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Prevention, Pesticides
And Toxic Substances
(7508P)

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Reregistration Eligibility Decision for Metaldehyde

List A

Case No. 0576

Reregistration Eligibility Decision (RED) Document

For

Metaldehyde

Approved by: _____/s/_____
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Date: __July 27, 2006__

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Glossary of Terms and Abbreviations

AGDCI	Agricultural Data Call-In
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
AR	Anticipated Residue
BCF	Bioconcentration Factor
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
EDWC	Estimated Drinking Water Concentration
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
G	Granular Formulation
GENEEC	Tier I Surface Water Computer Model
GLN	Guideline Number
HAFT	Highest Average Field Trial
IR	Index Reservoir
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
mg/kg/day	Milligram Per Kilogram Per Day

mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MUP	Manufacturing-Use Product
NA	Not Applicable
NAWQA	USGS National Water Quality Assessment
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/EXAMS	Tier II Surface Water Computer Model
Q_1*	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SCI-GROW	Tier I Ground Water Computer Model
SAP	Science Advisory Panel
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TGAI	Technical Grade Active Ingredient
TRR	Total Radioactive Residue
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UF	Uncertainty Factor
UV	Ultraviolet
WPS	Worker Protection Standard

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all data submitted to the Environmental Protection Agency. Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential risks arising from the currently registered uses of metaldehyde, to determine the need for additional data on health and environmental effects, and to determine whether or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FFDCA to require reassessment of all tolerances in effect on the day before it was enacted. In reassessing these tolerances, the Agency must consider, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility among infants and children, and the cumulative effects of pesticides that have a common mechanism of toxicity. When the Agency determines that aggregate risks are not of concern and concludes that there is a reasonable certainty of no harm from aggregate exposure, the tolerances are considered reassessed. EPA decided that, for those chemicals that have tolerances and are undergoing reregistration, tolerance reassessment will be accomplished through the reregistration process.

Risks summarized in this document are those that result only from the use of metaldehyde. The Food Quality Protection Act (FQPA) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity.” Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to metaldehyde, and metaldehyde does not appear to produce a toxic metabolite produced by other substances. Therefore, for the purposes of reregistration, EPA has not assumed that metaldehyde shares a common mechanism of toxicity with other compounds. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA’s Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism of toxicity on EPA’s website at http://www.epa.gov/pesticides/cumulative/.

Metaldehyde is a molluscicide used to control snails and slugs on a wide variety of sites, including turf, ornamentals, berries, citrus, and vegetables. Data on the usage of metaldehyde on nonagricultural sites are limited, but usage is likely less than 50,000 pounds of active ingredient per year (lbs ai/year). About 11,000 lbs ai/year is used on

citrus and about 7,000 lbs ai/year is used on artichokes. About 90% of metaldehyde is used in the Pacific Northwest, California, and Hawaii.

Metaldehyde was first registered in 1967. The sole technical grade metaldehyde registration in the U.S. is held by Lonza, Inc. Lonza maintains an agreement with end-use product formulators that stipulates consistency in formulation and labeling. The end-use product formulators are OrCal, Corry's, and Amvac, and there are additional sub-registrants that do not independently formulate metaldehyde products, including The Scotts Company LLC.

Metaldehyde products currently bear labeling for a large number of uses. The Agency allowed registration of these uses at a time when a determination had been made that metaldehyde was not taken up into plants and so tolerances were not needed. The Agency has since determined that residues of metaldehyde are present in plants and that tolerances are needed to account for residues in food and feed crops. Lonza is currently supporting a subset of the uses on metaldehyde product labels through the development of residue and other data; this subset comprises all the uses the Agency has evaluated for reregistration. The uses evaluated by the Agency for reregistration are: turf, dichondra, ornamentals, citrus, lettuce, cole crops and other leafy greens, tomato, strawberry, berries (including blackberry, blueberry, currant, elderberry, gooseberry, and raspberries), artichoke, and grass grown for seed.

This document presents EPA's decision regarding the reregistration eligibility of the registered uses of metaldehyde. The Agency has conducted human health and ecological risk assessments based on its review of the database supporting the uses of metaldehyde. This document summarizes these risk assessments and describes the mitigation measures needed to address risks identified during the reregistration process. As a result of this review, the Agency has determined that the following uses of metaldehyde are eligible for reregistration under FIFRA, provided that the risk mitigation measures detailed in this document are adopted and the data requirements set forth in this document are fulfilled: ornamentals, citrus, lettuce, cole crops and other leafy greens, tomato, strawberry, berries (including blackberry, blueberry, currant, elderberry, gooseberry, and raspberries), artichoke, and grass grown for seed. All other uses currently on metaldehyde product labels are not eligible for reregistration and must be deleted from product labels. The Agency has determined that a set of risk mitigation measures must be implemented, via labeling or reformulation, to address the risks associated with the uses of metaldehdye that are eligible for reregistration. These measures focus on risk reduction for domestic animals and wildlife. In addition, the Agency is requiring that certain data be submitted in support of the continued registration of metaldehyde. The Agency is releasing its reregistration eligibility decision for metaldehyde with a 60-day public comment period to solicit input on a number of mitigation measures. Once an Endangered Species assessment is completed for metaldehyde, further changes to metaldehyde registrations may be necessary, as explained in Section III of this document.

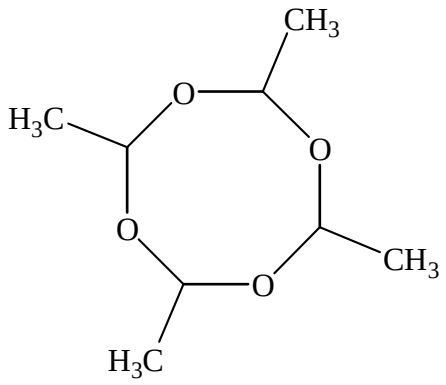
The Agency has also reassessed the lone existing tolerance for metaldehyde. The current tolerance expression for metaldehyde residues is adequate. A tolerance of "zero"

previously was established for residues of metaldehyde on strawberries [40 CFR §180.523(a)]. Residue data submitted since that time are adequate to support a tolerance of 6.25 ppm for residues in/on strawberry. This metaldehyde tolerance is considered reassessed.

The IR-4 program of the U.S. Department of Agriculture, which develops residue data for minor and specialty crops, has done research on a number of additional new uses for metaldehyde. At the current time, residue data for the use of metaldehyde on prickly pear cactus and watercress are in development. While these uses were included in the health effects and environmental risk assessments for metaldehyde, decisions on their registration will not be made in this reregistration eligibility decision.

II. Chemical Overview

- **Chemical Structure:**



- **Common Name**: Metaldehyde
- **Chemical Name**: 2,4,6,8-tetramethyl-1,3,5,7-tetraoxacyclooctane
- **CAS Registry Numbers:** 108-62-3
- **PC Code:** 053001
- **Common Trade Names**: Snail-N- Slug Beater, Bug-Geta Snail & Slug Pellets, Slugit, Deadline, Slug & Snail Death, Slug-Fest, Metarex
- **Basic Manufacturer**: Lonza Inc.
- **Use Sites** Uses currently listed on product labels include turf, ornamentals, citrus, cole crops, lettuce, tomato, strawberry, blueberry, caneberries, artichokes, seed crops, alfalfa, apples, asparagus, avocado, beans, celery, cereal grains, clover, cherries, corn, dryland taro, fallow land, garlic, ginseng, grapes, legumes, lumberyards, mint, papaya, peaches, potato, pumpkin, seed crops, and watermelon.
- **Mode of Action:** Active ingredient is ingested or absorbed; disrupting mucous membranes and dehydrating snails & slugs

- **Formulations:** granules, pellets, minipellets, meal, paste, viscous liquid
- **Methods of Application:** Dry materials may be scattered or shaken directly from the container; applied with a whirly-bird spreader, fertilizer spreader, or tractor-drawn spreader; or broadcast by air. Concentrates may be diluted and applied via hose-on application or sprinkler can. Liquids and pastes may be squeezed directly from bottle.
- **Use Rates:** Some labels do not provide clear use instructions. Application rates on current labels may be as high as 21 lb/A, or 0.15 lb ai/1000 square feet, or 2 oz./100 square feet.

Usage of metaldehyde on agricultural sites is summarized in Table 1. Sites in **boldface** type are among those assessed for this RED.

Table 1. Screening Level Estimates of Agricultural Usage, as of April 2005

Use Site	Pounds active ingredient	Percent crop treated	Maximum percent crop treated
Seed Crops	20,000	5	--
Lemons	8,000	10	25
Artichokes	7,000	25	40
Oranges	3,000	<1	5
Strawberries	2,000	5	5
Grapes	2,000	<1	<2.5
Watermelon	1,000	<1	<2.5
Avocado	1,000	<1	<2.5
Blackberries	<500 each	5	--
Blueberries		10	--
Cauliflower		<1	<2.5
Celery		<1	<2.5
Peaches		<1	<2.5
Peppers		<1	<2.5
Raspberries		<1	--
Sweet corn		<1	<2.5

III. Summary of the Metaldehyde Science Assessments

The following is a summary of EPA's human health, domestic animal, and ecological risk findings and conclusions for metaldehyde as presented in the risk assessments and supporting documents developed by the Agency. The risk assessments and related supporting documents are available in the public docket at www.regulations.gov . To find the correct docket and documents associated with it, select the Advanced Search function, and then select Docket Search. Enter the Docket Number OPP-2005-0231 in the Docket ID field and submit. Click on the Docket ID link,

and icons for viewing and downloading the supporting documents will appear. Your computer's "pop-up blocker" function must be turned off for you to view or download documents in the docket.

This section also summarizes the alternatives and benefits information the Agency has developed for consideration in the metaldehyde reregistration decision. The alternatives assessment is also available in the public docket at www.regulations.gov .

The purpose of this section is to help the reader better understand the risk management decisions reached by the Agency.

A. Human Health Risk Assessment

The complete metaldehyde human health risk assessment is found in the document "Metaldehyde: HED Chapter of the Reregistration Eligibility Decision Document," dated April 3, 2006, and can be accessed via www.regulations.gov as described above.

The Agency's assessment utilizes submitted and other data to evaluate the toxicology, product and residue chemistry, dietary exposure, and occupational and residential exposure associated with metaldehyde. The Agency has determined that these data are adequate to support a reregistration decision.

1. Acute Toxicity

Acute toxicity data for on metaldehyde are summarized in Table 2.

Table 2. Acute Toxicity Profile

Guideline No.	Study Type	MRID	Results	Toxicity Category
870.1100	Acute oral [rat]	00131435	LD_{50} = 283 mg/kg	II
870.1200	Acute dermal [rat]	00131434	LD_{50} = >5000 mg/kg	III
870.1300	Acute inhalation [rat]	00131429	LC_{50} = 314 mg/L/4 hrs	IV
870.2400	Acute eye irritation [rabbit]	42068801	mild irritant	III
870.2500	Acute dermal irritation [rabbit]	00131971	not an irritant	IV

2. FQPA Safety Factor

FQPA directs EPA, in setting pesticide tolerances, to use an additional tenfold (10X) margin of safety to take into account potential pre- and postnatal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. FQPA authorizes EPA to modify this tenfold safety factor only if reliable data demonstrate that the resulting level of exposure will be safe for infants and children. EPA has determined that the FQPA safety factor must be retained for metaldehyde to account for database uncertainties.

Neurological effects are suggested by clinical signs observed in studies in dogs and rats exposed to metaldehyde, including ataxia, twitching, tremors, and hindlimb paralysis. Developmental toxicity and 2-generation reproduction studies in rats and rabbits do not demonstrate an increased sensitivity or susceptibility in developing fetuses. Based on the observation of clinical signs indicating neurotoxicity in several studies, the Agency is requiring a developmental neurotoxicity study for metaldehyde. Because data on potential neurotoxic effects on the developing fetus are outstanding, the Agency is retaining the 10X safety factor for assessment of dietary, residential, and aggregate risks.

3. Endpoint Selection

Table 3 shows endpoints used in the metadehyde human health risk assessment.

Table 3. Toxicology Endpoint Selection

Exposure Scenario	NOAEL	Uncertainty Factors; Level of Concern	Study type; Test species; Toxic Effects (MRID#)
Acute Dietary (All populations)	75 mg/kg/day	10X interspecies, 10X intraspecies, 10X FQPA (1000X total); aPAD = 0.075 mg/kg/day	Developmental toxicity; rats; LOAEL = 150 mg/kg/day (mortality, ataxia, tremors, twitching, rapid respiration, decreased weight gain, ♀s) (MRID 41656001)
Chronic Dietary (All populations)	10 mg/kg/day	10X interspecies, 10X intraspecies, 10X FQPA (1000X total) cPAD = 0.01 mg/kg/day	Chronic oral toxicity; dogs; LOAEL = 30 mg/kg/day (mortality, atrophy of the testes and prostate) (MRID 46378401)
Residential Short-Term Incidental Oral (duration of exposure: 1-30 days)	30 mg/kg/day	10X interspecies, 10X intraspecies, 10X FQPA (1000X total) MOE = 1000	Chronic oral toxicity ;dogs; LOAEL = 90 mg/kg/day (clinical signs beginning Week 1) (MRID 46378401)
Residential Intermediate-Term Incidental Oral (duration of exposure: 1- 6 months)	10 mg/kg/day		Chronic oral toxicity; dogs; LOAEL = 30 mg/kg/day (mortality, atrophy of testes and prostate) (MRID 46378401)
Short-Term Inhalation (duration of exposure 1 - 30 days)	30 mg/kg/day (Inhalation absorption rate = 100%)	Residential 10X interspecies, 10X intraspecies, 10X FQPA (1000X total) MOE = 1000	Chronic oral toxicity; dogs; LOAEL = 90 mg/kg/day (clinical signs beginning Week 1) (MRID 46378401)

Exposure Scenario	NOAEL	Uncertainty Factors; Level of Concern	Study type; Test species; Toxic Effects (MRID#)
		Occupational 10X interspecies, 10X intraspecies (100X total) MOE = 100	
Intermediate-Term Inhalation (duration of exposure 1 - 6 months)	10 mg/kg/day (Inhalation absorption rate = 100%)	Residential 10X interspecies, 10X intraspecies, 10X FQPA (1000X total) MOE = 1000	Chronic oral toxicity; dogs; LOAEL = 30 mg/kg/day (mortality, atrophy of the testes and prostate) (MRID 46378401)
		Occupational 10X interspecies, 10X intraspecies (100X total) MOE = 100	
Long-Term Inhalation (duration of exposure > 6 months)	10 mg/kg/day (Inhalation absorption rate = 100%)	Residential 10X interspecies, 10X intraspecies, 10X FQPA (1000X total) MOE = 1000	
		Occupational 10X interspecies, 10X intraspecies (100X total) MOE = 100	
Dermal	No toxicological endpoint of concern is identified for dermal exposures		
Cancer	Weight of evidence is *suggestive* of carcinogenic potential.		

NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic), MOE = margin of exposure

Because the Agency could not identify an endpoint for dermal exposures, it did not conduct an assessment of the risk associated with dermal exposures in any exposure scenario (residential, occupational). As a matter of policy, the Agency does not quantify pesticide cancer risks when the evidence for carcinogenicity is "suggestive." In the case of metaldehyde, incidence of benign liver tumors was increased in both sexes of the mouse. Although the increased incidence of benign liver tumors in female rats relative to controls was statistically significant, it was just slightly higher than the upper end of the range for historical controls at the testing facility. No tumors were found in male rats in the same study. The mutagenicity data for metaldehyde are deficient and new data are required, but examination of the old data suggests that metaldehyde is not a mutagen.

4. Dietary Exposure and Risk from Food and Drinking Water

The dietary risk assessment is a function of both exposure and toxicity. In the case of metaldehydye, dietary risk is expressed as a percentage of a level of concern. The level of concern is the dose predicted to result in no unreasonable adverse health effects to any human population subgroup, including sensitive members of such population subgroups. This level of concern is referred to as the population adjusted dose (PAD). Risk estimates less than 100% of the PAD are below EPA's level of concern. The acute PAD (aPAD) is the highest predicted dose to which a person could be exposed on any given day with no adverse health effect expected. The chronic PAD (cPAD) is the highest predicted dose to which a person could be exposed over the course of a lifetime with no adverse health effects expected.

a) Drinking Water Concentrations

Drinking water concentrations of metaldehyde were estimated for both surface water and groundwater. Scenarios are modeled by the Agency for reasonable worst-case exposures. The drinking water assessment is detailed in the document entitled "Second Amended Tier II Estimated Drinking Water Concentrations (Surface and Ground Water) of the Molluscicide Metaldehyde," December 12, 2005, posted to the metaldehyde docket at www.regulations.gov. For surface water, estimated drinking water concentrations (EDWCs) were generated from a Tier II PRZM-EXAMS - Index Reservoir model based on the use of metaldehyde on cole crops and leafy vegetables in Florida and California. For groundwater, EDWCs were generated from a Tier I SCI-GROW analysis, based on use of metaldehyde on ornamental plants. Estimated drinking water concentrations for metaldehyde are provided in Table 4; values in bold were used in the dietary assessment.

Table 4. EDWCs for Metaldehyde

Source	Scenario	Acute EDWC	Chronic EDWC
Surface water	Cole crops, FL	**110 ppb**	8.4 ppb
	Leafy vegetables, CA	94.8 ppb	**55.8 ppb**
Groundwater	Ornamentals	**62.5 ppb**	

b) Food + Water Exposures

An unrefined Tier 1 acute dietary exposure assessment was conducted for all supported metaldehyde food uses based on upper-bound pesticide residue inputs (e.g., assuming 100% of registered crops are treated with metaldehyde and that residues are present at tolerance levels). For Tier 1 analyses, EPA presents results at the 95th percentile of exposure, which provides a high-end estimate of risk that is protective of human health. Dietary risk estimates are calculated for exposures to the general U.S. population and subpopulations from food and both surface water and ground water together.

c) Acute Dietary (Food and Drinking Water) Risk

For the general population and all subpopulations, acute dietary risk estimates are below 100% of the aPAD. Dietary risk estimates for the general population and the most highly exposed subpopulation are shown in Table 5 below.

d) Chronic Dietary (Food and Drinking Water) Risk

For the general population and all subpopulations, chronic dietary risk estimates are below 100% of the cPAD. Dietary risk estimates for the general population and the most highly exposed subpopulation are shown in Table 5.

Table 5. Summary of Food + Water Dietary Risk Estimates for Metaldehyde

	Acute Risk; Food +		Chronic Risk; Food +	
Population	**Surface Water**	**Groundwater**	**Surface Water**	**Groundwater**
General	12% aPAD	14% aPAD	29% cPAD	35% cPAD
Children 1-2 years old	26% a PAD	29% aPAD	59% cPAD	69% cPAD

5. Residential Exposure and Risk

Residents can be exposed to metaldehyde used on lawns, and ornamental, vegetable, and fruit plants as a result of both application and post-application activities, on a short -term exposure basis. Non-cancer risks are calculated by the margin of exposure (MOE) approach which relies on the ratio of the dose from a toxicological endpoint selected for risk assessment to the predicted exposure. Risk estimates are compared to levels of concern which reflect the endpoint and all relevant uncertainty factors. In this case, MOEs of greater than 1000 do not represent risks of concern. Since no dermal endpoint of concern has been identified for metaldehyde, dermal risks were not estimated. Intermediate- and long-term exposures are not expected for residential handlers because of the sporadic nature of applications by homeowners.

a) Residential Handlers

Metaldehyde is available in residential-use products s in the following formulations: liquid concentrate, ready-to-use liquid/paste, and ready-to-use granules/pellets/minipellets/meal baits. Most of the residential consumer products are formulated as granular baits. Methods of application include hose-end sprayers, trigger-pump sprayers, low pressure handwand sprayers, sprinkler cans, belly grinders, push-type spreaders, and applying ready-to-use products by hand. The Agency assessed eight residential handler short-term exposure scenarios, representing a range of possible exposures. MOEs for all of the residential handler scenarios assessed are greater than the target MOE of 1000, ranging from 56,000 to 6,000,000. The high MOEs result in part from application methods that do not create small droplets (of respirable size), the low volatility of metaldehyde, and dilution by ambient air. The Agency has determined that risks to residential handlers of metaldehyde are not of concern.

b) Residential Post-Application Exposure and Risk

Individuals potentially can be exposed to metaldehyde after application when they do yard or garden work or play within treated areas. No dermal endpoint has been identified for metaldehyde, and significant residential post-application inhalation exposures are not anticipated for metaldehyde, because of its limited volatility and dilution by ambient air. The Agency did assess the potential post-application risk for toddlers who play on treated turf and may be exposed through hand-to-mouth activities, object-to-mouth activities, and ingestion of treated soil. Short-term MOEs from these oral exposures are greater than 1000, with an MOE for exposure by all three routes together of 1600 on the day of application. These MOEs do not represent risks of concern.

The Agency also assessed risks associated with the direct ingestion of metaldehyde granular materials by toddlers. MOEs for ingestion of two different formulation types are estimated to be well below the target MOE of 1000, at 188 and 50. The Agency also determined that very low numbers of granules could result in exposures at the level of concern, depending on the size of the granules (estimated at 2 to 15 granules for the two formulations). A review of data from the American Association of Poison Control Centers (AAPCC) shows that a total of 1648 poisoning incidents in children were recorded for metaldehyde in the years 1993 through 2003. The most recent year for which data are available from the AAPCC is 2004, when 244 accidental exposures to metaldehyde were reported, with 105 incidents occuring in children younger than 6 years old. None of the reported incidents were associated with life-threatening conditions. Twenty-nine incidents were associated with minor symptoms that resolved quickly, and three were associated with more pronounced symptoms that had no residual ill effect.

Beginning in 2001, a bittering agent, denatonium benzoate, was added to metaldehyde home and garden products at a rate of 30 ppm. In late 2003, the concentration of denatonium benzoate was increased to 300 ppm. Denatonium benzoate is used in rodenticides and appears to be effective in deterring ingestion by children at a concentration of 300 ppm. As discussed below, the evidence for its effectiveness in dogs is less conclusive. Because consumer product may remain on store shelves and in the hands of consumers for a year or more, the industry believes that metaldehyde products containing the higher level of denatonium benzoate are beginning to dominate the market this year, so that the impact of the new formulation would not be evident in data from 2004.

Given the movement of product with the higher concentration of denatonium benzoate into the consumer market, the Agency believes that ingestion by toddlers of metaldehyde granules is unlikely, and that if ingestion occurs, the bitter taste would cause a toddler to spit out the material quickly, thus limiting exposure. Home and garden products containing metaldehyde already are labeled to require that users keep children out of areas where the product is stored or used, but the Agency believes that it is nevertheless prudent to require that this labeling be enhanced for visibility and content.

The Agency will continue to monitor poisoning data as the new mitigation comes into effect.

6. Aggregate Exposure and Risk

The FQPA amendments to the Federal Food, Drug and Cosmetic Act (FFDCA, Section 408(b)(2)(A)(ii)) require "that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposure and other exposures for which there is reliable information." In response to this requirement, the Agency conducts aggregate risk assessments to account for all potential non-occupational exposures when developing its reregistration decisions.

a) Acute Aggregate Risk

Only food and water exposures to metaldehyde are aggregated for this acute assessment. This assessment is described above and summarized in Table 5.

b) Short-Term Aggregate Risk

Dietary (food + water) exposures and post-application incidental oral exposures are aggregated for short-term exposures to metaldehyde. The dietary risk component is summarized in Table 5. Incidental oral exposures may result from children playing on treated turf and ingesting soil or inserting their hands in their mouths while playing or after playing on treated turf. Since these activities may occur simultaneously, the combined MOE is used in the aggregate assessment. Adult residential exposures are estimated to be greatest for handlers; these adult exposures are aggregated with dietary exposures. The target MOE for all short-term aggregate risks is 1000 for all scenarios. All aggregate MOEs for short-term exposure to metaldehyde are 1200 or greater, and so are not of concern. Short-term aggregate exposures and risk estimates are shown in Table 6.

Table 6. Short-term Aggregate Risk Estimates for Metaldehyde

	Exposure, mg/kg/day		**Aggregate MOE**
Population	**Residential**	**Food + Water**	**Residential + Food + Water**
Surface water source for drinking water			
Children	0.019	0.0059	1200
Adults	0.00054	0.0029	8700
Groundwater source for drinking water			
Children	0.019	0.0069	1200
Adults	0.00054	0.0035	7400

c) Chronic Aggregate Risk

Only food and water exposures to metaldehyde are aggregated for this chronic assessment, because there are no long-term residential exposures expected for

metaldehyde. This chronic dietary (food + water) assessment is described above and summarized in Table 5.

7. Cumulative Risk

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for metaldehyde and any other substances, and metaldehyde does not appear to produce a toxic metabolite produced by other substances. For the purposes of this reregistration eligibility and tolerance action, EPA has not assumed that metaldehyde has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/ .

8. Risk to Domestic Animals from Ingestion of Metaldehyde Granules in Residential Settings

Information from several sources indicates that there are a considerable number of poisonings of domestic animals, especially dogs, resulting from ingestion of metaldehyde, typically after such materials are used around the home, but occasionally when pets eat granules after tearing into or opening product containers.

For the years 2000-2004, NPIC, a toll-free telephone service that provides pesticide information without treatment advice to the general public and medical and veterinary professionals, collected data from reports of 104 cases (probable exposure to metaldehyde) and 156 cases (possible exposure) involving 274 animals. Most of the metaldehyde incidents reported to NPIC were dogs (92%). All but one of the remaining incidents was reported for cats. The number of probable cases increased yearly from 8 in 2000 to 43 in 2004. Numbers of possible cases held steady in 2000-2003 but increased in 2004. Most cases involved animals exposed via ingestion after metaldehyde applications to yards and gardens. Granular and bait formulations were most commonly ingested. For cases in which the outcome was reported, seventeen animals in the probable and five in the possible categories died, while 10 animals in the both categories combined recovered. NPIC refers callers reporting animals in need of immediate veterinary care to the ASPCA's Animal Poison Control Center (APCC).

The APCC maintains a 24-hour emergency hotline for animal poisoning incidents, similar to the services provided by human poison control centers. A representative of the APCC, in private communications with the Agency, has indicated that the APCC receives incident reports of "possible" to "observed" exposure certainty for metaldehyde on an annual basis in greater numbers than NPIC does for its analogous probable and possible exposure categories. In the two-year period 2004 through 2005, APCC handled almost 500 cases (an average of 250 cases/year for APCC vs. 65/year for

NPIC). The greater number of calls received by the APCC likely is attributable to several factors, including referral of NPIC callers to APCC, contracting by a subset of metaldehyde manufacturers directly to APCC for responding to incidents associated with their products and greater name recognition for the APCC among callers not obtaining telephone numbers from product labels. The APCC further advised the Agency that it considers metaldehyde calls as "immediate interrupts," warranting termination of data collection followed by immediate referral to veterinarians, because of the imminent hazard to the exposed animal.

Lonza, the registrant of technical grade metaldehyde, maintains a set of "Minimum Quality Requirements" (MQRs) with its formulators of home and garden products. One of the MQRs requires formulators to incorporate denatonium benzoate, a bittering agent, into their residential metaldehyde products, for the purpose of making the products unpalatable to children and domestic animals that might otherwise be attracted to and ingest the granules. Lonza originally required the incorporation of 30 ppm of denatonium benzoate into these products. In late 2003, the rate was increased to 300 ppm. Denatonium benzoate is a proven aversion agent for children and is used in rodenticides. The Agency has reviewed data that Lonza believes supports the efficacy of denatonium benzoate in preventing ingestion of metaldehyde granules by dogs, but is unable to determine the efficacy because of limitations in study design. Although denatonium benzoate appears to be an effective aversion agent for children, dogs are likely to be less sensitive to the taste, or at least less selective in what they eat, than children.

9. Occupational Risk Assessment

a) Handler exposures

Occupational handlers of metaldehyde may be exposed during mixing (for products which are diluted before application), loading, or applying metaldehyde products, or through a combination of these activities. Other workers may be exposed to metaldehyde when entering areas where metaldehyde previously has been applied.

The Agency believes that occupational handlers may be exposed to metaldehyde on a short-term (up to 30 days) or intermediate-term (30 days to several months) basis. The Agency's occupational handler risk assessment is based on 16 different scenarios defined by different handling tasks (e.g., mixer/loader, applicator) and application methods (e.g., liquids via airblast, granulars via tractor-drawn spreader). In the absence of a dermal toxicity endpoint, only inhalation exposures are assessed. The Agency assessed each of the 16 scenarios for increasing levels of inhalation protection from baseline PPE (handlers wearing long-sleeve shirts, long pants, shoes, socks, and no resprirator) to Engineering Controls (a closed tractor cab or closed loading system).

b) Handler risks

For all short- and intermediate-term occupational handler scenarios, risks are not of concern even at the baseline level of personal protection, without a respirator (i.e., all MOEs are greater than the target MOE of 100). The lowest MOE at baseline, 790, is associated with mixing and loading liquid concentrates to support application via chemigation; most scenarios are associated with MOEs in the thousands.

c) Occupational post-application risks

Occupational post-application exposures were not assessed for metaldehyde because no dermal hazard was identified and inhalation exposures are assumed to be negligible in outdoor post-application scenarios due to metaldehyde's low vapor pressure and dilution in outdoor air. Post-application inhalation exposures for indoor spaces (i.e., greenhouses) are also assumed to be minimal because the Worker Protection Standard for Agricultural Pesticides requires that greenhouses be well-ventilated following pesticide application. The current restricted entry intervals (REIs) specified on various metaldehyde labels range from 12 to 24 hours. The results of this assessment do not impact the current REIs.

B. Environmental Risk Assessment

The complete metaldehyde environmental risk assessment is found in the document "Level 1 Screening Ecological Risk Assessment for the Reregistration of Metaldehyde," March 30, 2006, and can be accessed via www.regulations.gov as described above.

1. Environmental Fate and Transport

Metaldehyde is highly mobile in soils, and is generally stable to abiotic degradation mechanisms such as hydrolysis and photolysis. Metaldehyde is primarily dissipated from soils through biodegradation under aerobic conditions, with a half-life of approximately 2 months. Under anaerobic conditions, the half-life of metaldehyde is much higher (>200 days). Its low vapor pressure and Henry's Law constant indicate that volatilization from soils and water surfaces will not be an important transport process. In addition, the results of a laboratory volatility study suggest that volatilization losses from soil surfaces will be minor.

Acetaldehyde is the primary degradation product of metaldehyde. Acetaldehyde is a relatively short-lived metabolite in the environment, and is readily oxidized to acetic acid and ultimately to carbon dioxide and water.

2. Ecological Risk

The Agency's ecological risk assessment compares toxicity endpoints to estimated environmental concentrations (EECs) modeled from environmental fate

characteristics and pesticide use parameters. To evaluate the potential risk to non-target organisms from the use of metaldehyde products, the Agency calculates a Risk Quotient (RQ), which is the ratio of the EEC to the most sensitive toxicity endpoint values, such as the median lethal dose (LD_{50}) or the median lethal concentration (LC_{50}). These RQs are then compared to Levels of Concern (LOCs) established by the Agency for interpreting potential risk to non-target organisms and the need for regulatory action. When the RQ exceeds the LOC for a particular category, the Agency presumes a risk of concern. These risks of concern may be addressed by further refinements of the risk assessment or mitigation measures. The Agency further considers levels of uncertainty in the assessment and any reported incidents to non-target terrestrial or aquatic organisms in the field (e.g., fish or bird kills) when characterizing risk.

Table 7. EPA's Levels of Concern and Associated Risk Presumptions

IF...	THEN the Agency presumes...
Mammals and Birds	
The acute RQ > LOC of 0.5	Acute risk to Federally-listed and non-listed species
The acute RQ > LOC of 0.1	Acute risk to Federally-listed species
The chronic RQ > LOC of 1	Chronic risk to Federally-listed and non-listed species
Fish and Aquatic Invertebrates	
The acute RQ > LOC of 0.5	Acute risk to Federally-listed and non-listed species
The acute RQ >LOC of 0.05	Acute risks to Federally-listed species
The chronic RQ > LOC of 1	Chronic risk to Federally-listed and non-listed species
Terrestrial and Aquatic Plants	
The acute RQ > LOC of 1	Acute risk to Federally-listed and non-listed species

a) Risk to Aquatic Organisms

(1) Toxicity to Fish and Aquatic Invertebrates

The results of acute toxicity studies with a surrogate freshwater fish (rainbow trout) show that metaldehyde is slightly toxic to freshwater fish on an acute basis. No acute toxicity data with estuarine/marine fish are available for metaldehyde.

In an acute toxicity study for a freshwater invertebrate (*Daphnia magna*), no treatment-related effects were observed at the highest concentration of metaldehyde tested. No acute toxicity data with estuarine/marine invertebrates are available for metaldehyde.

No chronic toxicity data are available for metaldehyde in freshwater fish and invertebrates. No toxicity data are available for acute or chronic exposures to estuarine/marine fish or invertebrates, or aquatic plants. No data on toxicity of

metaldehyde to non-target, aquatic mollusks are available. Toxicity data for aquatic organisms exposed to metaldehyde are summarized in Table 8.

Table 8. Metaldehyde Toxicity Values (mg ai/L) for Aquatic Organisms

Exposure Scenario	Species	Exposure Duration	Acute LC/EC_{50} or Chronic NOAEC	Reference (Classification)
Freshwater Fish				
Acute	Rainbow trout	96 hours	LC_{50} = 69 mg ai/L	MRID 42044004 (Supplemental)
Chronic	No data acceptable for quantitative risk assessment are available			
Freshwater Invertebrates				
Acute	Water flea	48 hours	LC_{50} >77.66 mg ai/L	MRID 42044005 (Supplemental)
Chronic	No data acceptable for quantitative risk assessment are available			
Estuarine/Marine Fish				
Acute	No data acceptable for quantitative risk assessment are available			
Chronic				
Estuarine/Marine Invertebrates				
Acute	No data acceptable for quantitative risk assessment are available			
Chronic				
Aquatic Plants				
Acute	No data previously required			
Chronic				

(2) Exposures of Aquatic Organisms to Metaldehyde

Exposure to aquatic organisms is assumed to occur through direct contact with contaminated surface water. The estimated environmental concentrations (EECs) of metaldehyde to which aquatic organisms can be exposed are generated using the Tier 1 model GENEEC2 (Generic Estimated Environmental Concentration). Maximum application rates and use patterns for citrus, brassica (cole crops), leafy vegetables (lettuce), strawberries, berries, artichokes, turf, and ornamentals are inputs to the model. The GENEEC2 model uses soil/water partition coefficients and degradation kinetic data to estimate run-off from a theoretical ten hectare field into a 1-hectare by 2-meter deep "standard" pond. This Tier I model uses conservative inputs such as maximum application rates and maximum number of applications from product labels, resulting in conservative exposure estimates. EECs represent the one-in-ten year concentrations so

that actual environmental concentrations are only expected to exceed the GENEEC-generated values once in ten years. Peak EECs used in the acute risk assessment for aquatic wildlife are shown in Table 9 below.

(3) Fish and Aquatic Invertebrate Risk Estimates

Acceptable toxicity studies on metaldehyde are only available for acute exposure to freshwater fish and invertebrates. RQs were not calculated for freshwater invertebrates since no mortalities were observed at the highest dose tested in *Daphnia*. Acute RQs for freshwater fish are summarized in Table 9. No acceptable toxicity data are available to assess acute risks to marine/estuarine fish and invertebrates, chronic risks to freshwater fish and risks to marine/estuarine fish, invertebrates, and aquatic plants.

Since no toxicity information is available for degradates of metaldehyde, RQs were derived only for the parent compound.

Table 9. Acute RQs for Freshwater Fish Exposed to Metaldehyde

Use Site	Peak EEC (µg ai./L)	Acute RQ (EEC/LC_{50})
Artichokes	238	0.003
Berries	185	0.003
Brassica (cole crops)	189	0.003
Citrus	271	0.004
Strawberries	145	0.002
Grass grown for seed	292	0.004
Dichondra / Turf	422	0.006
Ornamentals	1480	0.021

Acute RQs for freshwater fish are below the acute risk LOC (0.5) and the acute risk LOC for endangered species (0.05) for each of the use sites modeled.

(4) Risks to Aquatic Plants

No toxicity data are available to assess risk to aquatic plants. No adverse ecological incidents have been reported with regard to metaldehyde and aquatic plants. The Agency is requiring toxicity data for aquatic plants.

b) Terrestrial Risk

(1) Toxicity to Terrestrial Wildlife

Available data on the acute toxicity for terrestrial animals indicate that metaldehyde is moderately toxic to mammals and slightly to moderately toxic to birds on an acute exposure basis. Acute toxicity data for the rat are selected as the basis of the mammalian wildlife risk assessment. The endpoint for Japanese quail was selected as the basis of the avian acute risk assessment.

For the chronic assessments, parental systemic toxicity and toxicity to offspring are identified as the endpoint for mammalian wildlife. For birds, the chronic endpoint is based on reproductive effects (reductions in the ratios of number hatched to eggs laid, to eggs set, and to live embryos; and reduction in the ratio of hatchling survival to eggs set), as observed in a study conducted with mallard ducks.

Endpoints selected for the terrestrial assessment are shown in bold in Table 10.

Table 10. Metaldehyde Toxicity Values for Terrestrial Organisms

Exposure Scenario	Species	Study Type	Toxicity Value	MRID#
Mammals				
Acute Dose-based	Rat	Single oral dose	**LD_{50}(♀) = 398 mg/kg**	00131435
Chronic	Rat	reproduction	NOAEC = 1000 mg/kg diet NOAEL = 65 mg/kg bwt/day	42823101
Birds				
Acute Dose-based	Japanese quail	Single oral dose	**LD_{50} = 181 mg./kg**	41553201 (Supplemental)
Acute Dietary-based	Peking duck	5-day dietary	LC_{50} = 2,668 mg./kg	41553204 (Supplemental)
Chronic Dietary-based	Mallard duck	reproduction	NOAEC <49 mg/kg diet	42867902 (Supplemental)

(2) Other Terrestrial Wildlife

Predictably, toxic effects have been observed in clinical studies of snails and slugs, and have also been observed in the carabid beetle. Toxicity to earthworms appears to be low. None of these studies provide sufficient data for a quantitative risk analysis for other terrestrial animals.

(3) Terrestrial Plants

There are no toxicity data available for assessing risks to terrestrial plants. Metaldehyde is used to protect a wide variety of plant types. No adverse ecological incidents gave been reported with regard to metaldehyde and terrestrial plants. The Agency is requiring toxicity data for terrestrial plants.

(4) Potential Exposures for Terrestrial Wildlife

The Agency assessed potential exposures to terrestrial wildlife from the granular applications to all the supported uses of metaldehyde using the T-REX model. Input parameters to the model are summarized in Table 11.

Table 11. Input Parameters for Terrestrial EECs from Granular Applications

Input Variable	Parameter Value	Source
Maximum application rate	Artichokes: 0.8 lb ai/acre Berries: 0.8 lb ai/acre Cole crops: 1.0 lb ai/acre Citrus crops: 1.0 lb ai/acre Grass grown for seed: 1.6 lb ai/A Strawberries: 1.0 lb ai/acre Dichondra/turf: 1.0 lb ai/acre Ornamentals: 3.5 lb ai/acre	Registrant commitment
Maximum number of applications per year	Artichokes: 7 Berries: 5 Cole crops: 4 Citrus crops: 6 Grass grown for seed: 4 Strawberries: 3 Dichondra/turf: 12 Ornamentals: 12	Registrant commitment
Minimum application interval	Artichokes: 18 days Berries: 14 days Cole crops: 14 days Citrus crops: 14 days Grass grown for seed: 21 days Strawberries: 14 days Dichondra/turf: 21 days Ornamentals: 21 days	Product Labels
Foliar half-life	35 days	T-REX Default
% ai	100%	T-REX Guidance
Inputs for the LD_{50}/ft^2 Method for Granular Applications to Soil	Application method: broadcast	Product Label
	Formulation type: granular	Product Label

Exposure estimates are based on the assumption that 100% of the applied granules will be present on the surface of the soil. A summary of acute EECs generated by T-REX for granular applications of metaldehyde is presented in Table 12. The Agency currently has no standard methodology for assessing chronic exposures to terrestrial organisms from granular applications.

Table 12. Terrestrial EECs for Granular Applications

Use Site	EEC (mg ai./ft^2)
Artichokes	8
Berries	8
Cole crops	10
Citrus crops	10
Grass grown for seed	17
Strawberries	10
Dichondra/Turf	10.4
Ornamental Plants	36.4

(5) Terrestrial Risk Estimates

Acute RQs for granular broadcast applications of metaldehyde are derived by dividing the acute LD_{50} values for birds and mammals by the application rate expressed in terms of mg ai/ft^2. These RQs are shown in Table 13.

Table 13. Acute RQs for Birds and Mammals

Use Site	Birds		Mammals	
	Body Weight	Acute RQ (LD_{50}/ft2)	Body Weight	Acute RQ (LD_{50}/ft2)
Artichokes	20 g	3.05*	15 g	0.66 *
	100 g	0.48**	35 g	0.35 **
	1000 g	0.03	1000 g	0.03
Berries	20 g	3.05*	15 g	0.66 *
	100 g	0.48**	35 g	0.35 **
	1000 g	0.03	1000 g	0.03
Cole crops	20 g	3.81*	15 g	0.82 *
	100 g	0.6*	35 g	0.44 **
	1000 g	0.04	1000 g	0.04
Citrus	20 g	3.81*	15 g	0.82 *
	100 g	0.6*	35 g	0.44**
	1000 g	0.04	1000 g	0.04
Grass grown for seed	20 g	6.09*	15 g	1.32*
	100 g	0.96**	35 g	0.7**
	1000 g	0.07	1000 g	0.06
Strawberries	20 g	3.81*	15 g	0.82 *
	100 g	0.6*	35 g	0.44 **
	1000 g	0.04	1000 g	0.04

Use Site	Birds		Mammals	
	Body Weight	**Acute RQ (LD_{50}/ft2)**	**Body Weight**	**Acute RQ (LD_{50}/ft2)**
Dichondra/ Turf	20 g	3.81*	15 g	0.82*
	100 g	0.6*	35 g	0.44**
	1000 g	0.04	1000 g	0.04
Ornamentals	20 g	13.33*	15 g	2.89*
	100 g	2.09*	35 g	1.53*
	1000 g	0.15**	1000 g	0.12**

* RQs exceed the acute risk LOC for birds and mammals and for endangered species ("the acute risk LOC," RQ > 0.5)

** RQs exceed the acute risk LOC for endangered species (RQ >0.1)

Results of this screening level analysis indicate that small- and medium-sized birds and mammals may be at acute risk from exposure to granular applications. For all use sites, the acute RQs for the smallest birds exceed the acute risk LOC. For all use sites except artichokes and berries, acute RQs for the medium-sized birds exceed the acute risk LOC; for artichokes and berries, they exceed the acute risk LOC for endangered species. For ornamentals, the acute risk LOC for endangered species is exceeded for the largest birds.

For all use sites, acute RQs for the smallest mammals exceed the acute risk LOC. For medium-sized mammals, the acute risk LOC for endangered species is exceeded for all sites; for ornamentals, the acute risk LOC is also exceeded. The RQ for the largest mammals associated with applications to ornamentals exceeds the acute risk LOC for endangered species.

The Agency does not have standard procedures for estimating chronic risk to terrestrial wildlife from exposure to granular formulations. Thus, chronic risks to birds and mammals from granular applications of metaldehyde are not assessed.

c) Endangered Species

Risk quotients for metaldehyde, derived from a screening level analysis, indicate a potential for acute risks to endangered (listed) terrestrial species associated with granular applications to the modeled use sites, as noted below:

Birds (also representing potential risks to reptiles and terrestrial-phase amphibians)

- Acute RQs exceed the LOC for listed species for small- and medium-sized birds in artichokes, berries, cole crops, citrus, grass grown for seed, strawberries, and dichondra/turf
- Acute RQs exceed the LOC for listed species of all sizes of birds in ornamentals

Mammals

- Acute RQs exceed the LOC for listed species for small- and medium-sized mammals in artichokes, berries, cole crops, citrus, grass grown for seed, strawberries, and dichondra/turf
- Acute RQs exceed the LOC for listed species of all sizes of birds in ornamentals

Chronic risks were not assessed for terrestrial wildlife because the Agency lacks a methodology for assessing chronic exposures associated with direct ingestion of granules, so chronic risks to endangered birds and mammals cannot be ruled out. In addition, toxicity information for metaldehyde is lacking on acute and chronic effects on marine/estuarine fish and invertebrates (including mollusks), chronic effects on freshwater fish and invertebrates, and aquatic and terrestrial plant toxicity. Risks to these taxa cannot be precluded, and there is a potential for direct effects to Federally-listed species in these taxa. Furthermore, potential indirect effects to any species dependent upon species that experience effects from the use of metaldehyde can not be precluded based on the screening level ecological risk assessment conducted for this RED. These findings are based solely on EPA's screening level assessment and do not constitute "may affect" findings under the Endangered Species Act.

To address concerns about risks to endangered species from pesticide use, the Agency has developed the Endangered Species Protection Program (ESPP). The assessments of risk for aquatic and terrestrial wildlife described in this RED serve as a screening tool to determine the need for any species-specific assessments for listed species, in accordance with the ESPP. Such assessments would refine the screening level assessment by taking into account such factors as the geographic areas of pesticide use in relation to the listed species and the habits and habitat requirements of the listed species. If the Agency's species-specific assessments result in the need to modify the use of the pesticide in specific geographic areas, those changes will be undertaken through the process described in the Agency Federal Register Notice (54 FR 27984) on implementation of the ESPP.

C. Alternatives Assessment and Related Information

The Agency solicited information about critical uses and alternatives from the public and from the Regional IPM Centers and their field and academic contacts through the USDA's Office of Pest Management Policy. Additional information was gleaned from the IPM Centers' Crop Profiles (located at www.ipmcenters.org/CropProfiles/).

Comments were received on the critical need for metaldehyde in some of the agricultural and commercial crops assessed for this RED (especially strawberries, caneberries, citrus, and production ornamentals) and in some of the crops currently on product labels but not supported by the registrant. Respondents also reported on alternatives to metaldehyde that are used and may be efficacious for various use sites—iron phosphate for home lawns and parks, and for production ornamentals in the North Central States, and copper bands or sprays for citrus.

Respondents also mentioned cultural controls that provide adequate or supplemental controls in certain circumstances, particularly for residential and public land use. Cultural controls include hand-picking, removal of plant debris that can shelter slugs and snails, and watering in the morning rather than in the evening (snails and slugs favor damp conditions and feed at night). Ironically, no-till agriculture can reduce some pesticide inputs (i.e., herbicides), but can favor development of economically damaging slug and snail populations in plant debris on the ground. For strawberries and artichokes, which can be grown as either annuals or perennials, annual culture tends to reduce snail and slug populations relative to perennial culture so that fewer or no applications of metaldehyde may be needed.

The Agency conducted an assessment of alternatives for metaldehyde. The resulting document, entitled "Metaldehyde Alternatives Assessment," July 18, 2006 is accessible via the docket at www.regulations.gov. In summary, the Agency found that metaldehyde is the dominant molluscicide for control of snails and slugs in both agricultural crops and the residential/ornamental environment. Methiocarb is a Restricted Use carbamate pesticide and is registered only for a subset of the sites where metaldehyde and iron phosphate can be used: turf, and greenhouse and nursery ornamentals. Methiocarb has limited usage except in greenhouse ornamentals. Iron phosphate, a Reduced Risk pesticide, is a newer registration also with limited usage.

Data on the relative efficacy of metaldehyde and iron phosphate for most use sites are not available; however, the consensus of numerous publications is that efficacy of iron phosphate is variable in agricultural and production horticulture. Data suggest iron phosphate generally is somewhat less effective than metaldehyde, but may be used more effectively under high moisture conditions. In contrast, information received from Oregon indicates that iron phosphate does not hold up well under wet conditions in Oregon, suggesting that local environmental conditions may have a large influence on effectiveness. Growers may be reluctant to use iron phosphate because they consider it to be new and untested, and because it is more expensive ($1.55/lb vs. $1.25 for metaldehyde). In addition, non-chemical measures are typically considered to be either too expensive or too labor intensive for wide-scale use in agriculture.

The Agency believes that for residential use, iron phosphate and non-chemical control measures may both be acceptable alternatives to metaldehyde. Some ornamentals growers favor the use of iron phosphate because metaldehyde granules tend to become moldy; moldy granules are unsightly in pots and on soil surfaces and stick to the shoes of customers as they walk around greenhouses and retail nurseries.

In addition, the Agency believes that programs relying on the integration of different methods of slug and snail control (use of metaldehyde and iron phosphate and cultural methods) can allow a reduction in the number of times metaldehyde is applied. Experts representing specific grower groups have informed the Agency that the use parameters supported by Lonza, which are the basis of the Agency's risk assessments, overstate what is needed for economical control of control slugs and snails in some use sites. These experts have provided use site-specific information on reduced application

rates and numbers of applications which provide adequate control. Lonza itself has indicated that numbers of applications can also be reduced for other uses sites relative to the parameters it initially cited.

The Agency has considered this information in its development of the risk mitigation plan for metaldehyde.

IV. Reregistration Decision

A. Risks of Concern and Risk Mitigation

1. Dietary

There are no dietary risks of concern for metaldehyde.

2. Residential

There are no residential risks of concern. MOEs for post-application risk to toddlers are above the target MOE of 1000; the MOE for combined risk from post-application exposures is 1600. The Agency expects that the requirement for formulating metaldehyde home and garden products with a bittering agent (as described below) is effective in deterring direct ingestion of granules by children. At the same time, the Agency believes it is prudent to require label language on best practices that provides residential users with information on how to reduce exposures to children. Labeling requirements for metaldehyde products are detailed in Table 16.

3. Aggregate

Aggregated risks from dietary and residential exposures are below levels of concern. Aggregate risk estimates for toddlers are the highest of the aggregate exposures, with an MOE of 1200. As noted above, the Agency is requiring labeling to address potential post-application exposures to children.

4. Occupational

None of the occupational scenarios assessed by the Agency posed risks of concern, even at the baseline level (handlers wearing long-sleeved shirts, long pants, shoes, and socks, without respirators or gloves). Current labels typically require handlers to wear long-sleeved shirts, long pants, waterproof gloves (preferably chemically-resistant), and shoes and socks. Additional PPE may be required based on product label reviews.

Occupational post-application exposures were not assessed, but are not expected to pose risks of concern. REIs for metaldehyde products may be revised based on product label reviews.

5. General Concerns

All end-use product labels must be amended such that they are consistent with only those uses determined to be eligible for reregistration. All other uses must be deleted from all labels.

6. Domestic Animals

Based on the number of poisoning incidents involving ingestion of metaldehyde products by domestic animals (primarily dogs) after application in residential settings, and incident information suggesting that dogs also may ingest metaldehyde granules after opening product packaging, risks to domestic animals are of concern.

The Agency is implementing a performance-based mitigation program for residential uses of metaldehyde. The Agency believes that this mitigation program will bring risks below levels of concern. Nevertheless, the Agency will require registrants to evaluate the program and submit confirmatory data regarding its effectiveness in reducing numbers of domestic animal incidents and lethal poisoning incidents. If the data indicate that the risk mitigation program is not effective in reducing the numbers and/or severity of poisoning incidents among domestic animals, the Agency may require additional mitigation or the termination of metaldehyde registrations for non-agricultural uses.

The Agency is specifying a number of label requirements to address the risks to domestic animals. The required label language is detailed in Table 16. In summary, labels must be revised to include the following elements:

Labels for residential-use products must prominently display language advising users that:

- dogs and other domestic animals are attracted to metaldehyde products, both in the package and when applied
- metaldehyde ingestion or other exposures to metaldehyde can be lethal to domestic animals
- domestic animals must be excluded from treated areas during and after application, and until applied material is no longer visible
- application of metaldehyde granules is prohibited unless domestic animals can be excluded from the treated areas after application and until the material is no longer visible.
- metaldehyde products must be kept out of the reach of domestic animals and children.
- dogs have been known to ingest metaldehyde after opening or tearing packaging, and that resulting exposures can be fatal

These statements must be accompanied by a graphic that depicts the prohibition for allowing children and domestic animals access to treated areas (e.g., the words

"Children and Pets" within a red circle with a red bar running diagonally through the circle). Labels of residential use metaldehyde products already bear graphic images of this nature that instruct the user as to how pellets should be placed (stylized plants with granules distributed improperly are shown within a red circle with a diagonal red bar). The formulators of metaldehyde have commented that they believe a "Children and Pets" graphic of this nature could be misleading to consumers. The Agency is evaluating precedents for this type of graphic in other consumer products, and is specifically seeking public input in the comment period after the RED becomes available on how the directions to exclude children and domestic animals from treated areas may be enhanced via product labeling.

In addition, labels for all residential-use products:

- must prominently display directions for users in the case of domestic animal exposures, providing the information hotline number and instructing users or pet owners to contact their veterinarians as soon as possible after exposure occurs.

- must note that broadcast and foliar applications are prohibited.

- must note that applications to turf and dichondra are prohibited.

- will allow application only to non-turf areas directly surrounding plants (on soil or mulch) listed on product labels.

- will allow use only as a barrier around gardens or individual plants, with application prohibited within one foot of vegetable plants or fruit-bearing plants for which metaldehyde use is not allowed.

- will allow application for ornamentals, and garden vegetable and fruit-bearing plants only as a barrier treatment. The only allowable home garden use sites for metaldehyde are ornamentals, cole crops and other leafy greens (cabbage, broccoli, Brussels sprouts, cauliflower, kale, collard greens, etc.), lettuce, tomato, citrus, strawberry, blueberries, and caneberries (e.g., raspberries, blackberries) and other berries.

- must be amended to provide application directions in user-friendly terms, for example, "Apply pellets as a barrier around plants by distributing pellets evenly in a line at a rate of X tablespoons per X linear foot." The application rates described in this way must not represent use at an application rate greater than the 1.0 lb ai/A/application for ornamentals. Applications for ornamentals are limited to 6/year, at an interval not less than 21 days between applications. Application rates and other application parameters for other uses are as described below.

The technical registrant of metaldehyde, Lonza, has committed to expediting submission of residential-use products revised to reflect these requirements.

The following formulation requirements must be implemented for residential-use products containing metaldehyde:

- Formulation of metaldehyde in combination with carbaryl is prohibited unless the product is formulated to provide a single application rate that does not exceed the maximum allowable rate for either active ingredient.

- All residential use products containing metaldehyde must be formulated with denatonium benzoate, or another bittering agent approved by the Agency, at sufficient concentration to deter ingestion by domestic animals. The bittering agent will also serve as a deterrent for ingestion by children.

In addition, labels for metaldehyde-carbaryl combination products must bear language advising users that such products must not be applied unless both snails or slugs and target pests for carbaryl are present. Since metaldehyde products will no longer be permitted on turf, the utility of these combination products may be limited in the future.

Furthermore, the registrants are required to submit data demonstrating the effectiveness of the bittering agent incorporated into the residential-use metaldehyde products, at the concentration used in those formulations. Lonza has indicated that it is evaluating a new agent, which is composed of the original bittering agent, denatonium benzoate, plus an olfactory agent. The Agency is requiring palatability data for denatonium benzoate and any new bittering agent the registrants wish to employ, to confirm the effectiveness of such an approach in deterring ingestion by domestic animals. If the data indicate that the aversion agent used in metaldehyde formulations (at the concentration used in those formulations) is not efficacious in deterring ingestion by domestic animals, the Agency may require additional testing and implementation of additional mitigation measures.

The registrants are also required to implement a common reporting system for domestic animal poisoning incidents associated with all metaldehyde products, and are required to submit quarterly reports on incidents reported for the time period. The registrants are required to submit a protocol for the reporting program to EPA for review prior to implementing the program. The Agency's analysis of trends in the numbers and severity of poisoning incidents associated with metaldehyde, or other relevant information, will be the basis of decisions on additional requirements for risk mitigation.

The registrants are also required to submit data on the efficacy of metaldehyde products formulated with non-food-based inerts and bulking agents. If the Agency finds that products formulated with these materials are efficacious in controlling the target pests, the registrants will be required to reformulate accordingly.

7. Environmental

The Agency has assessed risks to nontarget wildlife associated with the residential and agricultural uses of metaldehyde.

Based on a screening level assessment, the Agency has concluded that acute RQs for birds and mammals exceed LOCs for acute risk and acute endangered species risk for all uses of metaldehyde for most size ranges of animals. Incident data for domestic animals and wildlife are supportive of the potential for risks of concern in mammalian wildlife. Metaldehyde itself, and the food-based materials the pesticide is formulated with, are reported to be attractive to animals. In contrast to the conservative nature of the Agency's screening level exposure assessment, preferential selection of metaldehyde granules as a food source would suggest that risks to non-target wildlife may be underestimated.

Metaldehyde is slightly toxic to freshwater fish on an acute basis. RQs for freshwater fish do not exceed LOCs as assessed. Testing of a representative freshwater invertebrate did not result in mortality even at the highest dose tested. There are significant data gaps for chronic toxicity to freshwater animals and for acute and chronic toxicity to estuarine/marine animals. There are no data to allow an assessment of the risks metaldehyde use poses to non-target aquatic mollusks, but because the pesticide is an effective molluscicide, it is reasonable to assume that there may be risks associated with exposures to non-target aquatic mollusks.

The Agency is specifying a number of risk mitigation measures to target risks to wildlife. Required label language is detailed in Table 16.

- Labels must allow use only on the following sites (maximum application rate/application, maximum number of applications/season, minimum retreatment interval):

  Citrus: 1.0 lb ai/A, 6 applications, 14 days
  Cole crops and other leafy greens: 1.0 lb ai/A, 3 applications, 14 days
  Lettuce: 1.0 lb ai/A, 3 applications, 14 days
  Tomato: 1.0 lb ai/A, 3 applications, 14 days
  Strawberry (when grown as perennials only): 1.0 lb ai/A, 3 applications, 14 days
  Blueberries: 0.8 lb ai/A, 2 applications, 14 days
  Caneberries and other berries: 0.8 lb ai/A, 3 applications, 14 days
  Grass grown for seed: 0.8 lb ai/A, 4 applications, 21 days
  Artichokes (when grown as perennials): 1.0 lb ai/A, 6 applications, 18 days
  Artichokes (when grown as annuals): 1.0 lb ai/A, 2 applications, 18 days
  Ornamentals: 1.0 lb ai/A, 6 applications, 21 days

Applications to turf and dichondra are prohibited. The mandated application rate for ornamentals is lower than the rate assessed for this RED (3.5 lbs ai vs. 1 lb ai), as it is for grass grown as seed (1.6 lbs ai vs. 0.8 lb ai). Numbers of applications are reduced

relative to what was assessed in the RED for lettuce, cole crops and other leafy greens, tomato, strawberries grown as perennials, caneberries and other berries, artichokes, and ornamentals. Reductions in maximum application rates and numbers of repeat applications reduce opportunities for exposure to domestic animals and wildlife, and promote the use of alternate methods of slug and snail control. Retreatment intervals are as proposed by Lonza and assessed by the Agency, and have not changed as a result of the risk assessments.

- For strawberries grown as annuals, pest populations are expected to be much lower than in strawberries grown as perennials. The use of metaldehyde on annual strawberries must be deleted from product labels. The Agency is soliciting public comment on this prohibition of use on strawberries grown as annuals, will consider any documentary evidence of grower need for metaldehyde on this crop.

- Certain cultural practices may reduce damage from snails and slugs, and may make metaldehyde applications more effective. Labels of residential use products must provide summary information about cultural controls (e.g., remove leaf litter and debris; during daylight hours, look for and remove slugs and snails in leaf litter, mulch, or other protected areas adjacent to plants they feed on; water or irrigate in the morning, when possible).

It should be noted that the Agency believes that a bittering agent likely would not be effective in preventing ingestion of metaldehyde by terrestrial wildlife species because of the great diversity of potentially exposed species and differences in how they perceive taste. The Agency believes that these mitigation measures discussed in this section will reduce potential environmental exposures to metaldeyhyde, for both aquatic and terrestrial organisms. The Agency is requiring additional ecotoxicity data to reduce the uncertainty in the ecological risk assessment.

8. Other Measures Addressing Both Domestic Animal and Ecological Risks

Based on the similarity in size of some pet foods/wildlife forage items and the larger pellet sizes of metaldehyde, and evidence suggesting that animals may mistake the pellets for food, the formulators of metaldehyde products will be prohibited from formulating granular materials at a rate of fewer than 35 pellets per gram.

Based on evidence that brightly colored granules may be less attractive to animals, formulators must incorporate a coloring agent into their granular formulations. Many metaldehyde products already are formulated with a blue color. It has been suggested that the blue color may attract children who could mistake the pellets for candy. Empirical or other evidence relating to the potential for reducing animal exposures with the colored pellets is limited. In addition, the formulators of metaldehyde have indicated that the use of colored pellets could affect the marketability of some kinds of produce if the blue color splashes or bleeds onto plant parts, while other sources have indicated that color transfer is not and should not be a problem for soil-applied baits. The

Agency is specifically seeking public input on this issue in the comment period after the RED becomes available.

The Agency believes that the risk mitigation measures required by the RED will be effective in reducing risks below levels of concern. The Agency is requiring certain confirmatory data to support the adequacy of those measures, and may require additional mitigation measures and testing.

The registrants are required to submit data on the efficacy of metaldehyde products formulated with non-food-based inerts and bulking agents. If the Agency finds that products formulated with these materials are efficacious in controlling the target pests, the registrants will be required to reformulate accordingly.

B. Tolerance Considerations

The Agency has reassessed the one existing tolerance for metaldehyde, and found a reasonable certainty of no harm to the U.S. population and all population subgroups from the use of metaldehyde. The Agency also has identified new tolerances that are needed for metaldehyde. The existing tolerance is a tolerance exemption of 0 ppm on strawberry. Both the tolerance exemption and the lack of other tolerances for metaldehyde are attributable to past belief by the Agency that residues of metaldehyde would not be taken up by plants. The tolerance reassessment and tolerances needed to support uses of metaldehyde are shown in Table 14.

Table 14. Tolerance Summary for Metaldehyde

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)
Tolerance Listed Under 40 CFR §180.523(a)		
Strawberry	0	6.25
Tolerances Needed under 40 CFR 180.523(a)		
Artichoke, globe	None	0.0625
Berry, group 13	None	0.15
Fruit, citrus, group 10	None	0.26
Prickly pear cactus	None	0.0625
Vegetable, brassica, leafy, group 5 (cole crops)	None	2.5
Lettuce	None	1.73
Vegetable, fruiting, group 8 (Tomato)	None	0.24

The use of metaldehyde on grass grown for seed necessitates development of residue data and establishment of a tolerance for metaldehyde, because screenings from

seed cleaning and grass hay from the treated fields may be used as animal feed. These data, in development by IR-4, are expected to be submitted to the Agency in the future, at which time the appropriate tolerance level can be identified.

C. Eligibility Decision

Metaldehyde products are currently labeled for many uses which are not being supported by the technical registrant. Only those uses that are supported by the registrant through development of required data have been assessed for this reregistration decision. The uses of metaldehyde that are being supported are: turf/dichondra, ornamentals, citrus, lettuce, cole crops and other leafy greens, tomato, strawberry, berries (including blackberry, blueberry, currant, elderberry, gooseberry, raspberries), and grass grown for seed, and artichoke. With the exception of the use on turf and dichondra, these uses of metaldehyde are eligible for reregistration, provided that the risk mitigation measures required by this RED are implemented, and the data submitted pursuant to the requirements identified in this RED are confirmatory.

The IR-4 program of the U.S. Department of Agriculture, which develops residue data for minor and specialty crops, has done research on a number of additional uses for metaldehyde. At the current time, residue data for the use of metaldehyde on prickly pear cactus and watercress are in development. While these uses were included in the health effects and environmental risk assessments for metaldehyde, decisions on their registration have not been made for this RED.

V. What Registrants Need to Do

A. Submissions for Technical-Grade Active Ingredient Products

1. Within 90 Days of Receipt of the Generic DCI

For each metaldehyde technical grade active ingredient product, the registrant needs to submit the following items within 90 days of receiving the Generic DCI:

- completed response forms to the generic DCI (i.e., DCI response form and requirements status and registrant's response form); and
- submit any time extension and/or waiver requests with a full written justification

2. Within Other Generic DCI Deadlines

Within the time limit specified in the generic DCI, the registrant must cite any existing generic data or submit new generic data in response to the DCI. Please contact Jill Bloom at (703) 308-8019 with questions regarding generic reregistration.

By US mail:
Document Processing Desk
(DCI/SRRD)
Jill Bloom
US EPA (7508P)
1200 Pennsylvania Ave., NW.
Washington, DC 20460

By express or courier service:
Document Processing Desk (DCI/SRRD)
Jill Bloom
Office of Pesticide Programs (7508P)
4th Floor, One Potomac Yard
2777 S. Crystal Dr.
Arlington, VA 22202

B. Submissions for End-Use Products Containing Metaldehyde

1. Within 90 Days

Within 90 days from the receipt of the product-specific data call-in (PDCI), the registrant must submit, for each product:

- completed response forms to the PDCI (i.e., PDCI response form and requirements status and registrant's response form); and
- any time extension or waiver requests with a full written justification.

2. Within Product DCI Deadlines

Within eight months from the receipt of the PDCI, the registrant must submit:

- two copies of the confidential statement of formula (EPA Form 8570-4);
- a completed original application for reregistration (EPA Form 8570-1). Indicate on the form that it is an "application for reregistration";
- five copies of the draft label incorporating all label amendments outlined in Table 47 of this document;
- a completed form certifying compliance with data compensation requirements (EPA Form 8570-34); and
- if applicable, a completed form certifying compliance with cost share offer requirements (EPA Form 8570-32); and
- the product-specific data responding to the PDCI.

Please contact Bonnie Adler at (703) 308-8523 with questions regarding product reregistration and/or the PDCI. All materials submitted in response to the PDCI should be addressed as follows:

By US mail:
Document Processing Desk
(PDCI/PRB)
Bonnie Adler
US EPA (7508P)
1200 Pennsylvania Ave., NW.
Washington, DC 20460

By express or courier service:
Document Processing Desk (PDCI/PRB)
Bonnie Adler
OPP (7508P)
4th Floor, One Potomac Yard
2777 S. Crystal Drive.
Arlington, VA 22202

C. Manufacturing-Use Products—Data Requirements

The Agency has determined that additional generic data are needed to confirm this reregistration eligibility decision. These data are summarized in Table 15, and cited in the Generic DCI for metaldehyde.

Table 15. Generic Data Requirements for Metaldehyde

Guideline or Special Study Name or Description	OPPTS Guideline No.
Developmental neurotoxicity study (rat)	870.6300
90 day inhalation toxicity study (rat)[1]	870.3465
Mutagenicity battery	870.5000 series
Field trials[2]	860.1500
Reference standard for metaldehyde[3]	860.1650
Field accumulation in rotational crop	860.1900
Turf dissipation study (TTR)[4]	875.2100
Aerobic Soil Metabolism[5]	835.4100
Anaerobic Aquatic Metabolism	835.4400
Aerobic Aquatic Metabolism	835.4300
Terrestrial Field Dissipation[6]	835.6100
Bivalve Acute (Embryo Larval) EC_{50}	850.1055
Estuarine/Marine Fish LC_{50}	850.1075
Estuarine/Marine Mollusk Shell Deposition EC_{50}	850.1025
Estuarine/Marine Mysid Shrimp EC_{50}	850.1035
Freshwater Fish Early Life-Stage	850.1400
Daphnid Chronic Life-Cycle	850.1300
Estuarine/Marine Invertebrate Life-Cycle[7]	850.1350
Freshwater Fish Full Life-Cycle[7]	850.1500
Seedling Emergence (Tier I)	850.4100

[1] The Agency will consider registrant submission of a waiver request for this data requirement supported by discussion of the volatility of metaldehyde and potential for occupational inhalation exposure, or other supporting information.
[2] Confirmatory field trial data are required on leafy lettuce (2 tests) to support permanent tolerances on the leafy vegetable crop group
[3] Reference Standard must be submitted to the National Pesticide Standards Repository
[4] Confirmatory data required to support intermediate-term exposure estimates
[5] Weight-of-evidence of laboratory and field data suggests that there is uncertainty with relying on a single aerobic soil metabolism test system. The submission of additional aerobic soil metabolism data is required in order to minimize this uncertainty.
[6] Soil samples were not tested at lower depths for metaldehyde. Study design must allow the Agency to distinguish between metaldehyde residues in upper soil layer and undissolved pellets.
[7] Requirement reserved pending review of related data

Guideline or Special Study Name or Description	OPPTS Guideline No.
Vegetative Vigor (Tier I)	850.4150
Aquatic Plant Toxicity (Tier I)	850.4400
Incident reporting program[8]	NA
Palatability of materials incorporating bittering agent[8]	NA
Efficacy of products utilizing non-food based inerts[8]	NA

D. Labeling

To ensure compliance with FIFRA, manufacturing-use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices, and applicable policies. Furthermore, all MUP labels must be amended to incorporate the risk mitigation measures outlined in this RED. Table 16 details how language on the labels must be amended. MUP labeling revised in this manner must be submitted within 90 days of receipt of the generic DCI issued pursuant to this RED.

In order to be eligible for reregistration, labeling for all end-use products containing metaldehyde must be amended to incorporate the risk mitigation measures outlined in this RED. Table 16 details how language on the labels must be amended. End-use product labeling revised in this manner must be submitted within eight months from the receipt of the PDCI issued pursuant to this RED

[8] Protocols required in advance of study initiation

Table 47. Labeling Changes for Products Containing Metaldehyde

Description	Amended Labeling Language	Placement on Label
	Manufacturing-Use Products	
For all Manufacturing- Use Products	"This product may be formulated into a molluscicide for the following use(s) only: artichokes, blueberries, caneberries (bingleberry, black raspberry, blackberry, boysenberry, dewberry, lowberry, marionberry, olallieberry, red raspberry, youngberry) and other berries (currant, elderberry, gooseberry, huckleberry, loganberry, lingonberry, juneberry, salal), citrus, lettuce, cole crops and other leafy greens (broccoli, Brussels sprouts, cabbage, cauliflower, cavalo, broccolo, collards, kale, kohlrabi, mizuna, mustard greens, spinach, rape greens), grass grown for seed, ornamentals, tomato, and strawberry (grown as perennials only)." "This product may not be formulated into end-use products for use on turf (except grass grown for seed), dichondra lawns, or strawberries grown as annuals." "This product may not be formulated into end-use granular or pelletized products unless those products are formulated to incorporate a bright blue coloring agent." "This product may not be formulated into end-use granular or pelletized products unless those products are formulated to contain more than 35 pellets per gram." "This product may not be formulated into end-use granular or pelletized products with directions permitting use at residential sites (i.e., in yards or gardens, around homes, apartments, schools, athletic fields, playgrounds, parks, etc.) unless such products contain denatonium benzoate at 300 ppm or another	Directions for Use

Description	Amended Labeling Language	Placement on Label
	bittering agent approved by the Agency. The bittering agent must be of sufficient concentration to deter ingestion by children and domestic animals." "This product may not be formulated into end-use products with directions permitting use at residential sites (i.e., in yards or gardens, around homes, apartments, schools, daycare facilities, athletic fields, playgrounds, parks, recreation areas, etc.) unless the labels of such products contain a graphic that depicts the prohibition on allowing children and domestic animals access to treated areas and specific warnings designed to reduce the numbers of incidents involving children and domestic animals."	
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."	Precautionary Statements
End Use Products Intended for Agricultural Use		

Description	Amended Labeling Language	Placement on Label
Domestic Animal Precautionary Statements	"This product can be fatal to children and dogs (and other domestic animals) when ingested. Children and dogs may be attracted to the product. Application of this product is prohibited unless children and domestic animals can be excluded from the treated area from the start of the application until applied material is no longer visible."	Precautionary Statements: Hazards to Humans and Domestic Animals
PPE Requirements Established by the RED[9]	"Mixers, loaders, applicators, and other handlers must wear: long-sleeved shirts and long pants, and shoes plus socks."	Immediately following/ below Precautionary Statements: Hazards to Humans and Domestic Animals
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry." "Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements

[9] PPE established on the basis of Acute Toxicity of the end-use product must be compared to the active ingredient PPE in this document. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

Description	Amended Labeling Language	Placement on Label
User Safety Recommendations	"User Safety Recommendations" "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet." "Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing." "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)
Environmental Hazard Statement	"This pesticide is toxic to fish and aquatic invertebrates. Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark except as noted on appropriate labels. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas. Do not contaminate water when disposing of equipment wash waters or rinsate. This pesticide is toxic to birds and mammals. Granules on soil surface may be hazardous to terrestrial wildlife. Cover or collect any such materials spilled during loading."	Precautionary Statements immediately following the User Safety Recommendations
Poisoning Hotline	"Seek medical care as soon as possible after exposure. Have the product container or label with you when you call a poison control center or doctor or when going for treatment. For information on this pesticide product (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Information Center at 1-800-858-7378. "For incidents involving animals, seek veterinary care as soon as possible after exposure. Have the product container or label with you when you call a poison	Precautionary Statements, under "First Aid" : Poisoning Hotline

Description	Amended Labeling Language	Placement on Label
	control center or veterinarian or when taking an exposed animal for treatment. For treatment advice and other information about exposures of animals to this pesticide, call [*registrant enters name of reporting service*] at [*registrant enters appropriate toll-free telephone number*].	
Restricted-Entry Interval for products with directions for use within scope of the Worker Protection Standard for Agricultural Pesticides (WPS)	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours. Exception: if the product is soil-injected or soil-incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated areas without restriction if there will be no contact with anything that has been treated."	Directions for Use, Under Agricultural Use Requirements Box
Early Entry Personal Protective Equipment for products with directions for use within the scope of the WPS	"PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is: * coveralls, * shoes plus socks * chemical-resistant gloves made of any waterproof material"	Direction for Use Agricultural Use Requirements box
General Application Restrictions	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. "	Direction for Use Immediately above the Agricultural Use Requirements box
Other Application Restrictions	"This product is intended solely for use on agricultural crops grown for commercial or research purposes. This product may not be applied to residential sites (i.e., in yards or gardens, around homes, apartments, schools, athletic fields, playgrounds, parks, etc.)." "Broadcast or foliar applications of this product are prohibited."	Directions for Use
Crop Specific Directions for	End-use product labels must be amended to contain directions for use only on	Directions for Use

Description	Amended Labeling Language	Placement on Label
Use	the following crop- and use-sites and only with the maximum application rate, maximum number of applications per growing season, and minimum retreatment intervals as listed below. All other crop- and use-sites must be removed from end-use product labels. Artichokes: - When grown as a perennial, the maximum application rate is 1.0 lb ai/A per application. A maximum of 6 applications are permitted per growing season at a minimum of retreatment interval of 18 days. - When grown as an annual, the maximum application rate is 1.0 lb ai/A per application. A maximum of 2 applications are permitted per growing season at a minimum of retreatment interval of 18 days. Blueberries: the maximum application rate is 0.8 lb ai/A per application. A maximum of 2 applications are permitted per growing season at a minimum of retreatment interval of 14 days. Caneberries (bingleberry, black raspberry, blackberry, boysenberry, dewberry, lowberry, marionberry, olallieberry, red raspberry, youngberry) and Other Berries (currant, elderberry, gooseberry, huckleberry, loganberry, lingonberry, juneberry, salal): the maximum application rate is 0.8 lb ai/A per application. A maximum of 3 applications are permitted per growing season at a minimum of retreatment interval of 14 days. Citrus: the maximum application rate is 1.0 lb ai/A per application. A maximum of 6 applications are permitted per growing season at a minimum of retreatment interval of 14 days. Lettuce, Cole Crops, And Other Leafy Greens: (broccoli, Brussels sprouts,	associated with the specific crop- or use-site

Description	Amended Labeling Language	Placement on Label
	cabbage, cauliflower, cavalo, broccolo, collards, kale, kohlrabi, mizuna, mustard greens, spinach, rape greens): the maximum application rate is 1.0 lb ai/A per application. A maximum of 3 applications are permitted per growing season at a minimum of retreatment interval of 14 days. Grass grown for seed: the maximum application rate is 0.8 lb ai/A per application. A maximum of 4 applications are permitted per growing season at a minimum of retreatment interval of 21 days. Applications to turfgrass (other than grass grown for seed) are prohibited. Ornamentals: the maximum application rate is 1.0 lb ai/A per application. A maximum of 6 applications are permitted per growing season at a minimum of retreatment interval of 21 days. Tomatoes: the maximum application rate is 1.0 lb ai/A per application. A maximum of 3 applications are permitted per growing season at a minimum of retreatment interval of 14 days. Strawberries (grown as perennials only): the maximum application rate is 1.0 lb ai/A per application. A maximum of 3 applications are permitted per growing season at a minimum of retreatment interval of 14 days. Applications to strawberries grown as annuals are prohibited.	
Storage Restrictions	"This product can be fatal to children and dogs (and other domestic animals) if ingested. Dogs have been known to ingest metaldehyde after opening or tearing packaging. Store this product in its original packaging, in a cool, secure location, and out of reach of children and pets. Do not store in any location where children and domestic animals can access the packaging or the product."	Storage and Disposal
Products Intended for Use at Residential Sites		

Description	Amended Labeling Language	Placement on Label
Precautionary Statement and Graphic Depiction for Products Intended for Use at Residential Sites	The label of any end-use product with directions for use at residential sites (i.e., in yards or gardens, around homes, apartments, schools, daycare facilities, athletic fields, playgrounds, parks, recreation areas, etc.) must contain a graphic that depicts the prohibition on allowing children and domestic animals access to treated areas. For example, the symbol may be a red circle with the words "Children" and "Pets" within the circle and with a red bar running diagonally through it. The following specific warning statements must be added to the label in close association to the above graphic: "Keep out of reach of children and domestic animals. This pesticide may be fatal to children and dogs (and other domestic animals) when ingested. Exclude children and pets from treated areas until the applied product is no longer visible. For additional precautionary measures, see "Directions for Use" and "Storage and Disposal."	Front panel
Precautionary Language	"IMPORTANT: This product may be fatal to children and dogs (and other domestic animals) if ingested. Keep out of reach of children and domestic animals. Children and dogs may be attracted to metaldehyde products. and their packaging. Keep children and dogs (and other domestic animals) out of treated areas from the start of application until the applied product is no longer visible."	Precautionary Statements: Hazards to Humans and Domestic Animals
Poisoning Hotline	"Seek medical care as soon as possible after exposure. Have the product container or label with you when you call a poison control center or doctor or when going for treatment. For information on this pesticide product (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Information Center at 1-800-858-7378. "For incidents involving animals, seek veterinary care as soon as possible after	Precautionary Statements, under "First Aid" : Poisoning Hotline

Description	Amended Labeling Language	Placement on Label
	exposure. Have the product container or label with you when you call a poison control center or veterinarian or when taking an exposed animal for treatment. For treatment advice and other information about exposures of animals to this pesticide, call [*registrant enters name of reporting service*] at [*registrant enters appropriate toll-free telephone number*].	
Environmental Hazard Statement for Residential Use Products	"This product is toxic to fish and aquatic invertebrates. Do not apply product near water or storm drains. Do not apply if heavy rain is expected. Apply this product only around gardens and ornamental plants. For granular or pelletized product, add: "This pesticide is toxic to birds and mammals. Sweep up or collect and remove any product that lands on the driveway, sidewalk, or other hard surface on which it is spilled."	Precautionary Statements
General Application Restrictions	"Do not apply this product in a way that will contact other persons or pets either directly or through drift. Keep people and pets out of the area during application."	Directions for Use under General Precautions and Restrictions
Other Application Restrictions	"This pesticide may be fatal to children, and dogs, and other domestic animals if ingested. Dogs and other domestic animals are attracted to metaldehyde products, both in the package and when applied. Children may also be attracted to these products. Children and dogs (and other domestic animals) must be kept out of treated areas from the start of application until the applied product is no longer visible." "Application of this metaldehyde product is prohibited unless children and dogs (and other domestic animals) can be excluded from the treated areas from the start of application until the applied product is no longer visible."	

Description	Amended Labeling Language	Placement on Label
	"Applications to turf and dichondra are prohibited. Application is permitted only to non-turf areas (i.e., on soil or mulch) directly surrounding plants listed for use on the label." "Broadcast and foliar applications of this product are prohibited. Application is permitted only as a barrier around gardens or individual plants. Application is prohibited within one foot of vegetable plants or fruit-bearing plants not listed on this label." "Certain cultural practices may reduce damage from snails and slugs, and may make metaldehyde applications more effective. Examples of cultural methods to reduce snail and slug populations include: -- removing leaf litter and debris to eliminate places for slugs and snails to hide during the day; -- looking for and removing slugs and snails during daylight hours in leaf litter, mulch, or other protected areas adjacent to plants they feed on; -- watering in the morning rather than the evening to reduce humidity during the night when snails and slugs are active."	
Crop- and Use-Site Specific Directions for Use NOTE: Application rates must be provided in user-friendly terms, for example, "Apply pellets as a barrier around plants by distributing pellets evenly in a line at a rate of X tablespoons per X linear foot."	End-use product labels must be amended to contain directions for use only on the following crop- and use-sites and only with the maximum application rate, maximum number of applications per growing season, and minimum retreatment intervals as listed below. All other crop- and use-sites must be removed from end-use product labels. Artichokes: - When grown as a perennial, the maximum application rate is 1.0 lb ai/A per application. A maximum of 6 applications are permitted per growing season at a minimum of retreatment interval of 18 days. - When grown as an annual, the maximum application rate is 1.0 lb ai/A per	Directions for Use associated with the specific crop- or use-site

Description	Amended Labeling Language	Placement on Label
	application. A maximum of 2 applications are permitted per growing season at a minimum of retreatment interval of 18 days. Blueberries: the maximum application rate is 0.8 lb ai/A per application. A maximum of 2 applications are permitted per growing season at a minimum of retreatment interval of 14 days. Caneberries (bingleberry, black raspberry, blackberry, boysenberry, dewberry, lowberry, marionberry, olallieberry, red raspberry, youngberry) and Other Berries (currant, elderberry, gooseberry, huckleberry, loganberry, lingonberry, juneberry, salal): the maximum application rate is 0.8 lb ai/A per application. A maximum of 3 applications are permitted per growing season at a minimum of retreatment interval of 14 days. Citrus: the maximum application rate is 1.0 lb ai/A per application. A maximum of 6 applications are permitted per growing season at a minimum of retreatment interval of 14 days. Lettuce, Cole Crops, And Other Leafy Greens (broccoli, Brussels sprouts, cabbage, cauliflower, cavalo, broccolo, collards, kale, kohlrabi, mizuna, mustard greens, spinach, rape greens): the maximum application rate is 1.0 lb ai/A per application. A maximum of 3 applications are permitted per growing season at a minimum of retreatment interval of 14 days. Ornamentals: the maximum application rate is 1.0 lb ai/A per application. A maximum of 6 applications are permitted per growing season at a minimum of retreatment interval of 21 days. Tomatoes: the maximum application rate is 1.0 lb ai/A per application. A	

Description	Amended Labeling Language	Placement on Label
	maximum of 3 applications are permitted per growing season at a minimum of retreatment interval of 14 days. Strawberries (grown as perennials only) the maximum application rate is 1.0 lb ai/A per application. A maximum of 3 applications are permitted per growing season at a minimum of retreatment interval of 14 days. Applications to strawberries grown as annuals are prohibited.	
Storage Restrictions	"This product can be fatal to children and dogs (and other domestic animals) if ingested. Dogs have been known to ingest metaldehyde after opening or tearing packaging. Store this product in its original packaging, in a cool, secure location, and out of reach of children and pets. Do not store in any location where children or domestic animals can access the packaging or the product."	Storage and Disposal