefore, a separate quantitative cancer risk assessment is not required (A. Protzel and E. Rinde, 09/15/1993, TXR#0052724). | | | |

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. $UF_A$ = extrapolation from animal to human (interspecies). $UF_H$ = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern. DAF = dermal absorption factor.

## 2.4 Dietary Exposure and Risk Assessment

There are no dietary exposures from the antimicrobial uses of tebuconazole, and as such no dietary risk assessment was conducted.

## 2.5 Residential (Non-Occupational) Exposure/Risk Characterization

### 2.5.1 Residential Handler Exposure

Residential handler exposures to materials preserved with tebuconazole (glues, adhesives, and sealants) are expected to be minimal, due to tebuconazole's low vapor pressure, small amounts used, infrequent use and minimal dermal contact with treated articles. Additionally, registered wood and MWF preservative uses are for industrial use only. Therefore, residential handler exposure and risk is expected to be minimal and a quantitative risk assessment was not conducted.

### 2.5.2 Post-Application Exposure

There is potential for post-application dermal and incidental oral exposures to occur when children play on treated decks and playsets constructed with wood that has been pressure treated with tebuconazole. These exposures are short- to intermediate-term in duration.

Dislodgeable Residue Study Description

The study **"**Determination of Dislodgeable Tebuconazole Residues from Spruce and Southern Pine (SYP) Boards Pressure Treated with Formulation JJT 4929-1" was submitted as MRID 502270-10. This study was reviewed by the Agency and found to be acceptable in D440220 (US EPA, 2018).

The study was done with a formulation composed of 0.15% imidacloprid, 1.5% triadimefon, and 1.5% tebuconazole as the active ingredients. Wooden boards of Spruce and Southern yellow pine (SYP) were pressure treated at commercial pressure treating facility with the formulation at a target retention rate of 0.002 pounds per cubic foot (pcf) for imidacloprid, 0.02 pcf for triadimefon and 0.02 pcf for tebuconazole.

Wipe samples were first collected from the boards at approximately 6 days after treatment and then at 13, 20, 34, 62, 77, 124, and 145 days after treatment. The wipe samples were collected using a 9 x 9 cm polyester wipe attached to the 8 cm x 8 cm bottom side of a 1.1 kg aluminum block. A wooden template with inside dimensions of 8.3 cm x 62.5 cm was secured to the board with clamps. After wetting the wipe with 1.3 mL of 0.9% saline solution, the wipe-covered aluminum block was placed on one end of the template demarcation area and was pulled back and forth for 5 strokes at a slow even pace. A stroke was considered one forward and back

movement along the track of 8 cm x 62.5 cm. The block was then rotated 90 degrees and the procedure were repeated for 5 strokes for a total of 20 passes. After the wiping procedure, the wipe was cut along the outermost edges of the bottom surface of the block and placed in screw cap bottles for subsequent extraction and analysis. The bottles were stored in a refrigerator and the samples were extracted and analyzed within 14 days of collection.

Tebuconazole was extracted from the wipes three times with ethyl acetate and then the ethyl acetate was exchanged with methanol. The methanol extracts were analyzed using High Performance Liquid Chromatography in accordance with analytical method CT-028. This method had been validated by measuring the recovery of tebuconazole from polyester wipes spiked with low (1.4 ug), mid (80.4 ug) or high (359.3 ug) levels of tebuconazole, which is equivalent to 0.0028, 0.16 and 0.72 ug/cm$^2$ based on a wipe area of 500 cm$^2$. Eight replicates were spiked at the low level and 7 replicates each were spiked at the mid and high levels. The recoveries were 97.5 $\pm$ 4.0 percent, 95.1 $\pm$ 3.3 percent and 101.2 $\pm$ 1.8 percent, for the low, mid, and high levels, respectively. The standard deviation (SD) of 0.06 ug of the low-level spikes was used to calculate a method detection limit of 0.17 ug/wipe (MDL = 2.988 X SD) and the limit of quantification of 0.34 ug/wipe (LOQ = 2 x MDL).

Dislodgeable Residue Study Results:

The dislodgeable residues and retentions measured during the study are summarized in Table 5. The dislodgeable residues for the Southern yellow pine boards ranged from 0.313 µg/cm$^2$ at day 6 after treatment (DAT) to 0.020 µg/cm$^2$ by DAT 145. The dislodgeable residues for the spruce boards ranged from 0.410 µg/cm$^2$ at DAT 6 to 0.015 µg/cm$^2$ by DAT 145. The average retentions were 0.023 and 0.030 pcf for the Southern Yellow Pine and spruce boards, respectively. The measured retentions were within the range of 0.0003 to 0.05 pcf recommended on the labels.

**Table 5. Dislodgeable Residues on Tebuconazole Treated Wood**

| Species | Retention | Dislodgeable Residues (µg/cm$^2$) | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Southern Yellow Pine** | 0.023 pcf | **DAT 6** | **DAT 13** | **DAT 20** | **DAT 34** | **DAT 62** | **DAT 77** | **DAT 124** | **DAT 145** |
| | | 0.313 | 0.106 | 0.055 | 0.048 | 0.040 | 0.030 | 0.031 | 0.020 |
| **Spruce** | 0.030 pcf | **DAT 6** | **DAT 13** | **DAT 20** | **DAT 34** | **DAT 62** | **DAT 77** | **DAT 124** | **DAT 145** |
| | | 0.410 | 0.112 | 0.038 | 0.036 | 0.017 | 0.016 | 0.015 | 0.015 |

DAT = Day after Treatment. Pcf = Pounds of active ingredient per cubic foot of wood

Use of the SHEDs Wood Model to Assess Post-Application Exposures to Treated Wood

The Antimicrobials Division's initial post-application exposure scenario for pressure-treated wood was developed collaboratively between the Office of Research and Development (ORD) and the Antimicrobial Division. ORD led this effort and developed the Stochastic Human

Exposure and Dose Simulation (SHEDS) wood model (US EPA, 2005).

SHEDS is a probabilistic exposure model and assesses children in contact with chromate copper arsenate (CCA) treated structures (*i.e.*, decks and playsets). It was vetted at the EPA's Science Advisory Panel (SAP) for use in the CCA assessment. The SHEDS model can be modified for other chemicals. However, using SHEDS is a resource-intensive effort. Therefore, a deterministic approach using knowledge obtained from the SHEDS assessment is presented herein. The high-end screening-level estimate presented herein is appropriate to determine "reasonable certainty of no harm." Input parameters, such as the transferable residue and the child surface area, as well as algorithms have been slightly modified from those presented in the SHEDS documents.

The SHEDS model includes the following exposure scenarios for children playing on treated structures:

- Dermal exposure to wood transferable residues;
- Incidental ingestion from hand-to-mouth activities (wood residues);
- Incidental ingestion from soil; and
- Dermal exposure to soil.

Based on the results of the CCA assessment, direct dermal and hand to mouth contact with the treated wood exhibit the highest potential for exposure. The leaching of wood preservative into the soil and subsequent exposure is much less (>10x) than that attributed to direct contact with the treated wood itself. Therefore, the exposure from soil is expected to be a minimal additional contribution compared to the exposure from contact with the treated wood, and only contact to treated wood is quantified in this assessment.

Calculation of Treated Wood Residential Dermal Dose

The potential daily dermal dose is estimated using the following modified equation from the SHEDS report (*i.e.*, SHEDS, Appendix 2, p. A2-5):

$$PDD = \frac{DLR \times SA \times CF1}{BW}$$

Where:

PDD = Potential daily dose (mg/kg/day);
DLR = Dislodgeable residue (µg/cm$^2$)
SA = Surface area of child exposed (cm$^2$);
BW = Body weight (kg);
CF1 = Unit conversion factor (0.001 mg/µg)

Assumptions:

- DLR for Southern Yellow Pine: The dislodgeable residue for Southern Yellow Pine is 0.68 µg/cm$^2$ based on the average of the three replicate values for the samples at 6 days after treatment (0.313 µg/cm$^2$) measured in MRID 50227010 and accounting for the difference in retention rates. The wood was treated to a retention of 0.023 pcf which is 2.17 times less than the highest label retention of 0.05 pcf specified on EPA Reg. No. 39967-157.
- DLR for Spruce: The dislodgeable residue for spruce is 0.68 µg/cm$^2$ based on the average of the three replicate values for the samples at 6 days after treatment (0.410 µg/cm$^2$) measured in MRID 50227010 and accounting for the difference in retention rates. The wood was treated to a retention of 0.030 pcf which is 1.67 times less than the highest label retention of 0.05 pcf specified on EPA Reg. No. 39967-157.
- SA (unclothed skin): It is assumed that the head, top of the feet and back of the hands are not exposed to treated wood. The surface area of unclothed skin exposed to the treated wood is 1270 cm$^2$. These surface areas are based on the average body part surface areas of a 1 < 2-year-old males and female children from Table 7-2 of the 2011 Exposure Factors Handbook (US EPA, 2011b). The surface areas likely to come in contact with treated wood of unclothed body parts during warm weather are as follows:
    - the exposed portion of the arms is 50%
    - the palmar surface area is assumed to be 50% of hand surface area;
    - the exposed portion of the legs is 50%
    - the bottom of the feet are assumed to be 50% of the feet.
- SA (clothed skin): The surface area of clothed skin exposed to the treated wood is 2,830 cm$^2$. The surface areas likely to come in contact with treated wood of clothed body parts during warm weather are as follows:
    - the trunk is clothed (assessed under clothed body parts);
    - the clothed portion of the arms is 50%
    - the clothed portion of the legs is 50%

A summary of the dermal surface areas is included in Table 6.

**Table 6. Dermal Surface Area of Children Exposed to Tebuconazole Treated Wood**

| Body Part | Surface Area[A] (cm$^2$) | Exposed to wood (warm weather) | % Surface Area Exposed | Surface Area Exposed[B] (cm$^2$) | Clothed Surface Area (cm$^2$) |
|---|---|---|---|---|---|
| Head | 870 | No | 0 | 0 | Not Applicable |
| Trunk | 1880 | No | 0 | 0 | 1880 |
| Arms | 690 | partial, short sleeves | 50 | 345 | 345 |
| Hands | 300 | Palms | 50 | 150 | Not Applicable |
| Legs | 1220 | partial, short pants | 50 | 610 | 610 |
| Feet | 330 | bottom of feet | 50 | 165 | Not Applicable |
| Total | 5,290 | | Not Applicable | **1,270** | **2,830** |

A. Average values for 1 to <2-year-old children from Table 7-2 of (US EPA, 2011b)
B. Surface Area Exposed (cm$^2$) = Surface Area (cm$^2$) * (% Surface Area Exposed/100)

Dermal MOEs for Tebuconazole in Pressure Treated Wood

The dermal MOE was calculated for tebuconazole using the dislodgeable residue data and body surface areas as outlined in Table 7. The exposure for the clothed surface area was divided by 10 to account for reduced penetration due to clothing. The MOE of 1,300 for both Southern Yellow Pine and spruce is greater than the LOC of 100 and not of concern.

**Table 7. Dermal MOE for Exposure to Tebuconazole Treated Wood**

| Dislodgeable Residue (µg/cm$^2$) | Unclothed Surface Area (cm$^2$) | Unclothed Area Exposure[C] (µg/day) | Clothed Surface Area (cm$^2$) | Clothed Area Exposure[D] (µg/day) | Daily Exposure[E] (mg/day) | Daily Dose[F] (mg/kg/day) | Dermal MOE[G] (LOC = 100) |
|---|---|---|---|---|---|---|---|
| 0.68[A,B] | 1,270 | 860 | 2,830 | 190 | 1.05 | 0.012 | 1,300 |

A. Dislodgeable residue (DLR) of 0.313 µg/cm$^2$ for the wipe samples collected 6 days after treatment from SYP boards treated to a retention of 0.023 pcf adjusted to account for the retention of 0.05 pcf specified on EPA Reg. No. 39967-157.
B. Dislodgeable residue (DLR) of 0.410 ug/cm$^2$ for the wipe samples collected 6 days after treatment from spruce boards treated to a retention of 0.030 pcf adjusted to account for the retention of 0.05 pcf specified on EPA Reg. No. 39967-157.
C. Unclothed Area Exposure (µg/day) = DLR (µg/cm$^2$) * Unclothed Surface Area (cm$^2$)
D. Clothed Area Exposure (µg/day) = DLR (µg/cm$^2$) * Clothed Surface Area (cm$^2$) * Clothing Penetration Factor (0.1)
E. Daily Exposure (mg/day) = [Unclothed Area Exposure (µg/day) + Clothed Area Exposure (µg/day) * 0.001 mg/µg]
F. Daily Dose (mg/kg/day) = [Daily Exposure (mg/day) * Dermal Absorption Factor (13%)] / BW (11 kg)
G. MOE = NOAEL / Dose where the NOAEL is 15 mg/kg/day and the LOC is 100.

Calculation of the Incidental Oral Exposure

To assess incidental oral exposures for hand to mouth contact with treated wood, the dislodgeable surface residue (DLR) values along with exposure algorithms and parameters from the probabilistic Stochastic Human Exposure and Dose Simulation (SHEDS) model (US EPA, 2005a) is used. Since the incidental oral toxicological endpoint of concern for tebuconazole is not based on long-term effects such as cancer, the amortization of exposure over time that is provided in the SHEDS model for CCA is not appropriate for this assessment. The frequency of exposure for tebuconazole is believed to be best represented by the short to intermediate-term duration (*i.e.*, 1 to 180 days of continuous exposure).

The potential daily dose (PDD) from the incidental oral route of exposure is estimated using the following modified equation from the SHEDS report (*i.e.*, SHEDS, Appendix 2, p. A2-8):

$$PDD = \frac{DLR \times SA \times FQ \times ET \times SE \times CF1}{BW}$$

where:

PDD = Potential daily dose (mg/kg/day);

DLR = Dislodgeable surface residue (µg/cm$^2$);
SA = Surface area of the hands that is in contact with both the treated area and the individual's mouth (20 cm$^2$/event) (US EPA, 2001);
FQ = Frequency of hand-to-mouth events (20 events/hr) (US EPA, 2001);
ET = Exposure Time (2 hr/day) (US EPA, 2001);
SE = Saliva extraction efficiency (50%) (US EPA, 2001);
CF1 = Unit conversion factor (0.001 mg/µg); and
BW = Body weight (11 kg for 1 to <2-year-old children) (US EPA, 2011).

Incidental Oral Exposure to Wood Pressure-Treated with Tebuconazole

The incidental oral MOE for children (ages 1 to <2) was calculated for tebuconazole as outlined in Table 8. The MOE of 600 for both Southern Yellow Pine and spruce is greater than the LOC of 100 and not of concern.

**Table 8. Incidental Oral MOE for Exposure to Tebuconazole Treated Wood**

| Dislodgeable Residue (µg/cm$^2$) | Hand Area Mouthed (cm$^2$/event) | Frequency of Hand to Mouth Events per Hour | Exposure Time (hours/day) | Exposure[C] (mg/day) | Dose[D] (mg/kg/day) | MOE[E] (LOC = 100) |
|---|---|---|---|---|---|---|
| 0.68[A,B] | 20 | 20 | 2 | 0.27 | 0.025 | 600 |

A. Dislodgeable residue (DLR) of 0.313 µg/cm$^2$ for the wipe samples collected 6 days after treatment from SYP boards treated to a retention of 0.023 pcf adjusted to account for the retention of 0.05 pcf specified on EPA Reg. No. 39967-157.
B. Dislodgeable residue (DLR) of 0.410 ug/cm$^2$ for the wipe samples collected 6 days after treatment from spruce boards treated to a retention of 0.030 pcf adjusted to account for the retention of 0.05 pcf specified on EPA Reg. No. 39967-157.
C. Exposure (mg/day) = DLR (µg/cm$^2$) * Hand Area Mouthed (cm$^2$/event) * Exposure Frequency (events/hr) * Exposure Time (hrs/day) * Saliva Extraction Factor (50%/100) * 0.001 mg/µg
D. Dose (mg/kg/day) = Exposure (mg/day) / BW (11 kg for 1 <2-year-old children)
E. MOE = NOAEL / Dose where the NOAEL is 15 mg/kg/day and the LOC is 100.

## 2.6 Aggregate Exposure/Risk Characterization

The aggregate exposure risk characterization for tebuconazole is included in the HED DRA (US EPA, 2021a). For short-and intermediate-term aggregate exposures, the selected residential post-application scenario comes from the antimicrobial use of tebuconazole and is the dermal and incidental oral exposure from high-contact activities on treated wooden decking and playsets. Combined with the applicable subpopulation dietary exposure, the short-term aggregate MOE of 212 for children 1 to 2 years old does not fall below HED's LOC (LOC = 100) and is not of concern.

## 2.7 Cumulative Exposure/Risk Characterization

Tebuconazole is a member of the triazole-containing class of pesticides. Although triazole fungicides act similarly in plants (fungi) by inhibiting ergosterol biosynthesis, there is not

necessarily a relationship between their pesticidal activity and their mechanism of toxicity in mammals. Structural similarities do not constitute a common mechanism of toxicity. Evidence is needed to establish that the chemicals operate by the same, or essentially the same, sequence of major biochemical events. In triazole fungicides, however, a variable pattern of toxicological responses is found; some are hepatotoxic and hepatocarcinogenic in mice. Some induce thyroid tumors in rats. Some induce developmental, reproductive, and neurological effects in rodents. Furthermore, the triazole fungicides produce a diverse range of biochemical events including altered cholesterol levels, stress responses, and altered DNA methylation. It is not clearly understood whether these biochemical events are directly connected to their toxicological outcomes. Thus, there is currently no evidence to indicate that conazoles share common mechanisms of toxicity and EPA is not following a cumulative risk approach based on a common mechanism of toxicity for the triazole fungicides. For information regarding EPA's procedures for cumulating effects from substances found to have a common mechanism of toxicity, see EPA's website at http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.

## 2.8 Occupational Exposure/Risk Characterization

There is potential for occupational handler short- and intermediate-term inhalation and dermal exposure when tebuconazole is added as a materials preservative during the manufacturing of plastics, glues, adhesives, sealants, and metalworking fluids, and when handling treated articles containing tebuconazole as a materials preservative. Dermal and inhalation exposure to machinists handling tebuconazole-preserved MWF is expected to be short-, intermediate- and long-term in duration. Dermal and inhalation exposure to occupational handlers of tebuconazole as part of the pressure- and sapstain-treatment process for wood preservation is expected to be short-, intermediate- and long-term in duration.

### 2.8.1 Occupational Handler Exposure/Risk Characterization

The MOEs for occupational handler inhalation exposures to tebuconazole as a materials preservative were assessed as outlined in Table 9. The MOE for the powder pour scenario is 1.2 and is of concern because it is less than the LOC of 100. The MOE is no longer of concern if the application rate is reduced to 4,500 ppm and when considering the use of label-required respiratory protection. The MOE for the liquid pour scenario is 160 and is not of concern because it is greater than the LOC of 100.

**Table 9. Occupational Handler Inhalation MOEs for Preservative-Use Tebuconazole**

| Scenario | Max Application Rate[A] | Amount Treated per day[B] | Amount a.i. Handled (lb/day)[C] | Unit Exposure (mg/lb a.i.) | Inhalation Daily Dose (mg/kg/day)[F] | MOE[G] (LOC = 100) |
|---|---|---|---|---|---|---|
| Materials Preservative Use (Plastics, Glues, Adhesives, Sealants, MWF) | | | | | | |
| Open Pour Liquid for Materials Preservation | 38,000 ppm | 20,000 lbs Treated Articles | 760 | 0.0017[D] | 0.0187 | 160 |
| Open Pour Powder for Materials Preservation | | | | 0.224[E] | 2.47 | **1.2[H]** |

A. Based on EPA Reg. No. 39967-157, and assuming treated MWF is a surrogate for other materials.
B. Standard assumptions used for occupational exposure assessments of AD chemicals.
C. Amount of a.i. Handled (lb/day) = (Application Rate (ppm) / 1,000,000) x Amount Treated (lbs/day).
D. Open pour value from the AEATF II human exposure liquid pour study (MRID 48917401).
E. Open pour value from the AEATF II human exposure solid pour study (MRID 49905201).
F. Inhalation Daily Dose (mg/kg/day) = [Amount a.i. Handled (lb/day) * Unit Exposure (mg/lb a.i.)] / BW (69 kg)
G. MOE = POD (3 mg/kg/day) / Inhalation Daily Dose (mg/kg/day).
H. MOE = 100 if application rate is reduced to 4,500 ppm and when considering the use of label-required respiratory protection (PF10).

Occupational Handler Dermal Exposures

The MOEs for occupational handler dermal exposures were assessed as outlined in Table 10. The MOE for the liquid pour scenario is 12 and is of concern because it is less than the LOC of 100. The MOE is no longer of concern if application rate is reduced to 4,500 ppm. The MOE for the powder pour scenario is 54 and is of concern because it is less than the LOC of 100. The MOE is no longer of concern if application rate is reduced to 20,000 ppm.

**Table 10. Occupational Handler Dermal MOEs for Preservative-Use Tebuconazole**

| Scenario | Max Application Rate[A] | Amount Treated per day[B] | Amount a.i. Handled (lb/day)[C] | Unit Exposure (mg/lb a.i.) | Dermal Exposure[F] (mg/day) | Dermal Dose[G] (mg/kg/day) | MOE[H] (LOC = 100) |
|---|---|---|---|---|---|---|---|
| Open Pour Liquid for Plastics Preservation | 38,000 ppm | 20,000 lbs Treated Articles | 760 | 1.0[D] | 760 | 1.24 | **12[I]** |
| Open Pour Powder for Plastics Preservation | | | | 0.226[E] | 170 | 53.7 | **54[J]** |

A. Based on EPA Reg. No. 39967-157, and assuming treated MWF is a surrogate for other materials.
B. Standard assumptions used for occupational exposure assessments of AD chemicals.
C. Amount of a.i. Handled (lb/day) = (Application Rate (ppm) / 1,000,000) x Amount Treated (lbs/day).
D. Open pour value from the AEATF II human exposure liquid pour study (MRID 48917401). Gloves worn.
E. Open pour value from the AEATF II human exposure solid pour study (MRID 49905201). Gloves worn.
F. Dermal Exposure (mg/day) = Amount a.i. Handled (lb/day) * Unit Exposure (mg/lb a.i.)
G. Dermal Dose (mg/kg/day) = [Dermal Exposure (mg/day) * DAF (13%/100)] / Body Weight (80 kg)
H. MOE = POD (15 mg/kg/day) / Dermal Dose (mg/kg/day)
I. MOE = 100 if application rate is reduced to 4,500 ppm.
J. MOE = 100 if application rate is reduced to 20,000 ppm.

### 2.8.2 Occupational Machinist Exposures to Tebuconazole in Metalworking Fluids

Tebuconazole is registered for use in metalworking fluids (MWFs); therefore, there is potential for machinists to be exposed when using treated MWFs. Short-, intermediate- and long-term dermal and inhalation exposures are anticipated.

Machinist Inhalation MOEs

The inhalation MOE of 11,000 was calculated as outlined in Table 11. This MOE is not of concern because it is greater than the LOC of 100.

**Table 11. Inhalation MOE for Machinists Using Tebuconazole-Treated MWF**

| Max Application Rate[A] | MWF Air Concentration ($mg/m^3$)[B] | Tebuconazole Air Concentration ($mg/m^3$)[C] | Inhalation Exposure (mg/day)[D] | Inhalation Dose[E] (mg/kg/day) | Inhalation MOE[F] (LOC = 100) |
|---|---|---|---|---|---|
| 1,900 ppm | 1.0 | 0.0019 | 0.019 | 0.000275 | 11,000 |

A. Maximum application rate for metalworking fluids (MWF) listed on EPA Reg No. 39967-157.
B. Average 8 hr TWA for oil mist air (n=544 samples) measured by OSHA (2000 to 2009), corrected for 25% volatilization loss based on McAneny (1995) and Park (2003).
C. Tebuconazole Air Concentration ($mg/m^3$) = Application Rate (ppm/1,000,000) * MWF Air Concentration (1.0 $mg/m^3$).
D. Inhalation Exposure (mg/day) = [Tebuconazole Air Concentration ($mg/m^3$) * Inhalation Rate (1.25 $m^3$/hr) * Exposure Time (8 hr / day)]
E. Inhalation Dose (mg/kg/day) = Inhalation Exposure (mg/day) / Body Weight (69 kg)
F. Inhalation MOE = NOAEL (3 mg/kg/day) / Inhalation Dose (mg/kg/day)

Machinist Dermal MOEs

The dermal MOE of 1,400 was calculated as outlined in Table 12. This MOE is not of concern because it is greater than the LOC of 100.

**Table 12. Dermal MOE for Machinists Using Tebuconazole-Treated MWF**

| Application Rate[A] | Quantity of MWF Remaining on Skin (Qu)[B] | Skin Surface Area[C] | Dermal Exposure[D] (mg/day) | Dermal Dose[E] (mg/kg/day) | Dermal MOE[F] (LOC = 100) |
|---|---|---|---|---|---|
| 1,900 ppm | 1.75 $mg/cm^2$ | 2,030 $cm^2$ | 6.75 | 0.011 | 1,400 |

A. Maximum application rate for metalworking fluids (MWF) listed on EPA Reg. No. 39967-157.
B. Qu = 1.75 $mg/cm^2$ based on mineral oil hand immersion with wiping results reported in Cinalli (1992).
C. Sum of hands (820 $cm^2$) and forearms (1210 $cm^2$) values from OCSPP Guideline 875.1200 (US EPA, 1996).
D. Dermal Exposure (mg/day) = Application rate (ppm/1,000,000) * Qu ($mg/cm^2$) * Skin Surface Area ($cm^2$)
E. Dermal Dose =Dermal Exposure (mg/day) * DAF (13%/100)] / BW (80 kg)
F. Dermal MOE = NOAEL (15 mg/kg/day) / Dose (mg/kg/day)

### 2.8.3 Occupational Exposure Assessment of Pressure Treatment Applications for Wood Preservation

Occupational handler exposures are anticipated to occur during pressure-treatment applications of tebuconazole for wood preservation. These exposures are anticipated to be short-, intermediate- and long-term in duration, and they can occur via the dermal or inhalation routes.

Pressure Treatment Worker Inhalation MOEs for Tebuconazole

A summary of the inhalation MOEs for pressure treatment workers is included in Table 13. The MOEs range from 300 to 1,200 and are not of concern because they are greater than the LOC of 100.

**Table 13. Pressure Treatment Workers Inhalation MOEs**

| Job Function | Max Application Rate[A] (% a.i.) | Inhalation Unit Exposure[B] (µg/percent a.i.) | Inhalation Exposure[C] (mg/day) | Inhalation Dose[D] (mg/kg/day) | Inhalation MOE[E] (LOC = 100) |
|---|---|---|---|---|---|
| Treatment Operator | 4.9 | 34.3 | 0.168 | 0.00245 | 1,200 |
| Wood Handler | | 140.1 | 0.686 | 0.00995 | 300 |

A. Application rate is based on EPA Reg. No. 39967-157.
B. Estimated Arithmetic Average (AMm) from the AEATF II Pressure Treatment Exposure Study (MRID 49434501) for Sites ABDE as listed in Tables 15 and 28 of Cohen (2018).
C. Inhalation Exposure (mg/day) = Application Rate (% a.i.) * Inhalation Unit Exposure (µg/% a.i.) * 0.001 mg/µg.
D. Inhalation Dose (mg/kg/day) = Inhalation Exposure (mg/day) / BW (69kg).
E. Inhalation MOE = NOAEL (3 mg/kg/day) / Inhalation Dose (mg/kg/day).

Pressure Treatment Worker Dermal MOEs for Tebuconazole

A summary of the dermal MOEs for pressure treatment workers is included in Table 14. The MOEs range from 370 to 2,200 and are not of concern because they are greater than the LOC of 100.

**Table 14. Pressure Treatment Workers Dermal MOEs for Tebuconazole**

| Job Function | Application Rate[A] (% a.i.) | Dermal Unit Exposure[B] (mg/% a.i.) | Dermal Exposure[C] (mg/day) | Dermal Dose[D] (mg/kg/day) | Dermal MOE[E] (LOC = 100) |
|---|---|---|---|---|---|
| Treatment Operator | 4.9 | 0.87 | 4.3 | 0.00693 | 2,200 |
| Wood Handler | 4.9 | 5.05 | 25 | 0.0402 | 370 |

A. Based on EPA Reg. No. 39967-157.
B. Estimated Arithmetic Average (AMm) from the AEATF II Pressure Treatment Exposure Study (MRID 49434501) for sites ABDE as listed in Tables 15 and 23 of Cohen (2106).
C. Dermal Exposure (mg/day) = Application Rate (% a.i.) * Unit Exposure (mg/% a.i.)
D. Dermal Dose (mg/kg/day) = [Dermal Exposure (mg/day) * DAF (13%/100)] / Body Weight (80 kg).
E. Dermal MOE =NOAEL (15 mg/kg/day) / Dermal Dose (mg/kg/day)

### 2.8.4 Occupational Exposure Assessment of Sapstain Treatment Applications for Wood Preservation

Occupational handler exposures are anticipated to occur during the process of applying tebuconazole as a wood preservative via dip or spray-treatment (sapstain treatment). These exposures are anticipated to be short-, intermediate- and long-term in duration, and they can occur via the dermal or inhalation routes.

Sapstain Treatment Worker Inhalation MOEs

The MOEs for sapstain treatment worker inhalation exposures to tebuconazole were assessed as outlined in Table 15. The MOE for the clean-up crew scenario is 38 and is of concern because it is less than the LOC of 100. The MOE is no longer of concern when considering the use of label-required respiratory protection. The remaining inhalation MOEs range from 810 to 1,400 and are not of concern because they are greater than the LOC of 100.

**Table 15. Sapstain Treatment Worker Inhalation MOEs for Tebuconazole**

| Application Rate | Job Function | Unit Exposure[B] ($mg/m^3$/% a.i.) | Exposure[C] ($mg/m^3$) | Daily Dose[D] (mg/kg/day) | Inhalation MOE[E] (LOC = 100) |
|---|---|---|---|---|---|
| 4.8 percent Tebuconazole in Treatment Solution[A] | Dip Tank Operator | 0.0052 | 0.026 | 0.0037 | 810 |
| | Millwright | 0.0031 | 0.015 | 0.0022 | 1,400 |
| | Chemical Attendant | 0.0043 | 0.021 | 0.0031 | 980 |
| | Clean-up Crew | 0.111 | 0.54 | 0.079 | **38**[F] |

A. Based on EPA Reg. No. 39967-157
B. Unit exposures are from the Sapstain Phase III study (MRID 45524301).
C. Exposure ($mg/m^3$) = Application Rate (% a.i.) * Unit Exposure ($mg/m^3$/% a.i.)
D. Dose (mg/kg/day) = Exposure ($mg/m^3$) * Inhalation Rate (1.25 $m^3$/hr) * Exposure Time (8 hrs/day)] / BW (69 kg)
E. Inhalation MOE = NOAEL (3 mg/kg/day) / Daily Dose (mg/kg/day)
F. MOE = 380 when considering label-required respiratory protection (PF10).

Sapstain Treatment Worker Dermal Exposures

The MOEs for sapstain treatment worker dermal exposures were assessed as outlined in Table 16. The MOE for the clean-up crew scenario is 26 and is of concern because it is less than the LOC of 100. The MOE is no longer of concern if the application rate is reduced to 12,500 ppm (1.25% tebuconazole in the treatment solution). The remaining dermal MOEs range from 110 to 630 and are not of concern because they are greater than the LOC of 100.

**Table 16. Sapstain Treatment Worker Dermal MOEs for Tebuconazole**

| Application Rate | Job Function | Unit Exposure[B] (mg/day/% a.i.) | Dermal Exposure[C] (mg/day) | Dermal Dose[D] (mg/kg/day) | Dermal MOE[E] (LOC =100) |
|---|---|---|---|---|---|
| 4.8 percent Tebuconazole in Treatment Solution[A] | Dip Tank Operator | 2.99 | 14.4 | 0.023 | 630 |
| | Millwright | 7.10 | 34.08 | 0.055 | 270 |
| | Chemical Attendant | 17.1 | 82.08 | 0.13 | 110 |
| | Clean-up Crew | 72.4 | 348 | 0.57 | **26**[F] |

A. Based on EPA Reg. No. 39967-157
B. Unit exposures are from the Sapstain Phase III study (MRID 45524301). Glove use was assumed.
C. Dermal Exposure (mg/day) = Application Rate (% a.i.) * Unit Exposure (mg/day/% a.i.)
D. Dermal Dose (mg/kg/day) = [Dermal Exposure (mg/day) * DAF (13%/100)] / BW (80 kg)
E. Dermal MOE = NOAEL (15 mg/kg/day) / Dermal Dose (mg/kg/day)
F. MOE = 100 if application rate is reduced to 1.25% Tebuconazole in treatment solution.

### 2.8.5 Occupational Post-Application Exposure and Risk Characterization

Occupational post-application dermal and inhalation exposures are not anticipated for the antimicrobial uses of tebuconazole based on the physical-chemical properties and registered use patterns. Tebuconazole has a low vapor pressure of 1.3 x $10^{-8}$ torr at 25°C (Table 1), which precludes inhalation exposures to vapors in areas containing tebuconazole-preserved materials. In addition, tebuconazole is not applied using methods such as fogging, which would result in the generation of small droplets that remain airborne for long periods after application.

## 2.9 Human Health Incidents

Based on a search of the Incident Data System (IDS) for individual incidents (i.e., those reported separately) from 2016 to January 29, 2021, there were no incidents identified for the AD uses of tebuconazole.

# 3 ENVIRONMENTAL RISK ASSESSMENT

Based on the current registered use patterns for the antimicrobial uses of tebuconazole, there are no uses that are expected to result in exposures to terrestrial organisms (including pollinators). There are some antimicrobial uses (*i.e.*, metal working fluid, wood preservative, and material preservation of plastics, glues, adhesives, and sealants) that could result in aquatic exposures. However, the antimicrobial uses of tebuconazole with the greatest potential for aquatic exposure are the wood preservative (treated wood used for docks) and metalworking fluid uses because of their direct discharge or leaching into aquatic areas. Therefore, results from the docks and MWF assessments are expected to be protective of other uses. The environmental risk assessment for tebuconazole below focuses on potential risks to aquatic organisms from wood products and metal working fluid use sites.

## 3.1 Environmental Fate

### 3.1.1 Available Data

Tebuconazole is generally persistent to both abiotic and biotic degradation but forms various primary degradation products at $\leq$10 % of parent compound with minimal mineralization to $CO_2$. Residues of tebuconazole are expected to be moderately mobile in the environment and be present in both the water and sediment phase in surface water.

The environmental fate data for tebuconazole from the Environmental Fate and Effects Division (EFED) "Tebuconazole: Draft Ecological Risk Assessment for Registration Review" (U.S. EPA, 2021b) are summarized in Table 17 below.

**Table 17. Environmental Fate Data for Tebuconazole**

| Study | System Details | Study Result[1] (half-life in days unless specified) | | | Source (MRID unless specified)/Study Classification/Comment[2] |
|---|---|---|---|---|---|
| **Persistence** | | | | | |
| Abiotic Hydrolysis | pH 5, 7, 9 | Stable | | | 40700957. Acceptable |
| Atmospheric Degradation | Hydroxyl Radical | 0.9 | | | Estimated value EPIWEB Version 4.1 |
| Aqueous Photolysis | pH 7, 22 - 32°C 39°N sunlight | Stable | | | 40700958 Acceptable |
| Soil Photolysis | Sandy loam, 16 - 27°C, pH 4.5 39°N sunlight | 192.5 days | | | 40700958. Acceptable |
| Aerobic Soil Metabolism | Sandy loam, 23±2°C | 796 days | | | 40700959 Acceptable |
| Aerobic Aquatic Metabolism | Gravel pit water, 22±2°C | 434 and 826 days | | | 48707405 Supplemental. Study indicates a half-life of greater than one year. |
| Anaerobic Aquatic Metabolism | Sandy loam, 22±1°C | 1,478 days | | | 48707403 Supplemental. Study indicates a half-life of greater than one year. |
| **Field dissipation** | | | | | |
| Terrestrial field dissipation | 9 soils | 163-349 days | | | 45359901 44108310 44108311 44108312 44108313 44108314 44108315 44108316 45359901 |
| **Mobility** | | | | | |
| Leaching-Adsorption-Desorption | 8 soils | **Soil/Sediment** | **$K_d$** | **$K_{OC}$** | 40995922 50681901, and 50681902 Acceptable. Slightly to Moderately Mobile (FAO classification system); $K_{OC}$ better predictor of sorption based on lower CV. |
| | | | | | |
| | | pH 5.2 | 12.7 | 906 | |
| | | pH 5.3 | 16.4 | 911 | |
| | | pH 5.6 | 7.69 | 1025 | |
| | | pH 5.2 | 15.9 | 1251 | |
| | | pH 7.6 | 13.0 | 463 | |
| | | pH 7.6 | 28.2 | 1084 | |
| | | pH 5.7 | 12.7 | 1057 | |
| | | pH 6.9 | 10.8 | 803 | |
| | | Mean | 14.7 | 938 | |
| | | CV | 39% | 23% | |

| Study | System Details | Study Result[1] (half-life in days unless specified) | Source (MRID unless specified)/Study Classification/Comment[2] |
|---|---|---|---|
| **Bioconcentration in fish** | | | |
| Fish Bioconcentration Factor (BCF) | **Species**<br>Bluegill Sunfish | BCF (unitless)<br>98.6 for whole fish<br>24.8 for edible tissue | 40995905, 40995906, 40995907, and 42487501<br><br>90% depuration at day 3. Full depuration at day 10. |

[1] The value used to estimate a model input value is the calculated via the single first order equation. The model chosen is consistent with that recommended using the, *Guidance for Evaluating and Calculating Degradation Kinetics in Environmental Media* (NAFTA, 2012). Some values were calculated using natural log transformed data to estimate the SFO half-life (designated with SFO-LN).
[2]Data taken from Tables 5-1, 5-2, and 5-3 of U.S. EPA 2021b.

In addition to the studies above used to support the conventional uses of tebuconazole, the Agency has received data on the fate of tebuconazole in a wastewater treatment plant (WWTP) and on leaching from treated wood. Table 18 contains these data.

**Table 18. WWTP Data and Wood Leaching Data for Tebuconazole**

| Guideline | Value | Reference (MRID)/Comments |
|---|---|---|
| Activated Sludge Sorption Isotherm (ASSI, 835.1110) | Average Kf value of 282 L/kg and Koc value of 776 L/kg<br><br>45.2 % of tebuconazole sorbed to sludge | 51167402 |
| Ready Biodegradability (835.3110) | 3 % degradation in 28 days | 50472402<br>Not readily biodegradable |
| Biodegradability in Activated Sludge (835.3280) | Parent degradation of 0 % by 6-8 hours (typical treatment time), 81 % degradation by 28 days. Formation of 3 major degradation products and 5 minor degradation products<br><br>6-14% of post-extraction residues were associated with sludge | 51167401<br><br>Both parent compound and degradation products (unidentified) will be present in effluent from WWTP |
| Wood Leaching (AWPA E11-12) | Leaching rate of 0.09 µg/cm$^2$/day for 0.15 PCF[1] and 0.25 µg/cm$^2$/day for 0375 PCF<br><br>1.8-4.6 % leached in study | 48901607<br>Leaching from submerged wood |

[1] PCF=Pounds per cubic foot

### 3.1.2 Environmental Fate Data Gaps

GDCI-128997-1598 required activated sludge respiration (ASRI, 850.3300) data, and data that can be used in risk assessment have not been submitted. These are data gaps for tebuconazole.

### 3.1.3 Degradates of Potential Concern

There are no degradates of concern for the antimicrobial uses of tebuconazole, as the parent compound is essentially stable or stable in environmental fate studies, and any degradates are formed in non-significant (<10%) quantities are low in toxicity compared to parent tebuconazole (US EPA, 2021b).

### 3.1.4 Water Quality – Total Maximum Daily Load

Based on a November 15, 2020 search, tebuconazole is not identified as a cause of impairment for any water bodies listed as impaired under Section 303(d) of the Clean Water Act. In addition, no Total Maximum Daily Loads (TMDLs) have been developed for tebuconazole. More information on impaired water bodies and TMDLs can be found at the Agency's website.

### 3.1.5 Monitoring Data

Water monitoring data for tebuconazole are provided in EFED water assessment (US EPA, 2021c). The maximum concentrations in surface water were 3.2-3.3 µg/L for surface water with detection rates of 1.5 % in the CADPR Surface Water database (CADPR) and 13 % in the USGS NWQA database. The maximum ground water concentration was 0.26 µg/L in ground water with a detection frequency of 0.08 % (Table 6, p. 13).

## 3.2 Ecological Effects

### 3.2.1 Ecotoxicity Data

Ecological effects data are used to estimate the toxicity of tebuconazole to surrogate species. The ecotoxicity data currently available for tebuconazole are studies for freshwater fish (acute and chronic), freshwater invertebrates (acute and chronic), estuarine/marine fish (acute and chronic), estuarine/marine invertebrates (acute and chronic), freshwater benthic invertebrates (chronic), estuarine/marine benthic invertebrates (chronic), aquatic plants (non-vascular and vascular), honeybee (acute) and avian species (acute and dietary). These studies have been reviewed by the Environmental Fate and Effects Division (EFED) and are suitable for use in a risk assessment.

### 3.2.2 Selected Ecotoxicity Endpoints

The most sensitive endpoints for each tested taxon for tebuconazole are listed in Table 19. The full ecotoxicity profile of tebuconazole is available in the EFED Draft Risk Assessment (US EPA, 2021b).

**Table 19. Ecological Effects Endpoints Selected for Tebuconazole**

| Receptor Group | Surrogate Species | Exposure Scenario | Toxicity Endpoint (µg a.i./L, unless otherwise specified) | Reference MRID |
|---|---|---|---|---|
| Birds | Bobwhite Quail (*Colinus virginianus*) | Acute | $LD_{50}$ = 1988 mg/kg body weight<br>Slightly toxic<br>(Acceptable) | 40700905 |
| | Bobwhite Quail (*Colinus virginianus*) | Dietary | $LC_{50}$ = $\geq$ 5000 mg a.i./kg feed<br>(Acceptable)<br>Practically non-toxic | 40700907 |
| Freshwater Fish | Rainbow trout (*Oncorhynchus mykiss*) | Acute | 96-hr $LC_{50}$ = 2270<br>(Supplemental – quantitative)<br>Moderately toxic | 46919204 |
| | Fathead minnow (*Pimephales promelas*) | Chronic | NOAEC = 11<br>LOAEC = 22<br>(Supplemental – quantitative)<br>Based on reduction in female growth | 48109802 |
| Freshwater Invertebrates | Waterflea (*Daphnia magna*) | Acute | 48-hr $EC_{50}$ = 2880<br>(Acceptable)<br>Moderately toxic | 46919205 |
| | Waterflea (*Daphnia magna*) | Chronic | NOAEC = 120<br>LOAEC = 230<br>(Acceptable)<br>Based on reduction in parental body length and reproduction | 40700915 |
| Freshwater Benthic Invertebrates | Freshwater amphipod (*Hyalella azteca*) | Chronic | 10-day OC-normalized sediment:<br>NOAEC = 220,000 µg ai/kg<br>LOAEC = 440,000 µg ai/kg<br>Pore water:<br>NOAEC = 52.2<br>LOAEC = 114<br>Overlying water:<br>NOAEC = undefined*<br>LOAEC = 4.16<br>Based on reduction in offspring/female and reproduction<br>(Acceptable) | 50938403 |
| Estuarine/Marine Fish | Sheepshead minnow (*Cyprinodon variegatus*) | Acute | 96-hr $LC_{50}$ = 5900<br>(Acceptable)<br>Moderately toxic | 40995904 |

| Receptor Group | Surrogate Species | Exposure Scenario | Toxicity Endpoint (µg a.i./L, unless otherwise specified) | Reference MRID |
|---|---|---|---|---|
| | Sheepshead minnow (*Cyprinodon variegatus*) | Chronic | NOAEC = 19<br>LOAEC = 43.6<br>(Supplemental – quantitative)<br>Based on reduction of offspring body length | 43009601 |
| Estuarine/Marine Invertebrates | Mysid (*Americamysis bahia*) | Acute | 96-hr $LC_{50}$ = 490<br>(Acceptable)<br>Highly toxic | 40995902 |
| | Mysid (*Americamysis bahia*) | Chronic | NOAEC = 35<br>LOAEC = 61<br>(Acceptable)<br>Based on reduction in reproduction | 42038201 |
| Estuarine/Marine Benthic Invertebrates | Marine amphipod (*Leptocheirus plumulosus*) | Chronic | 10-day OC-normalized sediment:<br>NOAEC = 1,900,000 µg ai/kg<br>LOAEC > 1,900,000 µg ai/kg<br>Pore water:<br>NOAEC = 1800<br>LOAEC > 1800<br>Overlying water:<br>NOAEC = 180<br>LOAEC > 180<br>No treatment-related effects<br>(Acceptable) | 50956903 |
| Aquatic Non-Vascular Plants | Saltwater diatom (*Skeletonema costatum*) | All | 96-hr $EC_{50}$ = 170<br>(Acceptable)<br>Based on area under the curve | 50533002 |
| Aquatic Vascular Plants | Duckweed (*Lemna gibba*) | All | $EC_{50}$ = 151<br>(Acceptable)<br>Based on frond density | 44246901 |
| Non-target Terrestrial Insects | Honeybee (*Apis mellifera*) | Acute | 48-hr $LD_{50}$ = >83 µg a.i./bee | 50533001 |

$LD_{50}$ = 50 percent lethal dose, $EC_{50}$ = 50 percent effect concentration, NOAEC = no observed adverse effect concentration, LOAEC = lowest observed adverse effect concentration
*A test record for overlying water was not generated because the lowest test level could not be analytically quantified (<LOQ).

## 3.3 Ecological Incidents

There were no reported ecological incidents related to the antimicrobial uses of tebuconazole in the Agency's Incident Data System (IDS) as of October 27, 2020.

### 3.3.1 Ecotoxicity Data Gaps

There are no ecotoxicity data gaps for the registered antimicrobial uses of tebuconazole.

## 3.4 Aquatic Exposure

**Exposure and Risk from Wood Preservatives and Metal Working Fluids**

Tebuconazole used for wood preservatives, and metal working fluids are expected to result in the highest aquatic exposures because of their direct discharge or leaching into aquatic areas. Other uses, such as material preservation of adhesives, plastics, and textiles have the potential for environmental exposure, but the MWF, and wood preservative use assessments were determined to be protective of these uses. This assessment focuses on the wood preservative and metal working fluid uses.

### 3.4.1 Exposure and Risk from Wood Preservatives

Tebuconazole used as a wood preservative has the potential to result in environmental exposure when leachate from treated surfaces runoff or leach directly into aquatic areas. Wood preservatives used in docks result in direct leaching into aquatic areas. Those used in terrestrial locations (*i.e.*, fences, decks) reach aquatic areas indirectly after passing over soil and/or other medium. The dock scenario is modeled below because it is expected to result in the highest aquatic exposures, and, thus, would be protective of the other wood preservative uses.

#### 3.4.1.1 Pressure Treated Wood Exposure Estimates

Leachable Wood Volume of a Medium Sized Dock

Based on the Organization for Economic Co-operation and Development (OECD) revised emission scenario document for wood preservatives a medium sized dock has the following dimensions and volume (OECD, 2013):

Length = 6 meters
Width = 1.2 meters
Thickness of the wood = 0.05 meter

Dock volume = 6 m x 1.2 m x 0.05 m = 0.36 $m^3$ = **12.7 $ft^3$**

Amount of Active Ingredient Applied to the Wood in a Dock

According to EPA Reg. No. 39967-157, tebuconazole can be used as a wood pressure treatment at a maximum concentration of 49000 a.i. in the final treatment solution. A leach rate study (MRID 48901607) reported a treatment rate of 0.375 (pcf). The calculation below goes through the amount of active ingredient (lbs) applied to the standard dock.

Amount of a.i. within a dock = 12.7 $ft^3$ x 0.375 lbs a.i./$ft^3$ = 4.768 lbs a.i. = 2,200,000 mg a.i.

Calculating Estimated Environmental Concentrations (EECs) for Wood

The leach rate data available for use of tebuconazole in wood preservatives indicate an average daily leach rate of 3.1% a.i./day (MRID 48901607). Additionally, the Agency assumes that the dock is on a water body that contains 20,000,000 liters of water. Therefore, the environmental concentration (EEC) of tebuconazole within the water body from use in wood preservatives is calculated in the following equation:

$$EEC\ per\ medium\ sized\ dock = \frac{mg\ a.i.\ in\ the\ Dock\ x\ Leach\ Rate}{L\ Water\ in\ a\ Water\ Body} = \frac{2162511\ mg\ a.i.\ x\ 3.1\%}{20{,}000{,}000\ L}$$

$$= 0.00335\ mg/L = 3.35\ \mu\boldsymbol{g/L}$$

Determining Risk from Wood Preservative Use

For tebuconazole leaching from a single medium sized pressure treated wood dock with a total surface area of 77.5 $ft^2$ into freshwater ecosystems, there are no acute risks to non-listed freshwater fish and invertebrates with up to 338-429 docks. Additionally, there are no risks to aquatic vascular or non-vascular plants with up to 45-51 docks. However, if 3 treated docks with a total surface area of 232 $ft^2$ (0.22% of a waterbody) or more were on a water body, the chronic LOC of 1 would be exceeded and risk would be expected for the most sensitive aquatic taxon (freshwater fish) (Table 20).

**Table 20. Tebuconazole Risk Quotients and Number of Docks Needed to Exceed an LOC for Wood Preservatives**

| Representative Species | EEC[1] | Toxicity Endpoint | RQ[2] | Number of Modeled Docks Needed to Exceed a LOC[3] |
|---|---|---|---|---|
| **Freshwater Organisms** | | | | |
| Acute Freshwater Fish[4] | 3.35 µg/L | $LC_{50}$ = 2270 µg a.i./L | 0.0015 | 338 |
| Acute Freshwater Invertebrate[5] | 3.35 µg/L | $EC_{50}$ = 2880 µg a.i./L | 0.0012 | 429 |
| Chronic Freshwater Fish[6] | 3.35 µg/L | NOAEC = 11 µg a.i./L | 0.305 | 3 |
| Chronic Freshwater Invertebrate[7] | 3.35 µg/L | NOAEC = 120 µg a.i./L | 0.028 | 36 |
| **Aquatic Plants** | | | | |
| Vascular Aquatic Plant[8] | 3.35 µg/L | $EC_{50}$ = 151 µg a.i./L | 0.022 | 45 |
| Non-Vascular Aquatic Plant[9] | 3.35 µg/L | $EC_{50}$= 170 µg a.i./L | 0.020 | 51 |

1: See equations above (this is per dock)

2: RQ = Exposure estimate (EEC) / Toxicity Endpoint

3: Approximate number of medium sized docks needed to exceed the level of concern for the representative species. Rounded to integer. Formula: LOC/RQ. (Acute LOC = 0.5, Chronic and Aquatic Plants LOC = 1).
4: Acute Freshwater Fish (Rainbow trout) MRID 46919204 $LC_{50}$ = 2270 µg/L
5: Acute Freshwater Invertebrate (Daphnia magna) MRID 46919205 $EC_{50}$ = 2880 µg/L
6: Chronic Freshwater Fish (fathead minnow) MRID 48109802 NOAEC = 11 µg/L
7: Chronic Freshwater Invertebrate (Daphnia magna) MRID 40700915 NOAEC = 120 µg/L
8: Vascular Aquatic Plant (Duckweed) MRID 44246901 $EC_{50}$ = 151 µg/L
9: Non-Vascular Aquatic Plant (Green algae) MRID 50533002 $EC_{50}$ =170 µg a.i./L

Wood Preservative Calculations Assumptions Uncertainties and Limitations

It should be noted that the wood preservative modeling presented above is a conservative, high-end, screening-level approach that uses many assumptions which may not be a good representation of conditions in the environment. The major assumptions are:

- The size and other specifications of the dock used for these calculations may not be representative of all docks which are built in water bodies.
- The dock is newly painted and 3.1% tebuconazole leaches on average per day
- Immediate dispersion throughout the modeled aquatic water body is assumed.
- Environmental conditions such as temperature, rainfall and pH, may affect the amount of leaching of the chemical from wood.
- The chemical and biological reactions which usually take place under regular environmental conditions are not considered in calculations for this report.
- All leachate goes into a water body with a volume of 20,000,000 liters and fate or degradation of tebuconazole within the water body is not accounted for in these calculations.

#### 3.4.1.2 Determining Risk from use of Metal Working Fluids

Aquatic Exposure from Metalworking Fluids (MWF)

The tebuconazole products used to preserve metalworking fluids are water-based and water-emulsifiable. Therefore, they are expected to enter the MWF effluent and have the potential to result in aquatic exposure. The methods and data used to estimate environmental releases of tebuconazole to surface water are based on OECD (2011), which is the latest revised draft of the "Emission Scenario Document on the Use of Metalworking Fluids." This document, initially prepared by the U.S. Environmental Protection Agency, is one of the documents in the OECD Environmental Health and Safety Publications Series on Emission Scenario Documents (ESDs). This ESD provides a generic scenario for industrial use of metalworking fluids and is intended to provide upper bound, screening-level estimates of environmental releases of chemicals used in metalworking operations.

To estimate surface water exposure to tebuconazole used in metalworking fluid applications, the Agency used the Industrial Release module within Exposure and Fate Assessment Screening Tool or E-FAST (more information about E-FAST in is provided in Appendix D).

Although endpoints for tebuconazole are available for organisms that represent estuarine/marine fish and invertebrates, the Industrial Release module is appropriate only for estimating exposures in flowing water bodies (streams) and cannot be used to estimate potential exposures to aquatic organisms in estuarine/marine environments.

In order to estimate environmental releases of tebuconazole used in MWF applications, the following assumptions were made:

- The number of operating days per year is 360 days. Although OECD (2011) recommends a default number of 247 days, there may be manufacturing plants which operate more than 247, therefore the 360-day scenario was used for this assessment. (refer to Appendix E to compare the results between 360-day and 247-day scenarios)
- The typical dilution of MWFs in water is 5% for machining operations and 3% for grinding operations, the two most common MWF operations (OECD, 2011). The Agency used 5% dilution. The default annual use volume of neat (undiluted) MWF is 12,000 gallons of neat MWF (end-use product) per site per year. This is the 90th percentile use volume of MWFs from a NIOSH study of 79 metalworking sites (OECD, 2011).
- The default number of MWFs containing tebuconazole used per site is 1 (OECD, 2011).
- The default number of different MWFs used per site is 1 to maximize the daily release per site (OECD, 2011).

The annual use rate of neat MWFs used per site was calculated as follows:

Annual Use Rate of Neat MWF Per Site:

= 12,000 gallons neat MWF/site/year x 3.785 L/gal x 1 kg/L (default density of neat MWF)

= 45,420 kg neat MWF/site/year

Based on the 5% dilution of MWF in water (OECD, 2011) and the product label stated maximum end-use fluid concentration of 1911 ppm a.i. when diluted for use, the concentration of tebuconazole in the concentrate prior to dilution with water would be 38220 ppm. This corresponds to 3.82% active ingredient. For the purpose of estimating the annual use rate of tebuconazole per site, the percentage of tebuconazole in neat MWF is assumed to be 3.82%.

Annual Use Rate of a.i. Per Site:

= (45,420 kg neat MWF/site/year x 0.0382 x 1 MWF containing tebuconazole per site) / 1 MWF used per site

= 1736 kg a.i./site/year

Based on the default number of operating days of 360 days per year, the daily throughput at a facility was calculated as follows:

Daily Use Rate of a.i. Per Site:

= 1736 kg a.i./site/year / 360 days/year

= 4.82 kg a.i./site/day

E-FAST is used to determine the magnitude and frequency of exposure of aquatic organisms from releases of tebuconazole to WWTPs from metalworking fluid facilities. In order to run E-FAST, various inputs about the release sites must be determined and are as follows:

- Wastewater treatment removal; total removal is 45.3%.
- Days per year of release; the default assumption is 360 days.
- Standard Industrial Classification (SIC) code analysis or facility analysis; the SIC code "Primary Metal Forming Manuf. (major users of metal working fluids)" was chosen because no specific facility was being analyzed.
- The number of use sites. The Agency used the estimate that only one site was using tebuconazole, as no data were available to determine how many use sites may be using tebuconazole.
- Results for both high-end (low flow) and average (higher flow) exposure including PDM runs were determined.

Aquatic Risk Estimates from Metalworking Fluid Uses

Table 21 presents values for input parameters used to run the General Population and Ecological Exposures for Industrial Releases Model within E-FAST. Table 22 presents high-end and average results from running the General Population and Ecological Exposures for Industrial Releases Model for release of industrial use of MWFs 360 days per year. Surface water concentrations are based on the distribution of plant flows and stream flows. Model results are expressed as days per year of exceedance of concentrations of concern for aquatic organisms downstream of a metalworking fluid site.

**Table 21. Input Data for Tebuconazole for General Population and Ecological Exposure from Industrial Releases Model**

| Model Input Parameter (Units) | Value |
|---|---|
| BCF in Fish (L/kg) | 99 |
| WWTP Removal Percentage (%) | 45.3 |
| Drinking Water Treatment Removal Percentage (%) | 0 (conservative assumption in the absence of measured or estimated drinking water treatment removal efficiency) |
| Total release to WWTPs after on-site treatment (kg/site/day) | 4.82 |
| Number of MWF facilities releasing tebuconazole to WWTPs following on-site treatment | 1 |

There were exceedances for all taxa assessed based on both the high-end and average case scenarios. Using the high-end scenario, there were 17 days of exceedance of COCs for acute freshwater fish and 13 days of exceedance for acute freshwater invertebrates. Chronic COCs for freshwater fish and invertebrates exceeded 333 and 148 days, respectively. Aquatic vascular plants had 120 days of exceedance, and aquatic non-vascular plants had 118 days of exceedance. The average case scenario showed exceedances for all species but the number of days of exceedances were lower than the high-end scenario. Using the average case scenario, acute freshwater fish and invertebrates had 2- and 1-day exceedances, respectively. Chronic freshwater fish and invertebrates had 119- and 24-days exceedances, respectively. Aquatic non-vascular plants had 20 days exceedance and vascular plants had 18 days exceedance.

**Table 22. Number of Days of Exceedances per Year Concentration of Concerns for Use of Tebuconazole in Metal Working Fluids.**

| Concentrations of Concern (COC) | 360 Days[1] | |
|---|---|---|
| | High-End | Average |
| **Acute** | | |
| Freshwater Fish (COC = 1135 µg a.i./L)[2] | 17 | 2 |
| Freshwater Invertebrate (COC = 1440 µg a.i./L)[3] | 13 | 1 |
| **Chronic** | | |
| Freshwater Fish (COC = 11 µg a.i./L)[4] | 333 | 119 |
| Freshwater Invertebrate (COC = 120 µg a.i./L)[5] | 148 | 24 |

| **Aquatic Plants** | | |
|---|---|---|
| Aquatic Vascular Plant Duckweed (COC = 151 µg a.i./L)[6] | 120 | 20 |
| Aquatic non-Vascular Plant Green Algae (COC = 170 µg a.i./L)[7] | 118 | 18 |

1. 4.82 kg Tebuconazole/site/day. Calculated in Appendix C.
2. Acute Freshwater Fish (Rainbow trout) MRID 46919204 $LC_{50}$ = 2270 µg/L * 0.5 =1135 µg/L
3. Acute Freshwater Invertebrate (Daphnia magna) MRID 46919205 EC50 = 2880 µg/L * 0.5=1440 µg/L
4. Chronic Freshwater Fish (fathead minnow) MRID 48109802 NOAEC = 11 µg/L
5. Chronic Freshwater Invertebrate (Daphnia magna) MRID 40700915 NOAEC = 120 µg/L
6. Vascular Aquatic Plant (Duckweed) MRID 44246901 $EC_{50}$ = 151 µg/L
7. Non-Vascular Aquatic Plant (Green algae) MRID 50533002 $EC_{50}$=170 µg a.i./L

Metalworking Fluid Modeling Uncertainties and Limitations for High-end and Average Scenarios

The MWF modeling has used the following conservative estimates and assumptions:

- The model does not account for degradation or removal, such as microbial degradation and drag out losses, of tebuconazole during metal shaping operations.
- The model does not account for degradation in surface water or sorption to suspended or bottom sediment.
- The Agency assumed 5% dilution of neat MWF in water, based on OECD (2011).
- The Agency assumed a default annual use volume of 12,000 gallons neat MWF/site/year.
- The Agency assumed 45.3% total removal of tebuconazole during wastewater treatment (MRID 51167401).
- The model assumes that all MWF sites in the United States discharge directly to a WWTP; in other words, 100% of tebuconazole is discharged directly to a WWTP. However, recent data indicate that the number of sites that discharge directly to a WWTP "has significantly decreased due to more stringent discharge limits" from 40 CFR §403.5(b)(6) (OECD, 2011, p. 48). Many MWF sites use on-site wastewater treatment prior to discharge to a WWTP, which would reduce the amount of tebuconazole entering a WWTP.
- Instead of going to wastewater treatment, some of the tebuconazole may end up in landfill or incineration.
- The input data (e.g., label, degradation and sorption rates, dilution rate) used may not provide the best representation of realistic environmental or use conditions.
- This risk assessment could be further refined with on-site wastewater treatment data and information on where/when tebuconazole is added during the metal shaping process. Additional data would likely result in a more refined risk assessment.
- This risk assessment could also be further refined with information on how many sites use tebuconazole. The current calculations indicate the annual use rate of tebuconazole is 1736 kg a.i./site/year.

## 3.5 Ecological Risk Characterization

Overall, risks to terrestrial taxa (including pollinators) are not expected from the currently registered antimicrobial uses of tebuconazole due to low exposure potential. Of the current uses, wood preservative and metal working fluid uses are expected to result in the highest aquatic exposures because of their direct discharge or leaching into aquatic areas. Other uses such as material preservation of plastics, glues, adhesives, and sealants have the potential for environmental exposure, but the wood preservative and metal working fluid assessments are expected to be protective of these uses.

### 3.5.1 Wood Preservative Use

When used in pressure wood treatment, tebuconazole may cause environmental risk. Based on an average leach rate of 3.1% (MRID 48901607), 3 to 429 docks treated with tebuconazole could cause risk to aquatic organisms. Exposure estimates did not reach the levels of concern for aquatic plants (vascular and non-vascular), freshwater invertebrates (acute and chronic), or freshwater fish (acute); therefore, risk to these organisms is not expected. However, 3 docks with a total surface area of 232.5 $ft^2$ (0.22% of the water body) may cause chronic risk to freshwater fish (most sensitive species).

Although an assessment on estuarine/marine species was not performed, tebuconazole's toxicity to estuarine/marine fish (chronic) and invertebrates (chronic) were similar to freshwater fish (chronic). Similarly, ecotoxicity data for benthic organisms indicate that tebuconazole is more toxic to freshwater benthic invertebrates (chronic) than it is to freshwater fish (chronic). No treatment related effects were reported in the ecotoxicity data submitted for estuarine/marine benthic organisms. Thus, risk to estuarine/marine benthic organisms is expected to be low.

Tebuconazole is persistent and only moderately mobile (MRID 40995922) in the environment. Therefore, it is likely to be found in both the water column and sediment phase in surface water. Furthermore, it has the potential to build up in a water body and can lead to chronic exposure to aquatic organisms based on the aerobic aquatic metabolism study representing surface water with half-lives of 434-826 days (MRID 48707405) and in the anaerobic aquatic metabolism study representing bottom sediment with a half-life of 1,478 days (MRID 48707403). Therefore, risk from chronic exposure is expected for freshwater fish, estuarine/marine fish, estuarine/marine invertebrates (water column), and freshwater benthic invertebrates when tebuconazole is used as a wood preservative.

### 3.5.2 Metal Working Fluid Use

For metal working fluid use, the Agency used 45.3% removal of tebuconazole during wastewater treatment (MRID 51167401). Despite this removal, aquatic risk estimates show that when effluent from WWTPs treating MWFs are released to streams, COCs are exceeded for both high-end and average scenarios for all aquatic taxa assessed. Average-end scenario exceedances ranged from 1 day for acute freshwater invertebrates (least sensitive species) to 119 days for

chronic freshwater fish (most sensitive species). High-end scenario exceedances ranged from 13 days to 333 days for acute freshwater invertebrates and chronic freshwater fish, respectively.

Ecotoxicity data indicates that tebuconazole is similar or higher in toxicity to estuarine/marine organisms when compared to freshwater organisms living in the water column. Based on these results, if effluent from WWTPs treating MWFs with tebuconazole were to be discharged into estuarine/marine environments, risk would be comparable to freshwater organisms.

According to ecotoxicity data for benthic organisms, tebuconazole is more toxic to freshwater benthic invertebrates than to freshwater invertebrates living in the water column. Because tebuconazole is fairly persistent and is only moderately mobile in the environment, it will likely be present in both the water and sediment phase in surface water. Freshwater benthic invertebrates are more sensitive to tebuconazole than freshwater invertebrates in the water column. Therefore, risk is expected for freshwater benthic invertebrates from the MWF use. No treatment related effects were reported in the ecotoxicity data submitted for estuarine/marine benthic organisms. Therefore, risk to estuarine/marine benthic organisms is expected to be low.

Based on tebuconazole's environmental fate properties (*i.e.*, it's persistence and moderate mobility) and ecotoxicity, the MWF use of tebuconazole is expected to result in risk to aquatic plants (vascular and non-vascular), freshwater fish and invertebrates (acute and chronic), estuarine/marine fish and invertebrates (acute and chronic) and freshwater benthic invertebrates (acute and chronic).

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# 5 APPENDIX A: Toxicology Profile

Please see the HED risk assessment for a complete tebuconazole acute toxicity profile (US EPA, 2020a).

**Table A1. Acute Toxicity Profile for Tebuconazole**

| Guideline No. | Study Type | MRID(s) | Results | Toxicity Category |
|---|---|---|---|---|
| 870.1100 | Acute oral [rat] | 40700917 | $LD_{50}$ (fasted) = > 5000 mg/kg (M); 3933 mg/kg (F); (unfasted)=4264 mg/kg (M); 3352 mg/kg (F) | III |
| 870.1200 | Acute dermal [rat] | 40700917<br>41290801 | $LD_{50}$ = >5000 mg/kg (M & F) | III |
| 870.1300 | Acute inhalation [rat] | 40700922 | $LC_{50}$ (4 h, aerosol) = >371 mg/m$^3$<br>$LC_{50}$ (4 h, dust)= >5093 mg/m$^3$ | II |
| 870.2400 | Acute eye irritation [rabbit] | 40700925<br>40700917 | Slight to Mild irritant | III |
| 870.2500 | Acute dermal irritation [rabbit] | 40700917<br>40995910 | Non-irritant | IV |
| 870.2600 | Skin sensitization [guinea pig] | 40700928<br>41290802 | No evidence of skin sensitization using the Buehler test | NA |

**Table A2. Subchronic, Chronic and Other Toxicity Profile for Tebuconazole Technical**

| Guideline No. Study Type | MRID No. (year) Doses/ Classification | Results |
|---|---|---|
| 870.3100<br>90-Day oral toxicity - rat | 40700930 (1986)<br>(0, 100, 400, 1600 ppm in diet);<br>0, 8.6, 34.8, 171.7 mg/kg/d (m);<br>0, 10.8, 46.5, 235.2 mg/kg/d (f)<br>Acceptable/guideline | Male: NOAEL = 34.8 mg/kg/d; LOAEL= 171.7 mg/kg/d based on decreased body wt., body wt. gain, and histopathology findings.<br>Female: NOAEL=10.8 mg/kg/d, LOAEL= 46.5 mg/kg/d based on histopathological changes in the adrenal gland. |
| 870.3150<br>90-Day oral toxicity - dog | 40700934 (1987)<br>(0, 200, 1000, 5000 ppm in diet);<br>0, 73.7, 368.3, 1749.1 mg/kg/d (m);<br>0, 73.4, 351.8, 1724.8 mg/kg/d (f)<br>Acceptable/guideline | NOAEL = 73.4/73.7 mg/kg/d (M/F)<br>LOAEL = 368.3/ 351.8 mg/kg/d (M/F) based on decreased body wt. gain, food consumption and increased liver enzyme activities. |
| 870.3200<br>21/28-Day dermal toxicity - rabbit | 40700937 (1984)<br>0, 50, 250, 1000 mg/kg/day<br>Acceptable/guideline | NOAEL = 1000 mg/kg/day.<br>No dermal or systemic toxicity was seen. |
| 870.3465<br>21-Day inhalation toxicity - rat | 40700938 (1985)<br>0, 1.2, 10. 6, 155.8 mg/m$^3$<br>Acceptable/non-guideline | NOAEL = 10.6 mg/m$^3$/day (≈2.0 mg/kg/day) LOAEL = 155.8 mg/m$^3$/d (≈28 mg/kg/day) based on clinical signs (bristling coat). |

| | | |
|---|---|---|
| 870.3700a<br>Prenatal developmental - rat | 40700943 (1988)<br>0, 30, 60, 120 mg/kg/d, GD 6-15<br>Acceptable/guideline | **Maternal** NOAEL = 30 mg/kg/day LOAEL=60 mg/kg/d based on increased liver weight and liver/body weight ratios.<br>**Developmental** NOAEL=30 mg/kg/day LOAEL =60 mg/kg/d based on delayed ossification of several bones and increased numbers of fetuses with supernumerary ribs. |
| 870.3700a<br>Prenatal developmental - rat (Dermal) | 41450801 (1988)<br>0, 100, 300, 1000 mg/kg/d, GD 6-15<br>Acceptable/guideline | **Maternal** NOAEL= 1000 mg/kg/d<br>**Developmental** NOAEL= 1000 mg/kg/d<br>No evidence of maternal or developmental toxicity seen via dermal route. |
| 870.3700a<br>Prenatal developmental - mouse | 40821501 (1988)<br>0, 10, 30, 100 mg/kg/d, GD 6-15<br>40821500 (1988)<br>Supplementary study<br>0, 10, 20, 30, 100 mg/kg/d GD 6-15<br>Acceptable/guideline | **Maternal** NOAEL = 30 mg/kg/d<br>LOAEL = 100 mg/kg/d based on increased hepatic triglycerides, pale lobular liver, increased severity of hepatic vacuoles and lipidosis.<br>**Developmental** NOAEL = 10 mg/kg/d<br>LOAEL = 30 mg/kg/d based on increased number of runts. |
| 870.3700a<br>Prenatal developmental - mouse | 43776201, 43776202(1995)<br>0, 10, 30, 100 mg/kg/d, GD 6-15<br>Supplementary group<br>0, 1, 3 mg/kg/d GD 6-15<br>Acceptable/guideline | **Maternal**: NOAEL = 3 mg/kg/d<br>LOAEL = 10 mg/kg/d based on increased hepatic enzyme induction and severity of vacuolization in liver cells.<br>**Developmental**: NOAEL=3 mg/kg/d LOAEL=10 mg/kg/d based on increased external, visceral, and skeletal malformation/variation in the head and skull. |
| 870.3700a<br>Prenatal developmental - mouse (Dermal) | 42010301 (1990)<br>0,100,300,1000 mg/kg/d GD 6-15<br>Acceptable/guideline | **Maternal** NOAEL= 1000 mg/kg/d<br>**Developmental** NOAEL= 1000 mg/kg/d<br>No evidence of maternal or developmental toxicity seen via dermal route. |
| 870.3700b<br>Prenatal developmental - rabbit | 40700945 (1987)<br>0, 10,30,100 mg/kg/d, GD 6-18<br>Acceptable/guideline | **Maternal** NOAEL = 30 mg/kg/d<br>LOAEL = 100 mg/kg/d based on decreased body weight gain and food consumption.<br>**Developmental** NOAEL = 30 mg/kg/d LOAEL = 100 mg/kg/d based on increased resorptions and post-implantation losses, decreased live fetuses/doe, and external and skeletal abnormalities. |
| 870.3700b<br>Prenatal developmental - rabbit | 43776201 (1995)<br>0, 10, 30, 100 mg/kg/day GD 6-18<br>Acceptable/guideline | **Maternal** NOAEL = Not established (<10 mg/kg/d)<br>LOAEL = 10 mg/kg/d based on increased incidence of single cell necrosis in liver cells. **Developmental** NOAEL = 10 mg/kg/d<br>LOAEL = 30 mg/kg/d based on increased external and visceral malformation/variations. |

| | | |
|---|---|---|
| 870.3800<br>Reproduction and fertility effects<br>- rat | 40700946 (1987)<br>0, 100, 300, 1000 ppm in diet (equivalent to 0, 5, 15, 50 mg/kg/day)<br>Acceptable/guideline | **Parental/Systemic** NOAEL = 15 mg/kg/day (M/F)<br>LOAEL = 50 mg/kg/day based on increased severity of splenic hemosiderosis (M/F), increased incidence of splenic hematopoiesis (M), and decreased weight gain during gestation (F)<br>**Reproductive** NOAEL = 50 mg/kg/day<br>LOAEL = not determined<br>**Offspring** NOAEL = 15 mg/kg/day<br>LOAEL = 50 mg/kg/day based on decreased pup body wt. |

**Table A3. Summary of Toxicological Doses and Endpoints for Tebuconazole for Use in Human Health Risk Assessments**

| Exposure/ Scenario | Point of Departure | Uncertainty/FQPA Safety Factors | RfD, PAD, Level of Concern for Risk Assessment | Study and Toxicological Effects |
|---|---|---|---|---|
| Acute Dietary (General Population, including Infants and Children) | NOAEL = 100 mg/kg/day | $UF_A$= 10x<br>$UF_H$=10x<br>FQPA SF= 1x | Acute RfD = 1.0 mg/kg/day<br><br>aPAD = 1.0 mg/kg/day | Acute Neurotoxicity Study – Rat (MRID 44449301, 44545701).<br>LOAEL = 250 mg/kg/day based on ataxia, decreased foot splay and decreased motor activity in females. |
| Acute Dietary (Females 13-49 years of age) | Developmental NOAEL = 3 mg/kg/day | $UF_A$= 10x<br>$UF_H$=10x<br>FQPA SF= 1x | Acute RfD = 0.03 mg/kg/day<br><br>aPAD = 0.03 mg/kg/day | Developmental Toxicity Study – Mice (MRID 43776201/43776202).<br>Developmental LOAEL = 10 mg/kg/day based on increased incidence of skull/neural tube defects including abnormalities of the eyes, head and skull (exencephaly, open eyes, cleft palate, acrania/partial acrania). |
| Chronic Dietary (All Populations except females) | Offspring NOAEL = 15 mg/kg/day | $UF_A$= 10x<br>$UF_H$=10x<br>FQPA SF= 1x | Chronic RfD = 0.15 mg/kg/day<br><br>cPAD =0.15 mg/kg/day | Two-generation reproduction toxicity study – Rat (MRID 40700946).<br>Offspring LOAEL = 50 mg/kg/day based on decreased pup body weight (11-22%; F1 and F2 generations). |
| Chronic dietary (females 13-49) | Developmental NOAEL = 3 mg/kg/day | $UF_A$= 10x<br>$UF_H$=10x<br>FQPA SF= 1x | Chronic RfD = 0.03 mg/kg/day<br><br>cPAD =0.03 mg/kg/day | Developmental Toxicity Study – Mice (MRID 43776201/43776202).<br>Developmental LOAEL = 10 mg/kg/day based on increased incidence of skull/neural tube defects including abnormalities of the eyes, head and skull (exencephaly, open eyes, cleft palate, acrania/partial acrania). |
| Incidental Oral Short-/Intermediate-Term (1-30 days/1-6 months) | Offspring NOAEL = 15 mg/kg/day | $UF_A$= 10x<br>$UF_H$=10x<br>FQPA SF= 1x | Residential LOC for MOE = 100 | Two-generation reproduction toxicity study – Rat (MRID 40700946)<br>Offspring LOAEL = 50 mg/kg/day based on decreased pup body weight (11-22%; F1 and F2 generations). |
| Dermal (All Durations) | Offspring NOAEL = 15 mg/kg/day<br><br>DAF=13% | $UF_A$= 10x<br>$UF_H$=10x<br>FQPA SF= 1x | Residential LOC for MOE = 100 | Two-generation reproduction toxicity study – Rat (MRID 40700946).<br>Offspring LOAEL = 50 mg/kg/day based on decreased pup body weight (11-22%; F1 and F2 generations). |
| Inhalation Short-/Intermediate-Term (1-30 days/1-6 months) | Developmental NOAEL = 3 mg/kg/day | $UF_A$= 10x<br>$UF_H$=10x<br>FQPA SF = 1x | Residential/Occupational LOC for MOE = 100 | Developmental Toxicity Study – Mice (MRID 43776201/43776202)..<br>Developmental LOAEL = 10 mg/kg/day based on increased incidence of skull/neural tube defects |

| | | | | |
|---|---|---|---|---|
| | | Inhalation and oral toxicity are assumed to be equivalent | | including abnormalities of the eyes, head and skull (exencephaly, open eyes, cleft palate, acrania/partial acrania). |
| Inhalation Long-Term (All Populations except females) | Offspring NOAEL = 15 mg/kg/day | $UF_A$= 10x<br>$UF_H$=10x<br>FQPA SF= 1x<br><br>Inhalation and oral toxicity are assumed to be equivalent | Residential LOC for MOE = 100 | Two-generation reproduction toxicity study – Rat (MRID 40700946).<br>Offspring LOAEL = 50 mg/kg/day based on decreased pup body weight (11-22%; F1 and F2 generations). |
| Inhalation Long-Term (females) | Developmental NOAEL = 3 mg/kg/day | $UF_A$= 10x<br>$UF_H$=10x<br>FQPA SF= 1x<br><br>Inhalation and oral toxicity are assumed to be equivalent | Residential LOC for MOE = 100 | Developmental Toxicity Study – Mice (MRID 43776201/43776202).<br>Developmental LOAEL = 10 mg/kg/day based on increased incidence of skull/neural tube defects including abnormalities of the eyes, head and skull (exencephaly, open eyes, cleft palate, acrania/partial acrania). |
| Cancer (oral, dermal, inhalation) | Classification: Group C- possible human carcinogen based on statistically significant increase in the incidence of hepatocellular adenoma, carcinoma, and combined adenoma/carcinomas in both sexes of NMRI mice. The chronic risk assessment is considered protective of any cancer effects; therefore, a separate quantitative cancer risk assessment is not required (A. Protzel and E. Rinde, 09/15/1993, TXR#0052724). | | | |

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. $UF_A$ = extrapolation from animal to human (interspecies). $UF_H$ = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern. DAF = dermal absorption factor.

# 6 APPENDIX B: Environmental Fate Profile

Please see the EFED risk assessment for complete tebuconazole toxicity profiles (US EPA, 2021b).

**Table B1. Soil Metabolism Studies and Degradation Summary Information for Tebuconazole**

| Study | Percent Distribution of Recovered Radioactivity | | | |
|---|---|---|---|---|
| | Parent | Degradate/transformation Product[1,2] | Unextractable Residues | Study ID |
| Aerobic Soil (phenyl 14C labeled) | 98.3-82% from Day 0-112; 78.8% @ 6 months; 67.4% at 12 months | 0.4-0.9% from Day 0-112; 0.9&2.6% @ 6 months; 1.1&2.1% @ 12 months | 0.8-16.2% from Day 0-112; 17% @ 6 months; 29.1% @ 12 months | MRID 40700959 |
| Aerobic Soil (triazole $^{14}C$ labeled) | 98.1-85.0% from Day 0-58 | 0.3-0.6% from Day 0-58[2] | 1.3-14.5% from Day 0-58 | MRID 40700959 |
| Anaerobic Soil | 73.1-70.3% from Day 0-60 | 0.4-2.2% from Day 0-60 4.1-7.5% (in flood water) from Day 0-60 | 19.5-23.4% from Day 0-60 | MRID 40700959 |
| Soil Photolysis | 96-86% from Day 0-35 | <1-3% from Day 0-60 | 2.6-5.5% from Day 0-60 | MRID 40700958 |
| Aqueous Photolysis | 94-95% from Day 0-30 | None observed | None observed | MRID 40700958 |

1. Extracted product(s) not identified (unknown)
2. 1,2,4-triazole not detected

# 7 APPENDIX C: Ecotoxicity Profile

For a complete discussion of the ecotoxicity of tebuconazole see the EFED DRA (US EPA, 2021b).

# 8 APPENDIX D: Ecological Risk Estimation Methods

Risk estimation integrates the results of the exposure and ecotoxicity data to evaluate the potential for the active ingredient and its transformation products to cause adverse effects to nontarget organisms. Depending on the uses being assessed, risk estimates are determined from calculations of acute and chronic risk quotients (RQs) or, for down-the-drain (DtD) assessments, from concentrations of concern (COCs).

**Risk Quotient Methodology**

The RQ method used by OPP compares the estimates of acute and chronic exposure (EECs) to the acute and chronic ecotoxicity endpoint values for each receptor group being assessed. EECs are developed through the use of various exposure models for the uses being assessed (e.g., antifoulant paint, pressure-treated wood). If available, relevant aquatic monitoring concentrations may be used as well. The acute and chronic ecotoxicity endpoints are obtained mainly from guideline ecotoxicity studies (850 harmonized series) submitted to support registration or, in some cases, from the open literature.

For animals (fish[1], aquatic invertebrates, birds[2], mammals), acute and chronic RQs are calculated as follows:

Acute RQ = acute EEC/$LC_{50}$ (or $EC_{50}$ or $LD_{50}$)
Chronic RQ = chronic EEC/NOAEC

For aquatic or semi-aquatic plants, because of the short life cycles, there is no distinction between acute and chronic exposure. The RQs for plants are determined as follows:

RQ for non-listed species = EEC/$EC_{50}$
RQ for listed species = EEC/NOAEC (or $EC_{05}$ if NOAEC not available)

The RQs are compared to OPP's levels of concern (LOCs) to identify potential acute and chronic risks to each receptor group. Exceedance of a LOC indicates a need to consider regulatory action to reduce these potential risks. The development of the LOCs is discussed in detail in the Agency's Overview Document[3]. OPP's LOCs are tabulated below for listed and nonlisted species. A listed species is a species that has been designated as endangered or threatened by the U.S. Fish and Wildlife Service or the U.S. National Marine Fisheries Service.

[1] Freshwater fish also may be used as a surrogate for aquatic-phase amphibians
[2] Birds also may be used as surrogate for terrestrial-phase amphibians and reptiles
[3] http://www.epa.gov/espp/consultation/ecorisk-overview.pdf

**Table C1. Risk Presumptions and LOCs**

| **Aquatic and Terrestrial Animals** | **LOC** |
|---|---|
| Acute presumption of risk to listed aquatic species | RQ ≥ 0.05 |
| Acute presumption of risk to listed terrestrial species | RQ ≥ 0.1 |
| Acute presumption of risk to nonlisted aquatic and terrestrial species | RQ ≥ 0.5 |
| Chronic presumption of risk to listed and nonlisted aquatic and terrestrial species | RQ ≥ 1.0 |
| **Risk Presumption for Aquatic/Semi-aquatic Plants** | **LOC** |
| Presumption of risk to listed species | RQ ≥1 |
| Presumption of risk to nonlisted species | RQ ≥1 |

**Industrial Release Methodology (E-FAST)**

Risks to aquatic organisms from antimicrobial chemicals with the potential to get into flowing surface water via municipal or industrial WWTPs are analyzed using the E-FAST. For discharges from industrial sources (e. g., paper mills), the General Population and Ecological Exposure from Industrial Releases Module (herein called the Industrial Release module) is used.

For antimicrobials disposed via point sources (i.e. WWTP or direct industrial discharge), the Probabilistic Dilution Model (PDM) option is used. This option estimates the number of days per year that the Concentrations of Concern (COC) are exceeded for freshwater fish, freshwater non-benthic invertebrates, and aquatic plants. Key input data for pulp and paper mills include: (1) percent removal of active ingredient during wastewater treatment; (2) acute and chronic ecotoxicity endpoints for each receptor group; (3) retention rate of the chemical on the paper; (4) an estimate of environmental release to a WWTP in kilograms per site per day; and (5) release site information. Key input data for metalworking fluid applications are similar, but instead of retention rate in paper, dilution of neat MWF in water is included.

The Agency has conducted a high-end (low-flow) and an average analysis to determine the conditions under which there might be exposure and potential adverse risks to freshwater aquatic organisms. The high-end scenario is based on the 10th percentile of the distribution of the ratio of 7Q10 stream flows to WWTP flows. The average case scenario is based on the median of the distribution of the ratio of 7Q10 stream flows to WWTP flows. The 7Q10 is the lowest 7 consecutive day stream flow over a 10-year period. For the high-end scenario, the ratio of stream flow to plant flow is relatively low since plant flows can contribute considerable volume to the flow of the stream and the resulting surface water concentrations can be relatively high. For the average case scenario, the ratio of stream flow to plant flow is more typical.

**Down-the-Drain Methodology**

The DtD module of E-FAST
(Exposure and Fate Assessment Screening Tool) is used when discharge into the aquatic environment is from municipal (*i.e*., domestic) waste-water treatment plants (WWTPs) or from industrial sources of discharge (*e. g*., cooling towers). The ecotoxicity data used in the model are the same as those used for RQ calculations. The levels of concern for listed and nonlisted aquatic organisms also are factored into the calculations for estimating the COCs.

For antimicrobials disposed to municipal WWTPs, the DtD module is used with the Probabilistic Dilution Model (PDM) option. This option estimates the number of days per year that the COC is exceeded for listed and nonlisted freshwater fish, freshwater invertebrates, and aquatic plants. Key input data include: (1) percent removal of active ingredient during wastewater treatment; (2) acute and chronic ecotoxicity endpoints for each receptor group; and (3) WWTP influent volume derived from such sources as production volume data, marketing data, and/or data on fraction of antimicrobial leached/removed from an end-use product.

For antimicrobials disposed to industrial WWTPs, the General Population and Ecological Exposure from Industrial Releases Module of E-FAST is used. This option estimates the number of days per year COCs are exceeded for listed and nonlisted fish, aquatic invertebrates, and aquatic plants. In addition to the input data required to run the DtD module, the Industrial Release module also requires an estimate of environmental release to surface water in kilograms per site per day, the number of release sites, and the number of days of release to surface water.

# 9 APPENDIX E: Metalworking Fluid Assessment

In the risk assessment, the Agency assumed 360 days of release to estimate environmental exposure from tebuconazole from MWF uses. OECD (2011) recommends 247 days, which is the average number of operating days. The Agency ran the Industrial Releases Model for each scenario and determined the 360-day scenario to be more appropriate because it was more conservative and demonstrated more days of exceedance of COCs per year. Although the daily use rate for 360 days (4.8 kg a.i./site/day) is lower than the daily use rate for 247 days (7.0 kg a.i./site/day19), which is to be expected, the 360-day scenario provided higher numbers of days of exceedance per year, which is the measure the Agency relied on for its ecological risk assessment.

Table E.1 shows the input values used in E-FAST to assess tebuconazole release over 360 days and over 247 days, and Table E.2 compares the results between the 360-day scenario and the 247-day scenario. As indicated in Table E.2, the 360-day scenario had more days of exceedance per year compared to the 247-day scenario.

**Table E1. Input Data for Tebuconazole Over 360 Days and 247 Days for General Population and Ecological Exposure from Industrial Releases Model**

| Model Input Parameter (Units) | Value |
|---|---|
| BCF in Fish (L/kg) | 99 |
| WWTP Removal Percentage (%) | 45.3 |
| Drinking Water Treatment Removal Percentage (%) | 0 (conservative assumption in the absence of measured or estimated drinking water treatment removal efficiency) |
| Total release to WWTPs after on-site treatment (kg/site/day) for 360-day scenario | 4.8 |
| Total release to WWTPs after on-site treatment (kg/site/day) for 247-day scenario | 7.0 |
| Number of MWF facilities releasing tebuconazole to WWTPs following on-site treatment | 1 |

**Table E2. Number of days of exceedances for use of tebuconazole in metal working fluids.**
Table E2 shows the number of days of exceedances for MWF use for both 360- and 247-day model runs.

| Concentrations of Concern (COC) | 360 Days[1] | | 247 Days[1] | |
|---|---|---|---|---|
| | High-End | Average | High-End | Average |
| **Acute** | | | | |
| Freshwater Fish (COC = 1135 µg a.i./L)[2] | 17 | 2 | 19 | 2 |
| Acute Freshwater Invertebrate (COC = 1440 µg a.i./L)[3] | 13 | 1 | 14 | 2 |
| **Chronic360** | | | | |
| Freshwater Fish (COC = 11 µg a.i./L)[4] | 333 | 119 | 237 | 96 |
| Freshwater Invertebrate (COC = 120 µg a.i./L)[5] | 148 | 24 | 125 | 23 |
| **Aquatic Plants** | | | | |
| Aquatic Vascular Plant Duckweed (COC = 151 µg a.i./L)[6] | 120 | 20 | 110 | 19 |
| Aquatic non-Vascular Plant Green Algae (COC = 170 µg a.i./L)[7] | 118 | 18 | 103 | 17 |

1. 4.82 kg Tebuconazole/site/day. Calculated in Appendix C.
2. Acute Freshwater Fish (Rainbow trout) MRID 46919204 $LC_{50}$ = 2270 µg/L * 0.5 =1135 µg/L
3. Acute Freshwater Invertebrate (Daphnia magna) MRID 46919205 $EC_{50}$ = 2880 µg/L * 0.5=1440 µg/L
4. Chronic Freshwater Fish (fathead minnow) MRID 48109802 NOAEC = 11 µg/L
5. Chronic Freshwater Invertebrate (Daphnia magna) MRID 40700915 NOAEC = 120 µg/L
6. Vascular Aquatic Plant (Duckweed) MRID 44246901 $EC_{50}$ = 151 µg/L
7. Non-Vascular Aquatic Plant (Green algae) MRID 50533002 $EC_{50}$=170 µg a.i./L