

US EPA ARCHIVE DOCUMENT



Amendment to the 2003 Imazalil RED

March 2005



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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Subject: Amendment to the 2003 Imazalil RED

Dear Registrant:

The Reregistration Eligibility Decision (RED) document for imazalil was completed in September 2003. A number of updates have been made to the 2003 imazalil RED label table for purposes of clarification. To access the documents supporting this amended decision please refer to docket number OPP-2003-0217 on the electronic docket web site at <http://www.epa.gov/edocket/>. The Agency has determined that products containing imazalil are eligible for reregistration provided the attached label table amendments are implemented. Label changes are the following:

1. Each formulation and use combination (i.e. liquid concentrate as spray or fog in chicken hatchery) was given its own description section on the label table.

2. Personal Protective Equipment for early entry was updated to include:

Handlers entering a fog-treated or smoke-treated chicken hatchery before the ventilation period is over must wear:

- Long-sleeved shirt and long pants,
- Shoes plus socks,
- Chemical-resistant gloves, and
- A NIOSH-approved respirator.

3. Labeling language for bags containing seeds treated with imazalil must be labeled as such, and that handlers must wear long-sleeved shirt, long pants, shoes, socks, and chemical-resistant gloves when opening the treated bag or loading/pouring the treated seed.

In addition to label table changes, EPA is no longer requiring a special study to determine the availability of imazalil on citrus as described in the Imazalil RED. A surrogate study that sufficiently described contaminant transfer from surface to hands was considered acceptable by the Agency after the Imazalil RED was signed. As a result, this study was removed from the DCI.

Lastly, guideline 830.7050 should be listed as a data gap in Appendix B. The study currently listed under this guideline (MRID # 44107207) is a melting point study and does not satisfy the guideline requirement for the *uv* absorption study.

If you have any questions on the imazalil RED or any of the revisions listed above, please contact the Chemical Review Manager, Meghan French at (703) 308-8004.

Sincerely,

Debra Edwards, Ph.D.
Director
Special Review and Reregistration Division

Attachments:

Table 14: Summary of Labeling Changes for Imazalil

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Description	Amended Labeling Language	Placement on Label
Manufacturing Use Products		
For all Manufacturing Use Products	“Only for formulation into a <i>fungicide</i> for the following use(s) [fill blank only with those uses that are being supported by MP registrant].”	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	<p>“This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).”</p> <p>“This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).”</p>	Directions for Use

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Description	Amended Labeling Language	Placement on Label
<p>Environmental Hazards Statements Required by the RED and Agency Label Policies</p>	<p>"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."</p>	<p>Precautionary Statements</p>

Table 14: Summary of Labeling Changes for Imazalil

Description	Amended Labeling Language	Placement on Label
End Use Products		
<p>PPE Requirements Established by the RED¹ for liquid concentrate formulations with directions for use as a spray or fog in chicken hatcheries</p>	<p>“Personal Protective Equipment (PPE)”</p> <p>“Some materials that are chemical-resistant to this product are” (<i>registrant inserts correct chemical-resistant material</i>). “If you want more options, follow the instructions for category” [<i>registrant inserts A,B,C,D,E,F,G,or H</i>] “on an EPA chemical-resistance category selection chart.”</p> <p>“All mixers, loaders, applicators, and other handlers must wear:</p> <ul style="list-style-type: none"> -Long-sleeved shirt and long pants, -Shoes plus socks, -Chemical-resistant gloves and chemical-resistant apron when mixing/loading, cleaning up spills, cleaning equipment, or otherwise exposed to the concentrate.” <p>“Handlers entering the treated area before the ventilation period is over must wear:</p> <ul style="list-style-type: none"> -Long-sleeved shirt and long pants, -Shoes plus socks, -Chemical-resistant gloves, and - A NIOSH-approved respirator with a dust/mist filter with MSHA/NIOSH approval number prefix TC-21C or any N², R, P, or HE filter.” 	<p>Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals</p>
<p>PPE Requirements Established by the RED¹ for liquid concentrate formulations with directions for use as a seed treatment and on citrus</p>	<p>“Personal Protective Equipment (PPE)”</p> <p>“Some materials that are chemical-resistant to this product are” (<i>registrant inserts correct chemical-resistant material</i>). “If you want more options, follow the instructions for category” [<i>registrant inserts A,B,C,D,E,F,G,or H</i>] “on an EPA chemical-resistance category selection chart.”</p> <p>“All mixers, loaders, applicators, and other handlers must wear:</p> <ul style="list-style-type: none"> -Long-sleeved shirt and long pants, -Shoes plus socks, -Chemical resistant gloves, <i>except</i> for bag sewers, seed planters, truck drivers, and sorters, -Chemical resistant apron when mixing/loading, cleaning up spills, cleaning equipment, or otherwise exposed to the concentrate.” 	<p>Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals</p>

Table 14: Summary of Labeling Changes for Imazalil

Description	Amended Labeling Language	Placement on Label
<p>PPE Requirements Established by the RED¹ for liquid concentrate formulations with directions for use on citrus only</p>	<p>“Personal Protective Equipment (PPE)”</p> <p>“Some materials that are chemical-resistant to this product are” (<i>registrant inserts correct chemical-resistant material</i>). “If you want more options, follow the instructions for category” [<i>registrant inserts A,B,C,D,E,F,G,or H</i>] “on an EPA chemical-resistance category selection chart.”</p> <p>“All mixers, loaders, applicators, and other handlers must wear:</p> <ul style="list-style-type: none"> -Long-sleeved shirt and long pants, -Shoes plus socks, -Chemical resistant gloves, except for truck drivers and sorters, -Chemical resistant apron when mixing/loading, cleaning up spills, cleaning equipment, or otherwise exposed to the concentrate.” 	<p>Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals</p>
<p>PPE Requirements Established by the RED¹ for liquid concentrate formulations with directions for use for seed treatment only</p>	<p>“Personal Protective Equipment (PPE)”</p> <p>“Some materials that are chemical-resistant to this product are” (<i>registrant inserts correct chemical-resistant material</i>). “If you want more options, follow the instructions for category” [<i>registrant inserts A,B,C,D,E,F,G,or H</i>] “on an EPA chemical-resistance category selection chart.”</p> <p>“All mixers, loaders, applicators, and other handlers must wear:</p> <ul style="list-style-type: none"> -Long-sleeved shirt and long pants, -Shoes plus socks, -Chemical resistant gloves, <i>except</i> for bag sewers and planters, -Chemical resistant apron when mixing/loading, cleaning up spills, cleaning equipment, or otherwise exposed to the liquid concentrate.” 	<p>Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals</p>

Table 14: Summary of Labeling Changes for Imazalil

Description	Amended Labeling Language	Placement on Label
<p>PPE Requirements Established by the RED¹ for smoke generator formulations</p>	<p>“Personal Protective Equipment (PPE)”</p> <p>“Some materials that are chemical-resistant to this product are” (<i>registrant inserts correct chemical-resistant material</i>). “If you want more options, follow the instructions for category” [<i>registrant inserts A,B,C,D,E,F,G,or H</i>] “on an EPA chemical-resistance category selection chart.”</p> <p>“All handlers must wear: -Long-sleeved shirt and long pants, -Shoes plus socks.”</p> <p>“Handlers entering the treated area before the ventilation period is over must wear: -Long-sleeved shirt and long pants, -Shoes plus socks, -Chemical-resistant gloves, and -A NIOSH-approved respirator with an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C) or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G) or an organic-vapor cartridge or canister with any N², R or P or HE prefilter.”</p> <p>“After the ventilation requirements have been met, anyone entering the treatment area to remove smoke canisters must wear chemical-resistant gloves.”</p>	<p>Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals</p>
<p>User Safety Requirements</p>	<p>“Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.”</p>	<p>Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements</p>

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Description	Amended Labeling Language	Placement on Label
User Safety Recommendations	<p>“User Safety Recommendations</p> <p>Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.</p> <p>Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.</p> <p>Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.”</p>	<p>Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following User Safety Requirements</p> <p>(Must be placed in a box.)</p>
General Application Restrictions	<p>“Do not apply this product in a way that will contact workers or other persons. Only protected handlers may be in the area during application.”</p>	<p>Directions For Use under General Precautions and Restrictions</p>
Application Restrictions for Citrus Drench	<p>“Do not enter or allow others to enter the treatment area until the citrus is treated and completely drained.”</p> <p>“The windows and doors of the transport vehicle must be closed prior to and during treatment.”</p>	<p>Directions For Use under General Precautions and Restrictions</p>

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Description	Amended Labeling Language	Placement on Label
<p>Application Restrictions for Smoke Generator use in Chicken Hatcheries</p>	<p>The following text must be added to the label:</p> <p>“This product may not be used when eggs or poultry are present.”</p> <p>“Keep everyone, except applicators, out of treatment site prior to and during application.”</p> <p>“Vacate the treated area immediately after lighting the smoke canister.”</p> <p>“Do not enter or allow others to enter the treated area if smoke is still visible.”</p> <p>“Do not enter or allow others to enter the treated areas until the area has been mechanically ventilated (fans) for at least 2 hours. If no mechanical ventilation is used, do not enter or allow others to enter the treated areas for at least 12 hours after application is complete. Early entry is permitted only in an emergency or to operate ventilation equipment, provided the person is wearing personal protective equipment required for such entry (see PPE requirements on this label).”</p> <p>“Post signs at the entrances to the hatchery before the application begins and keep the signs in place until the mechanical ventilation period is over or, if no mechanical ventilation is used, for at least 12 hours after application is complete. The signs must contain the following words in a size that can be easily read: Danger/Peligro, Do Not Enter/No Entre.”</p>	<p>Directions For Use</p>

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Description	Amended Labeling Language	Placement on Label
<p>Application Restrictions for use as a Spray or Fog in Chicken Hatcheries.</p>	<p>The following text must be added to the label:</p> <p>“This product may not be used when eggs or poultry are present.”</p> <p>“Keep everyone, except applicators, out of treatment site prior to and during application.”</p> <p>“Vacate the treated area immediately after the application is complete.”</p> <p>“Do not enter or allow others to enter the treated areas until the area has been mechanically ventilated (fans) for at least 2 hours. If no mechanical ventilation is used, do not enter or allow others to enter the treated areas for at least 12 hours after application is complete. Early entry is permitted only in an emergency or to operate ventilation equipment, provided the person is wearing personal protective equipment required for such entry (see PPE requirements on this label).”</p> <p>“Post signs at the entrances to the hatchery before the application begins and keep the signs in place until the mechanical ventilation period is over or, if no mechanical ventilation is used, for at least 12 hours after application is complete. The signs must contain the following words in a size that can be easily read: Danger/Peligro, Do Not Enter/No Entre.”</p>	<p>Directions For Use</p>
<p>Restricted-Entry Interval for uses with on-farm (hopper box, planter box) seed treatments</p>	<p>“Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 48 hours. Exception: once the seeds are planted in soil or other planting media, workers may enter the treated area without restriction if there will be no contact with the soil/media subsurface.”</p>	<p>Directions for Use, Agricultural Use Requirements Box</p>
<p>Early Entry Personal Protective Equipment for uses within the scope of the Worker Protection Standard</p>	<p>“PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated is:</p> <ul style="list-style-type: none"> -coveralls, -shoes plus socks, -chemical-resistant gloves made of any waterproof material, and -protective eyewear.” 	<p>Directions for Use, Agricultural Use Requirements Box</p>

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Description	Amended Labeling Language	Placement on Label
<p>Required labeling for seed that has been treated with this product and is then packaged or bagged for future use</p>	<p>“Seed that has been treated with this product and is then packaged or bagged for future use must contain the following labeling:”</p> <p>> “Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 48 hours. Exception: once the seeds are planted in soil or other planting media, workers may enter the treated area without restriction if there will be no contact with the soil/media subsurface.”</p> <p>> “Personal protective equipment required for early entry to treated areas that involves contact with anything that has been treated is:</p> <ul style="list-style-type: none"> -coveralls, -shoes plus socks, -chemical-resistant gloves made of any waterproof material, and -protective eyewear.” <p>> “This bag contains seed treated with imazalil. When opening this bag or loading/pouring the treated seed, wear long-sleeved shirt, long pants, shoes, socks, and chemical-resistant gloves.”</p> <p>> “Treated Seed - Do Not Use for Food, Feed, or Oil Purposes.”</p> <p>> “Cover or collect spilled seeds.”</p>	<p>Directions for Use</p>
<p>Environmental Hazards</p>	<p>“Environmental Hazards”</p> <p>“This chemical is toxic to fish. Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when cleaning equipment or disposing of equipment wash waters or rinsate. Apply this product only as specified on the label.”</p>	<p>Precautionary Statements under Environmental Hazards</p>

¹ PPE that is established on the basis of Acute Toxicity of the end-use product must be compared to the active ingredient PPE in this document. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

²If the product contains oil or bears instructions that will allow application with an oil-containing material, the “N” designation must be dropped.