US EPA ARCHIVE DOCUMENT

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

September 25, 2008

CERTIFIED MAIL

Dear Registrant:

The Reregistration Eligibility Decision (RED) document for propylene oxide (PPO) was signed on July 31, 2006. In accordance with the Environmental Protection Agency's (Agency) public participation process, a public comment period for the RED was conducted. The comment period opened August 9, 2006 and closed on October 10, 2006. The risk assessments and public comments can be found on the FDMS docket system, available at http://www.regulations.gov (docket EPA-HQ-OPP-2005-0253). The Agency has reviewed the public comments submitted and has responded to those that related specifically to the PPO RED. These responses are also available in the PPO docket. As a result of the Agency's review of the public comments and a modeling error which has since been corrected, the Agency is revising the PPO RED where appropriate. These revisions are listed below and the corresponding amended label language is included in Table 2.

(1) The maximum size enclosure that is allowed to be fumigated is 10,000 ft^3.
(2) For vacuum-sealed pressurized chambers
    a. For all applications of PPO between 150 lbs ai/1,000 ft^3 (2.4 oz/ft^3) and 75 lbs ai/1,000 ft^3 (1.2 oz/ft^3), the chamber must be equipped with equipment specifically designed to reduce PPO emissions by 95 percent.
    b. For chambers $\leq$ 5,000 ft^3 with application rates of PPO 75 lbs ai/1,000 ft^3 (1.2 oz/ft^3) and below, a chamber must have either a release height of at least 27 feet or the chamber must be equipped with equipment specifically designed to reduce PPO emissions by 95 percent.
    c. For chambers > 5,000 ft^3 and $\leq$ 10,000 ft^3 with application rates of PPO 75 lbs ai/1,000 ft^3 (1.2 oz/ft^3) and below, a chamber must have either a release height of at least 40 feet or the chamber must be equipped with equipment specifically designed to reduce PPO emissions by 95 percent.
    d. During the aeration period there must be a minimum of 20 air changes per hour.
(3) For non vacuum sealed pressurized chambers (atmospheric chambers or structures, railcars, trailers, air/sea transport containers, tents, and tarps)
    a. For chambers that are passively aerated, the buffer zones in Table 1 are required during treatment and aeration.

Table 1.

Enclosure Size	Buffer Zone
$\leq 1{,}000\ ft^3$	10 feet
$> 1{,}000\ ft^3$ and $\leq 2{,}000\ ft^3$	50 feet
$> 2{,}000\ ft^3$ and $\leq 5{,}000\ ft^3$	115 feet
$> 5{,}000\ ft^3$ up to $10{,}000\ ft^3$	200 feet

b. During aeration if the chamber is actively aerated with 20 air changes per hour with a 10 foot permanent or portable stack above the product, chamber, or structure, the required buffer zone that must be established around the treated chamber is 10 feet.

(4) If PPO air concentration level is measured to be 10 ppm or greater at any time when measured using a direct-read device or if PPO air concentration exceeds 2 ppm as an 8-hour time-weighted average, each person in the exposure area must wear either:

a. A supplied-air respirator(MSHA/NIOSH approval number TC-19C), or

b. A self-contained breathing apparatus (SCBA) (MSHA/NIOSH approval number prefix TC-13F), or

c. Any NIOSH-approve air-purifying respirator (APR) outfitted with an organic vapor canister/cartridge and an end-of-service-life indicator (ESLI) certified by NIOSH for the contaminant (APR is not approved for IDLH situations), or

d. Any NIOSH-approved APR outfitted with an organic vapor canister/cartridge for which, if there is no ESLI certified by NIOSH for the contaminant, the employer implements a change of schedule for canisters and cartridges that is based on documented objective information or data that will ensure that canisters and cartridges are changed before the end of their service life (APR is not approved for IDLH situations).

If you have questions on the PPO RED or any of the revisions listed above, please contact the Chemical Review Manager, Andrea Carone at (703) 308-0122 or carone.andrea@epa.gov. For questions about product reregistration please contact Veronica Dutch in the Product Review Branch at (703) 308-8585 or dutch.veronica@epa.gov.

Sincerely,

Steven Bradbury, Ph.D.
Director
Special Review and Reregistration Division

Table 2. Revised summary of required labeling changes for PPO products

Manufacturing-Use Products		
Description	**Amended Labeling Language**	**Placement on Label**
For all Manufacturing-Use Products	"Propylene oxide only can be formulated into end-use products containing directions for use that include acceptable air concentration levels of 2 ppm as an 8-hour time weighted average and other measures for ensuring that workers and other persons are not exposed to concentrations of propylene oxide that exceed this level unless appropriate respiratory protection is used." "Propylene oxide cannot be formulated into end-use products labeled for use on edible gums or birdseed. End-use product labels must be revised to delete all references to and use directions for edible gums or birdseed." "Propylene oxide only can be formulated into end-use products that are classified as and identified as Restricted Use."	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or use-pattern or all additional uses supported by a formulator or user group	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	**"ENVIRONMENTAL HAZARDS** This pesticide is toxic to birds and mammals. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."	Precautionary Statements
End-Use Products Intended for Occupational Use		
Description	**Amended Labeling Language**	**Placement on Label**
Restricted Use Pesticide	"RESTRICTED USE PESTICIDE DUE TO INHALATION TOXICITY For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification."	Top of Front Panel
Identify as a fumigant all propylene oxide end-use products	Prominently identify the end-use product as a **"Fumigant"**	Insert the word "fumigant" as part of the product name or close to the product name, either as part of the product-type

		identification or as a separate word or sentence
Add precautionary language in Spanish on propylene oxide end-use products	Add the following Spanish signal word and statement: "**PELIGRO** Si Usted no entiende la etiqueta, busque a alquien para que se la explique a Usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)"	On front panel of the label near the signal word DANGER.
Add acceptable air concentration language to propylene oxide end-use products	"**AIR CONCENTRATION LEVEL** The acceptable air concentration level for persons exposed to propylene oxide is 2 ppm (8 mg/m^3) as a time-weighted average."	In the Hazards to Humans and Domestic Animals section of the labeling immediately following the precautionary statements.
PPE Requirements Established by the RED for propylene oxide end-use products[a]	"**PERSONAL PROTECTIVE EQUIPMENT** Some materials that are chemical-resistant to this product are (*registrant inserts correct chemical-resistant material*). If you want more options, follow the instructions for category [*registrant inserts A,B,C,D,E,F,G,or H*] on an EPA chemical-resistance category selection chart. All handlers opening propylene oxide drums or tanks, cleaning up leaks or spills, or who otherwise may potentially contact liquid propylene oxide, must wear: > long-sleeved shirt and long pants, > chemical-resistant gloves, > chemical-resistant footwear plus socks, > chemical-resistant apron. > face-sealing goggles, and > full-face shield, unless a respirator that covers the entire face is worn. **Respirator Requirements:** Once propylene oxide has been introduced into an enclosure, the certified applicator supervising the fumigation must make sure that all persons in the exposure area (the treatment area and the buffer zone, if applicable) have appropriate respiratory protection or are removed from the exposure area. **Air Concentrations 10 PPM or Greater from a Direct-read Device or Air Concentrations Greater than 2 ppm as an 8-Hour Time Weighted Average:** If propylene oxide air concentration level is measured to be 10 ppm or greater at anytime when measured using a direct read device or if propylene air concentration exceeds 2 ppm as an 8-hour time weighted average, each person in the exposure area must wear either; • a supplied-air respirator (MSHA/NIOSH approval number TC-19C), or • a self-contained breathing apparatus (SCBA) (MSHA/NIOSH approval number prefix TC-13F). • any NIOSH-approved air purifying respirator (APR) outfitted with an organic vapor canister/cartridge and an end-of-service-life	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

	indicator (ESLI) certified by NIOSH for the contaminant (APR is not approved for IDLH situations); or • any NIOSH-approved air purifying respirator (APR) outfitted with an organic vapor canister/cartridge for which, if there is no ESLI certified by NIOSH for the contaminant, the employer implements a change schedule for canisters and cartridges that is based on documented objective information or data that will ensure that canisters and cartridges are changed before the end of their service life (APR is not approved for IDLH situations). **Air Concentrations lower than 10 ppm from a Direct-read Device, and Air Concentrations at or below 2 PPM as an 8-hour Time Weighted Average:** No respirator is required if the air concentration level of propylene oxide in the exposure area is measured to be lower than 10 ppm using a direct-read device *and* the air concentration is at or below 2 ppm as an 8-hour time weighted average."	
User Safety Requirements for all propylene oxide end-use products	"**WORK SAFETY REQUIREMENTS** Respirator Requirements: When a respirator is required for use with this product, the certified applicator supervising the fumigation must make sure that: a) Respirators must be fit tested and fit checked using a program that conforms with OSHA's requirements (described in 29 CFR Part 1910.134); b) Respirator users must be trained using a program that conforms with OSHA's requirements (described in 29 CFR Part 1910.134); c) Respirator users must be examined by a qualified medical practitioner to ensure the physical ability to safely wear the style of respirator to be worn; d) Respirators must be maintained according to a program that conforms with OSHA's requirements (described in 29 CFR Part 1910.134). -- If liquid fumigant splashes or spills on clothing, remove them at once, and place them outdoors in an isolated place to aerate, because fumes will be an intolerable source of irritation. -- Immediately after application remove personal protective equipment. Do not reuse the personal protective equipment until cleaned. Keep and wash the work clothing and personal protective equipment separately from other laundry. -- Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product. Do not reuse them. -- Follow manufacturer's instructions for cleaning/maintaining personal protective equipment."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following Personal Protective Equipment Requirements
User Safety Recommendations	"User Safety Recommendations Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following User Safety Requirements

<table>
<tr><td></td><td>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."</td><td>(Must be placed in a box.)</td></tr>
<tr><td>Application Restrictions</td><td>"The maximum size enclosure that is allowed to be fumigated is 10,000 ft^3."</td><td>In the Directions for Use section.</td></tr>
<tr><td>Restrictions for Vacuum-Sealed Pressurized Chambers</td><td>"Fumigation in Vacuum-Sealed Pressurized Chambers
• For all applications of propylene oxide between 150 lbs ai/1,000 ft^3 (2.4 oz/ft^3) and 75 lbs ai/1,000 ft^3 (1.2 oz/ft^3), the chamber must be equipped with equipment specifically designed to reduce propylene oxide emissions by 95 percent.
• For chambers ≤ 5,000 ft^3 with application rates of PPO 75 lbs ai/1,000 ft^3 (1.2 oz/ft^3) and below, a chamber must have either a release height of at least 27 feet or the chamber must be equipped with equipment specifically designed to reduce propylene oxide emissions by 95 percent.
• For chambers > 5,000 ft^3 and ≤ 10,000 ft^3 with application rates of PPO 75 lbs ai/1,000 ft^3 (1.2 oz/ft^3) and below, a chamber must have either a release height of at least 40 feet or the chamber must be equipped with equipment specifically designed to reduce propylene oxide emissions by 95 percent.
• During the aeration period there must be a minimum of 20 air changes per hour."</td><td>In the Directions for Use under "Fumigation in Vacuum-Sealed Pressurized Chambers"</td></tr>
<tr><td>Restrictions for Fumigation Not Contained within a Vacuum-Sealed Pressurized Chamber</td><td>"Fumigation in a Non Vacuum-Sealed Pressurized Chamber (atmospheric chambers or structures, railcars, trailers, air/sea transport containers, tents, and tarps)

For any fumigation that takes place in a non vacuum-sealed pressurized chamber the appropriate buffer zone (see below) must be established around the treated enclosure from the time propylene oxide is introduced into the enclosure and must remain in effect until the air concentration of propylene oxide being exhausted from the treated enclosure is measured to be 10 ppm or less.
• For chambers that are passively aerated the buffer zones in Table 1 are required during treatment and aeration.
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<tr><td>> 5,000 ft^3 up to 10,000 ft^3</td><td>200 feet</td></tr>
</table>
• During aeration if the chamber is actively aerated with 20 air changes per hour with a 10 foot permanent or portable stack above the product, chamber, or structure, the required buffer zone that must be established around the treated chamber is 10 feet.

Fumigation taking place in a vacuum-sealed pressurized chamber is limited to a maximum concentration of 0.0448 ounces of propylene oxide per cubic foot of fumigation enclosure.</td><td>In the Directions for Use under the heading: Fumigation Not Contained Within a Vacuum-Sealed Pressurized Chamber" immediately following "Fumigation in Vacuum-Sealed Pressurized Chambers"</td></tr>
</table>

	Buffer Zone Entry Restrictions Entry by the certified applicator supervising the fumigation, or persons under his/her direct supervision, is permitted in the buffer zone, provided either: -- the appropriate respirator is worn (see PPE requirements elsewhere in this labeling); *OR* -- the air concentration level for propylene oxide is at or below 2 ppm for an 8-hour time weighted average. The certified applicator supervising the fumigation must ensure that any person, except the certified applicator or persons under his/her direct supervision, is kept outside the buffer zone surrounding the treated enclosure from the time propylene oxide is introduced into the enclosure until the air concentration of propylene oxide being exhausted from the treated enclosure is measured to be 10 ppm or less."	
Onsite Notification for all propylene oxide end-use products	"**PLACARDING OF FUMIGATED ENCLOSURES** The certified applicator supervising the fumigation (or person under his/her direct supervision) must placard all entrances to the fumigation enclosure with signs bearing: -- skull and crossbones symbol -- "DANGER/PELIGRO," -- "Area under fumigation, DO NOT ENTER/NO ENTRE," -- "Propylene Oxide Fumigant in use," -- the date and time of fumigation, and -- name, address, and telephone number of the certified applicator supervising the fumigation." "The certified applicator supervising the fumigation must ensure that no person, except the certified applicator or persons under his/her direct supervision who are wearing appropriate respiratory protection, enters into the treated enclosure until the signs are removed. Such signs must only be removed when aeration has occurred and when the air concentration level of propylene oxide is monitored as described in this labeling and the monitoring indicates that workers can enter without respiratory protection. Signs must remain legible during entire posting period. The warning signs at entrances to fumigation enclosure may only be removed by the certified applicator supervising the fumigation or person under his/her direct supervision. Vehicles must be placarded with applicable U.S. Department of Transportation warning signs."	In the Directions for Use under the heading "PLACARDING OF FUMIGATED ENCLOSURES"
Environmental Hazards Statements	"**ENVIRONMENTAL HAZARDS** This pesticide is toxic to birds and mammals. 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 Pollutant Discharge Elimination System (NDPES) 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 plants authority. For	Precautionary Statements under Environmental Hazards

	guidance contact your State Water Board or Regional Office of the EPA."	
Storage and Disposal language of for all propylene oxide end-use products	"Persons moving, handling, or opening containers must wear the personal protective equipment (including prescribed respirators when necessary) specified in the Human Hazards section of this labeling. Store containers in a well-ventilated area."	Storage and Disposal section of the label
Spill and Leak Procedures of for propylene oxide end-use products	"**SPILL AND LEAK PROCEDURES** Evacuate everyone from the immediate area of the spill or leak. For entry into affected area to correct problem, wear the personal protective equipment (including prescribed respirators) specified in the Hazards to Humans section of this labeling. Move leaking or damaged containers outdoors or to an isolated location. Observe strict safety precautions. Work upwind, if possible. Allow spilled fumigant to evaporate. Only correctly trained and PPE-equipped handlers are permitted to perform such cleanup. Do not permit entry into the spill or leak area by any other person until the air concentration level of propylene oxide is measured to be at or below 2 ppm as an 8-hour time weighted average. Contaminated soil, water, and other cleanup debris is a toxic hazardous waste. Report spill to the National Response Center (800-424-8802) if the reportable quantity of 1000 lbs. is exceeded."	In the labeling section titled "Storage and Disposal" **or** by themselves under the heading "Spill and Leak Procedures"
General Application Restrictions	"**DIRECTIONS FOR USE** It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation."	Place in the Direction for Use directly below the heading "Directions for Use"

Use-Specific Application Restrictions (The product label must list the specified application rates in ounces or pounds of formulated product in place of ounces of active ingredient.)	For products with the following uses and use patterns please amend labels to include specified language and to reflect the following application rates: **If labels refer to "gums",** the label language must be changed to "non-edible gums". **If labels refer to "cocoa beans" or "cocoa",** the label language must be changed to "cacao beans" and "cocoa powder". Do not apply more than 2.0 oz ai/ft^3 per application when used in vacuum-sealed pressurized chambers. For all other fumigation methods, do not apply more than 0.0448 oz ai/ft^3. **If labels refer to "processed spices",** the label language must be changed to "dried or processed herbs and spices", "dried onions", and "dried garlic". Do not apply more than 2.0 oz ai/ft^3 per application when used in vacuum-sealed pressurized chambers. For all other fumigation methods, do not apply more than 0.0448 oz ai/ft^3. **If labels refer to "in-shell and processed nutmeats (except peanuts)",** the label language must be changed to "raw or processed tree nuts". Do not apply more than 2.0 oz ai/ft^3 per application when used in vacuum-sealed pressurized chambers. For all other fumigation methods, do not apply more than 0.0448 oz ai/ft^3.	Directions for Use Associated with the Specific Use Pattern

[a] 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.