15

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

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

31 May 2001

MEMORANDUM

SUBJECT: **REVISED** RESIDENTIAL EXPOSURE ASSESSMENT AND RECOMMENDATIONS FOR THE REREGISTRATION ELIGIBILITY DECISION DOCUMENT FOR DISULFOTON

FROM: Shanna Recore, Industrial Hygienist Shanna M. Recore 5/31/01
Christina Jarvis, Environmental Protection Specialist Christina Jarvis 5/31/01
Reregistration Branch 2
Health Effects Division (7509C)

TO: Christina Scheltema
Reregistration Branch 3
Special Review and Reregistration Division (7508W)

THRU: Al Nielsen, Senior Scientist Al Nielsen 5/31/01
Reregistration Branch 2
Health Effects Division (7509C)

Please find attached the residential review of disulfoton.

DP Barcode: D275170

Pesticide Chemical Codes: 032501

EPA Reg Nos.: 4-153, 4-253, 4-420, 16-171, 192-74, 192-119, 192-126, 192-164, 239-2134, 769-908, 802-426, 869-76, 869-223, 904-138, 3125-83, 3125-116, 3125-152, 3125-517, 5887-67, 5887-171, 7401-4, 4701-26, 7401-235, 7401-323, 9404-3, 8660-125, 8660-191, 11474-17, 32802-32, 42057-51, 46260-2, 46260-12, 46260-35, 59144-23

EPA MRID No.: 453334-01

PHED: Yes, Version 1.1

# EXPOSURE AND RISK ASSESSMENT/CHARACTERIZATION

## Purpose

In this document, which is for use in EPA's development of the disulfoton Reregistration Eligibility Decision document (RED), EPA presents the results of its review of the potential human health effects of residential exposure to disulfoton. This memorandum revises the residential exposure section of the February 7, 2000 memorandum titled "Revised Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document for Disulfoton."[2] The residential exposure and risk numbers presented in this document have been revised based on a new short-term dermal endpoint, new exposure assumptions in the Residential Standard Operating Procedures (SOPs), and a new disulfoton residential handler study submitted by Bayer Corporation.

## Criteria for Conducting Exposure Assessments

An occupational and/or residential exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is complete. For disulfoton, both criteria are met.

## Summary of Toxicity Concerns Relating to Residential Exposure

### Acute Toxicology Categories

Table 1 presents the acute toxicity categories based on the active ingredient as outlined in the Hazard Identification document.[12]

**Table 1: Acute Toxicity Categories for Disulfoton**

| Guideline No. | Study Type | MRID #(S). | Results | Toxicity Category |
|---|---|---|---|---|
| 81-1 | Acute Oral | Acc# 072293 | $LD_{50}$ = M: 6.2 mg/kg; F:1.9 mg/kg | I |
| 81-2 | Acute Dermal | Acc# 07793 | $LD_{50}$ = M: 15.9 mg/kg; F: 3.6 mg/kg | I |
| 81-3 | Acute Inhalation | Acc# 258569 | $LC_{50}$ = M: 0.06 mg/L; F: 0.89 mg/L | I |
| 81-4 | Primary Eye Irritation | None | Data requirement waived. | N/A |
| 81-5 | Primary Skin Irritation | None | Data requirement waived. | N/A |
| 81-6 | Dermal Sensitization | None | Data requirement waived. | N/A |
| 81-7 | Acute Delayed Neurotoxicity | 00129384 | Equivocal. | |
| 81-8 | Acute Neurotoxicity | 42755801 | Reversible neurotoxic signs consistent with the cholinesterase inhibition 1.5 mg/kg in female rats and 5.0 mg/kg in male rats. | N/A |

N/A = Not Applicable

## Residential Endpoints of Concern

The revised Hazard Identification document for disulfoton indicates that there are toxicological endpoints of concern for residential exposure. The endpoints used in assessing the residential risks for disulfoton are presented in the following Table 2.[12]

**Table 2: Endpoints for Assessing Residential Risks for Disulfoton**

| Test | Results |
|---|---|
| Short-term Dermal Exposure (1 to 7 days) | 0.5 mg/kg/day based on plasma and brain cholinesterase inhibition in a 3-day dermal study in rats (Uncertainty Factor = 100) |
| Intermediate-term Dermal Exposure (1 week to several months) | 0.03 mg/kg/day based on plasma, red blood cell, and brain cholinesterase inhibition in a special 6 month cholinesterase inhibition feeding study in rats (Uncertainty Factor = 100) ***this study also used for the incidental soil ingestion scenario*** |
| Inhalation Exposure (All-time periods) | 0.00016 mg/L or 0.045 mg/kg/day based on plasma, red blood cell, and brain cholinesterase inhibition in a 90-day inhalation study in rats (Uncertainty Factor = 100) |
| Dermal Absorption (applied to intermediate-term dermal endpoint only) | 36% |
| Inhalation Absorption | 100% |

### FQPA Safety Factor

The FQPA Safety Factor Committee met on January 24, 2000 to re-evaluate the hazard and exposure data for disulfoton, and recommended that the FQPA safety factor be removed (1X) for disulfoton.[10] The toxicity data base is complete, including neurotoxicity studies in rats and there is no evidence of either neurotoxicity or increased susceptibility of fetuses or offspring in prenatal and postnatal studies in rabbits or rats. The 1X FQPA factor is applicable for all populations.

### Cancer Classification

The HED RfD/Peer Review classified disulfoton as a Group E chemical, meaning that it is not classifiable for carcinogenicity based on a lack of evidence in a carcinogenicity study in mice and rats at dose levels adequate to test for carcinogenicity.[12]

## SUMMARY OF USE PATTERN AND FORMULATIONS

### Homeowner Use Products

The Agency acknowledges that this assessment includes some non-occupational uses that

are no longer supported by Bayer, but may be available on the market due to production by other registrants or "existing stock" provisions. The only non-occupational uses supported by Bayer, at the time of this assessment, are those stated on the Bayer ready-to-use one percent granular label (roses, ornamental flowers, and shrubs).

**Type of pesticide/target pests**

Disulfoton, (O,O-Diethyl S-[2-(ethylthio)ethyl] phosphorodithioate) is a selective systemic organophosphate insecticide used to control a variety of sucking insects. Insects that disulfoton controls include, but are not limited to, the following:[4]

- Aphids, Birch leaf miner, Elm leaf beetle, European elm scale, Lace bug, Leafhoppers, Mites, Thrips, Whiteflies, Birch leafminers, Camellia scale, Holly leafminer, Leafhoppers, Mimosa webworm, Pine tip moth, Soft scale, Spider mites, Tea scale, Thrips and Whiteflies.

**Formulation types and percent active ingredient for residential products**

Disulfoton is formulated as a technical product (98.5 percent active ingredient) and as a residential-use granular product (two, one, and 0.37 percent active ingredient). Bayer is currently only supporting the one percent granular product. Disulfoton is often formulated in combination with fertilizers.[4]

**Registered use sites[4,7]**

**Non-occupational-use sites**

The Agency acknowledges that some non-occupational use sites listed below are not supported by Bayer; however, these sites have been included for informational purposes because they may be supported by other registrants. Potential residential and non-occupational use sites may include indoor or outdoor residential sites (e.g., exposure to insecticide use on ornamentals). The non-occupational use sites in this RED have been grouped as follows:

- **Residential Ornamental Flowers**
- 
- **Residential Ornamental Shrubs and Trees**
- **Residential Rose Bushes**
- **Residential Vegetable Gardens**
- **Residential Potted Plants**

**Residential Application Rates**[4,7]

- **Residential Ornamental Flowers**: The maximum label application rate of the granular product not supported by Bayer is 0.3 lb ai/1,000 $ft^2$. The maximum application rate for the Bayer one percent granular product is 0.21 lb ai/1000 $ft^2$. The original assessment assumed a range of rates from 0.005 lb ai/1000 $ft^2$ to 0.3 lb ai/1000 $ft^2$.

- **Residential Ornamental Shrubs and Small Trees:** The maximum label application rate for the products not supported by Bayer is 0.016 lb ai/5-inch diameter tree for the insecticidal spikes. The maximum application rate for the Bayer one percent granular product is 0.010 lb ai/four foot shrub. The original assessment assumed a range of rates from 0.000321 lb ai/four-foot shrub to 1.32 lb ai/four-foot shrub.

- **Residential Rose Bushes:** The maximum label application rate to rose bushes using the insecticidal spikes, which are not supported by Bayer, is 0.048 lb ai/bush. The maximum application rate for both the Bayer one percent granular and the non-Bayer supported granular product is 0.00125 lb ai/bush. The original assessment assumed a rate of 0.00188 lb ai/bush.

- **Residential Vegetable Gardens:** The maximum label application rate is 0.069 lb ai/1000 $ft^2$. Bayer does not support this use. The original assessment assumed a range of rates from 0.0313 lb ai/1000 $ft^2$ to 0.1125 lb ai/1000 $ft^2$.

- **Residential Potted Plants:** The maximum label application rate for hand application of granulars to pots is 0.00034 lb ai/six inch pot. The maximum application using insecticidal spikes is 0.000063 lb ai/six inch pot. Bayer does not support this use. The original assessment assumed a rate of 0.00011 lb ai/six inch pot.

**Methods and Types of Equipment Used for Loading and Applying Residential Formulations:**[4,7]

The Agency acknowledges that some methods of application listed below are not supported by Bayer; however, these application methods and equipment have been included for informational purposes.

- **Residential Ornamental Flowers:** Belly grinder and push-type spreader applications can be used for preplanting treatment, or treatments can be applied using a spoon, measuring scoop, shaker can or by hand, and then soil incorporated. Regardless of application method, the revised assessment assumes that 1000 $ft^2$ are treated per day. The original assessment assumed 10,000 $ft^2$ were

treated per day using belly grinder equipment and 1000 $ft^2$ per day using all other equipment.

- **Residential Ornamental Shrubs**: Applications are made by distributing granules uniformly under the shrub canopy using a push-type spreader, spoon, measuring scoop, shaker can or by hand and soil incorporated and then watered in. Both the revised and original assessments assumed that 25 shrubs are treated per day.

- **Residential Rose Bushes:** Belly grinder applications can be made for preplanting treatment. At planting, or to established bushes, application of granulars is made using a push-type spreader, spoon, measuring scoop, shaker can or by hand. Both the revised and original assessments assumed that 50 rose bushes are treated per day.

- **Residential Vegetable Gardens:** Belly grinder or push-type spreader applications can be made for preplanting treatment. At planting application of granulars is made using a spoon, measuring scoop, shaker can or by hand. The revised assessment assumes that 1000 $ft^2$ are treated per day. The original assessment assumed that 10,000 $ft^2$ were treated per day.

- **Residential Potted Plants:** Applications are made by hand by punching a hole into soil and pouring granules into the holes or sprinkling granules on the soil and soil incorporating. Both the revised and original assessments assumed that 20 six inch pots are treated per day.

## RESIDENTIAL RISK ASSESSMENT AND CHARACTERIZATION

### Non-Occupational Exposure Scenarios

HED has determined that residential and other non-occupational handlers are likely to be exposed during disulfoton use. The anticipated use patterns and current labeling indicate several exposure scenarios based on the types of equipment that potentially can be used to make disulfoton applications. The Agency acknowledges that some exposure scenarios listed below are not supported by Bayer; however, these exposure scenarios have been included for informational purposes. These scenarios include: (1) loading/applying granulars with a belly grinder; (2) loading/applying granulars with a push-type spreader; (3) loading/applying granulars using a spoon, measuring scoop, shaker can or by hand; (4) loading/applying Bayer Advanced Garden 2-in-1 Systemic Rose and Flower Care® Disulfoton 1% granulars by hand using a measuring cup/lid; or (5) application of insecticidal spikes. Registrants indicate that only dry formulations (i.e., only granulars or pellets/tablets/spikes) are permitted to be used around residences.

**Handler Exposure Data - Surrogate**

***PHED***

Chemical-specific data for assessing human exposures during pesticide handling activities were not submitted to the Agency in support of the reregistration of disulfoton, with the exception of a homeowner garden study (MRID 453334-01). It is the policy of HED to use data from the Pesticide Handlers Exposure Database (PHED) Version 1.1 to assess handler exposures for regulatory actions when chemical-specific monitoring data are not available.[8]

The PHED Task Force is comprised of representatives from the U.S. EPA, Health Canada, the California Department of Pesticide regulation, and member companies of the American Crop Protection Association. PHED is a software system consisting of two parts: a database of measured exposure values for workers involved in the handling of pesticides under actual field conditions and a set of computer algorithms used to subset and statistically summarize the selected data. Currently, the database contains values for over 1,700 monitored individuals (i.e., replicates).[8]

Users select criteria to subset the PHED database to reflect the exposure scenario being evaluated. The subsetting algorithms in PHED are based on the central assumption that the magnitude of handler exposures to pesticides are primarily a function of activity (e.g., mixing/loading, applying), formulation type (e.g., wettable powders, granulars), application method (e.g., aerial, groundboom), and clothing scenarios (e.g., gloves, double layer clothing).[8]

Once the data for a given exposure scenario have been selected, the data are normalized (i.e., divided by) by the amount of pesticide handled resulting in standard unit exposures (milligrams of exposure per pound of active ingredient handled). Following normalization, the data are statistically summarized. The distribution of exposure values for each body part (e.g., chest upper arm) is categorized as normal, lognormal, or "other" (i.e., neither normal nor lognormal). A central tendency value is then selected from the distribution of the exposure values for each body part. These values are the arithmetic mean for normal distributions, the geometric mean for lognormal distributions, and the median for all "other" distributions. Once selected, the central tendency values for each body part are composited into a "best fit" exposure value representing the entire body.[8]

The unit exposure values calculated by PHED generally range from the geometric mean to the median of the selected data set. While data from PHED provide the best available information on handler exposures, it should be noted that some aspects of the included studies (e.g., duration, acres treated, pounds of active ingredient handled) may not accurately represent labeled uses in all cases. HED has developed a series of tables of standard unit exposure values for many occupational scenarios that can be utilized to ensure consistency in exposure assessments.[8]

In the revised assessment, PHED data are used to assess exposure from loading/applying granulars with a belly grinder. In the original assessment, PHED data were used to assess exposure from loading/applying granulars with belly grinder and push-type spreader equipment, and from loading/applying granulars by hand using a spoon, shaker can, or measuring scoop.

***ORETF***

Some of the handler exposure data used in this assessment are from the Outdoor Residential Exposure Task Force (ORETF). The task force recently submitted proprietary data to the Agency on hose-end sprayers, push-type granular spreaders, and handgun sprayers (MRID # 44972201). The ORETF data were used in this assessment in place of PHED data for the "loading/applying granulars using a push-type spreader" scenario. The ORETF data were designed to replace the present PHED data with higher-confidence, higher quality data that contains more replicates than the PHED data for those scenarios.[1]

***Other***

Handler exposure data from a proprietary granular mixer/loader/applicator study (MRID 452507-02) in bananas using fipronil (Regent 20GR) were used in place of PHED data for the "loading/applying granulars using a spoon, measuring scoop, shaker can or by hand" scenario. This fipronil study is considered to be an appropriate source of surrogate handler exposure data for disulfoton because formulation types are similar (granular) and application methods are similar (applying granulars with a spoon). The study is considered to be of sufficient quality for use in risk assessment.[3]

Several factors should be considered when using fipronil data in the disulfoton exposure assessment. Protection factors used to calculate disulfoton dermal unit exposure values, based on the fipronil unit exposure values, include a standard 50% protection factor for the torso, a 10% protection factor for legs, based on shorts, and a 10% protection factor for arms, based on a short-sleeved shirt. These protection factors represent the typical attire assumed to be worn by a homeowner during pesticide application (shorts and short-sleeved shirt). The 10% protection factor for shorts and the 10% protection factor for a short-sleeved shirt are not standard protection factors used by the Agency; rather, these values are based on the best professional judgement of Agency scientists and are appropriate for calculating range-finding estimates only.

Some other issues and limitations to be considered when using the fipronil study include the following:

- Agency guidelines require that 15 replicates be completed in exposure studies in three different locations. In the fipronil study, only ten replicates were completed using spoons, and at only one location. However, the events that were monitored seemed to be reasonable representations of actual agricultural practices, so it is unlikely that additional replicates would significantly alter the final unit exposure results. Additionally, it is

unlikely that cultural practices would significantly vary if the study was completed at different locations.

- The individual amounts of chemical applied were not recorded in this study. Instead, the investigators determined how much product was applied by the application teams used. Using this information, the investigators calculated the amount used for each individual by assuming that each was equally productive (i.e., dividing the total amount used per team by the number of team members).

- One applicator using the spoons had a spoon with no handle. The results for this individual were included with the other spoon applicators as it is a plausible variation of that application method.

The Agency notes that the geometric mean unit exposure value for spoon applications of fipronil was used for disulfoton risk assessment purposes.

**Handler Exposure Data - Chemical-Specific Data**

*Review of MRID # 453334-01:*
*Disulfoton 1% Granular Residential Applicator Exposure and Risk Estimates*[5]

In support of the reregistration of disulfoton Bayer Corporation submitted a study estimating handler exposures. The purpose of this study was to quantify potential dermal (forearm and hand) and inhalation exposure for residential applicators of Bayer Advanced Garden 2-in-1 Systemic Rose and Flower Care®, a granular formulation, which contains 1.04 percent disulfoton as the active ingredient. The maximum application rate for flower beds (4 ounces formulated product per 12 square feet) and for shrubs (4 ounces formulated product per 1 foot shrub height) was used in this study.

A total of 15 volunteers were monitored using passive dosimetry (hand/forearm wash solutions and personal air monitors). Application of the product was made by pouring the granules into the measuring cup/lid attached to the product package, and then distributing the granules onto the soil around the base of a shrub or onto a flower bed. The granules were then soil-incorporated with a garden rake. A total of 30 replicates were reported. The test site was a fallow test field, approximately 1 acre in size. Two sets of sub-plots were established: (1) shrub test-plots, each containing 10 oleander shrubs (approximately 48 inches high); and (2) flower-bed sub-plots, each containing simulated plants, (e.g., 12 to 14 inch high stakes placed on approximately 24 inch centers).

All of the inhalation exposure data were either non-detect or less than the limit of quantitation (LOQ = 0.3 µg). Most of the hand/forearm dermal washing samples returned results greater than the LOQ.

The study was conducted in compliance with the major technical aspects of OPPTS Group A: 875.1300, Inhalation Exposure -- Outdoor and 875.1100, Dermal Exposure -- Outdoor, and Series 875 Group B, Part C, as they relate to this study. Reviewers noted the following deficiency:

- EPA provided the registrant with comments on study outlines submitted to the Agency. The following comment was not fully addressed in the conduct of the study, as both real plants and simulated plants were used:

  Use of Simulated Plants: The Agency prefers that the study use real plants because it is difficult, if not impossible, to tell how closely the "simulated" plant environment reflects what is actually encountered by a homeowner. If the registrant could not find a study site with enough roses or shrubs to treat, the Agency recommended that the study at least include a subset of real plants in established beds to compare the "real" and the "simulated" plants.

Data from this study were used in place of PHED data for estimating residential handler exposure and risk from applying Bayer Advanced 2-in-1 Systemic Rose and Flower Care® to roses, flowerbeds, and shrubs by hand. The geometric mean unit exposure value was used for risk assessment purposes.

**Non-Occupational Handler Exposure Scenario Data and Assumptions**

Residential handler exposure assessments were completed by HED using a baseline exposure scenario. PHED values used to estimate daily unit exposure values were taken from the *Standard Operating Procedures (SOPs) for Residential Exposure Assessments* and the "Recommended Revisions to the Standard Operating Procedures for Residential Exposure Assessments" Science Advisory Council for Exposure Policy #12.[6,11] Table 3 summarizes the caveats and parameters specific to the surrogate data used for each scenario and corresponding exposure/risk assessment. The following assumptions and factors were used in order to complete this exposure assessment:

- Calculations are completed at the maximum application rates recommended by the available disulfoton labels to indicate worst-case risk levels associated with the various use patterns. Application rates and exposure values were calculated separately for Bayer 1% granular product labels.

- Generally, the use of PPE and engineering controls are not considered acceptable options for products sold for use by homeowners because they are not available, and/or inappropriate for the exposure scenario.

- PHED values represent a handler wearing typical residential clothing attire of short sleeve shirt, short pants, socks, shoes, and no gloves.

- The number of rose bushes assumed for treatment per day by a homeowner is 50 rose bushes.

- The number of pots assumed for treatment per day by a homeowner is 20 six-inch pots.

- The number of ornamental shrubs or trees assumed for treatment per day by a homeowner is 25 shrubs.

- The area treated with granulars for flower or vegetable gardens by a homeowner is assumed to be 1,000 $ft^2$. For pre-planting treatment of flower and vegetable gardens with a belly grinder or push-type spreader, the treatment area is assumed to be 1,000 $ft^2$.

- A respiratory rate of 16.7 L/min was assumed, based on the draft NAFTA recommended inhalation rates.

**Non-occupational Handler Exposure and Risk Estimates**

The calculations of daily dermal and inhalation exposure, short-term doses, and total short-term MOEs were made using the following formulae.[8]

Potential daily dermal exposure is calculated using the following formula:

$$Daily\ Dermal\ Exposure\left(\frac{mg\ ai}{day}\right) = Unit\ Exposure\left(\frac{mg\ ai}{lb\ ai}\right) \times Use\ Rate\left(\frac{lb\ ai}{A}\right) \times Daily\ Acres\ Treated\left(\frac{A}{day}\right)$$

The potential short-term dermal doses were calculated using the following formulae:

$$Short\text{-}term\ Daily\ Dermal\ Dose\left(\frac{mg\ ai}{kg/day}\right) = Short\text{-}term\ Daily\ Dermal\ Exposure\left(\frac{mg\ ai}{day}\right) \times \left(\frac{1}{Body\ Weight\ (kg)}\right)$$

The short-term MOEs were calculated using a NOAEL of 0.5 mg/kg/day. The previous assessment used a short-term dermal NOAEL of 0.4 mg/kg/day from a dermal rabbit study. The intermediate-term MOEs were calculated using a NOAEL of 0.03 mg/kg/day assuming 36 percent dermal absorption and 70 kg body weight.

Potential daily inhalation exposure was calculated using the following formula:

$$\text{Daily Inhalation Exposure}\left(\frac{mg\ ai}{day}\right) =$$
$$\text{Unit Exposure}\left(\frac{\mu g\ ai}{lb\ ai}\right) \times \text{Conversion Factor}\left(\frac{1\ mg}{1{,}000\ \mu g}\right) \times \text{Use Rate}\left(\frac{lb\ ai}{A}\right) \times \text{Daily Acres Treated}\left(\frac{A}{day}\right)$$

The potential short-term inhalation doses were calculated using the following formulae:

$$\text{Short-term Daily Inhalation Dose}\left(\frac{mg\ ai}{kg/day}\right) = \text{Short-term Daily Inhalation Exposure}\left(\frac{mg\ ai}{day}\right) \times \left(\frac{1}{\text{Body Weight (kg)}}\right)$$

For disulfoton, the inhalation doses were calculated using a 70 kg body weight and an inhalation absorption rate of 100 percent.

Table 4 presents residential dermal and inhalation exposures associated with the handling of disulfoton. Table 5 presents the short-term dermal and inhalation risks as well as total MOEs resulting from those exposures. The Agency only assessed for short-term non-occupational (residential) risks and not intermediate-term non-occupational (residential) risks since it is assumed that handlers will be exposed less than seven days at a time. The Agency acknowledges that some exposure scenarios presented in the following tables may not be supported by Bayer; however, they may be supported by other registrants.

**Summary of Concerns for Non-occupational Handlers, Data Gaps, and Confidence in Exposure and Risk Estimates**

Short-term dermal and inhalation risks for homeowner-handlers were assessed as well as the total risks associated with the handling of disulfoton.

**Handler Scenarios with Risk Concerns**

The calculations of short-term dermal and inhalation risks indicate that the following **total short-term MOEs** are **greater than 100** at baseline:

(2) loading/applying granulars using a push-type spreader

(3) loading/applying granulars using a spoon, measuring scoop, shaker can, or by hand for application to vegetable gardens, potted plants, and roses.

The calculations of short-term dermal and inhalation risks indicate that the following **total short-term MOEs** are **less than 100** at baseline:

(1) loading/applying granulars with a belly grinder for flower and vegetable gardens (pre-planting) using an application rate of 0.3 lb ai/1000 $ft^2$ (flower gardens, MOE = 1.1) and 0.069 lb

ai/1000 $ft^2$ (vegetable gardens, MOE = 4.6).

(3) loading/applying granulars, using a spoon, measuring scoop, shaker can or by hand, to flower gardens and ornamental shrubs/small trees using an application rate of 0.3 lb ai/1000 $ft^2$ (flower gardens, MOE = 34) and 0.01 lb ai/ four foot shrub (shrubs/small trees, MOE = 41).

The calculations of short-term dermal and inhalation risks indicate that all **total short-term MOEs** are **greater than 100** at baseline for Bayer's Advanced Garden 2-in-1 Systemic Rose and Flower Care®:

(4) loading/applying granulars using a measuring cup/lid at an application rate of 0.21 lb ai/1000 $ft^2$ (flowerbeds, MOE = 5500), 0.01 lb ai/four foot shrub (shrubs, MOE = 1500), and 0.0013 lb ai/bush (rosebushes, MOE = 5800).

The Agency notes that the Advanced Garden 2-in-1 product is the only homeowner product that Bayer intends to support. Residential risks from the use of this product are not of concern.

**Data Gaps**

Data gaps exist for the following scenario:

(5) applying insecticidal spikes to rose bushes, or ornamental shrubs and trees.

**Data Quality and Confidence in Assessment**

Several issues must be considered when interpreting the non-occupational exposure risks

- Factors used to calculate daily exposures to handlers (e.g. square footage treated per day, number of pots treated and number of shrubs or trees treated in a day) are based on the best professional judgement due to a lack of pertinent data.

**Non-occupational Postapplication Scenarios**

HED has determined that there are potential postapplication exposures to residents based on the following scenarios:

- transplanting, hoeing, and weeding treated ornamental shrubs and trees (including rose bushes);
- transplanting, hoeing, and weeding treated ornamental flowers;

- non-harvest activities such as weeding and hoeing of home vegetable crops;
- incidental granular ingestion; and
- incidental soil ingestion.

**Data Source Descriptions for Scenarios Considered**

A surrogate postapplication exposure assessment was conducted to determine potential risks for incidental soil ingestion. Other postapplication scenarios were not assessed because disulfoton granulars and insecticidal spikes are applied directly to the soil and EPA has no data upon which to base postapplication contact with treated soil through activities such as weeding, hoeing, and transplanting home ornamentals and vegetable crops or houseplants. Furthermore, it is HED's policy to routinely conduct screening level assessments (based on standard values in the Residential SOPs) for children's incidental ingestion of granules when a granular pesticide may be applied in residential settings; however, the Agency has no data upon which to base this postapplication scenario. The Agency requests information on particle density (number of particles per pound or gram), carrier type, granular color, and average granular size in order to conduct an exposure assessment for this scenario.

**Assumptions Used in Postapplication Exposure Calculations**

The assumptions used in the calculations for residential postapplication risks include the following items:

- The oral NOAEL of 0.03 mg/kg/day from the six-month feeding study in rats was used in the assessment.
- On the day of application, it was assumed that 20 percent of the application rate is located with the soil's uppermost 1 cm. The *Residential SOP's* specify a 100 percent assumption; however after disulfoton treatment followed by soil incorporation, the insecticide should be uniformly dispersed into the top 2 inches of soil.[6]
- The soil ingestion rate for children (ages 1-6 years) was assumed to be 100 mg/day.
- Application rates used in the residential assessment are described in a previous section.
- Toddlers (3 years old) used to represent the 1 to 6 year old age group, were

assumed to weigh 15 kg.

- Postapplication was assessed on the same day the pesticide is applied because it was assumed that the toddler could be exposed to soil immediately after application. Therefore, postapplication exposures were based on day 0.

**Postapplication Exposure and Risk Estimates**

Table 6 presents the postapplication risks from the incidental soil ingestion by toddlers of soil treated with disulfoton. The following equations were used:

Incidental Soil Ingestion:

$$ADD = (SR_t * IgR * CF1) / BW$$

where:

| | | |
|---|---|---|
| ADD | = | average daily dose (mg/kg/day) |
| $SR_t$ | = | soil residue on day "t" (µg/g), assuming average day of reentry "t" is day 0 |
| IgR | = | ingestion rate of soil (mg/day), assumed to be 100 mg/day |
| CF1 | = | weight unit conversion factor to convert the µg of residues on the soil to grams to provide units of mg/day (1E-6 g/µg) |
| BW | = | body weight (kg), assumed 15 kg for toddlers |

and

$$SR_t = AR * F * (1-D)^t * CF2 * CF3 * CF4$$

where:

| | | |
|---|---|---|
| AR | = | application rate (lb ai/acre) |
| F | = | fraction of ai available in uppermost cm of soil (fraction/cm), assumed to be 20 percent based on soil incorporation into top 2 inches of soil after application |
| D | = | fraction of residue that dissipates daily (unitless) |
| t | = | postapplication day on which exposure is being assessed |
| CF2 | = | weight unit conversion factor to convert the lbs ai in the application rate to µg for the soil residue value (4.54E8 µg/lb) |
| CF3 | = | area unit conversion factor to convert the surface area units ($ft^2$) in the application rate to $cm^2$ for the SR value (2.47E-8 acre/$cm^2$ if the application rate is per acre) |
| CF4 | = | volume to weight unit conversion factor to convert the volume units ($cm^3$) to weight units for the SR value (0.67 $cm^3$/g soil)[7] |
| t | = | postapplication day on which exposure is being assessed, assumed to be day 0 |

**Summary of Residential Postapplication Risks**

The target residential MOE is 100 for disulfoton. The resulting surrogate residential postapplication assessment for toddlers indicates that the disulfoton MOEs for incidental soil ingestion are greater than 100 for flower garden soil and vegetable garden soil (application rates 13 lbs ai/A and 3 lbs ai/A, respectively).

**Data Gaps**

Data gaps exist for the following scenarios:

- transplanting, hoeing, and weeding treated ornamental shrubs and trees (including rose bushes);
- transplanting, hoeing, and weeding treated ornamental flowers;
- non-harvest activities such as weeding and hoeing of home vegetable crops;
- incidental granular ingestion (information on particle density, carrier type, granular color, and average granular size)

## Table 3. Residential Exposure Scenario Descriptions for the Use of Disulfoton

| Exposure Scenario (Scenario #) | Data Source | Comments[a] | Standard Assumptions[6,11] |
|---|---|---|---|
| Loading/applying granulars using a belly grinder (1) | PHED V1.1 | **Baseline:** Dermal and hands data = ABC grades, inhalation = AB grade. Dermal 20-45 replicates; hands = 23 replicates; and inhalation = 40 replicates. Medium confidence for hands and dermal, and high confidence for inhalation.<br><br>**PPE and Engineering Controls**: Not required for assessment. | 1,000 $ft^2$ for pre-planting of flower/vegetable gardens per day |
| Loading/applying granulars using a push-type spreader (2) | Summary of HED's Reviews of Outdoor Residential Exposure Task Force (ORETF) Chemical Handler Exposure Studies; MRID 449722-01. April 30, 2001. | **Baseline:** Dermal, hands, and inhalation data = A/B grade. Dermal, hands, and inhalation data = 30 replicates. High confidence in all data.<br><br>**PPE and Engineering Controls**: Not required for assessment. | 1,000 $ft^2$ for pre-planting of flower/vegetable gardens and 25 shrubs per day |
| Loading/applying granulars using a spoon, measuring scoop, shaker can or by hand (3) | Review of fipronil granular mixer/loader/applicator study as a source of surrogate data, MRID 452507-01. J. Dawson memo, D270065, 1/5/01. | **Baseline:** A 90% protection factor was applied to gloved hands data to backcalculate "no glove" hand exposure. A standard 50% protection factor was used for the torso. A 10% protection factor was used to represent the protection afforded by shorts and a short-sleeved shirt.<br><br>**PPE and Engineering Controls**: Not required for assessment. | 1,000 $ft^2$ for pre-planting of flower/vegetable gardens, 25 shrubs, and 50 rose bushes per day |
| Loading/applying Bayer Advanced Garden 2-in-1 Systemic Rose and Flower Care® Disulfoton 1% granulars using a measuring cup/lid (4) | Disulfoton 1% Granular Residential Applicator Exposure and Risk Estimates: Report Number: 110137[5] | | 25 shrubs and 50 rose bushes per day |
| Application of insecticidal spikes (5) | NA | NA | NA |

[a] "Best Available" grades are defined by HED SOP for meeting Subdivision U Guidelines. Best available grades are assigned as follows: matrices with grades A and B data and a minimum of 15 replicates; if not available, then grades A, B and C data and a minimum of 15 replicates; if not available, then all data regardless of the quality and number of replicates. Data confidence are assigned as follows:

High = grades A and B and 15 or more replicates per body part
Medium = grades A, B, and C and 15 or more replicates per body part
Low = grades A, B, C, D and E or any combination of grades with less than 15 replicates

NA = Not Applicable

**Table 4: Residential Handler Dermal and Inhalation Exposures to Disulfoton at Baseline**

| Exposure Scenario (Scenario #) | Baseline Dermal Unit Exposure (mg/lb ai)[a] | Baseline Inhalation Unit Exposure (µg/lb ai)[b] | Maximum Application Rate[c] | Crop Type or Target[d] | Amount Handled Per Day[e] | Daily Dermal Exposure (mg/day)[f] | Daily Inhalation Exposure (mg/day)[g] |
|---|---|---|---|---|---|---|---|
| **Mixer/Loader/Applicator Exposure** | | | | | | | |
| Loading/applying granulars using a belly grinder (1) | 110 | 62 | 0.3 lb ai/1000 ft$^2$ | Flower Gardens (pre-planting) | 1,000 ft$^2$ | 33 | 0.019 |
| | | | 0.069 lb ai/1000 ft$^2$ | Vegetable Gardens (pre-planting) | 1,000 ft$^2$ | 7.8 | 0.0043 |
| Loading/applying granulars using a push-type spreader (2) | 0.68 | 0.91 | 0.069 lb ai/1000 ft$^2$ | Vegetable Gardens | 1,000 ft$^2$ | 0.047 | 6.3E-5 |
| | | | 0.3 lb ai/1000 ft$^2$ | Flower Gardens | 1,000 ft$^2$ | 0.20 | 2.7E-4 |
| | | | 0.01 lb ai/4 ft shrub | Ornamental Shrubs | 25 shrubs | 0.17 | 2.3E-4 |
| | | | 0.0013 lb ai/bush | Roses | 50 bushes | 0.043 | 5.7E-4 |

**Table 4: Residential Handler Dermal and Inhalation Exposures to Disulfoton at Baseline (continued)**

| Exposure Scenario (Scenario #) | Baseline Dermal Unit Exposure (mg/lb ai)[a] | Baseline Inhalation Unit Exposure (µg/lb ai)[b] | Maximum Application Rate | Crop Type or Target[d] | Amount Handled Per Day[e] | Daily Dermal Exposure (mg/day)[f] | Daily Inhalation Exposure (mg/day)[g] |
|---|---|---|---|---|---|---|---|
| Loading/applying granulars using a spoon, measuring scoop, shaker can or by hand (3) | 3.5 | 0.045 | 0.069 lb ai/1,000 $ft^2$ | Vegetable Gardens | 1,000 $ft^2$ | 0.24 | 3.1E-6 |
| | | | 0.3 lb ai/1000 $ft^2$ | Flower Gardens | 1,000 $ft^2$ | 1.04 | 1.4E-5 |
| | | | 0.01 lb ai/4 ft shrub | Ornamental Shrubs | 25 shrubs | 0.86 | 1.1E-5 |
| | | | 0.00034 lb ai/6" pot | Potted Plant | 20 pots | 0.023 | 3.0E-7 |
| | | | 0.0013 lb ai/bush | Roses | 50 bushes | 0.22 | 2.8E-6 |
| Loading/applying Bayer Advanced Garden 2-in-1 Systemic Rose and Flower Care® Disulfoton 1% granulars using a measuring cup/lid (4) | 0.03 | 0.013 | 0.21 lb ai/1000 $ft^2$ | Flowerbeds | 1,000 $ft^2$ | 0.0063 | 2.7E-6 |
| | 0.092 | 0.013 | 0.01 lb ai/4 ft. bush | Shrubs | 25 | 0.023 | 3.3E-6 |
| | 0.092 | 0.013 | 0.0013 lb ai/bush | Roses | 50 bushes | 0.0060 | 8.5E-7 |
| Application of insecticidal spikes (5) | No Data | No Data | No Data | No Data | No Data | No Data | No Data |

## Table 4: Residential Handler Dermal and Inhalation Exposures to Disulfoton at Baseline (continued)

Footnotes:

[a] Baseline Dermal Unit Exposure represents short pants, short sleeved shirt, no gloves, and open mixing/loading.
[b] Baseline Inhalation Exposure represents no respirator.
[c] Application Rates are maximum rate values found on disulfoton labels (EPA Reg. No. 4-153, 3125-517, 7401-323, 8660-191, 9404-3, 46260-2, 46260-12, 46260-35).
[d] Crop Type or Target provides a general description of the intended uses of disulfoton. Separate categories are presented because of the distinct differences in application rates and amount handled.
[e] Daily Amount Handled values are default estimates from Exposure SAC Policy 12, or the best professional judgement of square footage, or number of bushes, shrubs, or pots that could be treated in a single day for each exposure scenario. [12]
[f] Daily Dermal Exposure (mg/day) = Unit Exposure (mg/lb ai) * Appl. rate * Amount Handled per day.
[g] Daily Inhalation Exposure (mg/day) = Unit Exposure (µg/lb ai) * (1mg/1000 µg) Conversion * Application Rate (lb ai/A) * Acres treated (acres/day).
[h] Residential application of disulfoton using a belly grinder are applicable for pre-plant treatment applications only.
[I] Unit exposure data for application of granules by hand were used as surrogate values for these scenarios.
[j] Application rates for small vegetable gardens are based on 38-inch row spacing (EPA Reg. No. 7401-323).

## Table 5: Residential Handler Short-term Risks from Disulfoton at Baseline

| Exposure Scenario (Scenario #) | Crop Type or Target[a] | Amount Handled Per Day[b] | Maximum Application Rate | Baseline Dermal | | Baseline Inhalation | | Baseline Total |
|---|---|---|---|---|---|---|---|---|
| | | | | Daily Dose (mg/kg/day)[c] | Short-term MOE[d] | Daily Dose (mg/kg/day)[e] | Short-term MOE[f] | Short-term MOE[g] |
| **Mixer/Loader/Applicator Risks** | | | | | | | | |
| Loading/applying granulars using a belly grinder (1) | Flower Gardens (pre-planting) | 1,000 $ft^2$ | 0.3 lb ai/1000 $ft^2$ | 0.47 | 1.1 | 2.7E-4 | 170 | 1.1 |
| | Vegetable Gardens (pre-planting) | 1,000 $ft^2$ | 0.069 lb ai/1000 $ft^2$ | 0.11 | 4.6 | 6.1E-5 | 740 | 4.6 |
| Loading/applying granulars using a push-type spreader (2) | Vegetable Gardens | 1,000 $ft^2$ | 0.069 lb ai/1,000 $ft^2$ [h] | 6.7E-4 | 750 | 1.0E-6 | 5.0E4 | 740 |
| | Flower Gardens | 1,000 $ft^2$ | 0.3 lb ai/1,000 $ft^2$ | 0.0029 | 172 | 4.0E-6 | 1.2E4 | 170 |
| | Ornamental Shrubs/ Small Trees | 25 shrubs | 0.01 lb ai/4 ft. shrub | 0.0024 | 210 | 3.0E-6 | 1.4E4 | 200 |
| | Roses | 50 bushes | 0.00126 lb ai/bush | 6.1E-4 | 820 | 1.0E-6 | 5.5E4 | 810 |

**Table 5: Residential Handler Short-term Risks from Disulfoton at Baseline (continued)**

| Exposure Scenario (Scenario #) | Crop Type or Target[a] | Amount Handled Per Day[b] | Maximum Application Rate | Baseline Dermal | | Baseline Inhalation | | Baseline Total |
|---|---|---|---|---|---|---|---|---|
| | | | | Daily Dose (mg/kg/day) | Short-term MOE[d] | Daily Dose (mg/kg/day)[e] | Short-term MOE[f] | Short-term MOE[g] |
| **Mixer/Loader/Applicator Risks** | | | | | | | | |
| Loading/applying granulars using a spoon, measuring scoop, shaker can or by hand (3) | Vegetable Gardens | 1,000 $ft^2$ | 0.069 lb ai/1,000 $ft^2$ [h] | 0.0034 | 150 | 4.4E-8 | 1.0E6 | 150 |
| | Flower Gardens | 1,000 $ft^2$ | 0.3 lb ai/1,000 $ft^2$ | 0.015 | 34 | 1.9E-7 | 2.3E5 | 34 |
| | Ornamental Shrubs/ Small Trees | 25 shrubs | 0.01 lb ai/4 ft. shrub | 0.012 | 41 | 1.6E-7 | 2.8E5 | 41 |
| | Potted Plants | 20 pots | 0.00034 lb ai/6" pot | 3.3E-4 | 1500 | 4E-9 | 1.0E7 | 1500 |
| | Roses | 50 bushes | 0.00126 lb ai/bush | 0.0031 | 160 | 4.1E-8 | 1.1E6 | 160 |

## Table 5: Residential Handler Short-term Risks from Disulfoton at Baseline (continued)

| Exposure Scenario (Scenario #) | Crop Type or Target[a] | Amount Handled Per Day[b] | Maximum Application Rate | Baseline Dermal | | Baseline Inhalation | | Baseline Total |
|---|---|---|---|---|---|---|---|---|
| | | | | Daily Dose (mg/kg/day) | Short-term MOE[d] | Daily Dose (mg/kg/day)[e] | Short-term MOE[f] | Short-term MOE[g] |
| **Mixer/Loader/Applicator Risks** | | | | | | | | |
| Loading/applying Bayer Advanced Garden 2-in-1 Systemic Rose and Flower Care® Disulfoton 1% granulars using a measuring cup/lid (4) | Flowerbeds | 1000 $ft^2$ | 0.21 lb ai/1000 $ft^2$ | 9.0E-5 | 5600 | 3.9E-8 | 1.2E6 | 5500 |
| | Shrubs | 25 shrubs | 0.01 lb ai/4 ft shrub | 3.3E-4 | 1500 | 4.6E-8 | 9.7E5 | 1500 |
| | Roses | 50 bushes | 0.0013 lb ai/bush | 9.0E-5 | 5900 | 1.2E-8 | 3.7E6 | 5800 |
| Application of insecticidal spikes (5) | Roses/Trees | No Data | No Data | No Data | No Data | No Data | No Data | No Data |

Footnotes:

[a] Crop Type or Target provides a general description of the intended use of various products containing disulfoton. Separate categories are presented because of the distinct differences in application rates and acres treated.
[b] Amount Handled Per Day values are from default estimates of square footage or number of bushes, shrubs, or pots treated a single day for each exposure scenario of concern.
[c] Daily Dermal Dose (mg/kg/day) = Daily Dermal Exposure (mg/day)/ Body weight (70 kg).
[d] Short-term Dermal MOE = NOAEL (0.5 mg/kg/day)/ Daily Dermal Dose (mg/kg/day).
[e] Daily Inhalation Dose (mg/kg/day) = Daily Inhalation Exposure (mg/day)/ Body weight (70 kg).
[f] Short-term Inhalation MOE = NOAEL (0.045 mg/kg/day)/ Daily Inhalation Dose (mg/kg/day).
[g] Total Short-term MOE = 1/ [(1/ Short-term Dermal MOE) + (1/ Short-term Inhalation MOE)].
[h] Application rates for small vegetable gardens are based on 38-inch row spacing (EPA Reg No. 7401-323).

## Table 6. Residential Post-application Risks from Incidental Soil Ingestion of Disulfoton

| Scenario | Receptor | Application Rate Per Treatment (AR) (lbs ai/A)[a] | Srt (µg/g)[b] | IgR (mg/day) | BW (kg) | ADD (mg/kg/day) | MOE[d] |
|---|---|---|---|---|---|---|---|
| Incidental soil ingestion (flowerbeds) | Toddler | 13 | 20 | 100 | 15 | 0.00013 | 230 |
| Incidental soil ingestion (vegetable garden beds) | Toddler | 3 | 4.5 | 100 | 15 | 0.00003 | 1000 |

Footnotes:

a Application rate for flower and vegetable gardens
b Soil residue (ug/g) = [AR (lbs ai/A) * 4.54E+8 ug/lb * 2.47E-8 A/cm$^2$ * 0.67 cm$^3$/g soil * 0.2/cm].
c Average daily dose (ADD) (mg/kg/day) = [SRt (ug/g) * IgR (mg/day) * g/1,000,000 ug] / [BW (kg)].
d MOE = NOAEL (0.03 mg/kg/day) / ADD.

**References**

1) Bangs, G. (2001) Summary of HED's Reviews of Outdoor Residential Exposure Task Force (ORETF) Chemical Handler Exposure Studies; MRID 449722-01. Memorandum from Gary Bangs (HED) to Demson Fuller (Special Review and Reregistration Division), April 30, 2001.

2) Becker, J. (2000) Revised Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document for Disulfoton. Washington, D.C.: U.S. Environmental Protection Agency, Office of Pesticide Programs. February 7, 2000.

3) Dawson, J. (2001) Ethoprop. Review of fipronil granular mixer/loader/applicator study (MRID 452507-01) in bananas as a source of surrogate data and accompanying ethoprop risk assessment Washington, D.C.: U.S. Environmental Protection Agency, Office of Pesticide Programs. January 5, 2001.

4) Disulfoton Labels (4-153, 4-420, 16-171, 192-74, 192-119, 192-126, 192-164, 239-2134, 769-908, 802-426, 869-76, 869-223, 904-138, 3125-83, 3125-116, 3125-152, 3125-152, 3125-517, 5887-67, 5887-171, 7401-4, 4701-26, 7401-235, 7401-323, 9404-3, 8660-125, 8660-191, 11474-17, 32802-32, 42057-51, 46260-2, 46260-35, 59144-23).

5) Merricks, D. Larry. (2001) Determination of Dermal (Hand and Forearm) and Inhalation Exposure to Disulfoton Resulting from Residential Application of Bayer Advanced Garden 2-in-1Systemic Rose and Flower Care to Shrubs and Flower Beds. MRID # 45333401. February 8, 2001.

6) U.S. EPA (1997) Standard Operating Procedures (SOPs) for Residential Exposure Assessments, draft report. Washington, D.C.: U.S. Environmental Protection Agency, Office of Pesticide Programs. December 18, 1997.

7) U.S. EPA (1998) Disulfoton LUIS Table for Exposure Assessors (PRD report dated 11/06/96 and report run date 02/04/98).

8) U.S. EPA (1998) PHED Surrogate Exposure Guide, Version 1.1. Washington, D.C.: U.S. Environmental Protection Agency, Office of Pesticide Programs. August 1991.

9) U.S. EPA (1999) Use of Values from the PHED Surrogate Table and Chemical-Specific Data, Science Advisory Council for Exposure Policy No. 7. Washington, D.C.: U.S. Environmental Protection Agency, Office of Pesticide Programs. January 28, 1999.

10) U.S. EPA (2000) Disulfoton. Report of the FQPA Committee. Washington, D.C.: U.S.

Environmental Protection Agency, Office of Pesticide Programs. February 10, 2000

11) U.S. EPA (2001) Recommended Revisions to the Standard Operating Procedures (SOPs) for Residential Exposure Assessments, Science Advisory Council for Exposure Policy No. 12. Washington, D.C.: U.S. Environmental Protection Agency, Office of Pesticide Programs. February 22, 2001.

12) U.S. EPA (2001) Disulfoton: Revised (3rd) Report of Hazard Identification Assessment Review Committee. Washington, D.C.: U.S. Environmental Protection Agency, Office of Pesticide Programs. April 10, 2001.

cc: David Anderson, OPP/HED/RRB2
OREB Files