SERA TR-056-13-03-02b

Oryzalin:
WorksheetMaker Workbook Documentation

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REVISION NOTE

This report is a modification to SERA TR-056-13-03-01a, Oryzalin: WorksheetMaker Workbook Documentation, dated January 6, 2015. Changes to this workbook are based on the following comments from the Forest Service:

Notes from John Justin and Shawna Bautista in an EXCEL workbook (**`Mancozeb SAMPLE Workbook-SB-JJ.xlsm`**) via an email from Shawna Bautista dated 6/2/2015.

Comments from John Justin in a Microsoft Word file (**`Query Template for WSM Input Effort.docx`**) via an email from Shawna Bautista dated 12/30/2014.

The most recent set of comments (i.e., the EXCEL workbook from 6/2/2015) is given precedence when the feedback is inconsistent.

ACRONYMS, ABBREVIATIONS, AND SYMBOLS

AEL	adverse-effect level
a.e.	acid equivalent
a.i.	active ingredient
a.k.a.	also known as
a.s.	active substance
AOEL	acceptable occupational exposure limit
APHIS	Animal and Plant Health Inspection Service
ATSDR	Agency for Toxic Substances and Disease Registry
ASAE	American Society of Agricultural Engineers
BCF	bioconcentration factor
bw	body weight
calc	calculated value
CBI	confidential business information
CI	confidence interval
cm	centimeter
CNS	central nervous system
COC	crop oil concentrates
DAA	days after application
DAT	days after treatment
DER	data evaluation record
d.f.	degrees of freedom
EC	emulsifiable concentrate
EC_x	concentration causing X% inhibition of a process
EC_{25}	concentration causing 25% inhibition of a process
EC_{50}	concentration causing 50% inhibition of a process
ECOTOX	ECOTOXicology (database used by U.S. EPA/OPP)
EEC	expected environmental concentration
EFED	Environmental Fate and Effects Division (U.S. EPA/OPP)
ERA	ecological risk assessment
ExToxNet	Extension Toxicology Network
F	female
FH	Forest Health
FIFRA	Federal Insecticide, Fungicide and Rodenticide Act
FQPA	Food Quality Protection Act
g	gram
GLP	Good Laboratory Practices
ha	hectare
HED	Health Effects Division (U.S. EPA/OPP)
HHRA	human health risk assessment
HIARC	Hazard Identification and Assessment Review Committee (part of U.S. EPA/OPP/HED)
HQ	hazard quotient
HRAC	Herbicide Resistance Action Committee
IARC	International Agency for Research on Cancer
IRED	Interim Reregistration Eligibility Decision
IRIS	Integrated Risk Information System

k_a	absorption coefficient
k_e	elimination coefficient
kg	kilogram
$K_{o/c}$	organic carbon partition coefficient
$K_{o/w}$	octanol-water partition coefficient
K_p	skin permeability coefficient
L	liter
lb	pound
LC_{50}	lethal concentration, 50% kill
LD_{50}	lethal dose, 50% kill
LOAEL	lowest-observed-adverse-effect level
LOC	level of concern
LR_{50}	50% lethal response [EFSA/European term]
m	meter
M	male
mg	milligram
mg/kg/day	milligrams of agent per kilogram of body weight per day
mL	milliliter
mM	millimole
mPa	millipascal, (0.001 Pa)
MITC	methyl isothiocyanate
MOS	margin of safety
MRID	Master Record Identification Number
MSDS	material safety data sheet
MSO	methylated seed oil
MW	molecular weight
NOAEL	no-observed-adverse-effect level
NOEC	no-observed-effect concentration
NOEL	no-observed-effect level
NOS	not otherwise specified
N.R.	not reported
OPP	Office of Pesticide Programs
ppm	parts per million
RED	re-registration eligibility decision
RfD	reference dose
SERA	Syracuse Environmental Research Associates
T.G.I.A.	Technical grade active ingredient
UF	uncertainty factor
U.S.	United States
USDA	U.S. Department of Agriculture
U.S. EPA	U.S. Environmental Protection Agency
USGS	U.S. Geological Survey
WHO	World Health Organization

1. INTRODUCTION

1.1. General Information

This document supports the development of a WorksheetMaker EXCEL workbook for the subject pesticides. As detailed in SERA (2011a), WorksheetMaker is a utility that automates the generation of EXCEL workbooks that accompany Forest Service risk assessments, and these EXCEL workbooks are typically generated in the development of Forest Service risk assessments (SERA 2014).

The development of full Forest Service risk assessments, however, is resource intensive. For some pesticides that are used in only relatively small amounts and/or only in few locations, the development of full Forest Service risk assessments is not feasible. Nonetheless, the Forest Service may be required to develop risk analyses supported by WorksheetMaker EXCEL workbooks. To meet this need, an MS Word utility was developed to facilitate the addition of pesticides and pesticide formulations into the Microsoft Access database used by WorksheetMaker (SERA 2011b). With this addition, WorksheetMaker can be used to generate EXCEL workbooks typical of those that accompany Forest Service risk assessments.

The current document is designed to serve as documentation for the application of this general method for the pesticide discussed in Section 1.2. The major difference between this approach to using WorksheetMaker and the typical use of WorksheetMaker in the development of Forest Service risk assessments involves the level of documentation and the sources used in developing the documentation. While standard Forest Service risk assessments involve a relatively detailed review and evaluation of the open literature and publically available documents from the U.S. EPA, as discussed further in Section 1.2, the current assessment relies primarily on secondary sources with minimal independent evaluation of the data.

1.2. Chemical Specific Information

The current document concerns oryzalin. The initial information on oryzalin was identified at the U.S. EPA's Pesticide Chemical Search website (http://iaspub.epa.gov/apex/pesticides/f?p=CHEMICALSEARCH:1:11098277289067::NO:1::) using the search term "oryzalin". Other information was identified through custom searches of EPA and a NMFS (National Marine Fisheries Service) web site for the recent biological opinion involving oryzalin (NMFS 2012).

Oryzalin is a dinitroanaline preemergence herbicide. U.S. EPA's Pesticide Chemical Search website lists 4 E-Dockets on oryzalin and 59 cleared science reviews. TOXLINE (http://toxnet.nlm.nih.gov) contains 527 open literature citations using synonyms and 279 citations not using synonyms. The distinction between using and not using synonyms is important in that using synonyms may lead to irrelevant citations (most often due to formulation names), and not using synonyms may result in missing some relevant citations. Overall, the literature on oryzalin may be viewed as modest.

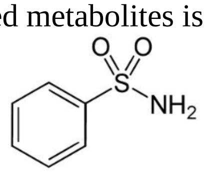
Information relating to the human health effects of oryzalin is taken primarily from the Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment Progress and Risk Management Decision (TRED) for Oryzalin (U.S. EPA/OPP 2004) supplemented by information from the RED on oryzalin (U.S. EPA/OPP 1994a). Information on ecological effects and the environmental fate of oryzalin is taken primarily from the EPA's assessment of the potential effects of oryzalin on the California tiger salamander, an endangered species (U.S. EPA/OPP/EFED 2010). Ecological effects data are also covered in the National Marine Fisheries Service biological opinion on oryzalin (NMFS 2012). The NMFS (2012) analysis covers pendimethalin and trifluralin as well as Oryzalin; thus, the document is somewhat unwieldy—i.e., about 30 megabytes with over 1000 pages. Consequently, NMFS (2012) was consulted but not reviewed in detail during the preparation of the current assessment on oryzalin. Additional information about oryzalin is taken from Tomlin (2004), ChemIDplus (2014) and EPI Suite (2011).

This document is accompanied by two MS Word files: **`Oryzalin WMS Formulation Inputs.docx`** and **`Oryzalin WSM Chemical Inputs.docx`**. These files can be used with the MS Word utility, SERA (2011b), to add oryzalin to the database used by WorksheetMaker. This document is also accompanied by a WorksheetMaker EXCEL workbook, **`Oryzalin SAMPLE Workbook.xlsm`**. Forest Service personnel may modify this workbook for program specific activities.

2. PROGRAM DESCRIPTION

Oryzalin is an herbicide registered in the United States since 1974. Oryzalin was developed in the late 1960s and was first marketed in Bulgaria in 1973 by Eli Lilly (now Dow AgroSciences). Oryzalin is used for preemergence control of both grasses and broadleaved weeds on a variety of crops, including cotton, fruit trees, nut trees, vines, ornamentals, soya beans, berries, rice, amenity turf and non-crop areas (Tomlin 2004). The U.S. EPA registration review program operates on a 15-year cycle. Oryzalin was reregistered in 1994 (U.S. EPA/OPP 1994a) and is currently under registration review, which is scheduled to be completed in 2016 (U.S. EPA/OPP 2011).

Table 1 summarizes the chemical and physical properties as well as environmental fate characteristics of oryzalin. Oryzalin is only moderately persistent, and photodegradation (in both soil and water) appears to be the major breakdown mechanism (U.S. EPA/OPP/EFED 2010, p. 16). At least 12 metabolites of oryzalin have been identified (e.g., U.S. EPA/OPP/EFED 2010, Table 2). A characteristic of all identified metabolites is that the benzenesulfonamide ring



remains intact. No metabolites of concern are designated in EOA risk assessments (i.e., U.S. EPA/OPP 1994a, 2004; U.S. EPA/OPP/EFED 2010), and the TRED for oryzalin specifically notes: *Oryzalin does not appear to produce a toxic metabolite produced by other substances* (U.S. EPA/OPP 2004, p. 4). Consequently, the EPA has not addressed cumulative risks from oryzalin with other substances having the same mode of action.

As of 2011 (the most recent year for which data are available), the USGS estimates an upper end annual use of oryzalin in the United States of about 900,000 pounds (http://water.usgs.gov/nawqa/pnsp/usage/maps/show_map.php?year=2011&map=ORYZALIN&hilo=L&disp=Oryzalin). As illustrated in Figure 1, oryzalin is currently used primarily on orchards and grapes.

Based on the most recent EPA risk assessment (i.e., U.S. EPA/OPP/EFED 2010, Table 2.3), the maximum single application rate for oryzalin is 6 lbs a.i./acre with a maximum cumulative annual application rate of 15 lbs a.i./acre. The PAN Pesticides Database currently lists 67 active formulations of oryzalin in the United States (Kegley et al. 2014).

While the current document is intended to be useful in any small scale application of oryzalin, it is focused on the use of oryzalin at the JH Stone Nursery in the Rogue River-Siskiyou National Forest. Based on information from this nursery, the Forest Service will use Surflan AS (40.4% oryzalin) (Justin 2014). According to the most recent label (May 18, 2014) at the EPA label site (http://iaspub.epa.gov/apex/pesticides/f?p=PPLS:8:8209936233516 ::NO::P8_PUID:2909), Surflan AS Specialty Herbicide (EPA Registration Number 70506-44) contains oryzalin as the sole active ingredient at a concentration of 4 lbs a.i./gallon. The maximum single application rate is 2 lbs a.i./acre. Up to 2 applications per year are permitted with a minimum application interval of 3 months. As with other formulations of oryzalin, Surflan AS is labelled for the control of both grasses and broadleaf weeds. This formulation is labeled for both backpack (directed foliar) and ground broadcast application.

At the JH Stone Nursery, oryzalin will be used at an application rate of 2 lbs a.i./acre and an application volume of 30 gallons/acre. Two applications will be made with a 3-month application interval as a broadcast spray through tractor mounted spray booms. Workers will apply oryzalin by ground broadcast through tractor mounted spray booms, and treatment will be made at a rate of 5 acres/hr for 4 hours. Thus, 20 acres will be treated for a total use of 40 lbs per application with 80 pounds being used at the nursery per year.

Based on other information from the Forest Service (the illustration in **`JH Stone Nursery Information-v3 Shawna Aug 21.docx`**), the JH Stone nursery is about 220 acres in size. Taking 20 acres as the treated area, a proportion of about 0.091 [20 acres ÷ 220 acres ≈ 0.090909…] of the nursery area will be treated. As discussed further in Section 3.2.2.1, this proportion is used to modify the water contamination rates.

3. HUMAN HEALTH

3.1. Hazard Identification

While full Forest Service risk assessments provide a detailed discussion of the available toxicity data on the pesticide under consideration, this approach is not taken in the current document, in the interest of economy. The toxicology of oryzalin is discussed in detail in the Reregistration Eligibility Decision (RED) document on oryzalin (U.S. EPA/OPP 1994a) as well as the Tolerance Reassessment Progress and Risk Management Decision (TRED) for oryzalin (U.S. EPA/OPP 2004).

As noted in Section 2, the EPA does not specifically address cumulative effects for oryzalin. The rationale for this approach is given below.

> *Unlike other pesticides for which EPA has considered cumulative risk based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for oryzalin. The Agency has found no information indicating oryzalin shares a common mechanism of toxicity with other substances. Oryzalin does not appear to produce a toxic metabolite produced by other substances. Therefore, for the purposes of the risk assessments, EPA has not assumed that oryzalin has a common mechanism of toxicity with other substances.*
>
> U.S. EPA/OPP (2004, p. 3)

While the toxicity of oryzalin is relatively well characterized in plants (Section 4.1), a specific mechanism of action in humans and other mammals is not identified in EPA risk assessments. Overall, oryzalin does not appear to be highly toxic to mammals on an acute basis. Oryzalin is classified as Category IV (least toxic category) in terms of acute oral toxicity and Category III in terms of acute dermal and inhalation toxicity as well as eye irritation. Oryzalin is also classified as non-sensitizing (U.S. EPA/OPP 1994a).

In terms of chronic effects, the most sensitive endpoint for toxicity appears to be the thyroid. As discussed further in Section 3.3, thyroid lesions along with decreased body weight gain and changes in hematology parameters are the basis of the chronic RfD (U.S. EPA/OPP 2004a). In addition to systemic toxicity, chronic exposures to oryzalin may cause cancer based on an increase in thyroid follicular cell tumors. Specifically, oryzalin is classified as "likely to be carcinogenic to humans" (U.S. EPA/OPP 2004, p. 15). Because of the toxicity and carcinogenicity of oryzalin to the thyroid, the EPA may require … *additional screening and/or testing to better characterize effects related to endocrine disruption when the Agency's Endocrine Disrupter Screening and Testing Advisory Committee develops appropriate screening and/or testing protocols* (U.S. EPA/OPP 2004, p. 4). The most recent EPA assessment relating to the registration review of oryzalin notes a concern for endocrine disruption but does not indicate if additional testing has been done on oryzalin (U.S. EPA/OPP 2011, p. 6). Endocrine disruption is also a concern in the ecological risk assessment; however, the most recent EPA ecological risk assessment on oryzalin does not discuss endocrine disruption (U.S. EPA/OPP/EFED 2010).

3.2. Exposure Assessment

3.2.1. Workers

3.2.1.1. General Exposures

As discussed in SERA (2014b), Forest Service risk assessments use a standard set of worker exposure rates (Table 14 in SERA 2014b). The current document is concerned with ground broadcast applications. As detailed in Table 14 of SERA (2014b), the occupational exposure rate for ground broadcast applications is 0.0001 (0.000002 to 0.005) mg/kg bw per lb a.i. handled based on the central estimate of exposure and 95% prediction intervals.

U.S. EPA/OPP (1994a) estimates exposure to ground broadcast workers as 0.01 mg/kg bw/day (U.S. EPA/OPP 1994a, Table 4, p. 19) based on the treatment of 80 acres/day (U.S. EPA/OPP 1994a, Table 4, p. 18) at an application rate of 6 lbs a.i./acre (U.S. EPA/OPP 1994a, Table 2, p. 17). This estimate corresponds to a worker exposure rate of 0.000021 mg/kg bw/day per lb a.i. handled [0.01 mg/kg bw ÷ (6 lb a.i./acre x 80 acres)].

The central estimate of the worker exposure rates from SERA (2014b) is about a factor of 5 higher than the corresponding rates from U.S. EPA/OPP (1994a) [0.0001 ÷ 0.00021 = 4.8]. As discussed in SERA (2014b), worker exposure rates are highly variable, and difference of a factor of 5 is large but not unusually so given the variability in worker exposure rates.

As detailed in SERA (2014b, Section 4.2 and Table 14), worker exposure rates for directed ground applications should be adjusted for dermal exposure rates of the chemical of concern, relative to the reference chemical on which occupational exposure rates are based. This is not the case for broadcast ground applications, for which the adjustment of dermal absorption is optional. As specified in SERA (2014b, Table 14), there is only one reference chemical for ground broadcast applications—i.e., 2,4-D with a first-order dermal absorption rate of 0.00066 $hour^{-1}$. As detailed in the following section, the estimated first-order dermal absorption rate for oryzalin is 0.0026 $hour^{-1}$, which is a factor of about 4 higher than the corresponding rate for 2,4-D [0.0026 $hour^{-1}$ ÷ 0.00066 $hour^{-1}$ ≈ 3.9393…]. Thus, adjusting the occupational exposure rate upward by a factor of 4 would lead to an occupational exposure rate higher than that from EPA by a factor of about [4.8 x 3.94 ≈ 18.912]. This difference from EPA is not justified by the available data, and the option to adjust the occupational exposure rate for oryzalin is not exercised in the current analysis.

3.2.1.2. Accidental Exposures

In addition to general exposures, four standard accidental exposure scenarios for workers discussed in SERA (2014a, Section 3.2.2.2) are also considered in the current assessment and detailed in Worksheets C02a,b and C03a,b.

Worksheets C03a,b involve accidental spills under the assumption of first-order dermal absorption. Based on a dermal absorption study in Rhesus monkeys, U.S. EPA/OPP (2004, p. 20) uses a dermal absorption factor of 2.3%. This factor is used for exposures over the course of a work day (8 hours) and corresponds to an estimated first-order dermal absorption rate of about 0.0029 $hour^{-1}$ [k_a = -ln(1-0.023)÷8 hours ≈ 0.00291 $hour^{-1}$].

In the absence of experimental data, Forest Service risk assessments use an algorithm based on the molecular weight and octanol water partition coefficient (K_{ow}) to approximate a first-order dermal absorption rate coefficient (see Eq. 23, Section 3.1.3.2.2 in SERA 2014a). As detailed in Worksheet B03b of the WorksheetMaker workbook that accompanies this report, the estimated first-order dermal absorption rate coefficient for oryzalin based on this algorithm is 0.0026 (0.0011 to 0.0062) hour^{-1} based on a molecular weight of 346.35 and K_{ow} of 5370 (Table 1 values from U.S. EPA/OPP 1994a for molecular weight and EPA/OPP/EFED 2010 for K_{ow}). The central estimate of the k_a (0.0026 hour^{-1}) is from the SERA (2014a) algorithm is virtually identical to the estimate of 0.0029 hour^{-1} from U.S. EPA/OPP (2004). Given the concordance of the two estimates, the current assessment uses the k_a values of 0.0026 (0.0011 to 0.0062) hour^{-1} from the SERA (2014a) algorithm to more explicitly account for the uncertainty of the estimate.

Worksheets C02a,b involve contaminated gloves under the assumption of zero-order dermal absorption. These scenarios require an estimate of the skin permeability coefficient (k_p in units of cm/hr). No experimental measurements of k_p were identified in the literature reviewed for this report (Section 1.2). Consequently, the k_p is estimated using an algorithm developed by the U.S. EPA's Office of Research and Development as discussed in SERA (2014a, 3.1.3.2.1). The application of this algorithm to oryzalin is detailed in Worksheet B03a of the WorksheetMaker workbook that accompanies this document. The values in Worksheets C02a,b are rounded to 0.0060 (0.0034 to 0.011) cm/hr and are used in all exposure scenarios based on zero-order dermal absorption.

3.2.2. General Public

As detailed in SERA (2014a, Section 3.2.3), Forest Service risk assessments provide a standard set of exposure scenarios for members of the general public. These exposure scenarios are applicable to standard forestry applications of pesticides and are included in the WorksheetMaker workbook that accompanies this document.

3.2.1.1. Surface Water

While most of the exposure scenarios given in the WorksheetMaker workbook are standard for Forest Service risk assessments, one notable exception is the surface water modelling. Full Forest Service risk assessments typically estimate concentrations of a pesticide in surface water using GLEAMS-Driver (SERA 2014a, Section 3.2.3.4.3). In the interest of economy, the current analysis uses FIRST (FQPA Index Reservoir Screening Tool). FIRST is a Tier 1 model developed by the U.S. EPA to estimate pesticide concentrations in surface water. Details of the FIRST model are available at http://www.epa.gov/oppefed1/models/water/first_description.htm.

The input parameters and the estimated surface water concentrations of oryzalin are summarized in Table 2. The model runs involved two applications of 1 lb a.i./acre with an application interval of 60 days. This is the number of applications and the application interval that is proposed for the JH Stone Nursery. Note that the upper bound of the K_{oc} is used to estimate the lower bound peak concentrations and the lower bound of the K_{oc} is used to estimate the upper bound of peak concentrations. For the upper bound estimates of concentrations in surface water, the opposite approach is taken—i.e., lower bound of the K_{oc} is used to estimate the upper bound of peak concentrations and the upper bound of the K_{oc} is used to estimate peak longer-term concentrations. This approach is taken because low values for K_{oc} (less soil binding) will lead to higher peak concentrations which in turn lead to lower longer-term concentrations.

One very important input parameter for FIRST is the proportion of the watershed that is treated. As indicated in Table 2, the FIRST modeling was conducted using a proportion of 1.0—i.e., the entire watershed is treated. As discussed in Section 2, the proportion of the JH Stone Nursery that will be treated is about 0.091. This factor is used in Table 2 to adjust the estimated water contamination rates. These adjusted water contamination rates are entered into Worksheet B04Rt as water contamination rates—i.e., mg/L per lb a.i./acre applied.

3.2.2.2. Vegetation

As detailed in SERA (2014a, Section 3.2.3.7), several scenarios involving the consumption of contaminated vegetation are included in workbooks produced by WorksheetMaker for pesticides applied to foliage. The major input parameters are application rate, number of applications, and application interval. As with surface water concentrations, the residues in vegetation are entered into WorksheetMaker as normalized rates in units of mg/kg vegetation per pound a.i. applied per acre.

For longer-term exposures, half-lives on vegetation are important parameters. Little information is available on vegetation half-lives of oryzalin. Knisel and Davis (2000) recommend a foliar half-life of 5 days, and U.S. EPA/OPP/EFED (2010, p. 70) uses a default half-life of 35 days adapted from Willis and McDowell (1987). Willis and McDowell (1987) do not list a foliar half-life for oryzalin. Based on these data, the lower and upper bounds of the foliar half-life for oryzalin are taken as 5 to 35 day. The central estimate of 13 days is used based on the geometric mean of the lower and upper bounds.

3.2.2.3. Bioconcentration

As discussed in SERA (2014a, Section 3.2.3.5), scenarios involving the consumption of contaminated fish are included in most WorksheetMaker workbooks. The major chemical specific inputs are the concentrations in surface water (discussed in Section 3.2.1.1 of this document) and the bioconcentration factor (BCF). For exposure scenarios involving humans, the BCF is based on the edible portion (muscle) in fish. For the ecological risk assessment, the BCF is based on whole fish. When adequate data are available, separate BCF values may be given for acute exposures and longer-term exposures.

Very little information on the bioconcentration of oryzalin is included in the documents consulted (Section 1.2). U.S. EPA/OPP (1994a, p. 29, MRID 40787501; U.S. EPA/OPP/EFED 2010) cite bioconcentration factors of about 32 in the edible portion of fish and 66 in whole fish. These values are used for both acute a longer-term exposure assessments involving the consumption of contaminated fish.

3.2.2.4. Dermal Exposure

As in the accidental exposure assessments for workers (Section 3.2.1.2 of the current document), dermal exposure scenarios involving both first-order and zero-order absorption are used in scenarios for members of the general public. Details of these exposure scenarios are given in SERA (2014a, Sections 3.2.3.3 and 3.2.3.6). The dermal absorption values used in these scenarios are identical to those used for workers (Section 3.2.1.2).

3.3. Dose-Response Assessment

The dose-response assessments for oryzalin are summarized in Table 3. All of the toxicity values are taken from EPA's tolerance reassessment for oryzalin (U.S. EPA/OPP 2004) with supplemental information taken from the Reregistration Eligibility Decision (RED) for oryzalin (U.S. EPA/OPP 1994a).

3.3.1. Acute Toxicity

The acute RfD for oryzalin is 0.25 mg/kg bw/day (U.S. EPA/OPP 2004, p. 14). This acute RfD uses an uncertainty factor of 100 and is based on a developmental study in rabbits in which the NOAEL is 25 mg/kg bw/day and the LOAEL is 55 mg/kg bw/day based on fetal toxicity—i.e., decreases in the number of live fetuses, increased resorptions, and increased post-implantation losses. U.S. EPA/OPP (2004) does not specify the study on which the acute RfD is based. The information in U.S. EPA/OPP (1994a) clearly indicates that the RfD is based on MRID 00026785. U.S. EPA/OPP (2004) applies this study only to women of childbearing age. Following the standard practice in Forest Service risk assessments, this acute RfD is applied to the general population.

3.3.2. Chronic Toxicity

The chronic RfD for oryzalin is 0.14 mg/kg bw/day (U.S. EPA/OPP 2004, p. 15). The chronic RfD also uses an uncertainty factor of 100 and is based on a chronic study in rats with a NOAEL of 14 mg/kg bw/day and a LOAEL of 43 mg/kg bw/day based on histopathological changes in thyroid tissue. U.S. EPA/OPP (2004) does not specify the study on which the chronic RfD is based. The information in U.S. EPA/OPP (1994a) suggests that the chronic RfD is based on MRIDs 00070569, 00026779, 00044332. Complex studies such as chronic studies in mammals are often associated with multiple MRID submissions. U.S. EPA/OPP (1994a) gives a slightly lower chronic RfD of 0.12 mg/kg bw/day. This minor inconsistency is not unusual and probably reflects either a subgroup in the study (e.g., males or females) or a recalculation of body weight and food consumption data.

The U.S. EPA/OPP sometimes derives a separate toxicity value for workers. This is not the case for oryzalin.

3.3.3. Carcinogenicity

U.S. EPA/OPP (2004) classifies oryzalin as "likely to be carcinogenic to humans" and sets a level of concern for carcinogenicity of 1 in 1-million (U.S. EPA/OPP 2004, p. 15) with a cancer potency factor of 0.0078 $(\text{mg/kg bw/day})^{-1}$ based on thyroid tumors. Potency factors are not used directly in WorksheetMaker. Instead, the values for carcinogenicity are based on a dose associated with a risk of 1-in-1 million. Risk is simply the product of potency and dose [Risk = Potency x Dose]. By rearrangement, the dose associated with a risk of 1-in-1 million (0.000001) is calculated as 0.000001 divided by the potency. Thus, the dose associated with a risk of 1-in-1 million is 0.00013 mg/kg bw/day mg/kg bw/day [$0.000001 \div 0.0078\ (\text{mg/kg bw/day})^{-1} \approx 0.0001282$ mg/kg bw/day].

U.S. EPA/OPP (1994a) gives a much higher cancer potency factor of 0.13 $(\text{mg/kg bw/day})^{-1}$ based on mammary gland tumors in both sexes and fibroadenomas in female rats. U.S. EPA/OPP (2004) does not discuss this higher potency factor or the reasons for using a lower potency factor based on thyroid tumors. A cursory review of cleared science reviews from EPA suggests that this decision is based on an EPA reassessment of the carcinogenicity data on oryzalin (U.S. EPA/OPP/HED 2003). While this reassessment was not reviewed in detail as part of the current effort, it is clear that EPA recommends the use of thyroid rather than mammary gland tumors for the assessment of cancer potency.

> *The Committee recommended that a linear low-dose extrapolation approach for the quantification of human cancer risk be applied to the experimental animal tumor data and that quantifications of risk be estimated for thyroid follicular cell tumors which were seen in both sexes in rats.*
>
> U.S. EPA/OPP/HED (2003, p. 36).

For the current analysis, the cancer potency factor of 0.0078 (mg/kg bw/day)$^{-1}$ based on thyroid tumors is used. Note that this potency factor is associated with lifetime risk. As detailed above, the dose associated with a lifetime risk of 1-in-1 million is 0.00013 mg/kg bw/day mg/kg bw/day.

For the analysis relating to the JH Stone Nursery, lifetime exposures are not anticipated. For less-than-lifetime exposures, the U.S. EPA recommends estimating a dose based on an equivalent lifetime exposure:

> *Unless there is evidence to the contrary in a particular case, the cumulative dose received over a lifetime, expressed as average daily exposure prorated over a lifetime, is recommended as an appropriate measure of exposure to a carcinogen. That is, the assumption is made that a high dose of a carcinogen received over a short period of time is equivalent to a corresponding low dose spread over a lifetime.*
>
> U.S. EPA/RAF (2005, p. 3-26).

The above approach is essentially identical to the application of Haber's Law as discussed in SERA (2014a, p. 145).

Taking 70 years as a standard value for a human lifetime, the number of days of exposure for a lifetime dose would be 25,000 day [70 years x 365.25 day = 25,567.5 days]. Thus, a lifetime dose of 0.00013 mg/kg bw/day would be equivalent to a single dose of about 3.32 mg/kg bw [0.00013 mg/kg bw/day x 25,000 days = 3.323775 mg/kg bw]. This dose may be viewed as the dose associated with a 1-day exposure resulting in a lifetime risk of 1-in-1 million. This dose is used in the workbook that accompanies the current risk assessment to estimate HQs for cancer that would be associated with an exposure for a single day. This risk is incremental. For example, an exposure for 10 days would be associated with a risk of 1-in-100,000.

3.4. Risk Characterization

3.4.1. Workers

As summarized in Worksheet E02, the HQs for workers associated with general exposures in the broadcast ground application of oryzalin are 0.03 (0.0006-1.4). Based on the central estimate of exposure (i.e., the most likely exposure), the HQ is below the level of concern by a factor of about 33 [1÷0.03 = 33.333…]. The upper bound of 1.4 modestly exceeds the level of concern. As discussed in SERA (2014b), the upper bound is based on a prediction interval, which is more conservative than a confidence interval. It seems reasonable to assert that concerns for the upper bound HQ could be adequately addressed by ensuring proper handling and proper use of PPE.

As summarized in Worksheet E05, the HQs for workers based on carcinogenicity are 0.001 (0.00002 to 0.06). As discussed in Section 3.3.3, these HQs are associated with a single day's exposure. Thus, based on the central estimate of the HQ, a worker would need to apply oryzalin for 1000 days [1 ÷ 0.001 day^{-1}] to reach a cancer risk of 1-in-1-million. Based on the upper bound of 0.06, however, only about 17 days would be required to reach this risk [1 ÷ 0.06 day^{-1} ≈ 16.666…]. Based on the information from the JH Stone Nursery, however, workers would apply oryzalin for only a single full day—i.e., 2 days at 4 hours/day. Thus, a single worker would need to apply oryzalin at this nursery for a period of about 17 years to exceed a cancer risk of 1-in-1 million.

As discussed in Section 3.2.1.1, the U.S. EPA/OPP (1994a) estimates an exposure of 0.01 mg/kg bw/day for workers applying oryzalin by ground broadcast application. Based on the cancer potency factor of 0.13 $(mg/kg\ bw/day)^{-1}$, the risk [Dose x Potency] to workers would be about [0.13 $(mg/kg\ bw/day)^{-1}$ x 0.01 mg/kg bw/day = 0.0013 or about 1 in 769]. The highest worker risk given in U.S. EPA/OPP (1994a, p. viii) is 2.6×10^{-4}. It seems possible that the EPA made adjustments for less-than-lifetime exposures in U.S. EPA/OPP (1994a), similar to those detailed in Section 3.3.3 of the current report.

3.4.2. General Public

As summarized in Worksheet E04, accidental exposure scenarios lead to HQs that exceed the level of concern based on an accidental spill. The highest HQs are associated with the consumption of contaminated fish by subsistence populations—i.e., HQs of 4 (0.9-9). In the event of an accidental spill, aggressive measures would be justified to limit exposures to the general public. For non-accidental exposures, the only HQs of concern (HQ>1) are those associated with the consumption of contaminated vegetation. The upper bound HQs for the consumption of contaminated vegetation are 13 for acute exposures and 11 for longer-term exposures. Concerns for these HQs can be mitigated by ensuring that members of the general public do not have access to edible vegetation at the nursery site.

As summarized in Worksheet E05, none of the HQs for cancer based in an incremental risk associated with a single exposure for 1 day exceeds the level of concern. Most HQs are far below the level of concern. One notable exception is the scenario for the consumption of contaminated vegetation, which result in HQs of 0.02 (0.00005 to 0.4). The upper bound HQ of 0.4 indicates that the consumption of contaminated vegetation might lead to a cancer risk in excess of 1-in-1-million over an exposure period greater than 2.5 days [1 ÷ 0.4 day^{-1}]. As above, concerns for the upper bound HQ can be mitigated by ensuring that members of the general public do not have access to edible vegetation at the nursery site.

4. ECOLOGICAL EFFECTS

4.1. Hazard Identification

As with the hazard identification for human health (Section 3.1), the hazard identification for ecological effects is highly abbreviated in the current document. The overall database for ecological effects is discussed in detail in U.S. EPA/OPP/EFED (2010), the most recent ecological risk assessment on oryzalin. Specific toxicity values for different groups of receptors are discussed in Section 4.3.

Oryzalin is a dinitroanaline herbicide that inhibits microtubule assembly in plants and is in the same chemical class as herbicides such as trifluralin (SERA 2011d). Oryzalin is absorbed by roots but is not well-absorbed by leaves and is not translocated in plants (NMFS 2012). The effect of oryzalin on microtubules is limited to plants does not affect microtubules in animals (U.S. EPA/OPP/EFED 2010, p. 34; NMFS 2012, p. 444). In terms of the potential for resistance, oryzalin is classified as WSSA Group 7, HRAC Group K1 (Mallory-Smith and Retzinger 2003). No metabolites of oryzalin are classified as metabolites of concern (U.S. EPA/OPP/EFED 2010, p. 15).

4.2. Exposure Assessment

4.2.1. Bioconcentration

Typically, bioconcentration values for whole fish are used in the ecological risk assessment, and bioconcentration factors for the edible portion of fish (i.e., muscle) are used in the human health risk assessment. As discussed in Section 3.2.2.3, very little information is available on the bioconcentration of oryzalin—i.e., a single estimate of 66 L/kg in whole fish from based on a registrant-submitted study (U.S. EPA/OPP 1994a, p. 29, MRID 40787501). In the absence of additional information, this BCF is applied to both acute and longer-term exposure scenarios involving the consumption of contaminated fish by wildlife.

4.2.2. Offsite Contamination of Soil

Rates for the offsite contamination of soil are typically handled in full or scoping level Forest Service risk assessments using GLEAMS-Driver modelling. In the interest of economy, the current effort uses a central estimate of 5% with a range of 1% to 10% of the nominal application rate. These values are similar to estimates of offsite losses noted in Forest Service pesticide risk assessments as well as assumptions often used in EPA risk assessments.

4.2.3. Surface Water

As with most full Forest Service risk assessments, the surface water concentrations used in the ecological risk assessment are identical to those used in the human health risk assessment (Section 3.2.1.1).

4.3. Dose-Response Assessment

The dose response assessment for nontarget organisms is summarized in Table 4 and is discussed in the following subsections on different groups of receptors.

With the exception of mammals (as discussed in Section 4.3.1.1), Forest Service risk assessments generally defer to dose-response assessments from U.S. EPA/OPP/EFED in the selection of endpoints and study selection in the dose-response assessments for ecological receptors, unless there is a compelling reason to do otherwise. For endpoints associated with acute toxicity, however, the Forest Service prefers to use NOAECs rather than estimates of 50% lethality (LD_{50} or LC_{50} values) which are used in EPA risk assessments. In the absence of an NOAEC, Forest Service risk assessments use LD_{50} or LC_{50} values to approximate an NOAEC by dividing the lethality value by a factor of 10 for terrestrial species or 20 for aquatic species. This approach is based on and consistent with the EPA variable level of concern approach, as detailed in SERA (2014, Section 4.3.2, Table 19). References to the use of this procedure are noted below as appropriate.

The dose-response assessments presented in the following sections are taken from U.S. EPA/OPP/EFED (2010). Appendix A of this EPA risk assessment provides details on some studies included in the following sections. In the interest of brevity, Appendix A from U.S. EPA/OPP/EFED (2010) is referenced simply as *EFED Appendix A* in the following sections.

4.3.1. Terrestrial Organisms

4.3.1.1. Mammals

For the dose-response assessment of mammalian wildlife, Forest Service risk assessments typically use the acute and chronic NOAELs from the human health risk assessment that form the basis of the acute and chronic RfDs. This approach is adopted for oryzalin.

As discussed in Section 3.3 and summarized in Table 3, the acute NOAEL is 25 mg/kg bw/day from a developmental study in rabbits with a corresponding LOAEL of 55 mg/kg bw/day based of fetal toxicity. Thus, for the ecological risk assessment, the NOAEL of 25 mg/kg bw/day is used for oryzalin.

For the chronic RfD, the NOAEL used in the human health risk assessment is 14 mg/kg bw/day (Table 3) with a corresponding LOAEL of 43 mg/kg bw/day based on changes in thyroid tissue. Again, for the same reason noted in the selection of acute NOAEL, the NOAEL of 14 mg/kg bw/day is used for risk characterization of longer-term exposures of mammalian wildlife to oryzalin.

4.3.1.2. Birds

4.3.1.2.1 Acute Toxicity

U.S. EPA/OPP/EFED (2010, p. 82) provides two toxicity values for birds—i.e., an acute LD_{50} of 506.7 mg/kg bw via gavage (MRID 00098462) and an acute dietary LOAEL of 625 ppm (mg a.i./kg food) in bobwhite quail (MRID 00072593).

A NOAEL for the gavage study is not specified in the main body of the EFED risk assessment or in EFED Appendix A. Dividing the LD_{50} by 10, a surrogate NOAEL of about 50 mg/kg bw/day can be estimated. This estimated NOAEL is only modestly higher than the NOAEL of 25 mg/kg bw/day in mammals (Section 4.3.1.1).

As indicated in a previous Forest Service risk assessment for which both body weights and food consumption rates in acute dietary studies were available for quail and mallards (SERA 2007b), approximate food consumption rates in acute dietary studies are about 0.4 kg food/kg bw for mallards and 0.3 kg food/kg bw for quail. These food consumption rates are from standard studies using very young birds. Using a food consumption rate of 0.3 chow/kg bw quail, the acute dietary LOAEL of 625 mg/kg chow corresponds to dose of 187.5 mg/kg bw/day [625 mg/kg chow x 0.3 chow/kg bw/day ≈187.5 mg /kg bw/day]. Dividing the LOAEL by a factor of 10, the NOAEL is approximated as 18.75 mg/kg bw/day. This estimated NOAEL is only modestly lower than the NOAEL of 25 mg/kg bw/day in mammals (Section 4.3.1.1).

For the current analysis, the lower NOAEL of 18.75 mg/kg bw/day is rounded to 19 mg/kg bw/day and is used as the basis for characterizing acute risks for birds exposed to oryzalin.

4.3.1.2.2 Chronic Toxicity

To characterize risks to birds associated with longer-term exposures to oryzalin, U.S. EPA/OPP/EFED (2010, Section 4.2.1.2, p. 83) uses a NOAEL of 132 mg/kg chow from a reproductive study in quail (MRID 44162201). The corresponding LOAEL is 311 mg/kg chow based on reduced body weight in females. Using a food consumption rate of 0.07 chow/kg bw for longer-term studies in quail and mallards (SERA 2007b), the dietary NOAEL of 132 mg/kg chow corresponds to dose of about 9 mg/kg bw/day [132 mg/kg chow x 0.07 chow/kg bw/day = 9.24 mg /kg bw] with a corresponding LOAEL of about 22 mg/kg bw/day [311 mg/kg chow x 0.07 chow/kg bw/day = 21.77 mg /kg bw]. Thus, for the current analysis, the NOAEC of 9 mg/kg bw/day is used to characterize risks associated with longer-term exposures of birds to oryzalin. As with acute toxicity, the estimated NOAEL of 9 mg/kg bw/day in birds is similar to the estimated NOAEL of 14 mg/kg bw/day in mammals (Table 4).

4.3.1.3. Amphibians, Terrestrial-Phase

Data on terrestrial-phase amphibians are not summarized in the EFED risk assessment, and birds are used as surrogates for terrestrial-phase amphibians (U.S. EPA/OPP/EFED 2010, p. 52). The Pauli et al. (2000) compendium of toxicity studies in reptiles and amphibians does not include information on oryzalin. Furthermore, the toxicity of oryzalin to amphibians is not addressed in the NMFS (2012) assessment.

4.3.1.4. Honey Bee

U.S. EPA/OPP/EFED (2010, p. 84 and Appendix A, Table A-8) summarizes a single study in the honeybee in which the acute contact LD_{50} is reported as >11 µg/bee. It is not clear if the indefinite LD_{50} represents a NOAEL or a dose associated with partial mortality. This study is used to classify oryzalin as …*practically non-toxic to honeybees on an acute contact basis*. This toxicity value is not used by EFED to characterize risks to terrestrial insects because the LD_{50} is indefinite (U.S. EPA/OPP/EFED 2010, p. 100). This approach is adopted in the current assessment, and risks to honeybees are not quantified.

4.3.1.5. Terrestrial Plants

As with most herbicides, a standard set of toxicity studies on monocots and dicots involving both seedling emergence (soil applications) and vegetative vigor (foliar applications) are available for oryzalin (U.S. EPA/OPP/EFED 2010, Appendix A, Table A-9, MRID 426024-01).

Based on reported NOAECs for foliar exposure, the most sensitive species are ryegrass (monocot), lettuce (dicot), and tomato (dicot), all with NOAECs of 0.0253 lb a.i./acre. The most tolerant species are onion (monocot) and soybean (dicot), each with NOAECs of 2 lb a.i./acre.

For soil application, the most sensitive species is tomato (dicot) with an EC_{05} (a functional NOAEL) of 0.0056 lb a.i./acre. The most tolerant species is soybean (another dicot) with an NOAEL of 6 lb a.i./acre.

The lower NOAECs for soil exposures, relative to foliar exposures, is consistent with the assessment in the EFED risk assessment that oryzalin is not well-absorbed by leaf surfaces (Section 4.1).

The EFED assessment does note the following cautionary language required on the formulation labels for oryzalin.

> *The labels for oryzalin caution not to apply this herbicide to Douglas fir, slender deutzia, Techny arborvitae, eastern hemlock, begonia, and coleus due to phytotoxicity on the above species.*
>
> U.S. EPA/OPP/EFED (2010, p. 34).

It is not clear if the NOAECs for sensitive species of plants from MRID 426024-01encompass the species listed above. The EFED risk assessment does not provide a summary of the open literature on the toxicity of oryzalin to terrestrial plants. While the open literature on oryzalin is not extensive (Section 1.2), it may contain information relating to the cautionary language required on oryzalin formulations.

4.3.2. Aquatic Organisms

As discussed in the following sections, most acute toxicity values are reported in U.S. EPA/OPP/EFED (2010) in units of mg/L, the same units used in the WorksheetMaker workbook that accompanies this report. For aquatic plants, however, some toxicity values are given by EFED in units of µg/L. To maintain consistency with the EPA source document, the units for concentration in the following sections are identical to those used by EFED. All toxicity values used in the WorksheetMaker workbook as well as Table 4, however, are also expressed in units of mg/L.

Forest Service risk assessments attempt to develop toxicity values for both tolerant and sensitive species, and this approach is used in the current document. The toxicity data on most groups for organisms, however, is not extensive, which makes it likely that the actual toxicity values for the most sensitive and most tolerant species within each group of organisms would span a perhaps much wider range, compared with the toxicity values used in the current assessment. This limitation, which is noted for the sake of transparency, is common to most ecological risk assessments. Given the few species on which data are available, toxicity values on both freshwater and saltwater aquatic animals are combined. This is a standard practice in Forest Service risk assessments, unless sufficient information is available to identify clear differences in the pattern of toxicity values for freshwater and saltwater organisms.

4.3.2.1 Fish

4.3.2.1.1. Peak Exposures

For assessing acute risks to fish, U.S. EPA/OPP/EFED (2010, Section 4.1.1.1, p. 77) uses an acute LC_{50} of 2.88 mg/L in bluegill sunfish (MRID 00072595). Based on a more detailed summary of this study in EFED Appendix A, the NOAEC of 1 mg/L is the lowest NOAEC reported for any species of fish. Thus, the NOAEC of 1 mg/L is used in the current assessment to characterize risks associated with peak exposures of sensitive species of fish to oryzalin.

EFED Appendix A summarizes studies in rainbow trout and sheepshead minnows. The highest reported LC_{50} is 3.45 mg/L in trout (MRID TN 1078). This study is not used in the current analysis, however, because EFED does not provide a NOAEC. The most tolerant species appears to be sheepshead minnow with a reported NOAEC of 3.04 mg/L. The NOAEC may be viewed as freestanding in the sense that 3.04 mg/L was the highest concentration tested and the NOAEC for oryzalin in this species could be substantially higher than 3.04 mg/L. Nonetheless, 3.04 mg/L is used as the NOAEC for potentially more tolerant species of fish.

4.3.2.1.2. Longer-term Exposures

U.S. EPA/OPP/EFED (2010, Appendix A, Table A-3) summarizes two acceptable early life-stage studies in fish, one in trout and the other in fathead minnows. The study in trout is a 66-day early life-stage study with an NOAEC of 0.46 mg/L, the highest concentration tested. Fathead minnows appear to be somewhat more sensitive, based on a 34-day early life-stage study with an NOAEC of 0.22 mg/L and a LOAEC of 0.43 mg/L based on a decrease in mean larval weights. Based on these studies, the NOAEC of 0.22 mg/L is used for sensitive species of fish and NOAEC of 0.46 mg/L is used for tolerant species of fish.

4.3.2.2 Amphibians (Aquatic-phase)

As with terrestrial-phase amphibians, toxicity data are not available for aquatic-phase amphibians. Noting this lack of data, the U.S. EPA/OPP/EFED (2010, p. 18) uses data on fish as a surrogate for aquatic-phase amphibians.

4.3.2.3. Aquatic Invertebrates

4.3.2.3.1. Peak Exposures

As with fish (Section 4.3.2.1.1), the acute toxicity of oryzalin is characterized in few species of aquatic invertebrates. As summarized in EFED Appendix A (Table A-2), the most sensitive species is the Eastern oyster with an EC_{50} (for shell deposition) of 0.285 mg/L and a corresponding NOAEC of 0.0994 mg/L (MRID 43887702). This NOAEC is to characterize risks to sensitive species of aquatic invertebrates.

The least sensitive species is grass shrimp with an LC_{50} of >3.11 mg/L and an NOAEC of 1.95 mg/L (MRID 43887701). This species is used to characterize risks in tolerant species of aquatic invertebrates.

Toxicity data on *Daphnia magna* are often used in ecological risk assessments. For oryzalin, however, daphnids appear to have an intermediate sensitivity with an EC_{50} (for immobility) of 1.5 mg/L and corresponding NOAEC of 0.62 mg/L (MRID 00072596).

4.3.2.3.2. Longer-term Exposures

Only one chronic study on an aquatic invertebrates is summarized in U.S. EPA/OPP/EFED (2010), a standard life cycle assay in Daphnia magna with a NOAEC of 0.358 mg/L and a corresponding LOAEC of 6.08 mg/L based on the dry weight of first generation offspring (MRID 43986901).

As discussed in the previous section, daphnids do not appear to be the most tolerant or the most sensitive species, based on the available acute toxicity data. As a conservative approach in the current assessment, the chronic NOAEC of 0.358 mg/L is applied to potentially tolerant species, and risks to more sensitive species are not characterized quantitatively.

4.3.2.4. Aquatic Plants

4.3.2.4.1. Algae

As summarized in Appendix A (Table A-4) of U.S. EPA/OPP/EFED (2010), toxicity studies were conducted on four species of non-vascular plants. Based on the reported NOAECs, the most tolerant species is *Anabaena flos-aquae*, a bluegreen alga, with an NOAEC of 8.1 mg/L. The most sensitive species is *Selenastrum capricornutum*, a green alga, with an NOAEC of 13.8 µg/L (0.0138 mg/L).

Unlike fish and invertebrates, the ratio of the NOAECs for the most tolerant to most sensitive species is substantial—i.e., about a factor of 900 [8.1 mg/L ÷ 0.0138 mg/L ≈ 586.96]. Based on the LC_{50} values (generally a better measure of relative potency), the difference in sensitivity is greater than a factor of about 260 [>13.5 mg/L for *Anabaena flos-aquae* ÷ 0.052 mg/L for *Selenastrum capricornutum* ≈ *>259.61*]. While these differences in sensitivity are substantial, the estimates of the differences in sensitivity are based on only four species.

4.3.2.4.2. Aquatic Macrophytes

Only one study is given for aquatic macrophytes in U.S. EPA/OPP/EFED (2010)—i.e., a standard study in *Lemna gibba* (a species of duckweed) with an EC_{50} of 13 µg/L (0.013 mg/L) based on frond count and a corresponding NOAEC of 5.48 µg/L (0.00548 m/L).

Based on this limited information, aquatic macrophytes may be much more sensitive than algae to oryzalin. In the absence of additional information, the NOAEC of 0.00548 mg/L is applied to potentially tolerant species of aquatic macrophyte, and risks to potentially sensitive species of aquatic macrophytes are not characterized quantitatively. Based on the differences in the potency of oryzalin to algae (Section 4.3.2.4.1), there is a reasonable possibility that some species of aquatic macrophytes may be more sensitive than duckweed to oryzalin.

4.4. Risk Characterization

The most recent EPA ecological risk assessment is focused on the California tiger salamander, an endangered amphibian. The EPA analysis suggests no direct adverse effects on aquatic phase amphibians. Based on the use of birds as a surrogate for terrestrial-phase amphibians, however, direct effects on terrestrial-phase amphibians are possible. Indirect effects based on changes to terrestrial vegetation are also possible (U.S. EPA/OPP/EFED 2010, pp. 18-20). Similarly, NMFS (2012) concludes that oryzalin is likely to impact fish and aquatic invertebrates based on modifications to aquatic plants (NMFS 2012, p. 538).

As summarized in Worksheet G02a (risk characterization for mammals) and Worksheet G02b (risk characterization for birds), many HQs associated with the acute and longer-term consumption of contaminated vegetation exceed the level of concern, some by large margins—i.e., upper bound HQs of up to 65 for mammals and 210 for birds. As discussed in SERA (2014a), these HQs are based on the underlying exposure assumption that 100% of the diet is contaminated. Given that only 20 acres of the nursery are treated with oryzalin, this assumption may not be applicable to the JH Stone Nursery. If this is the case, the residue rates in Worksheets B05a-d could be adjusted downward based on reasonable estimates of the contaminated proportion of an animal's diet. While somewhat *ad hoc*, the simplest way to make this adjustment uniformly would be to use the "*Drift*" factors in Worksheet A01.

As summarized in Worksheet G03, the HQs for aquatic organisms associated with an accidental spill are extremely high—i.e., upper bound HQs of 28 for fish, 61 for invertebrates, 439 for algae, and over 1000 for aquatic macrophytes. For non-accidental exposure scenarios, the only upper bound HQs that exceed a level of concern are those for macrophytes (upper bound HQ of 3) and algae (upper bound HQ of 1.2).

For terrestrial plants, HQs exceed the level of concern for exposure scenarios related to runoff (Worksheet G04) and direct spray/drift (Worksheet G05). HQs associated with irrigation water (Worksheet G06a) and wind erosion of soil (Worksheet G06b) are not of concern.

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{U.S. EPA/OPP 2012} U.S. EPA (U.S. Environmental Protection Agency/Office of Pesticide Programs). 2012. Occupational Pesticide Handler Unit Exposure Surrogate Reference Table. Report dated March, 2012. Available at: http://www.epa.gov/opp00001/science/handler-exposure-table.pdf. [Std]

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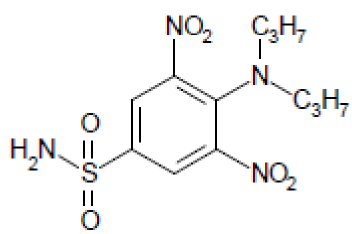
{U.S. EPA/RAF 2005} U.S. EPA/RAF (U.S. Environmental Protection Agency/Risk Assessment Forum). 2005. Guidelines for Carcinogen Risk Assessment. EPA/630/P-03/001F. Report dated March 2005. Available at: http://www.epa.gov/cancerguidelines/. [Std]

Table 1: Chemical and Physical Properties

Item	Value	Reference[1]
	Identifiers	
Common name:	Oryzalin	
CAS Name	4-(dipropylamino)-3,5-dinitrobenzenesulfonamide	Tomlin 2004
CAS No.	19044-88-3	U.S. EPA/OPP 1994a; Tomlin 2004
Chemical Group	Dinitroaniline	U.S. EPA/OPP 1994a; Mallory-Smith and Retzinger 2003
Development Codes	EL-119 (Lilly)	Tomlin 2004
IUPAC Name	3,5-dinitro-N^4,N^4-dipropylsulfanilamide	U.S. EPA/OPP 1994a; Tomlin 2004
Molecular formula	$C_{12}H_{18}N_4O_6S$	U.S. EPA/OPP 1994a; Tomlin 2004
Mechanistic group	Inhibition of mitosis via disruption of microtubules	Tomlin 2004; Strachan and Hess 1983; NMFS 2012
EPA PC Code	104201	U.S. EPA/OPP 1994a
Smiles Code	`CCCN(CCC) c1c(cc(cc1[N+](=O)[O-])S(=O)(=O)N)[N+](=O)[O-]`	Tomlin 2004
	`CCCN(CCC)c1c(cc(cc1N(=O)(=O))S(N)(=O)=O)N(=O)(=O)`	EPI Suite 2011
	`c1(c(cc(S(N)(=O)=O)cc1[N+](=O)[O-])[N+](=O)[O-])N(CCC)CCC`	ChemIDplus 2014
Structure		U.S. EPA/OPP 1994a
	Chemical Properties(1)	
Aqueous photolysis	5 hours [≈0.2 days]	U.S. EPA/OPP 1994a, p. 25
	0.06 days (direct)	U.S. EPA/OPP/EFED 2010, Table 2.1
Boiling point	N/A: Decomposes at 265 °C	Tomlin 2004
Density		
Form		
Henry's Law Constant	$<1.73\times10^{-4}$ Pa m3 mol^{-1} (25 °C, calc.)	Tomlin 2004
Hydrolysis	Stable at pH of 5 to 9.	U.S. EPA/OPP 1994a
K_{ow}	≈5370 [Log P = 3.73 at pH 7]	ChemIDplus 2014; EPI Suite 2014; Tomlin 2004; U.S. EPA/OPP/EFED 2010, p. 29
Molecular weight (g/mole)	346.36	EPI Suite 2014
	346.35	U.S. EPA/OPP 1994a
	346.4	Tomlin 2004
Melting point	141 °C	ChemIDplus 2014
	141-142 °C	Tomlin 2004
pKa (sulfonamide group, $–SO_2NH_2$)	9.4	ChemIDplus 2014
	8.6	U.S. EPA/OPP 1994a, p. 25 MRID 41378401
Soil Photolysis	22.4 hours [0.93 days]	U.S. EPA/OPP 1994a, p. 25

<table>
<tr><th>Item</th><th>Value</th><th>Reference[1]</th></tr>
<tr><td></td><td>3.8 days</td><td>U.S. EPA/OPP/EFED 2010, Table 2.1, MRID 41050001</td></tr>
<tr><td>Vapor pressure</td><td>0.0013 mPa</td><td>Tomlin 2004</td></tr>
<tr><td></td><td>$1x10^{-7}$ mm Hg at 25°C [0.013332 mPA]</td><td>U.S. EPA/OPP/EFED 2010, Table 2.1</td></tr>
<tr><td>Water solubility</td><td>2.5 mg/L (25 °C)</td><td>ChemIDplus 2014; Knisel and Davis 2000; U.S. EPA/OPP 1994a</td></tr>
<tr><td></td><td>2.6 mg/L (25 °C)</td><td>Tomlin 2004</td></tr>
<tr><td></td><td>Environmental Properties</td><td></td></tr>
<tr><td>Bioconcentration in fish (BCF)</td><td>Bluegills: 32.2 (edible) 66.1 (whole fish)</td><td>U.S. EPA/OPP 1994a, p. 29, MRID 40787501; also in U.S. EPA/OPP/EFED 2010</td></tr>
<tr><td>Field dissipation</td><td>58-77 days (initial phase)
138 to 146 (terminal phase)</td><td>U.S. EPA/OPP 1994a, p. 27,</td></tr>
<tr><td>Foliar washoff fraction</td><td>0.4</td><td>Knisel and Davis 2000</td></tr>
<tr><td>Foliar half-life</td><td>5 days</td><td>Knisel and Davis 2000</td></tr>
<tr><td></td><td>35 days (default value)</td><td>U.S. EPA/OPP/EFED 2010, p. 70</td></tr>
<tr><td>Kd</td><td><table>
<tr><th>Soil</th><th>OM [Prop.]</th><th>$K_{d(ads)}$</th></tr>
<tr><td>Sand</td><td>N/A</td><td>2.1</td></tr>
<tr><td>Sandy loam</td><td>0.014</td><td>4.9</td></tr>
<tr><td>Loam</td><td>0.018</td><td>8.4</td></tr>
<tr><td>Clay loam</td><td>0.02</td><td>12.9</td></tr>
</table></td><td>U.S. EPA/OPP 1994a, p. 27, MRIDs 41479802 and 41479801.</td></tr>
<tr><td>K_{oc} (L/kg)</td><td>Average: 809
Values: 722, 602, 803 and 1109
Note: Identical to values from U.S. EPA/OPP 1994a above except that the OM in sand was available.</td><td>U.S. EPA/OPP/EFED 2010, Table 2.1, MRID 41479802</td></tr>
<tr><td></td><td>600</td><td>Knisel and Davis 2000</td></tr>
<tr><td>Soil half-life (NOS)</td><td>20 days</td><td>Knisel and Davis 2000</td></tr>
<tr><td>Soil half-life, aerobic</td><td>2.1 months (24°C) [≈63 days]. Benzenesulfonamide ring is stable.</td><td>U.S. EPA/OPP 1994a, p. 25, MRID 41322801</td></tr>
<tr><td></td><td>63 days</td><td>U.S. EPA/OPP/EFED 2010, Table 2.1, MRID 41322801</td></tr>
<tr><td></td><td>189 days [used for PRZM/EXAMS input]</td><td>U.S. EPA/OPP/EFED 2010,Table 3.2</td></tr>
<tr><td>Soil half-life, anaerobic</td><td>Biphasic: 1.2 months/3 months [≈36/90 days]</td><td>U.S. EPA/OPP 1994a, p. 25, MRID 413228-02</td></tr>
<tr><td></td><td>10 days</td><td>U.S. EPA/OPP/EFED 2010, Table 2.1, MRID 413228-02</td></tr>
</table>

[1] There a many sources of information on some standard values – e.g., molecular weight and CAS number. In general, only two sources as cited for each value. More than two sources are cited only to highlight apparent discrepancies. Values in brackets [] indicate a conversion from the reported unit to another more common unit.

See Section 2 for discussion.

Table 2: Inputs and Outputs for FIRST Simulations

Parameter	Central Estimate of Concentration in Water	Lower Bound of Concentration in Water	Upper Bound of Concentration in Water
Aerobic soil metabolism half-life (days) [1]	109	63	189
Aerobic aquatic metabolism (days) [2]	218	126	378
K_{oc} (mL/g) [3]	941	1109 (Peak) 602 (Long-term)	602 (Peak) 1109 (Longer-term)
Photolysis half-life (days) [4]	0.06	0.06	0.06
Water solubility (mg/L) [4]	2.5	2.5	2.5
Gross Peak Concentration (µg/L)	68.402	56.487	90.963
Gross Longer-term Concentration (µg/L)	2.520	1.377	2.652
Proportion of Treated Watershed	0.091		
Peak Concentration Used in Analysis (µg/L)	6.225	5.14	8.278
Longer-term Concentration Used in Analysis (µg/L)	0.229	0.125	0.241

Other General Inputs: Application rate: 1 lb/acre, 2 applications with an application interval of 60 days; Proportion of watershed treated used for run: 1.0; Wetted in: No; Drift: None; Incorporation Depth: 0 cm.

[1] See Table 1. Experimental value and EPA input value used for range. Approximate geometric mean of range used as central estimate.

[2] No data available. Use 2x aerobic soil metabolism following approach from U.S. EPA/OPP/EFED 2010, Table 3.2.

[3] Central estimate from U.S. EPA/OPP/EFED 2010 and range from 4 values given in Table 1. See Section 3.2.1.1 for discussion

[4] From PRZM/EXAM inputs in U.S. EPA/OPP/EFED 2010, Table 3.2.

NOTE: In WorksheetMaker, the values shaded in yellow are rounded to 2 significant digits and entered in units of mg a.i./L per lb a.i. applied.

See Section 3.2. for discussion.

Table 3: Summary of toxicity values used in human health risk assessment

Acute – single exposure

Element	Derivation of RfD
EPA Document	U.S. EPA/OPP 2004, p. 14
Population	13-49 year old females
Study	Appears to be MRID 00026785 (U.S. EPA/OPP 1994a, pp. 11-10).
NOAEL Dose	25 mg/kg bw/day
LOAEL Dose	55 mg/kg bw/day
LOAEL Endpoint(s)	Decreased live fetuses, increased resorptions, and increased post-implantation loss.
Species, sex	Rabbits, female
Uncertainty Factor/MOE	100
Acute RfD	0.25 mg/kg bw/day

Chronic – lifetime exposure

Element	Derivation of RfD
EPA Document	U.S. EPA/OPP 2004, p. 15
Study	Appears to be MRIDs 00070569, 00026779, 00044332 (U.S. EPA/OPP 1994a, p. 12).
NOAEL Dose	14 mg/kg bw/day
LOAEL Dose	43 mg/kg bw/day
LOAEL Endpoint(s)	Increased microscopic findings in the thyroid
Species, sex	Rats, both
Uncertainty Factor/MOE	100
Equivalent RfD	0.14 mg/kg bw/day

Note: U.S. EPA/OPP (1994a, p. 12) gives a chronic RfD of 0.12 mg/kg bw/day.

Carcinogenicity

Element	Derivation of RfD
EPA Document	U.S. EPA/OPP 2004, p. 15
Cancer Potency	0.0078 (mg/kg bw/day)$^{-1}$ based on thyroid tumors. The dose associated with a risk of 1-in-1 million is [Risk=Potency x Dose; Dose = Risk/Potency; 0.000001÷0.0078 = 0.00013 mg/kg bw/day]
Note:	Used in the current assessment to assess cancer risks associated with the consumption of contaminated food and water. U.S. EPA/OPP (1994a, p. vi) gives a cancer potency of 0.13 (mg/kg bw/day)$^{-1}$ based on mammary gland tumors in both sexes and fibroadenomas in females.

See Section 3.3 for discussion.

Table 4: Summary of toxicity values used in ERA

Group/Duration	Organism	Endpoint	Toxicity Value (a.i.)	Reference
Terrestrial Animals				
Acute				
	Mammals (including canids)	Developmental NOAEL , rabbits	25 mg/kg bw/day	Section 4.3.1.1.
	Birds	Dietary LOAEL ÷ 10	19 mg/kg bw/day	Section 4.3.1.2.1
Longer-term				
	Mammals	Chronic NOAEL, rats	14 mg/kg bw/day	Section 4.3.1.1
	Bird	Reproductive NOAEL	9 mg/kg bw/day	Section 4.3.1.2.2.
Terrestrial Plants				
Soil	Sensitive	EC_{05} (tomato)	0.0056 lb/acre	Section 4.3.2.5.2
	Tolerant	NOAEC (soybean)	6.0 lb/acre	
Foliar	Sensitive	NOAEC (ryegrass, lettuce, tomato)	0.0253 lb/acre	Section 4.3.2.5.2
	Tolerant	NOAEC (soybean)	2.0 lb/acre	
Aquatic Animals				
Acute				
Fish	Sensitive	NOAEC (bluegill sunfish)	1 mg/L	Section 4.3.3.1
	Tolerant	NOAEC (sheepshead minnow)	3.04 mg/L	
Invertebrates	Sensitive	NOAEC (oyster, shell deposition)	0.0994 mg/L	Section 4.3.3.3
	Tolerant	NOAEC (grass shrimp)	1.95 mg/L	
Longer-term				
Fish	Sensitive	NOAEC (fathead minnow)	0.22 mg/L	Section 4.3.3.1
	Tolerant	NOAEC (trout)	0.46 mg/L	
Invertebrates	Sensitive	Not identified.	No data	Section 4.3.3.3
	Tolerant	NOAEC (*Daphnia magna*)	0.358 mg/L	
Aquatic Plants				
Algae	Sensitive	NOAEC (*S. capricornutum*)	0.0138 mg/L	Section 4.3.3.4
	Tolerant	NOAEC (*A. flow-aquae*)	8.1 mg/L	Section 4.3.3.4
Macrophytes	Sensitive	Not identified.	No data	Section 4.3.3.4
	Tolerant	NOAEC (*Lemna gibba*)	0.00548 mg/L	Section 4.3.3.4

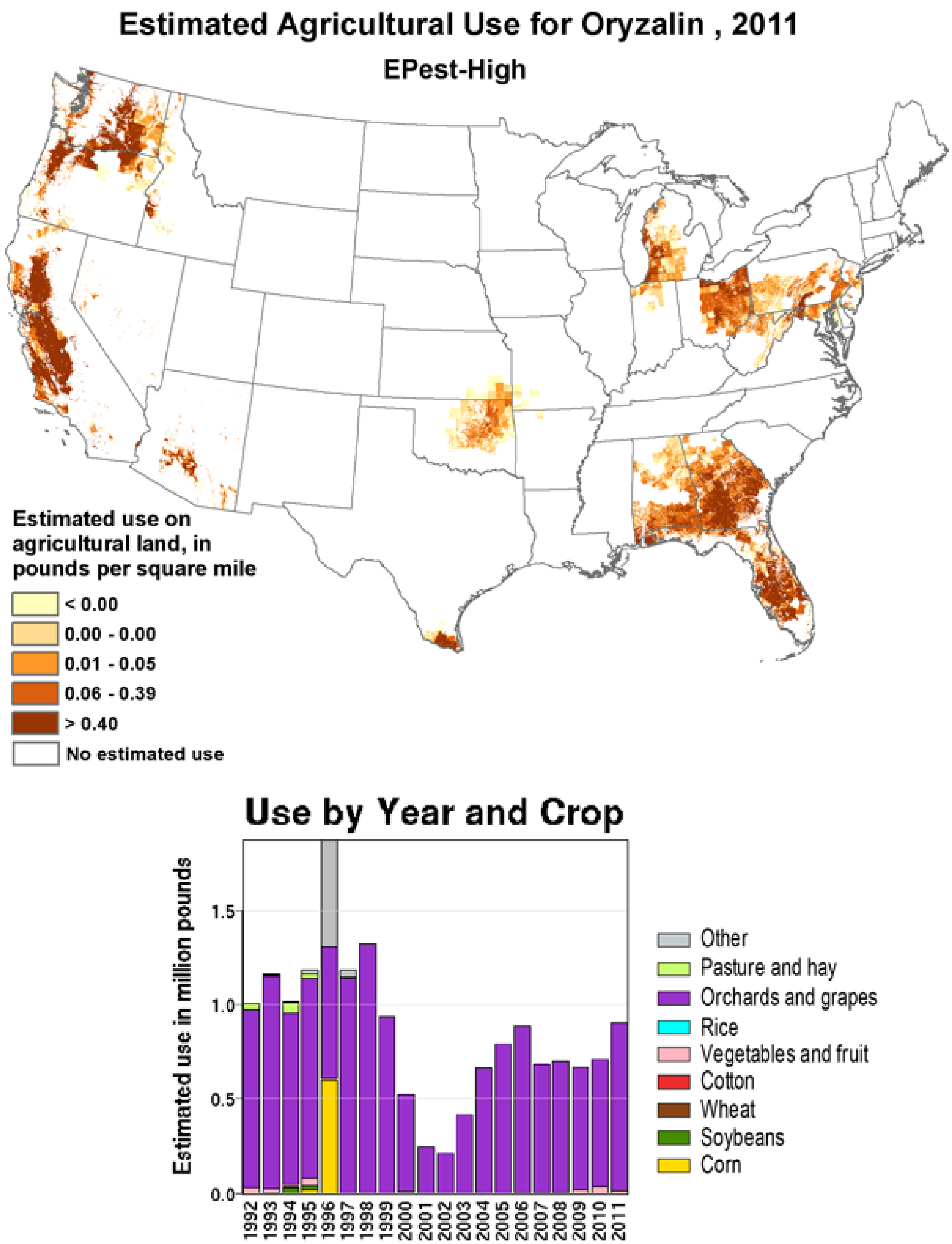


Figure 1: Current Uses of Oryzalin in the U.S.

Source:
http://water.usgs.gov/nawqa/pnsp/usage/maps/show_map.php?year=2011&map=ORYZALIN&hilo=L&disp=Oryzalin

See Section 2 for discussion.