# *Beauveria bassiana* strains 447 (PC Code 128815) ATCC 74040 (PC Code 128818) GHA (PC Code 128924) and HF23 (PC Code 090305)

Summary Document
Registration Review: Initial Docket
September 2010
Case 6057

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**PRELIMINARY WORK PLAN**

## Introduction

The Food Quality Protection Act (FQPA) of 1996 mandated the continuous review of existing pesticides. All pesticides distributed or sold in the United States must generally be registered by EPA, based on scientific data showing that they will not cause unreasonable risks to human health or the environment when used as directed on the product labeling. The registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the Agency periodically reevaluates pesticides to make sure that as change occurs, products in the marketplace can continue to be used safely. Information on this program is provided at: http://www.epa.gov/oppsrrd1/registration_review/.

The Agency has implemented the registration review program pursuant to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Section 3(g) and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration. The Agency will consider benefits information and data as required by FIFRA. The public phase of registration review begins when the initial docket is opened for each case. The docket is the Agency's opportunity to state what it knows about the pesticide and what additional risk analyses and data or information it believes are needed to make a registration review decision. After reviewing and responding to comments and data received in the docket during this comment period, the Agency will develop and commit to a final work plan and schedule for the registration review of *Beauveria bassiana.*

Four naturally occurring strains of *Beauveria bassiana*, as listed below and in Table 1, are registered for use as microbial pesticides under FIFRA Section 3(c). These fungal active ingredients are insect pathogens (entomopathogenic). They were all registered after 1984, and, therefore, not subject to reregistration.

1. *Beauveria bassiana* strain 447 (PC Code 128815) – referred to as 447
2. *Beauveria bassiana* ATCC 74040 (PC Code 128818) – referred to as ATCC 74040
3. *Beauveria bassiana* GHA (PC Code 128924) – referred to as GHA
4. *Beauveria bassiana* HF23 (PC Code 090305) – referred to as HF23

This Summary Document contains the Preliminary Work Plan (PWP) for these active ingredients registered in the Biopesticides and Pollution Prevention Division (BPPD). No new Fact Sheets are included in this Summary Document because the Agency is relying on previous Technical Documents and Biopesticide Registration Action Documents (BRADs) that were issued in connection with the registration and conditional registrations and amendments of the pesticides involved in this case. BRADs were developed previously for 447 and HF23 and are, respectively, available in this docket and on the BPPD website *http://www.epa.gov/pesticides/biopesticides.* Also on the BPPD website are previously issued Technical Documents for ATCC 74040 and GHA. These available documents contain summaries of data reviewed for registration and conditional registration of products in this case. A list of websites showing the locations of these documents is available in the docket. During registration review, the BRADs and Technical Documents and will be updated to reflect changes to the pesticide databases.

The following format is used in this Summary Document for *Beauveria bassiana.* The guideline data requirements are reported as OPPTS (now OCSPP) Microbial Pesticide Test Guideline Numbers in accordance with 40 CFR part 158. Studies are identified by their Master Record Identification (MRID) numbers and Agency reviews are cited as Data Evaluation Records (DERs).

Initially, the products containing *Beauveria bassiana* strains were all registered conditionally under FIFRA section 3(c)(7). When acceptable data were provided to satisfy the conditions of registration, *Beauveria bassiana* strain 447, *Beauveria bassiana* GHA and *Beauveria bassiana* HF23 met the requirements for unconditional registration under FIFRA Section 3(c)(5) as shown in Table 1. *Beauveria bassiana* ATCC 74040 is still registered conditionally under FIFRA Section 3(c)(7) with one condition of the conditional registration remaining for testing of non-target insects. The companies to which the strains are currently registered and the status of the active ingredients with regards to exemptions from tolerances are also shown in Table 1a.

Table 1a: Registration and exemption from tolerance for *Beauveria bassiana* strains

| Active ingredient | Registration dates | Company | Exemption from tolerance | 40 CFR citation & date |
|---|---|---|---|---|
| 447 | *September 27, 2002; **November 10, 2005 | Plant Defense Boosters, Inc. (Co. No. 81045) | None | Not a food use – no tolerance exemption required. |
| ATCC 74040 | *March 10, 1995 | Troy Biosciences, Inc. (Co. No. 53871) | All food commodities when applied or used as ground and aerial foliar sprays for use only on terrestrial crops. | 180.1205 (64 FR22796) April 28, 1999 |
| GHA | *May 26, 1995<br><br>**April 20,1999 | Laverlam (Co. No. 82074) | All raw agricultural commodities when applied to growing crops according to good agricultural practices. | 180.1146 (60 FR 18547) April 12, 1995 |
| HF23 | *December 27, 2006<br><br>**March 18, 2010 | JABB of the Carolinas (Co. No. 70787) | All food/feed commodities, when the pesticide is used for the treatment of chicken and livestock facilities, including the treatment of chicken and livestock manure. Revised to include livestock facilities. *Note: treated manure is to be composted prior to being used as fertilizer.* | 180.1273 (72 FR 1178) chicken facilities January 10, 2007 ---------- livestock facilities (75 FR 10190) March 5, 2010 |

*Registered under FIFRA Section 3(c)(7) with one condition of the conditional registration remaining for non-target insect testing.
** Registered under FIFRA Section 3(c)(5) following review of data to satisfy conditions of registration.

## Anticipated Risk Assessment and Data Needs

Where required, the Agency will take appropriate action to update the BRADs, Confidential Statements of Formula, labels of registered products, issues regarding inert ingredients, product chemistry, human health toxicology, environmental fate and effects (both direct and/or indirect) on non-target and beneficial organisms, including threatened/endangered species for all pesticide products containing *Beauveria bassiana* strains (447, ATCC 74040, GHA and HF23) as part of the registration review process. The updates will also include recently reviewed data and any newly reported information and data (including incident reports of adverse effects that are deemed relevant under Section 6(a)(2)) to ensure that all registered pesticides containing *Beauveria bassiana* strains meet the current requirements.

## 1. Product Analysis

40 CFR part 158.2120

The active ingredients, *Beauveria bassiana* strains, belong to the naturally occurring genus of fungi, *Beauveria*, which are ubiquitous soil fungi. They are registered for use as insecticides for control of a variety of insect pests. The primary mechanism through which this microbe controls insects is by germination and growth on the exoskeletons of target pests and secretion of enzymes into their soft tissue.

### *Beauveria bassiana* strains 447, ATCC 74040 and GHA

The Agency has reassessed the tolerance exemptions for inert ingredients used in pesticide formulations since the time these products were registered. Therefore, the product chemistry data for inert ingredients in products containing strains 447, ATCC 74040 and GHA will be reevaluated during registration review, to determine whether they continue to meet current requirements.

### *Beauveria bassiana* ATCC 74040

The manufacturing process changed for *Beauveria bassiana* ATCC 74040 and the EP (EPA Reg. No. 53871-9) was approved for food use on April 28, 1999. The Agency is reevaluating the product chemistry database of (EPA Reg. No. 53871-8) to ensure compliance with current requirements.

### *Beauveria bassiana* strain *GHA*

Twelve Pesticides containing *Beauveria bassiana* strain *GHA* were first registered to Mycotech Corporation in 1995. The company changed the manufacturing process in 1998 incorporating several minor modifications to the TGAI manufacturing process without any detectable changes in the biological or biochemical characteristics of the TGAI (DER Michael Watson to Sharlene Matten 04/28/98).

Five of Mycotech's twelve products were transferred to Emerald BioAgriculture on March 15, 2001, who transferred three of these to Laverlam International Co. Inc., the current owner,

on June 13, 2007. These three remaining *Beauveria bassiana* GHA products currently registered to Laverlam International Inc. are:

1. EPA Reg. No. 82074-1: Primary Brand Label (Mycotrol ES) Alternate brand name (BotaniGard ES);
2. EPA Reg. No. 82074-2: BotaniGard® 22WP; and
3. EPA Reg. No. 82074-3: Primary brand name: Mycotrol® 0 previously known as OrganiGard.

The Agency will reevaluate these pesticides, especially with respect to inert ingredients in these formulations, to determine compliance with current Agency requirements.

*Beauveria bassiana* strain HF23

The registration of *Beauveria bassiana* HF23 has been recently changed to a Section 3(c)(5) unconditional registration. The BRAD will be updated to reflect the reviews of the product chemistry data for *Beauveria bassiana* HF23 that led to:
(a) the revision of the tolerance exemption (40 CFR 180. 1273, 75 FR 10190; March 5, 2010), and
(b) unconditional registration of the labeled uses on March 18, 2010 under FIFRA Section 3(c)(5). At this time, the product chemistry requirements for HF23 are met and there are no data gaps for the currently labeled uses.

## 2. Human Health Risk Assessment Status

40 CFR part 158.2140

Below is a brief summary of the studies that were reviewed to support registrations for the currently registered *Beauveria bassiana* pesticide products. As part of the registration review process, these data will be reevaluated to determine if they continue to meet current FIFRA toxicology data requirements for microbial pesticides The review will also include the current status of both active and inert ingredients used in the formulations to determine if they are supported and satisfy FFDCA requirements for sites labeled for food use.

### *a. Toxicology Assessment - Technical*

Table 2a shows the Toxicity Categories assigned to the pesticide products containing the technical concentrations of the various strains of *Beauveria bassiana* based on laboratory tests or sound, scientific rationales to waive testing for certain data requirements. The modification of the manufacturing process for strain GHA products resulted in less primary eye irritation in the currently registered products. The MRID numbers for the laboratory tests used to support the guideline data requirement are noted in this table. These strains of the fungal active ingredients are not toxic, infective or pathogenic on the basis of those tests. For summaries of these tests see the previously developed 447 BRAD in this docket and the HF23 BRAD and Technical Documents for ATCC 74040 and GHA on the website *http://www.epa.gov/pesticides /biopesticides.*

| Table 2a -**TGAI /MP** Health Effects – Toxicity Categories and Citations (MRIDS) | | | | |
|---|---|---|---|---|
| Guideline | *Beauveria bassiana* strains | | | |
| | 447 | ATCC 74040 | GHA | HF23 |
| 885.3050 Acute oral toxicity/pathogenicity | IV 45144201 | IV 42413601 | IV 43057214 43057314 | IV 46526003 |
| 870.1200 Acute dermal toxicity | Waived – low exposure bait | IV 43382902 | III 43057215 43057315 | III 45626004 |
| 885.3150 Acute pulmonary toxicity/pathogenicity | IV 45085203 | III 43261301 43300601 | IV 43057216 43057316 | IV 45626005 |
| 885.3200 Acute injection toxicity/ pathogenicity/ (intraperitoneal) | Waived – low exposure bait | Not toxic, infective or pathogenic 43294201 44429801 | IV Not toxic, infective or pathogenic 43057217 43057317 | Not toxic, infective or pathogenic |
| 870.2400 Acute eye irritation | III 45085204 | III 43382906 for EP | III 44962402 44962403 | II 45626007 |
| 870.2500 Primary dermal irritation | Waived – low exposure bait | IV 43382902 | III 43057215 43057315 | Waived based on IV for acute dermal. |
| Non-guideline: Dermal Sensitization Conditionally required for EP- not for TGAI | NA – low exposure bait | Dermal Sensitizer; used 100% test material 44355801 | Not required | Not required – bait – low exposure |
| 885.3400 Hypersensitivity incidents | None reported | None reported; cited dermal study to support Hypersensitivity study | None reported | None reported |

*b. Toxicology Assessment - End-Use Products (EPs)*

There is no registered EP for *Beauveria bassiana* strain 447. Table 2b summarizes toxicity categories of pesticide EPs containing the other three strains.

| Table 2b: Toxicity Categories and Citations (MRID Nos.) – Health effects - End-use Products | | | |
|---|---|---|---|
| Guideline | *Beauveria bassiana* strains | | |
| | ATCC 74040 | GHA | HF23 |
| 870.1100 Acute oral toxicity/pathogenicity | Based on TGAI oral data and available mammalian toxicity data set. 42413601 | IV 44208701 44354602 44358002 | IV Based on acute oral TGAI and MSD sheets (MSDS). |
| 870.1200 Acute dermal toxicity | IV 43382905 | III Based on TGAI data and MSDS | III Based on acute dermal TGAI and MSDS. |

| Table 2b: Toxicity Categories and Citations (MRID Nos.) – Health effects - End-use Products | | | |
|---|---|---|---|
| Guideline | *Beauveria bassiana* strains | | |
| | ATCC 74040 | GHA | HF23 |
| 885.3150 Acute pulmonary toxicity/pathogenicity | III<br>Based on TGAI pulmonary data and MSD sheets. | IV<br>Based on TGAI data and MSD sheets. | IV<br>Waived – based on acute pulmonary and MSDS |
| 870.2400 Acute eye irritation | III<br>43382906 | III<br>44962401<br>44962402<br>44962403 | III<br>Based on acute eye for TGAI and MSDS. |
| 870.2500 Primary dermal irritation | III<br>43382905 | III<br>43057216<br>43057316 | IV<br>Waived based on IV for acute dermal for TGAI |
| Non- gdln: Dermal Sensitization | Sensitizer: dose at 100% rather than at 50% levels.<br>44355801 | Not required. | Not required |
| 885.3400 Hypersensitivity incidents | None reported | None reported | None reported |

MSDS* = Material Safety Data Sheets for inert ingredients.

At the time those data were originally evaluated, they met Agency guideline data requirements for pesticide registration of the active ingredient. Some of these EPs used an integrated manufacturing process to produce the pesticide without isolating and maintaining a separate registration for the Technical. All labels will be reviewed to determine that they include appropriate Personal Protective Equipment (PPE) to mitigate exposure and risk to workers.

*c. Tolerance exemptions*

No tolerance exemption was established for *Beauveria bassiana* strain 447, which is registered as an indoor bait for control of fire ants and is not intended for use in or near food establishments. Table 1a above lists the tolerance exemption status and 40 CFR citations for the other labeled strains of *Beauveria bassiana* (strains ATCC 74040, GHA, and HF23). The tolerance exemption for *Beauveria bassiana* strain HF23 was revised on March 5, 2010, and meets the current FFDCA requirements. The Agency will review the toxicology database of strains ATCC 74040 and GHA to determine if their existing tolerance exemptions continue to meet current FFDCA standards for food safety.

*d. Food Quality Protection Act Considerations* – strains ATCC 74040, GHA and HF23

The Agency's assessment regarding FQPA considerations, discussed below, occurred at the time of initial registration of the *Beauveria bassiana* pesticides. These assessments will be revisited to determine if the pesticides continue to meet current requirements.

For all the strains, FQPA risk considerations relevant to acute and chronic dietary risks, aggregate exposure and risk from multiple routes including dermal, oral, and inhalation, cumulative effects and occupational and residential exposure and risk were addressed at the time of registration. *Beauveria bassiana* strain 447 is not intended for food use so there is no tolerance exemption. Table 1a shows the exemptions from tolerances for the other three strains, *Beauveria bassiana* strains ATCC 74040, GHA and HF23. Only the tolerance

exemption for strain GHA was established prior to 1996, and it was reassessed on January 22, 1999, for compliance with FQPA. At the time of registration, the Agency concluded that the labeled uses of strains ATCC 74040, GHA and HF23 do not pose aggregate and/or cumulative risks to the general population, including infants and children. During registration review the Agency plans to evaluate all changes in the formulations and labeling that have occurred through FIFRA registrations and amendments that may affect these tolerance exemptions to determine if they continue to meet current requirements.

Below is a summary of the assessment that was used to determine FQPA compliance of strains ATCC 74040, GHA and HF23:

*(i) Dietary Exposure (including Drinking water)*

At the time of registration, the Tier 1 acute oral studies for these strains demonstrated a low acute oral toxicity (Category IV) and no infectivity or pathogenicity in guideline studies. Therefore, the Agency did not require subchronic and chronic dietary exposure studies. These naturally occurring microbial pesticides can be easily removed from foods by washing, peeling, cooking and processing, thus further minimizing the acute dietary exposure and risk. Similarly, chronic risks posed by dietary exposure to the pesticide are likely to be minimal to non-existent for sensitive subpopulations, such as infants and children.

The microorganism *Beauveria bassiana* is common in the soil. Pesticide products containing this active ingredient are not labeled for direct application to aquatic sites. They are not known as an aquatic microorganism, and, therefore, are not expected to proliferate in aquatic habitats. Drinking water is not being screened for any of the *Beauveria bassiana* strains as a potential indicator of microbial contamination. Both percolation through soil and municipal treatment of drinking water would reduce the possibility of exposure to *Beauveria bassiana* strains ATCC 74040, GHA and HF23 through drinking water. Therefore, the potential of significant transfer to drinking water is minimal to nonexistent. During the initial registration of *Beauveria bassiana* pesticides, the Agency concluded that even if negligible oral exposure should occur through drinking water, as a result of the pesticidal uses of these microorgansims, such exposure would present no risk due to the lack of acute oral toxicity (Category IV).

*(ii) Common Mode of Action*

None of the four registered *Beauveria bassiana* strains demonstrate a toxic mode of action. The toxicology studies performed on all strains of *B. bassiana* demonstrate a low toxicity potential for each fungal strain. Hence, EPA does not believe that there is any concern regarding the potential for cumulative effects of *Beauveria bassiana* strains due to a common mechanism of toxicity.

*(iii) Non-occupational dermal and inhalation exposure*

Non-occupational dermal and inhalation exposures are not expected from the registered *Beauveria bassiana* strains as a result of pesticide treatment. These soil fungi are naturally occurring, such that exposure is expected regardless of treatment. They are also applied at low rates and degrade easily at temperatures greater than 37°C and in UV and sunlight.

*Beauveria bassiana* strain ATCC 74040

*Dermal:* Strain ATCC 74040 is a dermal sensitizer based on tests conducted at 100% concentration. Temperature and light effects studies indicate that the active ingredient is not likely to persist in the environment following treatment of lawns and athletic fields. *Beauveria bassiana* ATCC 74040 is not known to be a human pathogen nor is it known to produce metabolites that are dermally absorbed. There is an REI of 4 hours to mitigate any potential bystander dermal effects.

*Inhalation:* The results of the acute pulmonary study classify strain ATCC 74040 as Toxicity Category III and also demonstrated the strain is not toxic, infective, or pathogenic. However, no mortality or toxic or pathogenic effects were found in the test animals dosed intratracheally with $2.5 \times 10^9$ cfu *B. bassiana* strain ATCC 74040/animal. No significant clinical signs were observed. Brown or tan lesions were noted in the lungs of all treated animals starting on day 4 and an inflammatory response was evident in microscopic examination. The presence of an inflammatory response is expected as a component of the normal recognition and clearance of microbes by the immune system. No inflammation was evident on tissues examined at the end of the study. Clearance was complete from the lungs within 15 days of dosing. Since this study was conducted the registrant changed its formulation and manufacturing process. When these pesticides were registered, the Agency considered clearance and the degradation of strain ATCC 74040 and the change in the manufacturing process that was likely to reduce potential toxicity and concluded that non-occupational inhalation exposure is not expected to cause harm to exposed populations. These decisions will be reevaluated during registration review to determine compliance with current requirements.

*Beauveria bassiana* strain GHA

Based on acute dermal and pulmonary toxicity tests *Beauveria bassiana* strain GHA is in Toxicity Category III and IV, respectively. Agricultural fields and outdoor terrestrial uses are not in the vicinity of residences and daycare facilities. Thus, non-occupational dermal and inhalation is expected to be minimal to non-existent to populations exposed to GHA. In addition, the natural occurrence of the organism indicates that exposure is expected regardless of treatment. Degradation of the active ingredient in UV and sunlight and inability to survive temperatures greater than 37°C also mitigate against potential non-occupational exposure.

*Beauveria bassiana* strain HF23

While treatment of chicken facilities may be considered an indoor use, direct or indirect exposure in residential areas and in the vicinity of daycares is not expected. Pesticides containing HF23 are not intended for direct agricultural use and treatment sites are not likely to be in the vicinity of residences and daycares. Manure from treated chicken and livestock facilities is composted prior to application as fertilizer on agricultural crops. HF23 is not expected to survive the high temperatures of composting. Furthermore, acute toxicity dermal and inhalation (pulmonary) testing indicated that *Beauveria bassiana* HF23 is of low toxicity to mammals. Hence, non-occupational residential and daycare exposure is not expected.

To summarize, *Beauveria bassiana* strains are naturally occurring, such that exposure is expected regardless of treatment. However, they are applied at low rates and degrade easily at temperatures greater than 37°C and in UV and sunlight. Thus, previous assessments indicated that residential, daycare and non-occupational dermal and inhalation exposure and risks are

expected to be minimal to non-existent from these *Beauveria bassiana* pesticides, if used as labeled.

*(iv) Aggregate Exposure and Risk from Multiple Routes Including Dermal, Oral, and Inhalation*

The Agency had considered the various routes of exposure (dietary, drinking water, and dermal and inhalation exposure from non-occupational sources). Based on the labeled use patterns, the general US population, including infants and children, are likely to be exposed to the active ingredients. However, the registered *Beauveria bassiana* strains are not known to be a human pathogen nor are they known to produce metabolites that are dermally absorbed. Acute toxicology studies for these three strains and for the non-food use strain 447, also demonstrated a low acute oral toxicity/pathogenicity Category IV potential. None of the registered strains was shown to be toxic, infective or pathogenic in these tests. In addition, there is a reasonable certainty that dietary exposure and risk will not harm the US population, including infants and children.

*Beauveria bassiana* strain ATCC 74040 is classified as acute Toxicity Category III according to acute pulmonary tests, while strains 447, GHA and HF23 are considered Toxicity Category IV. The Agency has considered non-occupational pulmonary exposure to be minimal to non-existent to exposed populations based on the application methods and non-persistence of these fungi at temperatures above human body temperature. The registered strains are also expected to degrade in UV and sunlight according to studies reported to the Agency.

With these considerations, the Agency determined that the potential risks to the general population from aggregate exposure to these naturally occurring, active ingredients were not likely to be significant. At the time of registration, this decision was based on the low toxicity/pathogenicity potential as demonstrated by the studies submitted in support of the registration of both the TGAI and the EPs and the methods of application of the pesticides. As previously noted, these decisions will be reevaluated during registration review.

*(v) Safety Factors*

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of exposure (safety) for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database. Alternatively, EPA can determine that a different margin of exposure (safety) will be safe for infants and children. In this instance, at the time of registration, EPA believed there are reliable data to support the conclusion that there are no threshold effects of concern to infants, children and adults when any of the *Beauveria bassiana* strains are used as labeled on food crops. As a result, the provision requiring an additional margin of exposure did not apply. This decision is subject to re-evaluation to determine compliance with current requirements.

*(vi) Cumulative Effects*

At the time of registration, the Agency concluded that there is a reasonable certainty that no harm will result from aggregate exposure to the U.S. population, including infants and children, to the registered *Beauveria bassiana* strains from the use patterns of these microbial pesticides. This includes all anticipated dietary exposures and all other exposures for which

there is reliable information. This conclusion is subject to reevaluation for compliance with current requirements.

*e. Occupational and Residential Exposure and Risk*

Occupational and residential exposure and risk have been assessed individually for each strain in accordance with their use patterns. Generally, dermal exposure is expected to be greater than inhalation exposure to workers who mix/load and apply the pesticide or to early entry workers engaged in post application and harvesting activities. Summaries of Tier I acute toxicity testing for *Beauveria bassiana* strains are available either in this docket or on BPPD's website as previously discussed. All strains show a low toxicity profile for dermal exposure, but ATCC 74040 is a potential dermal sensitizer and is placed in Toxicity Category III for pulmonary toxicity. For all the strains, appropriate Personal Protective Equipment (PPE), Restricted Entry Intervals and labeling are required, on a case-by-case basis, to mitigate occupational exposure and risk to pesticide handlers.

*(i) Occupational*

*Beauveria bassiana* strain *447*

Acute dermal toxicity/pathogenicity testing for strain 447 was waived based on the justification of low exposure potential to indoor bait applications. This strain was placed in acute Toxicity Category IV on the basis of pulmonary testing and is not toxic, infective or pathogenic. Dermal and inhalation exposure are expected to be minimal to non-existent because of the low exposure potential to the use of strain 447 as an indoor bait. The Agency will reevaluate the data for this strain to determine if the use patterns are in compliance with current requirements.

*Beauveria bassiana* strain ATCC 74040

Acute toxicity testing places strain ATCC 74040 in Toxicity Category IV for dermal effects, and it is not toxic or infective by this route of exposure. However, it is considered a dermal sensitizer. Acute pulmonary tests did not demonstrate toxicity or pathogenicity, but lesions, which may have been due to an inflammatory response to the tests, were noted in the lungs of treated animals. The test substance cleared from the lungs at the end of the study by day 15. On the basis of this test, the pesticide was classified as acute Toxicity Category III. For summaries of ATCC 74040 tests, see the Technical document on *http://www.epa.gov/pesticides/biopesticides*. Worker dermal and inhalation exposure are mitigated by appropriate PPE, including a NIOSH respirator with prefix N-95, P-95 or R-95, as labeled. The Agency will reevaluate the labels to determine compliance with these requirements.

*Beauveria bassiana* strain GHA

Strain GHA is placed in acute Toxicity Category III for dermal and IV for inhalation effects based on laboratory tests in mammals. Dermal and inhalation exposure are expected to be greatest to pesticide handlers. However, to mitigate worker exposure, the Agency has required appropriate PPE and REIs based on the acute toxicity potential and use patterns of the strain GHA pesticides and during registration review will reevaluate the labels to ensure compliance with these requirements.

*Beauveria bassiana* strain HF23

The evaluation of mammalian acute dermal and pulmonary toxicity data resulted in a categorization of the pesticide as Toxicity Category III for dermal and inhalation exposure. Pesticide application of the bait or spray at low rates does not pose a risk to workers as discussed in Chapter III of the BRAD on the BPPD website. However, to mitigate worker exposure, the Agency has required appropriate PPE and REIs based on the acute toxicity potential and use patterns of the *Beauveria bassiana* strain HF23 pesticides. HF23 labels were updated on March 18, 2010 and met current Agency requirements.

*(ii) Residential Exposure and Risk*

*Beauveria bassiana* strains ATCC 74040, GHA and HF23

Agricultural sites to be treated are not in the vicinity of residences and daycare facilities. HF23 baits are applied or sprayed at low rates to chicken and livestock facilities. Non-occupational dermal and inhalation exposure to ATCC 74040, GHA, and HF23 is expected to be minimal to non-existent as discussed under the Section I (d) above (see FQPA considerations). Thus, residential exposure and risk to all the strains are expected to be minimal to non-existent.

*Beauveria bassiana* strain *447*

Strain 447 is intended to be used indoors as a sticky bait in a plastic enclosure such that exposure and risk to adults, infants and children in school, residential and daycare facilities is expected to be minimal or non-existent.

## 3. Environmental Fate and Ecological Risk Assessment Status

40 CFR part 158.2150

The non-target organism and environmental fate data submitted to support the registration of the registered *Beauveria bassiana* pesticide products will be reevaluated to determine if they satisfy the current microbial pesticide data requirements for their currently labeled sites.

*Beauveria bassiana* strain 447

The Agency has performed an ecological risk assessment and determined that environmental exposure is expected to be very limited for *Beauveria bassiana* strain 447 due to the labeled use pattern as a bait. Its use pattern is limited to indoor applications only, which substantially limits non-target exposure. Justifiable rationales were accepted by the Agency to waive testing for ecological effects based on a low exposure scenario and no further data were required for ecotoxicology for the registered strain 447 sites.

*Beauveria bassiana* strains ATCC 74040 and GHA

At the time of registration, data reviewed for the ecological toxicology guideline requirements and for mammalian health effects for *Beauveria bassiana* ATCC74040 and strain GHA demonstrated no potential adverse effects to avian wildlife, wild mammals, freshwater and

marine/estuarine fish, aquatic invertebrate (*Daphnia*) and non-target plants. Based on the direct terrestrial application to food and non-food crops, lawns and ornamentals, ecological exposure of *Beauveria bassiana* ATCC74040 and strain GHA is likely to be higher than that expected for the other two strains (447 and HF23). However, the Agency considered that these microbes do not survive at temperatures greater than 37°C and also required labeling to mitigate potential effects on honey bees.

There is some concern for non-target beneficial insects based on the entomopathogenic nature of the fungi. Therefore, data from submitted studies and from the open literature regarding *Beauvaria* bassiana risks to beneficial insects (including honeybee) and host range will be re-evaluated during registration review. The Agency will take appropriate action to obtain any additional data or information that are deemed necessary to ensure that these pesticides comply with these data requirements.

*Beauveria bassiana* HF23

Exposure to *Beauveria bassiana* HF23 is not likely to cause adverse effects on avian wildlife, wild mammals, non-target invertebrates and honey bees, aquatic invertebrate (*Daphnia)* freshwater and marine/estuarine fish, and non-target plants based on the studies reviewed by the Agency and the labeled use patterns. Composting of HF23 treated manure that is used as fertilizer on crops further reduces the potential for ecological exposure of non-target organisms. No further ecotoxicology data are anticipated to be required for the current uses of strain HF23 that have been updated in March 2010.

## 4. Risk to Threatened and Endangered Species (ES)

The Agency has not conducted a risk assessment that supports a complete endangered species risk determination for *Beauvaria bassiana*. The ecological risk assessment planned during registration review will allow the Agency to determine whether *Beauvaria bassiana* will have a "no effect" or "may affect" Federally listed threatened or endangered species (listed species) or their designated critical habitats. When an assessment concludes that a pesticide's use "may affect" a listed species or its designated critical habitat, the Agency will consult with the U.S. Fish and Wildlife Service (FWS) and/or National Marine Fisheries Service (the Services), as appropriate.

## 5. Endocrine Disruptor Screening Program

As required under FFDCA section 408(p), EPA has developed the Endocrine Disruptor Screening Program (EDSP) to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine related effects caused by the substance, and establish a dose-response relationship between the dose and the E, A, or T effect.

Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. This list of chemicals was selected based on the potential for human exposure through pathways such as food and water, residential activity, and certain post-application agricultural scenarios. This list should not be construed as a list of known or likely endocrine disruptors.

The *Beauveria bassiana* strains are not among the group of 58 pesticide active ingredients on the initial list to be screened under the EDSP. Under FFDCA sec. 408(p) the Agency must screen all pesticide chemicals. Accordingly, EPA anticipates issuing future EDSP test orders/data call-ins for all Registration Review cases, including those for which EPA has already opened a Registration Review docket for a pesticide active ingredient.

For further information on the status of the EDSP, the policies and procedures, the list of 67 chemicals, the test guidelines and the Tier 1 screening battery, please visit our website: *http://www.epa.gov/endo/.*

## 6. Incidents

The National Pesticides Information Center (NPIC) database reported no incidents associated with products containing *Beauveria bassiana* strains.

However, the Office of Pesticide Programs' Incident Data System (IDS) indicates that there have been two reports of adverse human incidents for products containing *Beauveria bassiana* strains. There was one report of edema and another of rash on elbow and the worker recovered.

Incident reports will be evaluated during this registration review process. The Agency will also consider any incident data or comments submitted in response to this docket.

## 7. Timeline

The projected timeline for the *Beauveria bassiana* registration review appears in the table below.

**Table 4 Estimated Timeline - *Beauveria bassiana***

| Activities | Estimated Month/Year |
|---|---|
| Phase 1: Opening the docket | |
| Open Public Comment Period for *Beauveria bassiana* Docket | September 2010 |
| Close Public Comment Period | November 2010 |
| Phase 2: Case Development | |
| Develop Final Work Plan (FWP) | September 2011 |
| Phase 3: Registration Review Decision | |
| Open Public Comment Period for Proposed Reg. Review Decision | March 2013 |
| Close Public Comment Period | May 2013 |
| Final Decision and Begin Post-Decision Follow-up | September 2013 |
| Estimated Total (years) | Three years |

## 8. Guidance for Commenters

The public is invited to comment on EPA's preliminary registration review work plan and rationale. The Agency will consider all comments as well as any additional information or data provided in a timely manner prior to issuing a final work plan for the *Beauveria bassiana* case.

## 9. Environmental Justice

EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical, unusually high exposure to *Beauveria bassiana*, compared to the general population. Please comment if you are aware of any sub-populations that may have atypical, unusually high exposure compared to the general population.

## 10. Water Quality

*Beauveria bassiana* is not identified as a cause of impairment for any water bodies listed as impaired under section 303(d) of the Clean Water Act, based on information provided at http://iaspub.epa.gov/tmdl_waters10/attains_nation_cy.cause_detail_303d?p_cause_group_id=885. In addition, no Total Maximum Daily Loads (TMDL) have been developed for *Beauveria bassiana* strains, based on information provided at *http://iaspub.epa.gov/tmdl_waters10/attains_nation.tmdl_pollutant_detail?p_pollutant_group_id=885&p_pollutant_group_name=PESTICIDES*. More information on impaired water bodies and TMDLs can be found at *http://www.epa.gov/owow/tmdl/*. The Agency invites submission of water quality data for this pesticide. To the extent possible, data should conform to the quality standards in Appendix A of the *OPP Standard Operating Procedure: Inclusion of Impaired Water Body and Other Water Quality Data in OPP's Registration Review Risk Assessment and Management Process* (see: *http://www.epa.gov/oppsrrd1/registration_review/water_quality_sop.htm)* in order to ensure they can be used quantitatively or qualitatively in pesticide risk assessments.

## 11. Trade Irritants

Through the registration review process, the Agency intends to solicit information on trade irritants and, to the extent feasible, take steps toward facilitating irritant resolution. Growers and other stakeholders are asked to comment on any trade irritant issues resulting from lack of Maximum Residue Limits (MRLs) or disparities between U.S. tolerances and MRLs in key export markets, providing as much specificity as possible regarding the nature of the concern. In the case of *Beauveria bassiana*, there are currently no registered food uses or residue tolerances established for *Beauveria bassiana* strain 447. Additionally, there is no MRL established for the other three strains of *Beauveria bassiana* (ATCC 74040, GHA and HF23) which are exempt from tolerance in the US registered strains. There is no Codex tolerance or tolerance exemption for these strains of *Beauveria bassiana*. Therefore, the Agency does not anticipate current uses of *Beauveria bassiana* posing concerns as a trade irritant.

## 12. Additional Information

Stakeholders are also specifically asked to provide available information and data that will assist the Agency in refining the risk assessments, including any species-specific ecological effects determinations. The Agency is interested in obtaining the following information regarding the use of *Beauveria bassiana:*

1. Confirmation on the following label information:
    a. Sites of application
    b. Formulations
    c. Application methods and equipment
    d. Maximum application rates
    e. Frequency of application, application intervals and maximum number of applications
    f. Geographic limitations on use
2. Use or potential use distribution
3. Use history
4. Usage/use information for non-agricultural uses (e.g., materials preservation)
5. Typical application interval
6. State or local use restrictions
7. Monitoring data

### Next Steps

After the 60-day comment period closes, the Agency will review and respond to any comments received in a timely manner and then issue a Final Work Plan for the *Beauveria bassiana* Case 6057.

## Supplementary Information

*Beauveria bassiana* registration review case number: 6057

USEPA Contact Person

- Biopesticide and Pollution Prevention Registration Review Lead:
  - Shanaz Bacchus (bacchus.shanaz@epa.gov)

*Beauveria bassiana* strains

| Strains | PC Code | First registered | Products EPA Reg. Nos. | Company address |
|---|---|---|---|---|
| 447 | 128815 | 2002 | 81045-3 – label available as 70464-4 | Plant Defense Boosters, Inc. 1250 East Water Street Syracuse, NY 13210 previously registered to: GlycoGenesys, Inc., 31 St. James Ave., 8th Floor, Boston, MA 02116 |
| ATCC 74040 | 128818 | 1995 | 53871-9 | Troy BioSciences Inc., 2620 North 37th Drive, Phoenix, AZ 85009. |
| GHA | 128924 | 1995 | 82074-1 82074-2 82074-3 | Laverlam International Corporation, Inc., 117 South Parkmont; P0 Box 4109, Butte, MT 59702 |
| HF23 | 090305 | 2006 | 70784-1 70784-2 70784-4 | JABB of the Carolinas, 456 E. Main St., P.O. Box 310, Pine Level, NC |

### Labels and Products

Labels for *Beauveria bassiana* strains can be obtained from the Pesticide Product Label System (PPLS) website: *http://oaspub.epa.gov/pestlab1/ppls.home* by searching on the EPA Registration Number.

## 1. References

### A. *Beauveria bassiana* strain 447

**(i) Citations for *Beauveria bassiana* strain 447 are available in the BRAD in this docket** EPA-HQ-OPP-2010-0564.

**(ii) FR Notices - *Beauveria bassiana* strain 447**

September 19, 2001. Federal Register (66 FR 48256). Notice of Receipt of Application to Register a Pesticide.

January 22, 2003. Federal Register (68 FR 3025). Pesticide Product Registrations; Conditional Approval.

Citations in Preliminary Work Plan
*Beauveria bassiana* strain 447

| MRID | Citation Reference – *Beauveria bassiana* strain 447 |
|---|---|
| 45144201 | Mega, W. (2000) Toxicity/Pathogenicity Testing of Beauveria bassiana Following Acute Oral Challenge in Rats: Lab Project Number: 1179 SN3. Unpublished study prepared by IIT Research Institutes. 70 p. {OPPTS 885.3050} |
| 45085203 | Mega, W. (2000) Toxicity/Pathogenicity Testing of Beauveria bassiana Following Acute Intratracheal Challenge in Rats: Lab Project Number: 1179 SN2. Unpublished study prepared by IIT Research Institute. 94 p. {OPPTS 885.3150} |
| 45085204 | Moore, G. (1999) Primary Eye Irritation Study in Rabbits (Beauveria bassiana): Lab Project Number: 8505: P324. Unpublished study prepared by Product Safety Labs. 16 p. {OPPTS 885.2400} |

### B. *Beauveria bassiana* strain ATCC 74040

**(i) Citations in PWP for *Beauveria bassiana* strain ATCC 74040**

| MRID | Citation Reference – *Beauveria bassiana* strain ATCC74040 |
|---|---|
| 42413601 | Jones, J. (1992) Acute Oral Toxicity/Pathogenicity Study of Beauveria bassiana in Rats: Final Report: Lab Project Number: G-7393.222.006: FCI.92 EUP1B1. Unpublished study prepared by Microbiological Assoc., Inc. 33 p. |
| 43382902 | Wenk, M. (1994) Acute Dermal Toxicity Study of Fermone Boverin in Rabbits: Final Report: Lab Project Number: TBINATLRG94F5: G-7474.232R. Unpublished study prepared by Microbiological Associates, Inc. 74 p. |
| 43261301 | Microbiological Assoc., Inc. (1994) Intratracheal and Intraperitoneal Range Finder for Fermone Boverin (Beauveria bassiana ATCC 74040) in Rats: Final Report: Lab Project Number: G-7474.229.002: TBI.REG94NATLC1. Unpublished study. 96 p. |
| 43300601 | Jones, M. (1994) Acute Pulmonary Toxicity/Pathogenicity Study of Fermone Boverin (Beauveria bassiana ATCC 74040) in Rats: Final Report: Lab Project Number: G/7474/228/003: TBI/ REG94NATLE1. Unpublished study prepared by Microbiological Associates, Inc. 106 p. |
| 44429801 | Jones, M. (1993) Acute Intraperitoneal Toxicity/Pathogenicity Study of Beauveria bassiana (ATCC# 74040) in Rats: Final Report: Lab Project Number: G-743.226.003: 1602.226.003. Unpublished study prepared by Microbiological Associates Inc. 32 p. |
| 43382902 | Wenk, M. (1994) Acute Dermal Toxicity Study of Fermone Boverin in Rabbits: Final Report: Lab Project Number: TBINATLRG94F5: G-7474.232R. Unpublished study prepared by Microbiological Associates, Inc. 74 p. |

| MRID | Citation Reference – *Beauveria bassiana* strain ATCC74040 |
|---|---|
| 44355801 | Wnorowski, G. (1997) Dermal Sensitization Test--Buehler Method (in Guinea Pigs): Naturalis-L: Lab Project Number: 5266: TB0176: P328. Unpublished study prepared by Product Safety Labs. 41 p. |
| 43382905 | Wenk, M. (1994) Acute Dermal Toxicity Study of Naturalis-L (225) in Rabbits: Final Report: Lab Project Number: TBINATLRG94F4: G-7463.232. Unpublished study prepared by Microbiological Associates, Inc. 532 p. |
| 43382906 | Wenk, M. (1994) Primary Eye Irritation Test of Naturalis-L (225) in Albino Rabbits: Final Report: Lab Project Number: TBINATLRG94F2: G-7463.230. Unpublished study prepared by Microbiological Associates, Inc. 48 p. |

(ii) FR Notice – *Beauveria bassiana* ATCC 74040

June 10, 1998. Federal Register (63 FR 31771). Notice of Filing of a Pesticide Petition.

April 28, 1999. Federal Register (64 FR 22796). *Beauveria bassiana* (ATCC #74040); Exemption from the Requirement of a Tolerance

## C. *Beauveria bassiana* strain GHA

### (i) Citations in PWP for *Beauveria bassiana* strain GHA

| MRID | Citation Reference – *Beauveria bassiana* strain GHA |
|---|---|
| 43057214 | Barbera, P. (1993) Toxicity/Pathogenicity Testing of *Beauveria bassiana* Strain GHA Following Acute Oral Challenge in Rats: Final Report: Lab Project Number: L08433: L08433 SN6: 6. Unpublished study prepared by IIT Research Institute. 55 p. |
| 43057314 | Barbera, P. (1993) Toxicity/Pathogenicity Testing of *Beauveria bassiana* Strain GHA Following Acute Oral Challenge in Rats: Final Report: Lab Project Number: L08433: L08433 SN6: 6. Unpublished study prepared by IIT Research Institute. 55 p. |
| 43057215 | Johnson, W. (1993) Acute Dermal Toxicity Study of Beauveria bassiana GHA in Rabbits: Final Report: Lab Project Number: L08433: L08433SN3: 3. Unpublished study prepared by IIT Research Institute. 25 p. |
| 43057216 | Barbera, P. (1993) Pulmonary Toxicity/Pathogenicity Testing of Beauveria bassiana Strain GHA Following Acute Intratracheal Challenge in Rats: Final Report: Lab Project Number: L08433: L08433 SN4: 4. Unpublished study prepared by IIT Research Institute. 111 p. |
| 43057217 | Barbera, P. (1993) Toxicity/Pathogenicity Testing of Beauveria bassiana Strain GHA Following Acute Intraperitoneal Challenge in Rats: Final Report: Lab Project Number: L08433: L08433 SN5: 5. Unpublished study prepared by IIT Research Institute. 592 p. |
| 43057218 | Johnson, W. (1993) Primary Eye Irritation Study of Beauveria bassiana GHA in Rabbits: Final Report: Lab Project Number: L08433: L08433SN2: 2. Unpublished study prepared by IIT Research Institute. 21 p. |
| 43057219 | Johnson, W. (1993) Primary Eye Irritation Study of Mycocide-B GH Oil Flowable (OF) in Rabbits: Final Report: Lab Project Number: L08433: L08433SN11: 11. Unpublished study prepared by IIT Research Institute. 21 p. |
| 43057315 | Johnson, W. (1993) Acute Dermal Toxicity of Beauveria bassiana GHA in Rabbits: Final Report: Lab Project Number: L08433: L08433SN3: 3. Unpublished study prepared by IIT Research Institute. 25 p. |
| 43057316 | Barbera, P. (1993) Pulmonary Toxicity/Pathogenicity Testing of Beauveria bassiana Strain GHA Following Acute Intratracheal Challenge in Rats: Final Report: Lab Project Number: L08433: L08433 SN4: 4. Unpublished study prepared by IIT Research Institute. 111 p. |

| MRID | Citation Reference – *Beauveria bassiana* strain GHA |
|---|---|
| 43057316 | Barbera, P. (1993) Pulmonary Toxicity/Pathogenicity Testing of Beauveria bassiana Strain GHA Following Acute Intratracheal Challenge in Rats: Final Report: Lab Project Number: L08433: L08433 SN4: 4. Unpublished study prepared by IIT Research Institute. 111 p. |
| 43057317 | Barbera, P. (1993) Toxicity/Pathogenicity Testing of Beauveria bassiana Strain GHA Following Acute Intraperitoneal Challenge in Rats: Final Report: Lab Project Number: L08433: L08433 SN5: 5. Unpublished study prepared by IIT Research Institute. 59 p. |
| 44208701 | Johnson, W. (1997) Acute Oral Toxicity Study of Mycotrol ES9601 in Rats (Limit Test): Final Report: Lab Project Number: L08608: L08608SN10: 10. Unpublished study prepared by IIT Research Institute. 18 p. |
| 44354602 | Johnson, W. (1997) Acute Oral Toxicity Study of Mycotrol WP9616b in Rats (Limit Test): Final Report: Lab Project Number: L08608SN15: L08608. Unpublished study prepared by IIT Research Institute. 18 p. |
| 44358002 | Johnson, W. (1997) Acute Oral Toxicity Study of Mycotrol WP9616b in Rats (Limit Test): Final Report: Lab Project Number: L08608: 15: L08608SN15. Unpublished study prepared by IIT Research Institute. 18 p. |
| 44962401 | Glaza, S. (1998) Primary Eye Irritation Study of ES9601 in Rabbits: Final Report: Lab Project Number: COVANCE 80500910: TP3015. Unpublished study prepared by Covance Laboratories Inc. 33 p. |
| 44962402 | Glaza, S. (1998) Primary Eye Irritation Study of TGAI (Lot 95-19A) in Rabbits: Final Report: Lab Project Number: COVANCE 80203952: TP3015. Unpublished study prepared by Covance Laboratories Inc. 34 p. |
| 44962403 | Glaza, S. (1998) Primary Eye Irritation Study of TGAI (Lot 97-09-1) in Rabbits: Final Report: Lab Project Number: COVANCE 80203953: TP3015. Unpublished study prepared by Covance Laboratories Inc. 34 p. |

(ii) FR Notices - *Beauveria bassiana* strain GHA

April 12, 1995. Federal Register (60 FR 18547). *Beauveria bassiana* Strain GHA; exemption from the requirement of a tolerance.

(iii) Data Evaluation Record - *Beauveria bassiana* strain GHA

April 07, 1998. USEPA Data Evaluation Record from Michael Watson and John Kough to Sharlene Matten (BPPD). BPPD Review of Data Submitted for the Registration of Mycotrol 22-WP (ID# 65626-RR) and BotaniGard 22-WP (ID# 65626-RN).

**D. Citations in this PWP for *Beauveria bassiana* strain HF23**, are in the BRAD (includes summaries of the studies) on the BPPD website: *http://www.epa.gov/oppbppd1/biopesticides/ingredients/tech_docs/brad_090305.pdf* and can be easily obtained by copying and pasting this url into your browser.

## II. Glossary of Terms & Abbreviations

| | |
|---|---|
| ai | Active Ingredient |
| CSF | Confidential Statement of Formula |
| DCI | Data Call-In |
| DWLOC | Drinking Water Level of Comparison |
| EC | Emulsifiable Concentrate Formulation |
| EDWC | Estimated Drinking Water Concentration |
| EEC | Estimated Environmental Concentration |
| EPA | Environmental Protection Agency |
| EP | End-Use Product |
| EUP | Experimental Use Permit |
| FDA | Food and Drug Administration |
| FIFRA | Federal Insecticide, Fungicide, and Rodenticide Act |
| FFDCA | Federal Food, Drug, and Cosmetic Act |
| FQPA | Food Quality Protection Act |
| GENEEC | Tier I Surface Water Computer Model |
| 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 |
| LOAEL | Lowest Observed Adverse Effect Level |
| 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 submitted studies. |
| MUP | Manufacturing-Use Product |
| NA | Not Applicable |
| NAWQA | USGS National Ambient Water Quality Assessment |
| NPDES | National Pollutant Discharge Elimination System |
| NR | Not Required |
| NOAEL | No Observed Adverse Effect Level |
| OPP | EPA Office of Pesticide Programs |
| OPPTS | EPA Office of Prevention, Pesticides and Toxic Substances |
| PAD | Population Adjusted Dose |
| PHI | Preharvest Interval |
| ppb | Parts Per Billion |
| PPE | Personal Protective Equipment |
| ppm | Parts Per Million |
| PRZM/EXAMS | Tier II Surface Water Computer Model |
| RAC | Raw Agriculture Commodity |

| | |
|---|---|
| RED | Reregistration Eligibility Decision |
| REI | Restricted Entry Interval |
| RfD | Reference Dose |
| SCI-GROW | Tier I Ground Water Computer Model |
| SF | Safety Factor |
| TGAI | Technical Grade Active Ingredient |
| TEP | Typical End-Use Product |
| USDA | United States Department of Agriculture |
| UF | Uncertainty Factor |
| WPS | Worker Protection Standard |