



**US Environmental Protection Agency
Office of Pesticide Programs**

**Reregistration Eligibility Decision (RED)
for Dazomet**

July 9, 2008



United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7508P)

EPA 738-R-08-007
July 2008

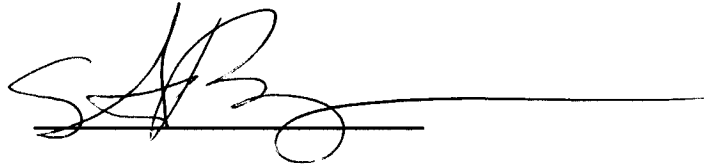
Reregistration Eligibility Decision for Dazomet

Dazomet RED

List B

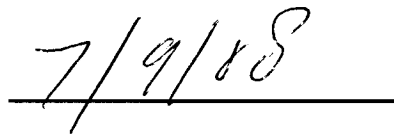
Case No. 2135

Approved by:

A handwritten signature in black ink, appearing to be 'SAB', is written over a horizontal line.

Steven Bradbury, Director
Special Review and Reregistration Division

Date:

A handwritten date '7/9/88' in black ink is written over a horizontal line.

Glossary of Terms and Abbreviations

AGDCI	Agricultural Data Call-In
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
BCF	Bioconcentration Factor
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formulation
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DNT	Developmental Neurotoxicity
EC	Emulsifiable Concentrate Formulation
EDWC	Estimated Drinking Water Concentration
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
GLN	Guideline Number
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 a 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
MATC	Maximum Acceptable Toxicant Concentration
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligram Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification Number. EPA's system for recording and tracking studies submitted.
MUP	Manufacturing-Use Product
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
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Pre-harvest 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
RQ	Risk Quotient
SCI-GROW	Tier I Ground Water Computer Model
SAP	Science Advisory Panel
SF	Safety Factor
SLC	Single Layer Clothing
TGAI	Technical Grade Active Ingredient
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UF	Uncertainty Factor
UV	Ultraviolet
WPS	Worker Protection Standard

Table of Contents

Abstract	8
I. Introduction	9
II. Chemical Overview	9
A. Chemical Identity	9
B. Use and Usage Profile	10
C. Regulatory History	12
III. Dazomet Risk Assessments	12
A. General Overview of Soil Fumigants	12
1. Human Health Risk	12
2. Environmental Fate, Ecological Effects and Risk	15
3. Benefits	17
B. Antimicrobial Risk	18
IV. Risk Management and Reregistration Decision	19
A. Determination of Reregistration Eligibility	19
B. Public Comments and Responses	20
C. Regulatory Position	21
1. Regulatory Rationale	21
a. Dazomet Soil Uses	21
i. Rate Reduction and Use Sites	22
ii. Human Health Risk Management	22
aa. Bystander Risk Mitigation	23
1. Buffer Zones	24
2. Posting	37
bb. Occupational Risk Mitigation	40
1. Handler Definition	40
2. Handler Requirements	40
3. Dermal Protection for Handlers	41
4. Respiratory Protection for Handlers	41
5. Tarp perforation and removal	44
6. Entry Prohibitions	45
cc. Other Risk Mitigation	49
1. Restricted Use Classification	49
2. Good Agricultural Practices	50
3. Fumigant Management Plans (FMPs)	51
4. Emergency Preparedness and Response	55
5. Notice to State Lead Agencies	60
6. Soil Fumigation Training for Applicators and Other Handlers	60
7. Community Outreach and Education Programs	64
iii. Environmental Risk Management	65
b. Dazomet Antimicrobial Uses	66
2. Endocrine Disruptor Effects	67
3. Endangered Species Considerations	67
D. Conclusion	68
V. What Registrants Need to Do	69

A. Manufacturing Use Products.....	70
1. Additional Generic Data Requirements	70
2. Labeling for Manufacturing-Use Products.....	75
B. End-Use Products.....	76
1. Additional Product-Specific Data Requirements	76
2. Labeling for End-Use Products	76
Appendix A(1): Dazomet (PC Code 035602) Soil Fumigant Uses Eligible for Reregistration .	103
Appendix A(2): Dazomet (PC Code 035602) Antimicrobial Uses Eligible for Reregistration .	103
Appendix B. Table of Generic Data Requirements and Studies Used to Make the Reregistration Decision...	111
Appendix C. Technical Support Documents	112

Dazomet Reregistration Eligibility Decision Team

Office of Pesticide Programs:

Health Effects Risk Assessment

Charles Smith, Risk Assessor
Anna Lowit, Toxicology
Sherri Kinard, Residue Chemistry
Ruth Allen, Epidemiology
Judy Facey, Toxicology

Office of General Council:

Andrea Medici

Office of Enforcement and Compliance:

David Stangel

Biological and Economic Analysis Assessment

TJ Wyatt, Senior Agricultural Economist
Jonathan Becker, Senior Science Advisor
Bill Chism, Senior Agronomist
David Donaldson, Agricultural Economist, Team Leader
Colwell Cook, Entomologist
Nicole Zinn, Biologist
Stephen Smearman, Economist
Leonard Yourman, Plant Pathologist
John Faulkner, Economist

Environmental Fate and Effects Risk Assessment

Mah Shamim, Branch Chief
Faruque Khan, Senior Fate Scientist
James Felkel, Wildlife Biologist
Gabriel Rothman, Environmental Scientist

Registration Support

Mary Waller, Product Manager
Tamue Gibson, Product Reviewer
Kathy Monk, Senior Advisor

Antimicrobial Risk Assessment Team

Heather Garvie, Chemical Review Manager
Diane Isbell, Reregistration Team Leader
Cassi Walls, Ph.D., Chemist
Timothy Dole, Industrial Hygienist
Rick Petrie, Senior Agronomist, Team Leader

Risk Management – Soil Uses

Nikhil Mallampalli, Team Leader
Dirk Helder, Team Leader
Cathryn O'Connell, Chemical Review Manager

Abstract

This document presents the Environmental Protection Agency's (hereafter referred to as EPA or the Agency) decision regarding the reregistration eligibility of the registered soil and antimicrobial uses of dazomet. The Agency has determined that products containing dazomet for these uses are eligible for reregistration provided that: (1) current data gaps are addressed; (2) the risk mitigation measures identified in the document are adopted; and (3) labels are amended to implement these measures.

Generally, registered dazomet uses fall into two basic categories, soil fumigation or antimicrobial use. Soil fumigation includes use on golf greens or tees, nonbearing crops, turf sites, ornamental sites, field nurseries, compost piles, potting soils, and strawberries and tomatoes in California only. Antimicrobial uses include: 1) as a treatment during the production of pulp and paper; 2) as a material preservative treatment for coatings, adhesives, epoxy flooring compounds, slurries, and high viscous suspensions; 3) as a biocide treatment used during petroleum operations; 4) as a biocide treatment to recirculating cooling water systems; and 5) as a remedial wood treatment to utility poles.

Concurrent to EPA's review of the soil fumigant uses of dazomet, EPA assessed the risks and developed risk management decisions for four other soil fumigant pesticides, including: chloropicrin, metam sodium/potassium, methyl bromide, and a new active ingredient, iodomethane. Risks of a fifth soil fumigant, 1,3-dichloropropene (1,3-D), were also analyzed along with the other soil fumigants for comparative purposes; its risk management decision was completed in 1998. The Agency evaluated these soil fumigants concurrently to ensure that human health risk assessment approaches are consistent, and that risk tradeoffs and potential economic impacts were considered appropriately in reaching risk management decisions. This review is part of EPA's program to ensure that all pesticides meet current health and safety standards.

EPA has identified potential human health risks of concern associated with the registered soil fumigant uses of dazomet from acute inhalation exposure to handlers, bystanders, and workers. To reduce these exposures and to address risks of concern, EPA is requiring a number of mitigation measures, such as buffer zones, posting, handler protection, restrictions on the timing of tarp perforation and removal operations, extending the entry prohibitions, restricted use classification (for soil uses only), mandatory good agricultural practices (GAPs), site-specific fumigant management plans (FMPs), emergency preparedness and response, notice to state and tribal lead agencies, training for applicators and handlers, and required community outreach and education programs. In addition the registrants have agreed to reduce the maximum rate from 530 lbs ai/A to 425 lbs ai/A which will directly reduce the potential risks to both humans and non-target organisms. The ecological risk assessment identified potential acute risks of concern for birds and mammals that could be exposed to unincorporated dazomet granules.

The Agency also has identified potential human health risks of concern associated with the registered antimicrobial uses of dazomet. To reduce these exposures, the Agency is requiring

a number of mitigation measures, including additional PPE for handlers engaged in these applications: pulp and paper use, cooling tower use, and metering pumps. For the epoxy flooring uses, the labels must be amended to reduce the amount of dazomet formulated in end use products.

The Agency is issuing this decision document for dazomet, as announced in a Notice of Availability published in the Federal Register. Due to the broad scope of the decision for the soil fumigant group, there will be a 60-day public comment period for this document to allow stakeholders the opportunity to review and provide comments on issues related to the implementation of the risk mitigation measures.

I. Introduction

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

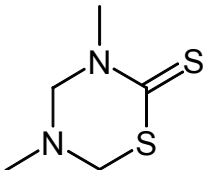
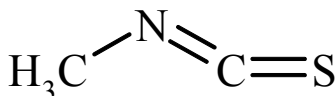
This document presents the EPA decision regarding the reregistration eligibility of the registered uses of dazomet. Dazomet is used as a non-selective soil fumigant with fungicidal, herbicidal, and nematocidal properties. It is also used as an algaecide, bacteriostat, fungicide, microbiocide, mildewcide in a number of antimicrobial use sites. When dazomet is applied, it is quickly broken down into several degradates; the major degrade being methyl isothiocyanate (MITC). The Agency made its reregistration eligibility determination based on the required data, the current guidelines for conducting acceptable studies to generate such data, and published scientific literature. The Agency has found that currently registered uses of dazomet are eligible for reregistration provided the mitigation and labeling outlined in this RED are implemented.

The document consists of five sections. Section I contains the regulatory framework for reregistration. Section II provides a profile of the use and usage of the chemical. Section III provides a general fumigant overview and also summarizes dazomet's risk assessments. Section IV presents the Agency's reregistration eligibility and risk management decisions. Section V summarizes label changes necessary to implement the risk mitigation measures outlined in Section IV. Unless otherwise noted, all Agency references in this document are available for review in the dazomet docket (EPA-HQ-OPP-2005-0128) at www.Regulations.gov.

II. Chemical Overview

A. Chemical Identity

When dazomet is applied to soil, either to the surface or incorporated, it quickly breaks down. The major degradate is MITC, but formaldehyde, monomethylamine, hydrogen sulfide and (in acid soils) carbon disulfide, are also formed. All of these degradates are gases or volatile liquids which diffuse through the spaces in the soil, killing living organisms with which they come in contact. This reregistration eligibility decision considers risks of exposure of dazomet and the major degradate, MITC, as a result of dazomet applications. Table 1 provides a summary of the dazomet and MITC nomenclature.

Table 1: Dazomet and MITC Nomenclature		
<u>Properties</u>	<u>Dazomet</u>	<u>MITC</u>
Chemical Structure		
Chemical Group	Dithiocarbamate	Isothiocyanate
Common Name	Dazomet	Methyl isothiocyanate
Molecular formula	C ₅ H ₁₀ N ₂ S ₂	C ₂ H ₃ NS
Molecular Weight	162.28	73.12
CAS No.	533-74-4	556-61-6
PC Code	035602	068103
Case Number	2135	Not Applicable

B. Use and Usage Profile

Soil Uses

Pesticide Type:	Broad spectrum soil fumigant with herbicidal, nematocidal, and fungicidal properties
Target pests:	Weeds, nematodes and various soil-borne pathogens
Use patterns:	Golf greens/tees, nonbearing crops (such as orchard crops, berries, and flower bulbs), turf sites (establishing or renovating), ornamental sites (establishing or renovating), field nurseries (establishing or renovating), compost piles, potting soils, and strawberries and tomatoes in California only
Formulations:	Granular
Methods of	Tractor drawn spreaders and handheld equipment such as belly

Application:	grinders and push-type spreaders
Application Rates:	Maximum application rate for incorporated applications is 530 lbs ai/acre and for surface applications is 265 lbs ai/acre
Technical registrant:	Certis USA, LLC
Annual Usage:	Approximately 15,000 pounds of dazomet are used annually ¹ as a soil fumigant.

Antimicrobial Uses

Pesticide Type:	Algaecide, bacteriostat, fungicide, microbiocide, mildewcide
Target pests:	Fungi, bacteria, mildew, algae
Use patterns:	Dazomet may be used in a variety of ways including: 1) as a treatment during the production of pulp and paper; 2) as a material preservative treatment for coatings, adhesives, epoxy flooring compounds, slurries, and high viscous suspensions; 3) as a biocide treatment used during petroleum operations; 4) as a biocide treatment to recirculating cooling water systems; and 5) as a remedial wood treatment to utility poles.
Formulations:	Pelleted/tableted, liquid (soluble concentrate and flowable concentrate) solutions, water soluble packaged solids, ready to use solutions
Methods of Application:	Open pour (for both solid and liquid formulations), metering pump, and water-soluble packaged solid mixing
Application Rates:	Rates vary by application use site and method. Maximum rates are included in Table 4.1 of the Revised Occupational and Residential Antimicrobial Exposure Assessment (Walls, C. 2/14/08)
Technical registrant:	BASF

¹ USDA Agricultural Chemical Usage 2003 Nursery and Floriculture Summary, September 2004, <http://usda.mannlib.cornell.edu/MannUsda/viewDocumentInfo.do?documentID=1001>.

C. Regulatory History

Dazomet, (PC code 035602) and the sodium salt, tetrahydro-3,5-dimethyl-2H-1,3,5-thiadiazine-2-thione (PC Code 035607) are included in pesticide reregistration case number 2135. Currently, there are 23 products registered containing dazomet and there are no active products registered containing the sodium salt.

Dazomet has both agricultural and antimicrobial uses. Dazomet was first registered in the United States in 1967 as an algacide, a bacteriostat, and a microbicide in a variety of commercial and industrial applications such as pulp and paper mills, cooling tower waters, and adhesives.

In the late 1980s pre-plant soil uses of dazomet were registered. Dazomet is registered for use on non-bearing orchard crops, ornamentals, and turf to control plant pathogens, nematodes, and weeds. Unlike other soil fumigants, dazomet is applied as a dry granule and incorporated into the soil or applied to the soil surface and watered into the soil to activate it.

A Phase IV data call-in (DCI) was issued for dazomet in January 1991 and included data requirements for ecotoxicity, toxicology, and environment fate. A follow-up DCI was issued in May of 1992 that included data requirements for neurotoxicity and the nature of residue in plants. Dazomet was also included in the October 1995 agricultural reentry data call-in.

III. Dazomet Risk Assessments

A. General Overview of Soil Fumigants

Soil fumigants are pesticides that form gasses when applied to soil. Once in the soil, the fumigants work by controlling pests that can disrupt plant growth and crop production. Soil fumigants play a very important role in agriculture, but they also have the potential to pose risk concerns to people involved in application of the chemicals (handlers), workers who re-enter fumigated fields (workers), and people who may be near the treated area (bystanders).

1. Human Health Risk

When dazomet is applied and mixes with moist soil, it is quickly broken down into several products. One of these products is MITC that accounts for most of the fumigant activity. The main risk of concern for handlers, workers, and bystanders associated with the soil uses of dazomet is from acute inhalation exposure to MITC as a result of fumigant off-gassing. Dazomet handlers also are at risk from direct fumigant exposure during applications. The term *handler* refers to persons involved in the application of dazomet. For soil applications, handlers also include persons involved in perforating and removing of tarps. The term *worker* in this document refers to persons performing non-handler tasks within the application block, after the fumigation process has been completed, such as planting. The term *bystander* refers to any person who lives or works in the vicinity of a fumigation site.

In addition to soil use, dazomet is also used as an antimicrobial pesticide in the following ways: 1) as a treatment during the production of pulp and paper; 2) as a material preservative treatment for coatings, adhesives, epoxy flooring compounds, slurries, and high viscous suspensions; 3) as a biocide treatment used during petroleum operations; 4) as a biocide treatment to recirculating cooling water systems; and 5) as a remedial wood treatment to utility poles.

Estimating exposure to fumigants is different from non-fumigant pesticides due to fumigants' volatility and ability to move off site during and after application. For example, pesticide spray drift is the physical movement of pesticide particulate or droplets from the target site during the application and soon thereafter. In the case of soil fumigants, the pesticide moves as a gas (not as particulate or droplets) and movement off-site can occur for an extended period after application. Importantly, fumigants have a well-documented history of causing large-scale human exposure incidents up to several thousand feet from treated fields. Assessing fumigant exposure takes into account the size of the fumigated field, the amount of fumigant applied, and the rate at which the fumigant escapes from the treated field.

The term "flux rate" or "emission rate" defines the rate at which a fumigant off-gasses from a treated field. Many factors influence the rate of emissions from treated fields. Factors such as the application method, soil moisture, soil temperature, organic matter levels, water treatments, the use of tarps, biological activity in the soil, soil texture, weather conditions, soil compaction, and others influence the amount of fumigant that comes off the field and is available to move off-site to areas where bystanders may be located.

The human health risk assessment indicates that acute inhalation exposures to MITC concentration of 22 ppb or greater for a 1 to 8 hour time period for non-occupational (residential) bystanders and occupational handlers could pose risks of concern. The 22 ppb concentration is based on a reversible endpoint from a human eye irritation and odor threshold study for acute exposures to MITC. The lowest observable adverse effect level (LOAEL) was 800 ppb, and the human concentration (HC) based on the no observable adverse effect level (NOAEL) from this study is 220 ppb. The NOAEL of 220 ppb being used by EPA is similar to a benchmark concentration level of 200 ppb submitted by the group Toxicology Excellence in Risk Assessment (TERA) on behalf of the metam sodium registrants. The benchmark concentration analysis thus supports the Agency's toxicity endpoint. Since the study is a human exposure study for acute eye exposures to MITC, the standard 10X for animal to human extrapolation is not needed. A 10X uncertainty factor for intraspecies variability was included, which when applied to the HC, results in the target concentration for acute inhalation exposures of 22 ppb.

California Pesticide Illness Surveillance Program data from 1992-2003 confirm that eye effects from MITC exposure as seen in this human study provide a sensitive endpoint for regulating acute inhalation exposures. In many incident cases, people complain of eye effects. However, many reported cases also report systemic or respiratory effects, while some are effects without eye irritation. Compared to eye irritation, the systemic and respiratory effects are more adverse in nature. Unfortunately, the available toxicity data in animals or humans do not allow a

quantitative comparison of the dose response curves of the eye, systemic, and respiratory effects to determine at the exact doses those effects occur. However, the Agency believes eye irritation provides a surrogate for other toxic effects and thus makes this the appropriate endpoint to regulate. To ensure that this endpoint is protective of any effects from repeated and longer term exposures, EPA is requiring data to evaluate developmental, reproductive, chronic, and cancer hazards and has encouraged the registrants to pursue additional studies to characterize the dose response curves of different target organs.

In assessing risks from dazomet, the Agency considered multiple lines of evidence, using the best available information from monitoring studies, modeling tools, and from incidents.

- **Monitoring:** For the human health risk assessments completed for dazomet and the other soil fumigants within the group, several field-scale monitoring studies were considered. These studies quantify dazomet concentrations in and around fields at various times and distances during and after applications. Many of these data indicate that there can be risks of concern associated with dazomet use at a broad range of distances from treated fields. However, these data are limited in their utility because they provide results only for the specific conditions under which the study was conducted.
- **Modeling:** Models enable the use of data from monitoring studies to estimate concentrations and potential risks under a wide range of conditions and use patterns. EPA used the Version 2.1.4 of the **P**robabilistic **E**xposure and **R**isk model for **F**umigants (also called the PERFUM model) to evaluate potential risks at distances around treated fields. PERFUM incorporates actual weather data and flux distribution estimates, and then accounts for changes and altering conditions. Analyses based on a variety of model outputs were used to compare the potential risks at a range of distances. The PERFUM model and users manual are public domain and can be downloaded at <http://www.exponent.com/perfum/>.
- **Bystander, handler, and worker incident reports:** Incidents for the soil fumigants generally occur at a low frequency relative to the total number of fumigant applications performed annually. However, when incidents occur, there are often many people involved. Incidents involving handlers and workers tend to occur more often than incidents with bystanders.

Reconstructing incidents to examine the exact factors which led to the incident can be difficult, especially when bystanders are involved since all the factors that contributed to the incident may not have been documented. Some of the factors that have been linked to incidents in the past have included equipment failure, handler accidents, applicator failure to adhere to label recommendations and/or requirements, and temperature inversions. Bystander incidents have occurred both close to fumigated fields and up to two miles away from the fumigated field, although these types of incidents have not been reported specifically for dazomet.

Based on these lines of evidence and as described in more detail in the risk assessments, EPA has determined that dazomet risks to handlers, workers, and bystanders are of concern given current labels and use practices. The human health risk assessments indicate that inhalation exposures to bystanders who live and work near agricultural fields where dazomet fumigations occur have the potential to exceed the Agency's LOC without additional mitigation measures. There are also risks of concern for occupational handlers involved in dazomet applications and for workers who may re-enter treated area shortly after fumigation or tarp perforation has been completed.

For more information about the specific information in the Agency's human health risk analysis for dazomet, refer to the documents listed below, all of which can be found in the dazomet docket # EPA-HQ-OPP-2005-0128 at <http://www.regulations.gov>:

- *Dazomet: Updated Final Revised HED Chapter of the Reregistration Eligibility Decision Document (RED)*. (Smith, C. et al., Dated June 2008)
- *Mode of Action, Eye Irritation, and the Intra-Species Factor: Comparison of Chloropicrin and MITC*. (Lowitt, A. and Reaves, E., Dated June 25, 2008)

2. Environmental Fate, Ecological Effects and Risks

The Agency's environmental fate and ecological effects risk assessments indicate that there are some concerns for non-target organisms that may be exposed to fumigants. Exposure to terrestrial organism such as birds and mammals could occur two ways, as either oral exposure to dazomet granules or by the inhalation route of exposure to the breakdown product MITC. Potential exposure to aquatic organisms may occur from surface runoff/leaching and/or volatilization and deposition of MITC in water bodies.

Hazard

Dazomet is considered moderately toxic on an acute oral basis to both birds ($LD_{50} = 424$ mg/kg) and mammals ($LD_{50} = 415$ mg/kg). MITC is considered highly toxic on an acute oral basis to mammals ($LD_{50} = 55$ mg/kg), and moderately toxic via the inhalation route. Acute oral and inhalation toxicity data with MITC are needed for birds.

MITC is considered very highly toxic to both fish (lowest $LC_{50} = 51.2$ ppb) and aquatic invertebrates (lowest $LC_{50} = 55$ ppb).

Exposure

Terrestrial (Dazomet and MITC)

Direct exposure of mammals and birds to dazomet granules was estimated using the model T-REX, Version 1.2.3 (T-REX, 2005). T-REX was run for tomato and strawberry crops (also applicable to turf, ornamental and other pre-plant incorporated uses) for a single application of dazomet applied at the maximum rate of 530 lb a.i./A. In addition, exposure of terrestrial

animals to the volatile degradation product MITC was evaluated using a preliminary LD₅₀/square foot risk screening method. The Industrial Source Complex Short Term (ISCST3) model together with information about MITC emissions from a treated field was used to evaluate the range of MITC concentrations which might be found under different conditions of application rate, weather, source size and shape (e.g., field size in acres) and distance from the treated field.

Aquatic (MITC)

For exposure to fish and aquatic invertebrates, EPA considers surface water only, since most aquatic organisms are not found in ground water. The aquatic exposure assessment for MITC relied on Tier II aquatic models. The Pesticide Root Zone Model (PRZM version 3.1.2 beta) simulates fate and transport on the agricultural field, while the water body is simulated with Exposure Analysis Modeling System (EXAMS version 2.98.04). Simulations are run for multiple (usually 30) years and the reported EECs represent the values that are expected once every ten years based on the thirty years of daily values generated during the simulation.

PRZM/EXAMS simulates a 10 hectare (ha) field immediately adjacent to a 1 ha pond, 2 meters deep with no outlet. The location of the field is specific to the crop being simulated using site specific information on the soils, weather, cropping, and management factors associated with the scenario. The crop/location scenario in a specific state is intended to represent a high-end vulnerable site on which the crop is normally grown. Based on historical rainfall patterns, the pond receives multiple runoff events during the years simulated. PRZM has limited capabilities in capturing the amount of a volatile chemical in air, water and sediment. The estimated concentrations of chemicals like MITC in surface water bodies may be upper bound.

To simulate field application of dazomet, multiple scenarios were selected representing proposed dazomet usage areas based on geography and weather. PRZM and EXAMS models and relevant scenarios were used to estimate MITC estimated exposure concentrations (EECs) in surface water based on label information for dazomet application to tomatoes, strawberries, turf and ornamental trees at the highest application rate. The scenario with the highest concentration of MITC from dazomet applications was the California strawberry scenario.

Risk

Terrestrial Risk (Dazomet and MITC)

Available dazomet toxicity studies allow the assessment of acute oral exposure of birds and mammals. Inhalation toxicity studies for MITC are only available for mammals. There are currently no studies available to estimate chronic terrestrial risks.

The Agency's levels of concern are exceeded for acute oral consumption of dazomet granular product for both mammal and bird species that are not Federally-listed as endangered or threatened as well as for 'listed' species. However, for mammal inhalation exposure to MITC all of the estimated risks are below the Agency's LOC for both listed and non-listed species. The inhalation effects observed and assessed in mammals included both metaplasia of respiratory

epithelium and lethality. There were no data available to assess inhalation risk to birds, and additional data is required. At the present time there are no registrant-submitted toxicity studies, or studies published in the open literature, that evaluates the toxicity of dazomet or MITC to terrestrial plants.

Aquatic Risk (MITC)

None of the estimated acute fish or aquatic invertebrate risks were above the Agency's LOC for freshwater non-listed or listed species. However, no MITC studies are available for marine/estuarine organisms. For chronic risk from MITC the only data available to evaluate chronic effects on aquatic organisms are for freshwater invertebrates, which predict risks below the Agency's LOC. However, no MITC data are available to evaluate the chronic effects on freshwater and estuarine/marine fish, or estuarine/marine invertebrates. All of the estimated risks for aquatic plants were below the Agency's levels of concern.

Due to the current data gaps for dazomet and MITC, the Agency is requiring additional eco-toxicity studies for both terrestrial and aquatic organisms. For more information on the Agency's environmental fate and ecological effects risk analysis:

- *Revised Environmental Fate and Ecological Risk Assessment For Dazomet.* (Khan. F. and Felkel, J., Dated April 8, 2008)

3. Benefits

Soil fumigation can provide benefits to both food consumers and growers. For consumers it means more fresh fruits and vegetables can be cheaply produced year-round because severe pest problems can be efficiently controlled. Growers benefit because crops grown in fumigated soil produce fewer blemished products, which translates into an increase in marketable yields. Fumigation can also provide benefits to growers by increasing crop management flexibility. This includes shorter crop rotational intervals (i.e., less time when fields are left fallow), improved ability to meet quarantine requirements (which are imposed when states or other jurisdictions require a pest-free harvested product), and consistent efficacy against critical pests. The magnitude of benefits depends on pest pressure, which varies over space and time, and the availability and costs associated with the use of alternatives.

There are a number of benefits assessments that have been completed by the Agency to estimate the value of these chemicals to various industries, which are listed below.

- EPA-HQ-OPP-2005-0123-0321, Assessment of the Benefits of Soil Fumigation with Chloropicrin, Metam-Sodium, and Methyl Bromide in Eggplant Production
- EPA-HQ-OPP-2005-0123-0322, Assessment of the Benefits Soil Fumigants (Methyl Bromide, Chloropicrin, Metam-Sodium, Dazomet) Used by Forest Tree Seedling Nurseries
- EPA-HQ-OPP-2005-0123-0323, Assessment of the Benefits of Soil Fumigation with Methyl Bromide, Chloropicrin, Dazomet, Metam Potassium and Metam Sodium for Use

in Raspberry Nurseries, Fruit and Nut Deciduous Tree Nurseries, and Rose Bush Nurseries in California

- EPA-HQ-OPP-2005-0123-0324, Assessment of the Benefits of Soil Fumigation with Chloropicrin and Metam-sodium In Onion Production
- EPA-HQ-OPP-2005-0123-0325, Assessment of the Benefits of Soil Fumigation with Methyl Bromide, Chloropicrin and Metam-sodium In Grape Production
- EPA-HQ-OPP-2005-0123-0326, Assessment of the Benefits of Soil Fumigation with Methyl Bromide, Chloropicrin and Metam-sodium In Tree Nut Production
- EPA-HQ-OPP-2005-0123-0327, Assessment of the Benefits of Soil Fumigation with Chloropicrin, and Methyl Bromide In Pome Fruit Production
- EPA-HQ-OPP-2005-0123-0328, Assessment of the Benefits of Soil Fumigation with Methyl Bromide, Chloropicrin, and Metam Sodium In Stone Fruit Production
- EPA-HQ-OPP-2005-0123-0329, Assessment of the Benefits of Soil Fumigation with Chloropicrin, Methyl Bromide, and Metam-Sodium in Bell Pepper Production
- EPA-HQ-OPP-2005-0123-0330, Assessment of the Benefits of Soil Fumigation with Metam-sodium in Potato Production
- EPA-HQ-OPP-2005-0123-0331, Assessment of the Benefits of Soil Fumigation with Chloropicrin, Methyl Bromide, and Metam-sodium In Strawberry Production
- EPA-HQ-OPP-2005-0123-0332, Assessment of the Benefits of Soil Fumigation with Chloropicrin, Methyl Bromide, Metam-sodium, and Dazomet In Strawberry Nursery Runner Production
- EPA-HQ-OPP-2005-0123-0333, Assessment of the Benefits of Soil Fumigation with Chloropicrin, Methyl Bromide and Metam-sodium In Sweet Potato Production
- EPA-HQ-OPP-2005-0123-0334, Assessment of the Benefits of Soil Fumigation with Chloropicrin In Tobacco Production
- EPA-HQ-OPP-2005-0123-0335, Assessment of the Benefits of Soil Fumigation with Chloropicrin, Methyl Bromide, and Metam-sodium in Tomato Production
- EPA-HQ-OPP-2005-0123-0336, Assessment of the Benefits of Soil Fumigation with Metam Sodium in Carrot Production
- EPA-HQ-OPP-2005-0123-0337, Assessment of the Benefits of Soil Fumigation with Metam Sodium in Peanut Production
- EPA-HQ-OPP-2005-0123-0338, Assessment of the Benefits of Soil Fumigation with Chloropicrin, Methyl Bromide, Metam Sodium and Dazomet in Ornamental Production
- EPA-HQ-OPP-2005-0123-0339, Summary of the Benefits of Soil Fumigation with Methyl Bromide in Crop Production
- EPA-HQ-OPP-2005-0123-0340, BEAD's Planned Impact Assessments on Agricultural Sites with Significant Use of Soil Fumigants

B. Antimicrobial Risk

In addition to the use of fumigants to sterilize soil before planting, there are a number of antimicrobial uses that the Agency has assessed in this RED. Dazomet may be used as an antimicrobial chemical in the following ways: 1) as a treatment during the production of pulp and paper; 2) as a material preservative treatment for coatings, adhesives, epoxy flooring

compounds, slurries, and high viscous suspensions; 3) as a biocide treatment used during petroleum operations; 4) as a biocide treatment to recirculating cooling water systems; and 5) as a remedial wood treatment to utility poles.

All of the occupational handler risks were below the Agency's LOC except for some scenarios with the following uses: preservation of epoxy flooring compounds, pulp and paper slimicide use, and microbe control in large water cooling systems.

For more information on these antimicrobial uses:

- *Dazomet Antimicrobial Risk Mitigation Paper*. (Garvie, H., Dated June 2008)
- *Dazomet: Revised Occupational and Residential Exposure Assessment of Antimicrobial Uses for the Reregistration Eligibility Decision (RED) Document*. (Walls, C., Dated June 2008)

Please refer to the RED Appendix for the complete document citations, which are also available in the dazomet docket (OPP-2005-0128) at www.regulation.gov.

IV. Risk Management and Reregistration Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient-specific) data to support reregistration of products containing dazomet. The Agency has completed its assessment of the residential, occupational, and ecological risks associated with the use of pesticides containing the active ingredient dazomet.

In Phase 5, the Agency published a risk mitigation options paper.² This document detailed potential mitigation options and sought public comment on these options. The following is the list of mitigation options discussed in the Agency's paper:

- Buffer zones;
- Sealing methods;
- Timing of applications;
- Application block size limitations;
- Respiratory protection;
- Tarp perforation/removal procedures;
- Entry-restricted period;

² EPA-HQ-OPP-2005-0128-0031, Risk Mitigation Options to Address Bystander and Occupational Exposures from Soil Fumigant Applications

- Application method/practice restrictions;
- Fumigant management plans (FMPs);
- FMP certification;
- Responsible parties;
- Record keeping/reporting/tracking;
- Restricted Use Pesticide Classification;
- Notification and posting;
- Good agricultural practices;
- Fumigant manuals; and
- Stewardship programs.

Based on a review of the dazomet database and public comments on the Agency's assessments for dazomet, the Agency has sufficient information on the human health and ecological effects of dazomet to make decisions as part of the reregistration process under FIFRA. The Agency has determined that dazomet products are eligible for reregistration provided that (i) required product specific data are submitted, (ii) the risk mitigation measures outlined in this document are adopted, and (iii) label amendments are made to implement these mitigation measures, as outlined in Chapter V. Appendix A summarizes the uses of dazomet that are eligible for reregistration.

The Agency's decision takes into account the best available information on the potential risks and benefits of metam use. In reaching its reregistration decision and developing the dazomet mitigation proposal, EPA considered a range of factors, including: characteristics of bystander and other populations exposed to dazomet; hazard characteristics of dazomet and MITC; available information on levels of exposure, feasibility, cost, and effectiveness of various risk mitigation options; incident information; public comments; potential impacts of mitigation on growers ability to produce crops; availability of efficacious alternatives; comparative risks of alternative control methods; and the uncertainties and assumptions underlying the risk and benefit assessments.

A substantial amount of research is currently underway or is expected to begin in the near term to (1) address current data gaps, and (2) refine understanding of factors that affect fumigant emissions. Additionally, a number of new methods and technologies for fumigation are emerging. EPA plans to move the soil fumigants forward in Registration Review, from 2017 to 2013, which will allow EPA to consider new data and information relatively soon, determine whether the mitigation included in this decision is effectively addressing the risks as EPA believes it will, and to include other soil fumigants which are not part of the current review.

The Registration Review process for dazomet and the other soil fumigants will also include a comprehensive endangered species assessment. Once that endangered species assessment is completed, further changes to dazomet labels may be necessary.

B. Public Comments and Responses

The Phase 3 public comment period on the preliminary risk assessments and related documents for dazomet lasted from July 13 through October 12, 2005. EPA-HQ-OPP-2005-0128-0062 contains the Agency responses to Phase 3 public comments related to dazomet uses.

EPA revised its risk assessments and developed benefits and risk mitigation options during Phase 4. The Phase 5 public comment period on revised risk assessments, benefits analysis, and risk management options took place from May 2 to November 3, 2007. Comments on issues which were significant to many stakeholders and directly influenced EPA's decisions are highlighted in this document as well as EPA's responses to those comments. The following documents include EPA's responses to comments related to dazomet which may be found in the dazomet docket.

- *The Health Effects Division's Response to Comments on EPA's Phase 5 Reregistration Eligibility Decision Document for Dazomet.* (Smith, C., Dated June 2008)
- *Response to Phase 5 Public Comments on the Phase 4 Dazomet Environmental Fate and Ecological Risk Assessment.* (Khan, F., and Felkel, J., Dated April 2, 2008)
- *Response to Phase 5 BEAD Related Public Comments Received on the Reregistration of Chloropicrin, Dazomet, Metam Potassium, Metam Sodium, and Methyl Bromide.* (Donaldson, D. et al., Dated June 2008)
- *Review of Stakeholder Submitted Impact Assessments of Proposed Fumigant Buffers, Comments on Initial Buffer Zone Proposal, and Case Studies of the Impact of a Flexible Buffer System for Managing By-Stander Risks of Fumigants.* (Wyatt, T., et al, Dated June 2008)
- *Phase 6 Response to Substantive Public Comments on Antimicrobials Division's Occupational and Residential Assessments for the Reregistration Eligibility Decision (RED) Documents for the following chemicals: Methylisothiocyanate (MITC), Metam Sodium, Dazomet, and Chloropicrin.* (Walls, C., Dated February 14, 2008)
- *SRRD's Response to Phase 5 Public Comments for the Soil Fumigants.* (Dated July 2008)

C. Regulatory Position

1. Regulatory Rationale

The Agency has determined that dazomet is eligible for reregistration provided the risk mitigation measures outlined in this document are adopted and label amendments are made to reflect these measures. The following is a summary of the rationale for managing risks associated with the use of dazomet. Where labeling revisions are warranted, specific language is set forth in the summary table in Section V of this document.

a. Dazomet Soil Uses

i. Rate Reduction and Use Sites

Rate

The current maximum application rates for dazomet are 530 lbs ai/A for incorporated applications and 265 lbs ai/A for surface applications. According to the dazomet soil use registrant, Certis, USA LLC, the actual use rate of dazomet is usually much lower for most uses of dazomet. The turf and ornamental use rarely requires the maximum rate, except for golf course or turf renovation. For crop uses, the rate generally ranges from 200-300 lbs ai/A, although there are some cases where an application up to 400 lbs ai/A is needed. Therefore, the registrant has agreed to lower the maximum use rate of dazomet to 425 lbs ai/A for all registered uses except for golf course/turf renovation. The maximum rate for golf course/turf renovation will remain at 530 lbs ai/A.

Use Sites

Dazomet is not used in greenhouses; however current labels include some instructions for use in greenhouses on labels. The registrant has confirmed that dazomet is not supported for use in greenhouses, and all labels will be amended to delete references to use in greenhouses and add a statement prohibiting use in greenhouses. See Table 4, the label table for additional information.

ii. Human Health Risk Management

For details on the dazomet human health risk assessment for soil uses, please refer to the Human Health Risk Assessments referenced in Section III of this document. These documents are also available in the public docket EPA-HQ-OPP-2005-00128, located on-line in the Federal Docket Management System (FDMS) at <http://www.regulations.gov>.

Dietary Risk

Based on the currently registered use patterns for dazomet, dietary exposure, including exposure from drinking water, is not expected and no dietary risk mitigation is warranted for dazomet at this time.

Bystanders, Workers, and Handlers

The human health risk assessments indicate that inhalation exposure to bystanders who live and work near agricultural fields, nurseries, golf courses, and other areas where dazomet fumigations occur, and to handlers involved in the application of dazomet have the potential to exceed the Agency's LOC without additional mitigation measures.

To reduce the potential for exposure to bystanders, handlers, and workers and to address subsequent risks of concern, EPA is requiring a number of mitigation measures which include:

- Reducing maximum application rates;
- Clarifying use sites;
- Buffer zones;
- Dermal protection for handlers;
- Respiratory protection and air monitoring for handlers;
- Restrictions on the timing of perforation and removing of tarps;
- Posting;
- Good agricultural practices;
- Fumigant management plans;
- Emergency preparedness and response plans; and
- Notice to state lead agencies.

The Agency also believes that registrant developed training and community outreach and education programs, which are also implemented by the registrant, will help reduce risk. Additionally, EPA is interested in working with registrants to identify additional measures that could be implemented as part of product stewardship. These additional measures should include efforts to assist users' transition to the new label requirements.

Some of the required mitigation measures only address one group of potentially exposed individuals (i.e., bystanders, handlers, or workers), while other measures will help reduce risk to more than one group. All mitigation measures are designed to work together to reduce exposures, enhance safety, and facilitate compliance and enforcement. The Agency has based its risk mitigation decision on a flexible approach which EPA believes will be protective and allow users to make site-specific choices to reduce potential impacts on benefits of the use. While some of these measures, buffer zones for example, can be used to estimate MOEs, others such as emergency preparedness and response and community education will contribute to bystander safety, but are difficult to express in terms of changes to quantitative risk estimates such as MOEs. However, EPA has determined that these measures, working together, will prevent unreasonable adverse effects on human health.

aa. Bystander Risk Mitigation

Bystanders are persons who live and/or work near fumigated fields and are potentially exposed to fumigant emissions that travel off-site. In some cases the bystanders are workers performing agricultural tasks in nearby fields. If they are employed by the grower who has control of the fumigated field, they are more likely to be aware that a fumigant application has occurred.

Bystander risks for people that live near treated fields differ from other human health risks evaluated under FIFRA, for example residential and worker reentry risks. Unlike residential exposures resulting from use of products to control pests in and around the home, non-occupational bystanders receive no direct benefit from the pesticide which was applied elsewhere. These bystanders have not made a decision to purchase a pest control product or

service, and as a result they have little access to information about the product (e.g., hazards, safety information, first aid, etc.) or symptoms of exposure. Additionally, non-occupational bystander exposures to fumigants are largely involuntary and unanticipated. In this regard non-occupational bystander exposure is similar to dietary exposure in that people consuming foods or drinking water expect to be safe from possible adverse effects associated with pesticide residues that could be present in their food and drinking water.

Unlike workers, non-occupational bystanders typically receive no safety information or training related to the pesticide to which they may be exposed. Whereas workers are generally expected to play an active role in protecting themselves from pesticide risk, no such expectation exists for non-occupational bystanders. Workers who experience symptoms of pesticide exposure are also more likely to link their symptoms to the pesticide and take steps to receive appropriate treatment. Conversely, bystanders are much less likely to attribute adverse effects to pesticide exposures or to have access to information needed to take appropriate steps to mitigate the effects of the exposure. Thus, EPA's mitigation includes elements for emergency preparedness and response, notice to state lead agencies, training, and community outreach and education as well as labeling changes.

1. Buffer Zones

The human health risk assessment indicates bystanders may be exposed to MITC air concentrations from applications of dazomet that exceed the Agency's LOC. In general, the risk from inhalation exposures decreases as the distance from the field to where bystanders are located increases. Because of this relationship, the Agency is requiring that a buffer zone be established around the perimeter of each application block where dazomet is applied. The Agency acknowledges that buffer zones alone will not mitigate all inhalation risks and eliminate incidents caused by equipment failure, human error, and weather or other events (e.g., temperature inversions). The Agency however does believe that buffer zones along with other mitigation measures required by this decision described below will mitigate risks so that bystanders will not experience unreasonable adverse effects.

The Agency considered various buffer zone schemes ranging from fixed buffer zones for every application to site-specific buffer zones. During the most recent comment period, the Agency received input in favor of a flexible buffer approach that would allow fumigant users to determine the buffer zone distance based on site conditions and application practices. While the Agency believes that site-specific buffer zones would provide the most flexibility for users, the EPA currently does not have sufficient data to support this scheme. As a result, the Agency has developed a scalable buffer zone system that does provide flexibility by setting buffer zones for different application methods at various acreages and application rates.

Version 2.1.4 of the **Probabilistic Exposure and Risk** model for **Fumigants** (also called the PERFUM model) combined with monitoring data and incident data were used to characterize the risk for specific buffer zone distances corresponding to the range of application scenarios anticipated. Additional information on the PERFUM inputs and outputs can be found in Agency risk assessment, (EPA-HQ-OPP-2005-0123-0285), in a June 2006 a peer-reviewed article

describing the model (<http://www.sciencedirect.com/science/journal/13522310>), and/or the PERFUM user's guide which can be download from the internet (<http://www.exponent.com/perfum/>). A CD containing all of the PERFUM input/output files and files with the PERFUM MOE/air concentration analysis that were considered for this decision are available upon request at the OPP Docket Office.

General Buffer Zone Requirements

The following describes the general buffer zone requirements for dazomet and other soil fumigants currently going through the reregistration process:

- “Buffer zone” is an area established around the perimeter of each application block where a soil fumigant is applied. The buffer zone must extend from the edge of the application block perimeter equally in all directions.
- All non-handlers including field workers, nearby residents, pedestrians, and other bystanders, must be excluded from the buffer zone during the buffer zone period except for transit (see exemptions section).
- An “application block” is a field or portion of a field treated with a fumigant in any 24-hour period (see Figures 1 and 2 below for further explanation).
- The “buffer zone period” starts at the moment when any fumigant is delivered or dispensed to the soil within the application block and lasts for a minimum of 48 hours after the fumigant has stopped being delivered/dispensed to the soil.

Buffer zone distances

- Buffer zone distances must be based on look-up tables on product labels (25 feet is the smallest distance regardless of site-specific application parameters).

Authorized entry to buffer zones

- Only authorized handlers who have been properly trained and equipped according to EPA's Worker Protection Standard (WPS) and label requirements may be in the buffer zone during the buffer zone period.

Buffer zone proximity

- To reduce the potential for off-site movement from multiple fumigated fields, buffer zones from multiple MITC generating application blocks may not overlap (including blocks fumigated by adjacent property owners, see below for exemptions for areas not under the control of owner/operator of application block).
- No fumigant applications will be permitted within 0.25 miles of schools, state licensed day care centers, nursing homes, assisted living facilities, elder care facilities, hospitals, in-patient clinics and prisons if occupied during the buffer zone period.

Exemptions for transit through buffer zones

- Vehicular and bicycle traffic on public and private roadways through the buffer zone is permitted. "Roadway" means that portion of a street or highway improved, designed or

ordinarily used for vehicular travel, exclusive of the sidewalk or shoulder even though such sidewalk or shoulder is used by persons riding bicycles. In the event a highway includes two or more separated roadways, the term "roadway" shall refer to any such roadway separately. (This definition is based on the definition of roadway in the Uniform Vehicle Code prepared by the National Committee on Uniform Traffic Laws and Ordinances. See <http://www.ncutlo.org/> for more details)

- Bus stops or other locations where persons wait for public transit are not permitted within the buffer zone.
- See posting section for additional requirements that may apply.

Structures under the control of owner/operator of the application block

- Buffer zones may not include buildings used for storage such as sheds, barns, garages, etc., **UNLESS**,
 1. The storage buildings are not occupied during the buffer zone period, and
 2. The storage buildings do not share a common wall with an occupied structure.
- See posting section for additional requirements that may apply.

Areas not under the control of owner/operator of the application block

- Buffer zones may not include residential areas (including yards), employee housing, private property, buildings, commercial, industrial, and other areas that people may occupy **UNLESS**,
 1. The occupants provide written agreement that they will voluntarily vacate the buffer zone during the entire buffer zone period, and
 2. Reentry by occupants and other non-handlers does not occur until air monitoring after the buffer zone periods end indicates that the air concentrations within the structure/space is less than the acceptable air concentration on the label, as determined by air monitoring requirements described on product labels.
- Buffer zones may not include agricultural areas owned/operated by persons other than the owner/operator of the application block, **UNLESS**
 1. The owner/operator of the application block can ensure that the buffer zone will not overlap with a buffer zone from any adjacent property owners, and
 2. The owner/operator of the areas that are not under the control of the application provides written agreement to the applicator that they, their employees, and other persons will stay out of the buffer zone during the entire buffer zone period.
- Buffer zones may not include publicly owned and/or operated areas (e.g., parks, rights of way, side walks, walking paths, playgrounds, athletic fields, etc), **UNLESS**,
 1. The area is not occupied during the buffer zone period,
 2. Entry by non-handlers is prohibited during the buffer zone period, and
 3. Written permission to include the public area in the buffer zone is granted by the appropriate state and/or local authorities responsible for management and operation of the area.
- See posting section for additional requirements that apply.

PERFUM Model Inputs

The major input parameters for the modeling were: application rates, application block sizes, application method emission profiles, weather conditions, and the target air concentration (based on acute inhalation endpoint and uncertainty factors). The following summarizes the key points for each of these *input* parameters.

Rates

The maximum rates for soil applications of dazomet are 530 lbs ai/A for incorporated applications and 265 lbs ai/A for surface applications. Since there is limited use information on typical dazomet rates, a range of rates was modeled. The rates used in the model included the maximum, along with rates at 75%, 50%, and 25% of the maximum for both surface and incorporated applications.

Rates for bedded or strip applications (lb ai per treated area) were converted to broadcast equivalent application rate to determine the minimum buffer zone distance. In Figures 1 and 2 (shown below), the dashed line represents the perimeter of the field, the shaded area is the portion of the field that is treated, and the un-shaded area is the untreated portion of the field. Assuming both fields are 10 acres, and only 50% of field in Figure 2 is fumigated, the *rate per treated acre* is 400 lbs ai/A for both Figure 1 and 2. The *broadcast rate* for Figure 1 is 400 lb ai/A but the *effective broadcast equivalent rate* for Figure 2 is 200 lbs ai/A. Labels may express rates as lbs per treated acre under the application instructions but they must identify buffer zone distances based on the broadcast or effective broadcast equivalent rates.



Figure 1. Broadcast Application

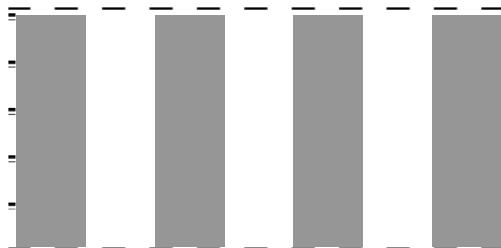


Figure 2. Bedded Application

Block Sizes

The Agency has limited information available on the size of application blocks treated in a given day but according to the registrants, dazomet is generally applied to a smaller number of acres than other fumigants, typically from 5 to 20 acres. The modeling did consider block sizes up to 40 acres per day for dazomet, and so based on the registrant comment the application block size will be limited to 40 acres for dazomet.

The application block size pertains to size of the field and not the size of the area treated. The area inside the dashed lines in both Figures 1 and 2 is the application block. In this example

the application block size for both figures is 10 acres. For both figures, 10 acres would be used to determine the buffer zone distance.

Emission Studies

The Agency's Phase 5 risk assessment includes modeling of the two main ways that dazomet is applied, surface or soil-incorporated. Details of these emission studies can be found in Appendix D of the *Dazomet: Final Revised HED Chapter of the Reregistration Eligibility Decision Document (RED)*.

Weather

It is estimated that the major use of dazomet is in California and Washington. Some use in Michigan and Florida (or elsewhere in those regions) is also estimated. As a result, weather data for the following locations were included in this assessment: Bakersfield, CA; Ventura, CA; Flint, MI; Tallahassee, FL; Bradenton, FL; and Yakima, WA. Each modeling run used five years of weather (i.e., 1,825 potential application days) for each weather data set. Generally, Ventura, and Bradenton weather data result in the largest buffer zone distances, Bakersfield, Tallahassee, and Yakima data fall in the middle, and Flint data resulted in the smallest buffers.

Target Air Concentration

As described in the Human Health Risks section of Chapter III, the 22 ppb target air concentration is based on a reversible sensitive endpoint from a human eye irritation and odor threshold study for acute exposures to MITC, with a 10X uncertainty factor for intraspecies extrapolation. The lowest observable adverse effect level (LOAEL) was 800 ppb and the human concentration (HC) based on the no observable adverse effect level (NOAEL) from this study is 220 ppb.

PERFUM Model Outputs

The PERFUM model outputs are presented in percentiles for “whole field” and the “maximum distance” distributions. The model also provides outputs as distributions of air concentrations from which MOEs can be estimated. The following summarizes the key points for each of these *output* parameters.

The maximum distance distribution is a compilation of the farthest predicted buffer distances (i.e., the farthest downwind points) over 5 years of weather. The whole field distribution differs because it includes all points around the perimeter for the same period. Another way to consider the difference between the distributions is that maximum distance results are a subset of the whole field results and that maximum distances allow for more resolution at the upper percentiles of this distribution. Version 2.1.4 of PERFUM also allows for direct consideration of air concentrations at various distances around treated fields. These air concentrations and MOEs were also considered in the decision making process.

An analysis based on a variety of PERFUM outputs was used in the buffer distance determinations. This involved consideration of not only the typical maximum and whole-field results, which are predictions of the distances at which a target concentration of concern (i.e., the human concentration adjusted by applicable uncertainty factors) is achieved at varying percentiles of exposure. In addition, a complementary approach, which determined the percentiles of exposure for maximum and whole-field buffers at predetermined buffer distances, was employed. Air concentration data were also used to calculate risk estimates (i.e., MOEs) at predefined buffer distances and varied percentiles of exposure.

This overall approach allowed the Agency to utilize more of the information available from PERFUM so that a more comprehensive view of the risks could be considered. Buffer distances indicated by this type of analysis along with information from monitoring studies and incidents were valuable in determining buffer distances to manage potential risks from dazomet use when coupled with other mitigation measures.

Buffer Zone Distances

The Agency has developed buffer zones distances based on application rate and application block size (rounding up to nearest rate and block size). These distances are summarized in Table 2.

For each of the soil emission studies, distances were first chosen for the rates identified in the risk assessment as the 100%, 75%, 50%, and 25% of the maximum rates for each application method, as shown by the bolded red font in the table. For example, for surface applications the rates were 265 lbs ai/A, 200 lbs ai/A, 132 lbs ai/A, and 66 lbs ai/A; and for incorporated applications the rates were 530 lbs ai/A, 400 lbs ai/A, 265 lbs ai/A, and 132 lbs ai/A, with application block sizes of 5, 20, and 40 acres. Distances for the other rates in the buffer zone tables were scaled by assuming a linear relationship between the 100%, 75%, 50%, and 25%, and maximum rates (e.g., distance at 37.5% rate = [distance at 25% rate + distance at 50% rate]/2) with some adjustments for whole numbers. This scaling was necessary to provide an incremental spread of rates. It should be noted that the distances in the lookup tables are not model outputs, although the model outputs were used for their development.

Minimum and Maximum Buffer Zone Distances

For dazomet, the largest buffer distance is 1,080 feet for applications at a rate of 530 lbs ai/A and a 40 acre block size. Applications to larger block sizes and higher rates will be prohibited for dazomet, based on comments from the registrants that dazomet users do not apply to large areas at the very highest rates on current labels. A minimum buffer zone of 25 feet will be required regardless of site-specific application parameters. In some instances the PERFUM model predicts that the risks reach the target at the edge of the field, but the Agency believes that a 25 foot minimum buffer is a good agricultural practice. While modeling may support no buffer in some cases, a minimum buffer is being required because of variability in emission rate over a field and other factors not accounted for in the modeling.

Table 2: Buffer zone distances (in feet) for all dazomet soil applications

Block Size (acres)	Application Rates for either surface or incorporated applications (lbs ai/acre)																		
	530	400	390	380	370	360	350	340	330	320	310	300	290	280	270	265	260	250	240
1 or less	200	75	72	69	66	63	60	57	54	51	48	45	42	39	36	33	30	25	25
2	200	100	96	92	88	84	80	76	72	68	64	60	56	52	48	44	40	36	32
5	200	150	147	144	141	138	135	132	128	124	120	116	112	108	104	100	89	78	67
10	350	239	233	226	219	213	207	201	194	187	179	172	164	158	156	152	141	130	119
15	500	329	318	308	298	287	278	269	259	250	237	227	216	208	208	204	193	182	170
20	650	440	426	412	398	384	370	356	343	330	317	305	288	275	260	250	245	234	223
30	812	599	582	565	548	531	514	496	480	460	446	430	411	400	383	369	360	345	330
40	1080	770	750	730	710	690	670	650	630	610	590	565	545	524	505	500	490	471	452
Block Size (acres)	Application Rates for either surface or incorporated applications (lbs ai/acre)																		
	230	220	210	200	190	180	170	160	150	140	132	130	120	110	100	90	80	70	66
1 or less	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25
2	28	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25
5	56	46	36	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25
10	108	98	87	79	76	74	71	68	65	62	58	58	53	48	43	38	33	28	25
15	160	149	139	133	128	122	117	111	105	99	92	92	82	72	62	52	42	32	25
20	212	201	190	187	179	171	163	154	145	136	125	125	110	95	80	65	50	35	25
30	323	308	293	281	268	255	242	229	215	202	188	188	164	141	117	94	70	47	25
40	433	414	395	375	357	339	321	303	285	267	250	250	218	186	154	122	90	58	25

The buffer zone distances were not based on the selection of a specific percentile or distribution from the PERFUM modeling results. Rather, EPA used a weight of evidence approach to set the buffers which included consideration of the hazard profile of MITC, information from incident reports, monitoring data, stakeholder comments along with comprehensive analysis of results from PERFUM modeling and consideration of results using other models (e.g., the Fumigant Emissions Modeling System or FEMS). Each model was reviewed by the FIFRA Scientific Advisory Panel (SAP) in 2004 during the August and September meetings (<http://www.epa.gov/oscpmont/sap/meetings/2004/index.htm>). The analysis of PERFUM results considered distances at various percentiles of the whole field and maximum distance distributions, and predicted MOEs for various distances. The risk assessment characterizes additional types of analysis that were performed. EPA's goal for risk management was to achieve buffer distances where associated risks were at or above target concentration levels at high percentiles of exposure. The following characterizes the risks associated with the buffer zone distances summarized in Table 3:

- This table shows the various buffer distances for each rate and block size. It also shows the percentile for the whole and maximum distribution for each distance, as well as the MOE at the 95th percentile air concentration of PERFUM2.
- The target MOE for dazomet is 10, and the MOEs at these distances range from about 7 up to 30. Although the target air concentration is not below our LOC at all the distances, at the lowest MOE of 7, the predicted air concentration would be 28 times lower than the lowest observable adverse effect level (LOAEL) that is the level where the eye irritation effects were first observed in the human study.
- All of the whole field percentiles are above 90 percent, and the max percentiles range from 37 to 99 percent.
- As a result of the two flux studies the registrant submitted there is little apparent difference in risk between the two methods when similar rates are compared. A greater change in risk appears to come from altering the rate. Therefore, the buffer tables for dazomet do not distinguish between the two methods of application; the tables are broken down by rate and block size.
- The use of GAPs, FMPs, and other mitigation measures required by this decision will contribute to an additional decrease in risk (see GAP and FMP sections below on pages 50 and 51 respectively).

Example

Table 3 shows the required buffer zone distances and corresponding PERFUM modeling results for the soil uses of dazomet using both the maximum distribution and the whole field distribution to the target concentration based on an MOE of 10, as well as the MOE from the air concentration outputs from PERFUM at the 95th percentile. The weather data selected here are from Ventura, CA, since only California has agricultural uses registered which typically involve larger application blocks than dazomet's other soil uses.

Focusing on the incorporated application method in the top row, using a 265 lbs ai/A rate on a 40 Acre block size, the buffer zone required for that application is 500 feet. The blocks referenced in this example are shaded in gray in Table 3.

- At this distance using the PERFUM model to predict both the whole field and maximum distributions the results indicate 91st percentile for whole field and 57th percentile for maximum, as shown in the next two columns in the table.
 - The risk level corresponding to this buffer zone distance at the 91st percentile whole field distribution is equivalent to saying a person at any location on the perimeter of the buffer zone during the 24 hour period following the fumigation of a specific field during a 5-year period would have at least a 91 percent chance of having of an exposure below the LOC (i.e., MOE of ≥ 10).
 - The risk level corresponding to the buffer zone distances at the 57th percentile maximum distribution is equivalent to saying a person at the location on the perimeter of the buffer zone where the maximum concentration occurs during the worst case 24 hour period following the fumigation of a specific field during a 5-year period would have a 57 percent chance of having of an exposure below the LOC (i.e., MOE of ≥ 10) for these typical use scenarios.
- Using the PERFUM 2 model outputs of air concentrations to predict MOEs at the 95th percentile, at 500 feet for these application parameters, the MOE is about 9 which is not significantly below the target MOE of 10.

Table 3: Dazomet's Buffers and Risk Estimates

Incorporated applications																
	530 lbs ai/A (100%) Max incorporated rate				400 lbs ai/A (75%)				265 lbs ai/A (50%)				132 lbs ai/A (25%)			
Block Size (acres)	Buffer Distance (feet)	Percentile using PERFUM at MOE of 10		MOE at 95th percentile of PERFUM 2	Buffer Distance (feet)	Percentile using PERFUM at MOE of 10		MOE at 95th percentile of PERFUM 2	Buffer Distance (feet)	Percentile using PERFUM at MOE of 10		MOE at 95th percentile of PERFUM 2	Buffer Distance (feet)	Percentile using PERFUM at MOE of 10		MOE at 95th percentile of PERFUM 2
		Whole	Max			Whole	Max			Whole	Max			Whole	Max	
40	1080	93	46	7	770	93	50	7					250	96	72	11
20	650	93	43	7	440	93	49	7	250	91	53	8	125	98	73	12
5	200	92	44	7	150	92	74	8	100	96	63	11	25	99	98	19
Surface applications																
	265 lbs ai/A (100%) Max surface rate				200 lbs ai/A (75%)				132 lbs ai/A (50%)				66 lbs ai/A (25%)			
Block Size (acres)	Buffer Distance (feet)	Percentile using PERFUM at MOE of 10		MOE at 95th percentile of PERFUM 2	Buffer Distance (feet)	Percentile using PERFUM at MOE of 10		MOE at 95th percentile of PERFUM 2	Buffer Distance (feet)	Percentile using PERFUM at MOE of 10		MOE at 95th percentile of PERFUM 2	Buffer Distance (feet)	Percentile using PERFUM at MOE of 10		MOE at 95th percentile of PERFUM 2
		Whole	Max			Whole	Max			Whole	Max			Whole	Max	
40	500	92	43	8	375	91	52	8	250	96	71	11	25	99	98	15
20	250	91	37	7	187	92	52	9	125	96	72	11	25	99	98	18
5	100	93	50	9	25	93	63	10	25	99	91	15	25	99	99	30

- Ventura Weather Data is used to calculate all the numbers in this table since it was one of the worst weather scenarios and for the agricultural uses of dazomet there is more use in California than Florida.
- Shaded areas represent the numbers explained in the example above.
- All values are approximate.

The Agency believes that the buffer zone distances described above, combined with other risk mitigation described herein, will provide protection against unreasonable adverse effects.

Buffer Zone Reduction Credits

The Agency has undertaken a significant effort to evaluate available empirical data, modeling, and literature regarding the factors and control methods that may reduce emissions from soil fumigants. For details on the Agency's analysis please see the June 9, 2008 memo "Factors Which Impact Soil Fumigant Emissions - Evaluation for Use in Soil Fumigant Buffer Zone Credit Factor Approach,"³ in the dazomet docket. The Agency has also coordinated and led forums to discuss this issue at the 2006 and 2007 Methyl Bromide Alternatives Outreach (MBAO) Conferences with leading researchers and other stakeholders. A general description of the MBAO sessions can be found at <http://mbao.org>.

Based on the Agency's analysis of the current data, the Agency has developed dazomet buffer zone reduction credits for: soils with high organic matter, and for soils with high clay content. The Agency believes that in addition to reducing bystander risk and the size of buffer zones, these credits have the potential to also decrease application rates. Applicators will be required to document any information about buffer zone credits that apply in the Fumigant Management Plan (FMP).

Soil Conditions

Soil conditions like the amount of organic matter and type of soil do have an impact on fumigant emissions. However, soil conditions differ from other credits because they are essentially beyond a grower's ability to change. Although a grower may not be able to manipulate organic matter or soil type, the Agency's factors document indicates that soil conditions can reduce fumigant emissions, and is offering credits for these conditions. EPA acknowledges that some variability in soil characteristics within a given field is likely. If users are unsure whether the fields they intend to treat meet the criteria for a credit, they may consult with their local agriculture extension office or soil conservation district for assistance in determining soil characteristics.

The Agency's factors document not only reviews available literature regarding soil conditions, but also describes modeling exercises that estimate the impact of organic matter and soil type using Chain_2D. Chain_2D is a first principles model that takes into consideration factors such as boundary layers or moisture that could impact fumigant emissions. The Agency used Chain_2D as modified by Dow AgroSciences' Steve Cryer and Ian van Wesenbeek in the sensitivity analysis⁴. Cryer and van Wesenbeek modified the original source code to create a more usable graphical user interface; this included incorporating a new air/soil boundary

³ Factors Which Impact Soil Fumigant Emissions – Evaluation for Use in Soil Fumigant Buffer Zone Credit Factor Approach, June 9, 2008, DP Barcode: 306857.

⁴ Cryer, S.A. (2007) Air/Soil Boundary Conditions For Coupling Soil Physics and Air Dispersion Modeling. Unpublished report of Dow AgroSciences LLC (Report # DN241493)

condition proposed by Wang in 1998⁵. See the Agency's factors analysis for further details about the CHAIN_2D model⁶.

Based on the review of available literature and modeling with the CHAIN_2D model, EPA believes 10 percent buffer zone credits are appropriate if the application block contains soil with organic matter of greater than 3 percent and/or for clay content of at least 27 percent.

The Agency's Chain-2D sensitivity analysis suggests that organic matter can have a small impact on emissions. There is generally a high correlation between the organic matter content of the soils and the dissociation constant (K_d) value. Increasing K_d value by 10 or 25 percent generally reduced emissions by 10 or 20 percent. Decreasing the K_d value by 10 or 25 percent increased emissions by 10 or 20 percent (see figures 147 to 154 of the factors analysis for further details).

Generally, clay loam and sandy clay loam soils tended to show significantly lower emissions than other soil types, sometimes showing 50 percent lower reductions. Conversely, loamy sand and loam soils tended to show higher emissions than other soil types (see figures 167 to 174 of the factors analysis for further details).

Dazomet buffer zone credits are additive and can not exceed 20 percent in total (e.g., 20 percent credit would apply for using > 3 percent organic content and >27 percent clay content).

For example, if an application block is 10 acres and the applicator is planning to apply 230 lbs of dazomet per acre, the buffer distance from the look up tables is 108 feet. If after the applicator tests the soil and determines the soil contains greater than 27 percent clay content, then the buffer zone may be reduced by 10 percent. By calculating 10 percent of 108 feet (108 feet x 10% = 10.8 feet buffer credit) and then subtracting the original buffer distance by the credit (108 feet – 10.8 feet = about 97 feet) the final buffer distance required is 97 feet.

Other Buffer Zone Credits Considered

Currently the dazomet label allows for use of tarps when making applications, but there is little information to suggest that growers are currently using tarps with dazomet. Since there is no information available about how dazomet reacts with tarps, and since other data for metam sodium suggests that standard tarps may not be very effective in trapping MITC vapors, there is no tarp credit for dazomet at this time. If additional tarps or other emission factor data become available to show the emissions from dazomet applications are decreased, the Agency will consider adding those to the dazomet label. More information on the type of data the Agency is looking for can be found in the *Health Effects Division Recommendations for Fumigant Data Requirements* (J. Dawson, C. Smith, dated June 2008).

⁵ Wang, D; Yates, S.R.; Jury, W.A. (1998) Temperature Effect on Methyl Bromide Volatilization: Permeability of Plastic Cover Films. J. Environ. Qual. 27, 821-827.

⁶ Factors Which Impact Soil Fumigant Emissions - Evaluation for Use in Soil Fumigant Buffer Zone Credit Factor Approach, June 9, 2008, DP Barcode: 306857

EPA (through OPP's Environmental Stewardship Branch) has proposed to co-fund a grant with USDA-ARS for several flux studies in the southeastern U.S. These studies would provide (1) field data on the emission reduction potential of certain low permeability barrier films to support possible, additional, buffer reduction credits as well as to (2) help develop an affordable and reliable hybrid field/lab test to evaluate the many barrier films available to growers. EPA has also prepared a document to describe possible research and study designs to reduce uncertainties in understanding emission factors in the context of different films and seals, agricultural practices, and environmental conditions.⁷ During the 60-day comment period the Agency anticipates learning more about ongoing and planned research from the scientific community that will address these uncertainties to help the Agency identify potential studies that would help refine the current risk-based mitigation decisions. The EPA will defer decisions regarding calling-in any data to address uncertainties identified with regard to these and other factors until comments provided during the 60-day comment period have been reviewed.

Other factors such as soil moisture content, field preparation, water sealing, and application depth could not be used to justify credits based on the available data. However, EPA has established mandatory good agricultural practices (GAPs) for these conditions. See the GAP section on page 50 for further discussion. If additional data on such emission reduction methods becomes available, EPA will consider developing further credits.

Buffer Zone Impacts

EPA acknowledges that even with the use of credits, there could be significant economic impacts to some growers who may not be able to accommodate large buffers based on their current application practices. As part of the most recent public comment period on fumigant risk assessments and proposed mitigation, several stakeholders submitted analyses estimating the impact of buffer zones around fumigated agricultural fields. The Agency's review of these studies and discussion of an EPA contracted study using the same approach for Kern County, California is included in the docket⁸. While buffers may restrict certain application practices, this decision allows growers the flexibility to modify their practices to achieve smaller buffers; for example treat smaller application blocks, or switch to a lower emission application method. Available data indicate that for some crops and regions, pest control efficacy may be improved with high barrier tarps which may enable growers to use the buffer zone credits and utilize lower application rates, resulting in further reductions of the buffer zone distances. Some growers in the Southeast are commonly using high barrier tarps and lower rates at present.

The Agency has also looked at how buffer zones have impacted California practices⁸. Buffer zones are currently required in California for methyl bromide pre-plant soil fumigations, as well as for dazomet use on strawberries and tomatoes. The Agency's document explains how

⁷ Health Effects Division Recommendations for Fumigant Data Requirements. June 2008. DP Barcode 353724

⁸ Review of Stakeholder Submitted Impact Assessments of Proposed Fumigant Buffers, Comments on Initial Buffer Zone Proposal, and Case Studies of the Impact of a Flexible Buffer System for Managing By-Stander Risks of Fumigants (DP# 353940)

California strawberry growers have modified their fumigation practices as a result of the buffer zones, and also the impact of these changes.

2. Posting

Posting is recognized as an effective means of informing workers and others about areas where certain hazards and restrictions exist. Current soil fumigant labels require treated areas to be posted, and handlers are required to wear specific PPE when they are in a treated area. For buffer zones to be effective risk mitigation, bystanders, including agricultural workers in nearby areas, need to be informed of the location and timing of the buffer to ensure they do not enter areas designated as part of the buffer zone.

In addition to alerting bystanders, posting a buffer zone will help handlers determine where and when they are required to use PPE. As described below, handlers working in buffers during the buffer zone period must use label-specified PPE and meet other requirements under the Worker Protection Standard (WPS). Therefore, EPA has determined that to ensure the protectiveness of buffers for bystanders and handlers, the perimeter of the fumigant buffer zones must be posted as described below and in the example that follows.

- Posting of a **buffer zone** is required **except** when one of the following conditions exist:
(1) a physical barrier that is reasonably likely to prevent bystander access to the buffer zone (e.g., a fence or wall) separates the edge of the buffer zone from bystander access.
OR
(2) the area within 300 feet of the edge of the buffer zone is controlled by the application block owner/operator. That is, if land under someone else's control is within 300 feet from the edge of the buffer zone, the buffer zone must be posted.

A buffer within 300 feet of an area that includes worker housing must be posted even if the area is under the control of the land owner/operator.

- Buffer zone posting signs must:
 - Be placed at all usual points of entry and along likely routes of approach from areas where people not under the land operator's control may approach the buffer zone.
 - When there are no usual points of entry, be posted in the corners of the buffer zone, between the corners of the buffer zone, and along sides so that one sign can be viewed (not read) from the previous one. Some examples of points of entry include, but are not limited to, roadways, sidewalks, paths, and bike trails.
- Buffer zone posted signs must meet the following criteria:
 - The printed side of the sign must face away from the treated area toward areas from which people could approach.
 - Signs must remain legible during entire posting period and must meet the general standards outlined in the WPS for text size and legibility (see 40 CFR §170.120).
 - Signs must be posted before the application begins and remain posted until the buffer zone period has expired.

- Signs must be removed within 3 days after the end of the buffer zone period.
- Registrants must provide generic buffer zone posting signs which meet the criteria above at points of sale for applicators to use.

Exception: If multiple contiguous blocks are fumigated within a 14-day period, the entire periphery of the contiguous blocks' buffer zones may be posted. The signs must remain posted until the last buffer zone period expires and signs may remain posted until 3-days after the buffer zone period for the last block has expired.

Additional requirements for treated area posting:

- The treated area posted signs must remain posted for no less than the duration of the *entry restricted period* after treatment.
- Treated area signs must be removed within 3 days after the end of the entry-restricted period.
- Signs must meet the general standards in the WPS for placement, text size, and location (40 CFR §170.120).

Contents of Signs

The **treated area** sign (currently required for fumigants) must state the following:

-- Skull and crossbones symbol



-- "DANGER/PELIGRO,"
 -- "Area under fumigation, DO NOT ENTER/NO ENTRE,"
 -- "[Name of fumigant] Fumigant in USE,"
 -- the date and time of fumigation,
 -- the date and time entry prohibition is lifted
 -- Name of this product, and
 -- name, address, and telephone number of the certified applicator in charge of the fumigation.

The **buffer zone** sign must include the following:

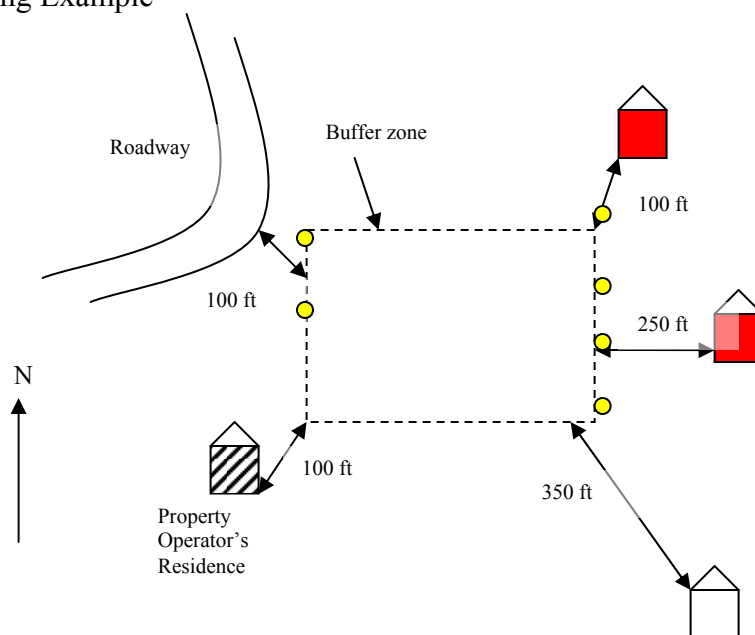
-- Do not walk sign



-- "DO NOT ENTER/NO ENTRE,"
 -- "[Name of fumigant] Fumigant BUFFER ZONE,"
 -- the date and time of fumigation,
 -- the date and time buffer zone restrictions are lifted (i.e., buffer zone period expires)
 -- Name and EPA registration number of the product applied, and
 -- name, address, and telephone number of the certified applicator in charge of the fumigation

To clarify the posting requirements, the following example has been included.

Figure 3. Posting Example



Red Houses = Structure within 300 feet of the buffer zone edge. Yellow dots = posted signs

- The structures in **red** are (1) within 300 feet of the edge of the buffer zone, and (2) there is no physical barrier between the two structures and the buffer zone, and (3) the land operator does not control these structures.
- Although the **property operator's building** (striped building) is within 100 feet of the edge of the buffer zone, since it is controlled by the property operator, **no posting** of the buffer zone is necessary here.
- There is a **road** within 100 feet of the edge of the buffer zone. Since there is a possibility of people from the road entering the buffer zone area, the buffer zone needs to be posted in the northwest corner.

Buffer Zone Posting Considerations

The Agency received comments on the burden for applicators to post the entire perimeter of a buffer zone due to the large distance it covers. In an effort to reduce the burden on growers, but retain the posting requirement for situations where people are most likely to enter a buffer zone, EPA believes posting area where people are most likely to enter buffers will be protective. USDA also noted that as growers break their fields into smaller application blocks to result in smaller buffer zones, the posting requirements would be burdensome in that users would need to put up and take down signs for multiple adjacent, sequential applications. To address this concern, EPA is allowing signs for contiguous application blocks to be placed on the edge of the buffer zone area for all blocks treated within a 14-day period. EPA believes this will be protective and potentially less burdensome.

bb. Occupational Risk Mitigation

1. Handler Definition

Based on stakeholder comments, a clarification of EPA's definition of *handler* activities, as currently defined in the Worker Protection Standard (WPS) and fumigant labels, is needed. Persons engaged in any of the following activities will be defined as *handlers* on product labels.

- Persons participating in the application as supervisors, drivers, co-pilots, shovelers, or as other direct application participants;
- Persons taking air samples to monitor fumigant air concentrations;
- Persons cleaning up fumigant spills;
- Persons handling or disposing of fumigant containers;
- Persons cleaning, handling, adjusting, or repairing the parts of fumigation equipment that may contain fumigant residues;
- Persons installing, repairing, operating irrigation equipment in the fumigant application block or surrounding buffer zone during the buffer zone period;
- Persons entering the application site or surrounding buffer zone during the buffer zone period to perform scouting or crop advising tasks;
- Persons installing, perforating (cutting, punching, slicing, poking), removing, repairing, or monitoring tarps - until
 - After tarps are perforated and removed if tarp removal is completed less than 14 days after application, or
 - 14 days after application is complete if tarps are not perforated and removed during those 14 days, or
 - 48 hours after tarps are perforated if they will not be removed prior to planting.

2. Handler Requirements

Since many fumigant incidents are caused by human error and equipment failure, EPA believes the presence of onsite trained personnel would help to reduce these risks. Therefore, a certified applicator must maintain visual contact with any fumigant handler during the entire period while the fumigant is being incorporated into the soil. The person monitoring other handlers may also be engaged in fumigant handling tasks during the monitoring period and two qualified monitors may monitor one another simultaneously.

Before applying this product the certified applicator supervising that application must have, within the preceding 12 months, successfully completed a dazomet training program made available by the registrant (see the Soil Fumigation Training for Applicators and Other Handlers section on page 60). The Fumigant Management Plan, discussed later in this document must document when and where the training program was completed.

For cases when the certified applicator leaves the site after the application portion of the fumigation process is complete and other parties will be performing handler tasks (e.g., tarp cutting/removal, water application, etc.), the certified applicator must communicate in writing to

the site owner/operator and other handlers key information needed to comply with label requirements (e.g. PPE requirements, location of buffers, when buffer zone ends, reentry restrictions, minimum times for cutting tarps, etc.).

When handlers are fixing tarps, moving irrigation equipment or performing other handling tasks as defined above, the Agency is requiring at least two WPS trained handlers be present for all activities. Due to the volatile nature of the fumigants there is a possibility that handlers could be overcome with the vapors and have difficulty leaving the area while they are performing handling tasks. Therefore, EPA is requiring at least two WPS trained handlers be on site during all post-fumigation handling activities.

3. Dermal Protection for Handlers

The dazomet dermal risk assessment indicated potential risks of concern for handlers for some scenarios. For handlers loading and applying dazomet for tractor drawn spreaders, there were potential risks for short term exposures assuming applications to 80 acres per day. According to information from the registrant in the phase 3 comments, dazomet is not typically applied to large acres, but more typically applied to blocks 5-20 acres in size. The Agency is prohibiting applications to block sizes over 40 acres, so the short term concerns for dermal risk to handlers loading and applying with tractor drawn spreaders is acceptable.

For intermediate term dermal risk, there are potential risk concerns for loaders and applicators, with MOEs below 100, the intermediate dermal LOC. MOEs for loaders range from 13 for handlers wearing baseline PPE, up to 650 for handlers using closed systems. For applicators, there is only data for handlers applying with closed cabs, and the MOE is 52 for a 40 acre field. Due to the amount of dazomet applied, and the small area it is typically applied to, it is not likely a single handler will be exposed to the amount assumed in the risk assessment over the intermediate time frame of 1 to 6 months. Current dazomet labels require handlers to wear double layers (coveralls over short-sleeved shirt and short pants) and chemicals resistant gloves to protect from dermal exposures. The Agency does not calculate risks with this level of PPE since there is no data to assess coveralls over short-sleeved shirt and short pants. However, since the current labels require this level of protection, the short-term risks were acceptable and the amount of dazomet exposure assumed in the intermediate term assessment are higher than would be expected based on dazomet's use patterns, the Agency is requiring all handlers to wear double layers consisting of coveralls over short-sleeved shirt and short pants with gloves. In addition, handlers will have an option to reduce the dermal protection if application equipment (i.e., enclosed cabs) that provides dermal protection is used.

For hand held applications there are potential dermal risks of concern when making applications with baseline PPE. The registrants have indicated that they will not be continuing to support applications with hand held equipment, and labels will be amended to prohibit hand held equipment.

4. Respiratory Protection for Handlers

The Agency's human health risk assessment for dazomet indicates that inhalation risks for many handler tasks exceed the Agency's LOC for the acute exposure to the parent (dazomet) and MITC.

The Agency has received comments from applicators that respirators are not necessary because (1) the possibility of eye irritation and the nature of the smell of MITC (i.e., sulfur, rotten eggs) to alert handlers if there has been an unsafe exposure, (2) respirators inhibit communication which could cause an accident; and (3) in warm weather respirators can cause heat stress and other ailments. On the other hand, some stakeholders are in favor of mandatory respiratory protection because there is currently no accurate, inexpensive, easy to use monitoring equipment that is sensitive enough to show that acute levels of concern have not been exceeded. These stakeholders have also stated based on their experience that handlers will not be given access to respirators and other PPE unless it is required on the label.

The currently available monitoring tubes detect MITC at levels as low as 100 ppb, which is higher than the Agency's LOC for acute exposure of 22 ppb. However, at a level of 100 ppb, handlers would be exposed to levels of MITC that are 8 times lower than effects seen at the LOAEL of 800 ppb from the human study, which is about equal to an MOE of about 2. In addition, the eye effects from MITC exposure act as a biomarker or surrogate that protects for more adverse systemic and respiratory effects. The available toxicity data in animals or humans do not allow us to compare the dose response curves of the eye, systemic, and respiratory effects, so there is uncertainty in how close the more adverse effects may be as compared to the eye irritation effect. As stated in EPA's review of the endpoint selection:

"With respect to respiratory impairment, arguably, eye irritation is less severe compared to other possible effects associated with inhalation exposure to MITC, particularly given the expected reversible nature of the eye irritation effects at lower concentrations. Nonetheless, eye (as well as nose and throat) irritation is uncomfortable and could potentially interfere with everyday tasks or activities. Due to the limitations in the existing *inhalation* toxicology database for MITC, the degree to which eye irritation predicts more serious outcomes is unclear. However, in the absence of more robust dose-response data from acute exposures, eye irritation can be considered as a biomarker and surrogate for potential respiratory effects." (D293349)

Based on (1) the reversible sensitive endpoint selected, (2) the limited monitoring technology currently available, (3) the potentially physically stressful response to respirators, and (4) the apparent fact that current technology allows detection at levels 8 times lower than the LOAEL of 800 ppb selected, the Agency is allowing a monitoring program for MITC in place of respirators for handlers, as long as detected MITC levels remain at or below 100 ppb.

Therefore, the Agency is requiring handlers potentially exposed to MITC vapors from dazomet applications to either wear at least a half-face respirator during the handling activity, or follow the monitoring program detailed below. For some handling tasks described below, respirators are required to be worn at all times due to the short duration of the task and the potentially high concentration of MITC exposure. The certified applicator supervising the fumigant application must ensure that any handler who enters the buffer zone (including tractor drivers, loaders, irrigators, tarp cutters, removers, etc.) is either wearing respiratory protection or

is following the handler monitoring requirements, with respirators immediately available to each handler.

Continuous monitoring for task over a long duration

An air purifying PF10 respirator only provides 10 times the inhalation protection from the air concentration in an area. If a concentration of 100 ppb is measured in the breathing zone of the handling task, then an air purifying PF10 respirator must be worn by that handler. The respirator is designed to protect the handler from 10 times the concentrations of MITC in the air, i.e., $100 \text{ ppb} \times 10 = 1000 \text{ ppb}$ (1 ppm). At air concentrations greater than 1000 ppb the respirator is not designed to provide continuous protection, and in such a situation, even a respirator may not protect handlers from inhaling more than 100 ppb of MITC. Therefore, the handler must continue to monitor once respirators are donned. If concentrations of MITC exceed 1000 ppb or if eye irritation occurs, then the operations must cease until levels of MITC are measured to be below 1000 ppb from consecutive air samples taken at least 15 minutes apart.

Long Duration Tasks

For handlers such as applicators supervising or making the application, tractor drivers, tractor co-pilots, shovelers, and tarp cutters, the respiratory requirements include:

- Mandatory monitoring in the breathing zone of handlers at least once an hour, even if a respirator is worn.
- Air-purifying respirators must be put on if one of the following occurs:
 - MITC concentrations are $\geq 100 \text{ ppb}$, or
 - Handlers experience sensory irritation.
- All activities must cease if one of the following occurs:
 - MITC concentrations are $\geq 1000 \text{ ppb}$, or
 - Handlers experience sensory irritation while wearing respirators.
- In order to remove the respirator or resume work activities:
 - Two air samples for MITC must be taken in the treatment area at least 15 minutes apart.
 - The samples must be less than 100 ppb to remove the respirator and below 1000 ppb for work activity to resume with a respirator.
 - During the collection of samples an air purifying respirator must be worn.

Respirators cannot be removed until monitoring indicates that levels have decreased below the triggers listed above, and if handlers are not experiencing eye irritation.

Short Duration Tasks

Handlers that may be exposed to high concentrations of MITC and who are engaged in tasks that occur over a short time frame, such as mixers/loaders, handlers installing/repairing irrigation systems during application, irrigation operators during application, and or tarp handlers repairing the tarp, must wear respirators at all times. No monitoring measure is required since the scope of these tasks is relatively short in duration and the monitoring would not be effective

in capturing spikes in MITC. However, if a handler experiences eye irritation the activity must stop until corrective steps have been taken (e.g., add water to the application site, stop the mixing/loading activities, etc.) to reduce the air concentration of MITC.

Additional Respiratory Requirements

In the dazomet risk assessment, a respirator was considered for MITC exposure since there were inhalation risk concerns without additional protection. A protection factor (PF) of 10 for a half-face air purifying respirator was utilized. The protection factor is based on the following assumptions: 1) the respirator is fit-tested, 2) proper respirator training occurs, and 3) an annual medical evaluation and clearance is done. Without these requirements, it is unclear whether the reduction in inhalation exposure that is assumed by the protection factor is actually achieved. In order to ensure that the respiratory protection EPA is assuming is being achieved in the field, respiratory requirements for MITC generators will include fit testing, respirator training, and annual medical evaluation. In addition, respirators must be made available to all handlers that may be exposed to MITC vapors. The language to be added to labels is listed below and in Table 4.

“Employers must also ensure that all handlers are:

- Fit-tested and fit-checked using a program that conforms to OSHA’s requirements (see 29CFR Part 1910.134)
- Trained using a program that confirms to OSHA’s requirements (see 29CFR Part 1910.134)
- Examined by a qualified medical practitioner to ensure physical ability to safely wear the style of respirator to be worn. A qualified medical practitioner is a physician or other licensed health care professional (PLHCP) who will evaluate the ability of a worker to wear a respirator. The initial evaluation consists of a questionnaire that asks about medical conditions (such as a heart condition) that would be problematic for respirator use. If concerns are identified, then additional evaluations, such as a physical exam, might be necessary. The initial evaluation must be done before respirator use begins. It does not need to be repeated unless the health status or respirator use conditions change.

The employer of the fumigant handlers must make sure that all handlers in the application block and the surrounding buffer zone are provided and correctly wear the required PPE. The PPE must be cleaned and maintained as required by the Worker Protection Standard for Agricultural Pesticides.”

5. Tarp perforation and removal

The Agency’s risk assessment indicates that there is a risk concern for handlers during the perforation (cutting, poking, punching, or slicing) and removal of tarps, particularly when high barrier tarps are used. In addition to respiratory protection requirements described above, the Agency is requiring the following to mitigate risks from inhalation exposure:

- Tarps cannot be perforated until a minimum of 5 days (120 hours) have elapsed after the fumigant injection into the soil is complete (e.g., after shank injection of the fumigant

product and tarps (if used) have been laid or after drip lines have been purged and tarps have been laid, unless an adverse weather condition exists for broadcast applications).

- If tarps will be removed after perforation, tarp removal cannot begin until at least 24 hours after tarp perforation is complete.
- If tarps will not be removed after perforation, planting or transplanting cannot begin until at least 48 hours after tarp perforation is complete.
- If tarps are left intact for at least 14 days after fumigation injection into the soil is complete, planting or transplanting may occur while the tarps are being perforated.
- Adverse Weather Conditions Exemption for Broadcast Applications Only, see Figure 9: Tarps may be removed before the required 5 days (120 hours) if adverse conditions will compromise the integrity of the tarp, provided that:
 - At least 48 hours have passed after the fumigant injection is complete,
 - The buffer zone period is extended until 24 hours after tarp removal is complete, and
 - Subsequent fumigations of untreated areas within the application block do not occur for at least 24 hours after tarp removal is complete.
- To reduce exposure to handlers perforating tarps
 - Tarps used for fumigations must be perforated only by mechanical methods.
 - Perforation by hand or with hand-held tools is prohibited.
- Each tarp panel used for broadcast fumigations must be perforated using a lengthwise cut. This measure is to reduce the likelihood of the tarp blowing away prior to tarp removal.

6. Entry Prohibitions

Current dazomet labels allow reentry to the treated field by workers 24 hours after application. The risk assessment indicates that risks could exceed EPA's LOC for workers entering fields at this time period. Stakeholder comments indicate that non-handler entry to perform post-application tasks is generally not needed for at least 10 to 14 days following the completion of the application.

Due to the volatile nature of MITC and the potential for exposure to unprotected workers, the Agency will prohibit entry into the treated area or buffer zone by anyone other than a protected handler. The prohibition differs from a Restricted Entry Interval (REI) that are currently required for most conventional pesticides which contains exceptions for workers doing certain tasks before the REI has expired (e.g., scouting). Workers permitted entry under the REI are prohibited for soil fumigants.

EPA believes that risks will not exceed the Agency's LOC provided entry (including early entry that would otherwise be permitted under the WPS) by any person – other than a correctly trained and PPE-equipped handler who is performing a handling task – is prohibited from the start of the application until:

- 5 days (120 hours) after application has ended for untarped applications, or

- After tarps are perforated and removed if tarp removal is completed less than 14 days after application, or
- 48 hours after tarps are perforated if they will not be removed prior to planting, or
- 5 days (120 hours) after application is complete if tarps are not perforated and removed 14 days after the application is complete.

Figures 4, 5, 6, 7, and 8 provide a graphical depiction of mitigation required to mitigate worker risk in various fumigant application scenarios.

Figure 4. Untarped Application

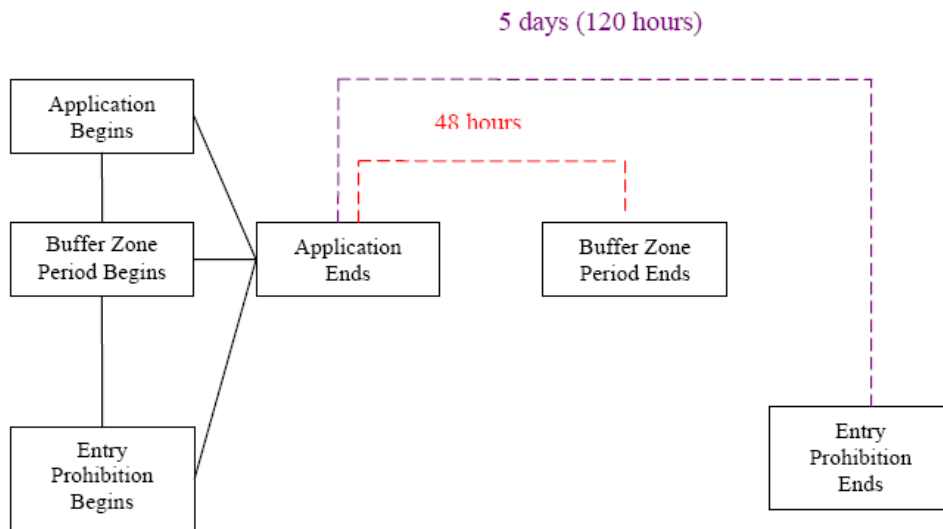


Figure 5. Tarps removed before planting

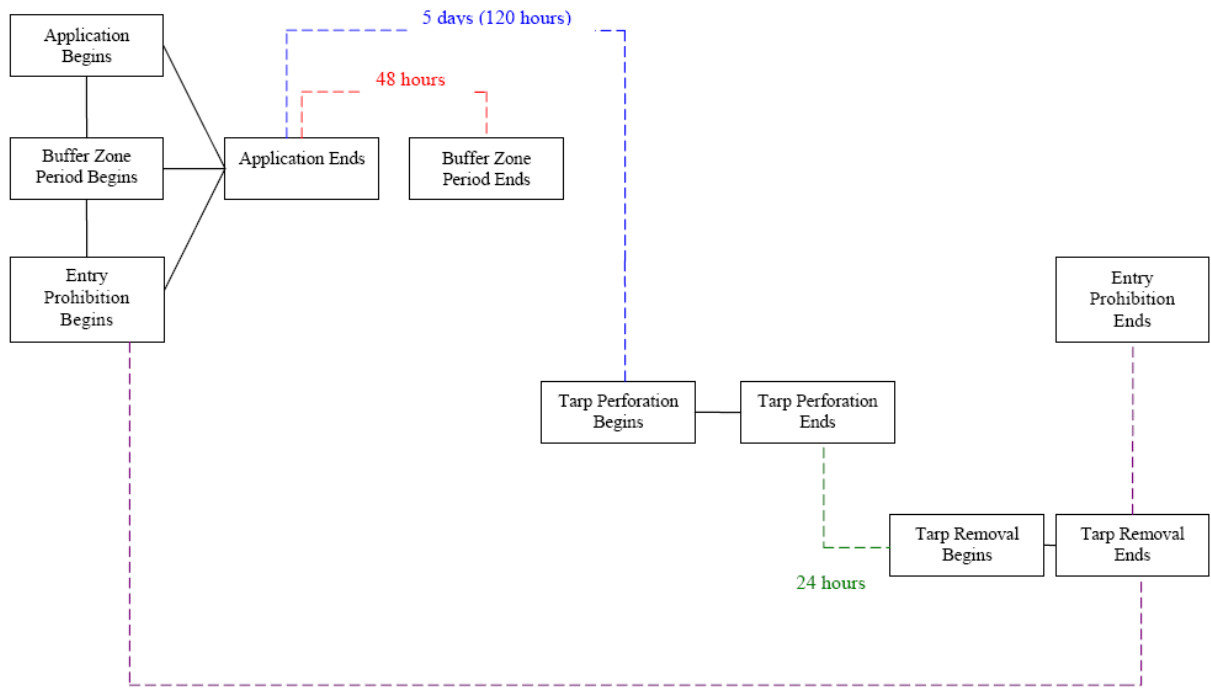


Figure 6. Tarps NOT Removed Before Planting

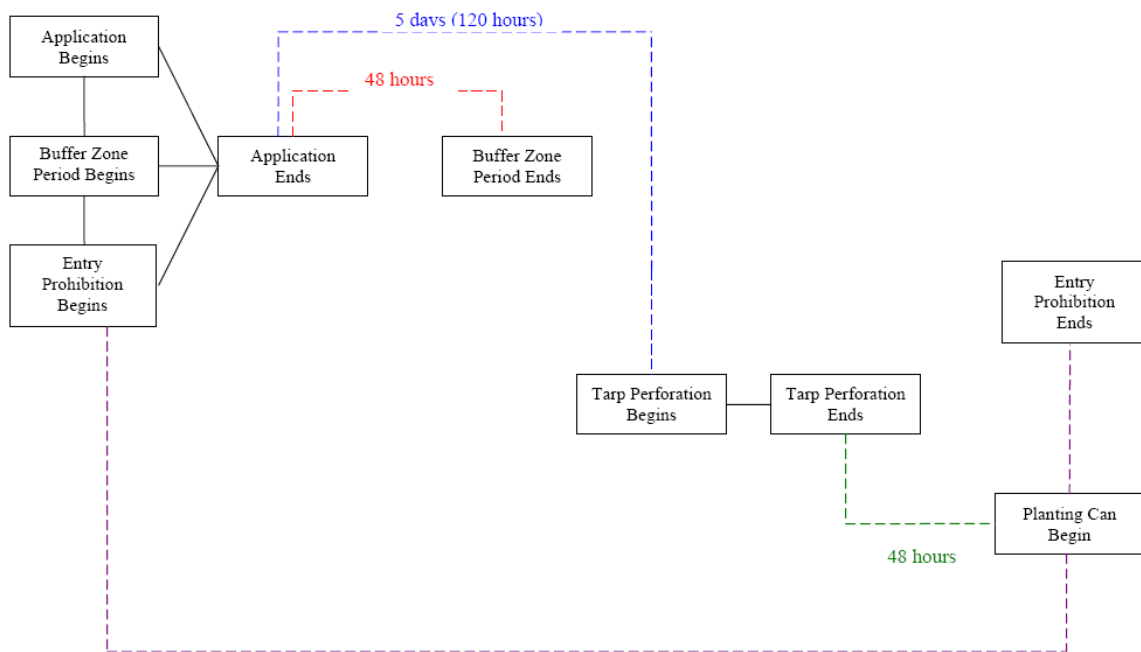


Figure 7. Tarps NOT Removed Before Planting and NOT punched until 14 days after the application

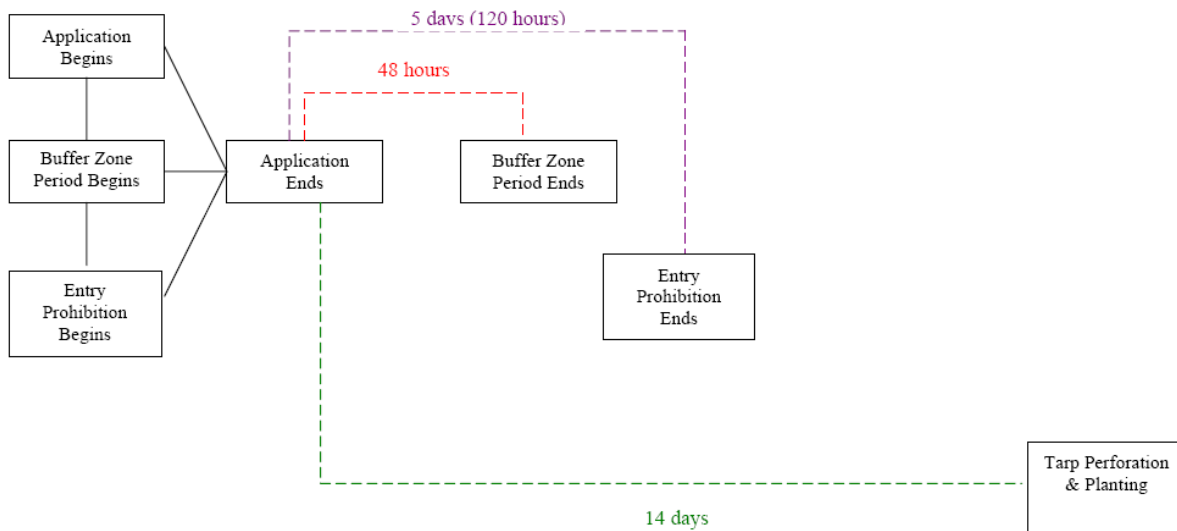
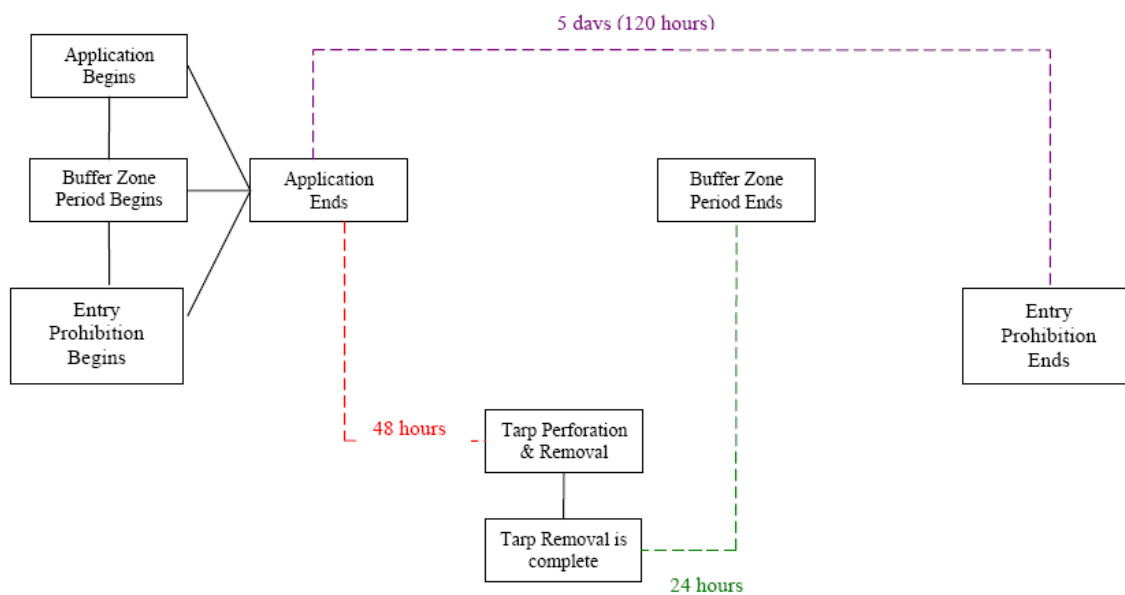


Figure 8. Adverse Weather Conditions Exemption (Broadcast tarp applications ONLY)



cc. Other Risk Mitigation

Below are requirements for FMPs, GAPs, emergency preparedness and response, notice to lead agencies, training, and community outreach and education that the Agency concludes are needed to mitigate risks and the likelihood of incidents caused by human error, equipment failure, and weather events such as temperature inversions.

1. Restricted Use Classification

All soil fumigant products containing methyl bromide, 1,3-dichloropropene (1,3-D), iodomethane, and chloropicrin are currently classified as RUPs. Soil fumigant products containing dazomet and metam sodium/potassium are currently unclassified. However, MITC, the byproduct of dazomet and metam sodium/potassium, has characteristics that meet the criteria for restricted use for both human hazard criteria (as specified in 40 CFR 152.170(b)) and from other evidence (as specified in 40 CFR 152.170(d)) the use history and incident data from exposure to MITC.

Human Hazard Criteria

The acute toxicity profile of MITC shows it is more acutely toxic (toxicity categories are all I or II) than dazomet (mostly toxicity categories III and IV). While the product toxicity of dazomet does not meet the hazard criteria for classification as restricted use, the degrade product of MITC, that both handlers and bystanders can be exposed to, does meet the criteria.

Other Evidence

If any soil fumigant is not applied correctly, bystanders may be exposed to concentrations that exceed levels of concern and that could cause significant adverse effects. There is a history of incidents involving fumigants in which multiple bystanders experienced illness/injury despite being several hundred to several thousand feet from the treated area. The application of soil fumigants can pose risk for several hours from the time of application to several days after application. Depending on the situation, worker and/or area air monitoring may be required to ensure that exposure limits are not exceeded. Special equipment is often needed to apply soil fumigants safely and accurately (e.g., compaction rig, tarp equipment, and self-contained breathing apparatus). To apply soil fumigants safely and ensure bystanders and applicators are not adversely affected, handlers also need specialized competencies.

In sum, dazomet meets the standard for restricted use because:

- The application of fumigants involves complex operations requiring specialized training and/or experience.
- Fumigant label directions call for specialized apparatus and protective equipment that is not available to the general public.
- A minor failure to follow label directions may result in severe adverse effects.

- Even if directions for use are followed, use may result in discernible adverse effects, of both direct and indirect nature, on non-target organisms.

Therefore, the Agency has determined that all dazomet soil fumigant products must be classified as restricted use. Label requirements will include the following, which is also contained in Table 4.

Requirement on Labels

“Restricted Use Pesticide Due to acute inhalation toxicity to humans.”

“For retail sale to and use by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator’s certification.”

In order to ensure that a certified applicator is at the application site, the label will also state, “the certified applicator supervising the application must be at the fumigant application site and able to maintain visual contact with every handler participating in the application starting when the fumigant is first introduced into the soil and ending after the fumigant has stopped being delivered/dispensed to the soil and the soil is sealed.”

2. Good Agricultural Practices

Since the application methods and work practices of the handlers have direct impact on the amount of fumigant applied and emitted, the Agency believes that labeling should describe proven practices that will reduce risks to handlers, bystanders, and the environment. Registrants, applicators, growers, and other stakeholders have consistently reported to the Agency that good agricultural practices (GAPs) are the best mitigation measure to reduce the amount of fumigants applied and emitted.

The following are mandatory GAPs that already appear on dazomet product labels. Some of the measures have been updated to clarify the language and be consistent among the fumigant chemical product labels.

- Do not use dazomet when the soil temperature is extremely high (over 90° F at 2” deep).
- Do not apply dazomet if ambient air temperature exceeds 103° F.
- Do not apply within 3-4 feet of growing plants or closer than the drop line of trees and large shrubs. If slopes are treated with this product, take precautions to prevent the chemical from washing downward to growing plants.
- The area intended for treatment should be in seedbed condition with a fine tilth, free of clods. Do not apply dazomet to dry or improperly tilled soil. Repeated cultivation before treating will improve control of perennial weeds. Ditching around the site will prevent weed seeds, nematodes, and fungi from washing into the treated area and contaminating it.
- For optimal effect, the soil to be fumigated must have sufficient moisture for good plant growth (at least 50% field capacity) for 5-14 days (depending on temperature) before the treatment.

- After application, the soil must be kept uniformly moist for 5-7 days. As soon as possible after incorporation, the soil must be sealed to retain the concentration of gases in the soil which can be achieved by:
 - Compacting the soil surface after incorporation with a roller attached behind the compacting implement.
 - Moistening the surface after incorporation so a crust forms.
 - Lightly moistening the soil on the third and fourth days after treatment in case the weather dries out the soil surface to avoid surface cracks.
 - In difficult situations best results may be obtained by tarping the treated area.
- Do not store dazomet in an open spreader overnight.
- Do not apply dazomet when wind may cause granules to drift from target area.
- Do not apply dazomet through any type of irrigation equipment.
- Before using dazomet be aware that the three most critical factors for a successful fumigation program are: soil preparation, soil temperature, and soil moisture.

In addition to the statements that may already appear on dazomet soil labels, the following weather condition statements must be added to all labels.

Weather Conditions

- Prior to fumigation the weather forecast for the day of the application and the 48-hour period following the fumigant application must be checked.
- Do not apply fumigant if ground-level winds are less than 2 mph.
- Applications must not occur during a temperature inversion or when temperature inversions are forecasted to persist for more than 6 consecutive hours for the 36-hour period after application.
 - Visual features indicating an inversion include misty conditions which occur anytime or clear skies with stars visible at night.
- Detailed local forecasts for sky conditions, weather conditions, wind speed, and forecasted temperature inversions may be obtained on-line at <http://www.nws.noaa.gov>.
- For further guidance, contact the local National Weather Service Forecasting Office.

All measurements and other documentation planned to ensure that the mandatory label requirements are achieved must be recorded in the FMP and/or the post application summary report.

3. Fumigant Management Plans (FMPs)

The Agency is requiring FMPs to be completed before a fumigant application occurs. FMPs will reduce risks by requiring that applicators develop a series of performance criteria for their given application situation. These criteria are intended to minimize risks according to the Agency's guidance provided below. Applicators must then review those criteria before a fumigant application occurs. The FMPs will also require that applicators verify compliance with the criteria after application events are completed. In cases where errors may have occurred, a post-application summary may also prevent similar problems from occurring during future

applications. As an additional benefit, the Agency believes FMPs will ensure directions on the product labels have been followed and that the conditions for the fumigation are documented.

FMPs should aid in the proper response of the applicator or others involved in the application should an incident occur. A proper and prompt response will reduce the potential risk to bystanders from high exposure situations (e.g., readily available first responder contact information could reduce response times to impacted bystanders).

There is information from various sources that health and safety plans, FMPs in this context, typically reduce workplace injuries and accidents by prescribing a series of operational requirements and criteria. In fact these plans are widely implemented in a variety of industries and are recommended as standard approaches for occupational health and safety management by groups such as American Industrial Hygiene Association⁹ (i.e., through “Administrative” and “Workplace” controls). The Centers for Disease Control provides guidance for developing health and safety plans in agricultural settings.¹⁰ The effectiveness of similar plans has also been evaluated in the literature. Examples include “lookback” reviews conducted by the Occupational Safety and Health Administration (OSHA) which essentially implemented standards in various industries then reviewed their effectiveness in this process as they are required to determine whether the standards should be maintained without change, rescinded or modified. OSHA is required by Section 610 of the Regulatory Flexibility Act (5 U.S.C. 610) and Executive Order 12866 to conduct the lookback reviews. These reviews are conducted to make the final standards more effective or less burdensome in achieving their objectives, to bring them into better alignment with the objectives of Executive Order 12866, and to make them consistent with the objectives of the Regulatory Flexibility Act. Two examples of “lookback” reviews that support the use of FMPs for soil fumigant health and safety management include: ethylene oxide use as a fumigant/sterilant, and grain handling facilities requirements.¹¹

According to stakeholder comments, most of the information required for the site-specific FMP is already being documented by users. Most industry stakeholders support mandatory FMPs provided they are not too restrictive and do not result in an administrative burden.

Each site specific FMP must contain the following elements:

- ❖ General site information
 - Site address or description of location,
 - Site operator/owner’s name, address, and, phone number

⁹ Ignacio and Bullock (2006) A Strategy For Assessing and Managing Occupational Exposures (Third Edition), American Industrial Hygiene Association, AIHA Press 2700 Prosperity Avenue, Suite 250 Fairfax VA 22031 (ISBN 1-931504-69-5)

¹⁰ Karsky (2002) Developing a Safety and Health Program to Reduce Injuries and Accident Losses, Centers For Disease Control National Ag Safety Database, available at <http://www.cdc.gov/nasd/docs/d001501-d001600/d001571/d001571.html>

¹¹ United States Department of Labor, Occupational Safety and Health Administration (2008) Lookback Reviews available at <http://www.osha.gov/dea/lookback.html>

- Map, aerial photo, or detailed sketch showing field location, dimensions, buffer zones, property lines, public roads, bus stops, water bodies, wells, rights-of-ways inside buffers, nearby application blocks, surrounding structures (occupied and non-occupied), locations of posted signs for buffers, and sites requiring ¼ mile buffer zones (e.g., prisons, schools, hospitals, state licensed day care centers) with distances from the application site labeled
- ❖ Applicator information (license #, address, phone, contact information for person supervising the fumigation)
- ❖ Authorized on-site personnel (Names of all handlers and the tasks they are authorized and trained to perform)
- ❖ Application procedures
 - Fumigation window (target application date, earliest and latest possible date of fumigation, duration of fumigation)
 - Product information (brand name, registration number)
 - Type of fumigation (e.g., shank, broadcast, drip, raised bed, strip, etc.)
 - Target application rate and application block size
- ❖ Good Agricultural Practices (GAPs)
 - Description of applicable mandatory GAPs (registrants may also include optional GAPs)
 - Measurements and other documentation planned to ensure GAPs are achieved (e.g. measurement of soil and other site conditions; tarp repair/perforation/removal plans; etc.)
- ❖ Buffer zones
 - Calculations and rationale for buffer zones distances (e.g. specify table from label that distances are based on, rate and block size, applicable credits)
 - Start and stop times for buffer zones
- ❖ Respirators and other personal protective equipment (PPE) for handlers (respirator type, respirator cartridge, and other PPE selection; identification of tasks that require respirators; verification that respirator training/fit-testing/medical exams is current; and maintenance/storage procedures)
- ❖ Air monitoring
 - Type of samples that will be collected (e.g., occupational, in occupied structures, outside buffer zone if fumigation site monitoring is conducted, etc.)
 - When and where samples will be collected
 - Duration of samples
 - Sampling methods and equipment
 - Name, address, and, phone number of person taking samples
- ❖ Posting (names of persons who will post signs, location of posting signs, procedures and timing for posting and sign removal)
- ❖ Site specific response and management
 - Fumigation site monitoring
 - Description of who, when, where, and procedures for monitoring buffer zone perimeter
 - Response information for neighbors
 - List of residences and businesses informed (neighboring property owners)
 - Method of sharing information
- ❖ State and tribal lead agency notification
 - Include information that is sent to the lead agency

- ❖ Plan describing how communication will take place between applicator, land owner/operator, and other on-site handlers (tarp cutters/removers, irrigators, etc.)
- ❖ Record keeping procedures
- ❖ Emergency procedures (evacuation routes, locations of telephones, contact information for first responders, local/state/federal contacts, key personnel and emergency procedures/responsibilities in case of an incident, equipment/tarp/seal failure, odor complaints or elevated air concentration levels outside buffer zone suggesting potential problems, or other emergencies).
- ❖ Hazard communication (product labels, material safety data sheets, etc.)

For situations where an initial FMP is developed and certain elements do not change for multiple fumigation sites (e.g. applicator information, authorized on-site personnel, record keeping procedures, emergency procedures, etc.) only elements that have changed need to be updated in the site-specific FMP provided the following:

- The certified applicator supervising the application has verified that those elements are current and applicable to the application block before it is fumigated and has documented the verification in the site-specific FMP.
- Recordkeeping requirements are followed for the entire FMP (including elements that do not change)

Once the application begins, the certified applicator and owner/operator of the application block must provide a copy of the FMP to handlers who are involved in the fumigation, workers in adjacent areas to the application block, and Federal/State/local enforcement personnel, upon request.

Within 30 days of completing the application portion of the fumigation process, the certified applicator supervising the application must complete a post fumigation application summary that describes any deviations from FMP that have occurred, measurements taken to comply with GAPs as well as any complaints and/or incidents that have been reported to him/her. The summary must include the actual date of the application, application rate, and size of application block fumigated. This summary must be kept along with the FMP.

In addition to recordkeeping requirements from 7 CFR part 110 “Recordkeeping Requirements for Certified Applicators of Federally Restricted Use Pesticides,” this decision requires that both the applicator and owner/operator of the application block must keep a signed copy of the site-specific FMPs and the post-application summary record for 2 years from the date of application.

Applicators and other stakeholders have the flexibility to prepare FMPs templates or use software with certain elements listed above in check-list and/or fill in the blank format. Below are examples of other FMP templates available on the internet for structural fumigations that may be useful to users when developing FMPs for dazomet soil applications:

- <http://www.cardinalproproducts.com/Misc/FMP%20Version%203.pdf>
- http://www.pestcon.com/techlibrary/fum_mgmt_plan.doc
- http://www.agr.state.ne.us/division/bpi/pes/fumigation_plan.pdf
- http://www.agr.state.ne.us/division/bpi/pes/fumigation_plan2.pdf
- <http://nmdaweb.nmsu.edu/pesticides/Management%20Plans%20Required%20for%20Fumigations.html>

4. Emergency Preparedness and Response

EPA believes measures for ensuring preparedness for situations when accidents or emergencies occur are an important part of the suite of measures necessary to address risks posed by fumigants. Therefore, EPA is requiring such measures at the community level in the form of education for first responders, and information for specific sites to ensure early detection and quick response to situations as they arise.

Although EPA believes buffers and other mitigation will prevent many future incidents, it is likely that some incidents will still occur due to accidents, errors, and/or unforeseen weather conditions. Early detection and appropriate response to accidental chemical releases is an effective means of reducing risk, as well as addressing the source of the release. Reducing risks associated with incidents that may occur in the future is a key part of EPA's soil fumigant decisions. By combining buffers with GAPs, FMPs, and effective emergency response, EPA is able to reach a "no unreasonable adverse effects" finding under FIFRA.

To ensure that appropriate response mechanisms are in place in the event of a fumigant exposure incident, EPA is requiring that registrants provide training and information, in the context of their community outreach and education programs (see the Community Outreach and Education section on page 64), to first responders in high-fumigant use areas and areas with significant interface between communities and fumigated fields. In addition, applicators must provide on-site monitoring of buffer zone perimeters in areas where residences and other occupied structures are present. As an alternative to on-site monitoring, applicators may provide emergency response information directly to neighbors. Each element is discussed in more detail below.

First Responder Education

EPA is requiring registrants through their community outreach and education programs (see the Community Outreach and Education Section on page 64), to ensure that emergency responders have the training and information that they need to effectively identify and respond to fumigant exposure incidents. EPA believes this will help ensure, in the case of a fumigant accident or incident, that first responders recognize the exposure as fumigant related and respond appropriately. The information/training to be provided to first responders will include: how to recognize the early signs and symptoms of fumigant exposure, how to treat fumigant exposures, how fumigant exposure differs from other pesticide exposure, plus the material safety data sheet(s) (MSDS) for the fumigant(s) applied.

The Agency is interested in comments from state and/or local officials about the extent to which first responders are currently receiving information on soil fumigants, for example can they recognize fumigant exposures, and are they aware of the appropriate steps to take to mitigate the exposures and address the source of the exposure. In California, for example, where soil fumigation is common in many areas, the state administers training and education for first responders to help raise awareness and improve skills in responding to incidents. If registrants can document that effective state programs are already in place, additional training may not be required. However, registrants must work with state and local emergency response coordinators to identify needs and opportunities to supplement any information already included in state and local training for first responders about soil fumigants specifically.

Site Specific Response and Management

Fumigation Site Monitoring

EPA has determined that monitoring of the buffer zone perimeter would be an effective approach to protect bystanders. Under this approach, if measured concentrations anywhere along the buffer perimeter reach a LOC specified on product labels, or if the person monitoring the air concentrations experiences eye irritation, an early sign of exposure to concentrations that exceed the Agency's LOC, then the emergency response plan stated in the FMP (see the FMP section on page 51) must be implemented. If other problems occur, such as a tarp coming loose, then the appropriate control plan must be activated. Because data indicate that peak concentrations sometimes occur on the second day following applications, EPA decided that this monitoring must be done for the full buffer zone period to ensure concentrations do not exceed the action level which will be specified on product labels.

Specific requirements include:

- Monitoring must take place from the beginning of the fumigant application until the buffer zone period expires.
- Monitoring must be conducted by a certified applicator or someone under his/her supervision.
- Monitoring of air concentration levels of the fumigant must take place in the area between the buffer zone and the residences or other occupied structures.
- The person monitoring the air concentration levels must take readings starting approximately 30 minutes from the start of application and at least once each hour during the entire application and buffer zone period.
- A direct reading detection device, such as a Draeger device with a sensitivity of at least 100 ppb for MITC must be used to monitor the air concentration levels of MITC.
- If at any time (1) MITC concentrations are greater than or equal to 100 ppb, OR (2) the person monitoring the air concentrations experiences sensory irritation, then the emergency response plan stated in the FMP must be immediately implemented by the person monitoring the air concentrations
- If other problems occur, such as a tarp coming loose, then the appropriate control plan must be activated.

- The results of the air concentration monitoring must be recorded in the FMP.

EPA is interested in comments from fumigant users, researchers, and equipment manufacturers about the extent to which mechanical devices are available or are under development that can both monitor air concentrations and also notify the person responsible for the fumigation when air concentrations approach levels of concern. Such devices are routinely used to monitor environmental conditions in laboratories, and could represent an effective alternative to posting a person on site.

While protective, this site monitoring might be burdensome for users fumigating in areas with few or no people. Therefore, EPA is allowing users the alternative option of providing emergency response information directly to neighbors.

Response Information for Neighbors

As an alternative to on-site monitoring, the certified applicator supervising the fumigation (or someone under his/her direct supervision) would need to ensure that residences and businesses that meet the criteria outlined below have been provided the information below at least 48 hours prior to fumigant application in a specified field. If after 2 weeks, the fumigation has not yet taken place, the information must be delivered again.

- Information that must be provided includes:
 - Location of the application block
 - Name of fumigant products(s) applied including EPA Registration number
 - Applicator and property owner/operator contact information
 - Location of buffer zones
 - Time period in which the fumigation is planned to take place and the duration of buffer zone period
 - Early signs and symptoms of exposure to the fumigant(s) applied, what to do, and who to call if you believe you are being exposed (911 in most cases).

The method for distributing information to neighbors must be described in the FMP and may be accomplished through mail, telephone, door hangers, or through other methods that can be reasonably expected to effectively inform residences and businesses within the required distance from the edge of the buffer zone.

Who Needs to be Informed?:

If the buffer zone is less than or equal to:

Buffer $\leq$ 100 feet
 100 feet $<$ Buffer $\leq$ 200 feet
 200 feet $<$ Buffer $\leq$ 300 feet

People within this distance from the edge of the buffer zone must be informed:

50 feet
 100 feet
 200 feet

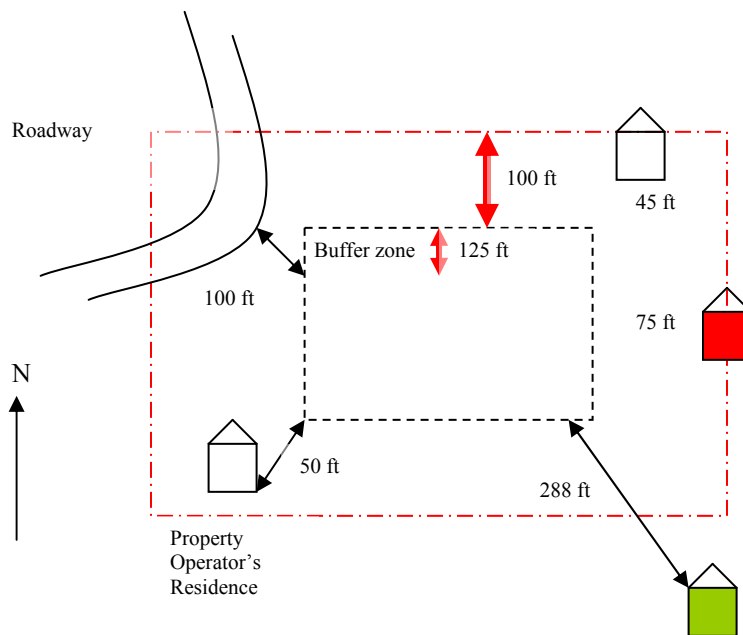
Buffer > 300 feet

300 feet

To clarify this option, the following example is provided:

- IF the buffer zone is **125 feet**, people within 100 feet of the buffer zone must be provided emergency response information. So the **red** houses would need to be informed, **but** the **green** house would not.
- This requirement does not impact the roadway or the property operator's residence (striped).

Figure 9. Example Site Map for Informing Neighbors



If there are no residences or other occupied structures within 300 feet of the edge of the buffer zone, no site monitoring or advising of neighbors will be required.

Emergency Preparedness and Response Considerations

EPA received comments from many stakeholders about the Agency's Phase 5 proposal for notification. Users have commented that notification is burdensome and that it is unnecessary if buffer zones are also required. However, community groups have commented on the importance of bystanders being informed when fumigations are occurring, since this group of pesticides, compared to other pesticides, has a greater potential to move off site and affect people not involved in the application. State regulators have different views on this requirement. Some support the sharing of information with neighbors, and some states have notification requirements for fumigations with certain products or for certain application methods. In addition, some states require notification to chemically sensitive individuals in proximity to

pesticide applications. Others also had concerns about the enforceability of this type of measure and the possible burden on the states to enforce a notification requirement.

California currently requires notification of persons within 300 feet of a methyl bromide buffer zone. California strawberry growers consider the 300 foot notification area for methyl bromide applications to be an extension of the buffer zone. In areas where a large number of people would need to be notified about a planned methyl bromide application, strawberry growers state that they would rather not use methyl bromide because some communities could mobilize to prevent the fumigation from taking place. Some stakeholders also commented that it would be protective and less burdensome if EPA required the user to monitor fumigant air concentrations at the edge of the buffer for 24 hours after the application to ensure the fumigant does not move beyond the buffer at concentrations that exceed EPA's LOC. If concentrations of concern were detected, the user would be required to implement the emergency response measures specified in the fumigant management plan.

EPA has concluded that bystanders could take steps to protect themselves if they had basic information about fumigations and the appropriate steps to take if they experienced symptoms of exposure. In a number of fumigant incidents that have occurred, the magnitude and severity of the incident could have been significantly reduced if people had such information. Similarly, having on-site monitoring will enable site managers to take remedial action (i.e., activate the control plan in the FMP) to lower emissions sooner, also resulting in fewer and less severe exposures. And, if necessary, site managers would activate the emergency response elements of the FMP.

Providing communities with information about local chemical releases is an important part of emergency preparedness programs and is recognized as an effective means of addressing risk at the local level. Some states, like Florida and Wisconsin, have requirements for providing information to chemically-sensitive individuals about chemicals used nearby so they can take steps to protect themselves from potentially harmful exposures (see <http://edis.ifas.ufl.edu/pi004> and <http://www.legis.state.wi.us/rsb/code/atcp/atcp029.pdf>). Wisconsin also requires fumigators applying metam sodium products through chemigation to provide written notice to the county public health agency and to every individual or household within ¼ miles of the chemigation application site (see <http://www.legis.state.wi.us/rsb/code/atcp/atcp030.pdf>). EPA agrees that information about how to recognize and address exposures can help citizens reduce potential risk.

EPA understands that difficult challenges exist when agricultural land borders urban or suburban communities. While EPA's decisions for the fumigants will not alleviate challenges that already exist, EPA is allowing options for ensuring emergency preparedness in an effort to lessen potential impact on growers.

If users opt, based on their site conditions, to provide emergency response information to neighbors rather than monitor, EPA believes that scaling the size of the informed area will be protective and helps address concerns expressed by some fumigant users. When the informed area is scaled to the size of the buffer, small buffers which generally result from applications to

small areas, at low application rates, and/or using low-emission application techniques, will have small or no areas to inform, while larger applications will have larger areas to inform.

EPA is not requiring a specific method of providing the information to neighbors, but rather that it be done in a way that effectively communicates, in a manner the recipients will understand. Some methods may not result in documentation that would be retained. To address concerns about enforcement, EPA is requiring that information on how and when the emergency response information was delivered and to whom, be included in the FMP.

EPA is interested in input on the importance and usefulness of information specifying the location of the application block and buffer. EPA recognizes that such information may be difficult to convey clearly and concisely, especially if there are no easily recognizable land marks nearby. While such information may be helpful, it may not be critical to ensuring an appropriate response to early signs and symptoms of exposure.

5. Notice to State Lead Agencies

EPA believes that when state, tribal and local enforcement officials have information about when and where applications take place they are better able to plan and execute compliance assistance and assurance activities. Therefore, EPA is requiring notification of the appropriate state or tribal lead agency before an application begins to assist enforcement agencies in compliance monitoring.

The information that must be provided includes the following:

- Applicator contact information (name, telephone number, and applicator license number)
- Property owner/operator contact information
- Location of the application block
- Name of fumigant(s) products(s) applied including EPA Registration number
- Time period in which the fumigation is planned to take place and the duration of buffer zone period

Assuring compliance with new label requirements is an important component of the fumigant risk mitigation package. Notice to enforcement officials allows them to target inspections around periods when fumigations are expected to occur to ensure label requirements designed to mitigate risks of concern for bystanders, handlers, and workers, have been followed and that the conditions for the fumigation have been documented in the FMP. In states such as California, where permitting processes are already in place, additional notice to state and tribal lead agencies will not be required.

6. Soil Fumigation Training for Applicators and Other Handlers

Soil fumigation is an inherently complex activity involving specialized equipment and application techniques. Additionally, the mitigation measures required as part of these decisions

will introduce new requirements in the form of more detailed instructions and restrictions on soil fumigations. Failure to adequately manage fumigant applications increases risks to handlers involved in the fumigation, workers nearby, and other bystanders. Incident data show that a number of fumigant incidents are the result of misapplications, failure to follow label requirements and safe use procedures, and other errors on the part of fumigant applicators. Although states have certification programs, some of which include a specific category for soil fumigation, there currently is not a consistent standard across states and regions where soil fumigation is done, and the federal certification program currently has no category for soil fumigation. Proposed changes in the federal certification program and worker safety regulations to include a soil fumigation category are not, however, anticipated in the near future.

EPA believes that training is an effective way to increase applicators' skill and knowledge so they are better prepared to effectively manage soil fumigation and are able to understand and comply with revised labeling. EPA has determined that training, developed and implemented by registrants to foster product stewardship, will help reduce potential risks associated with failure to adequately manage the complexities of fumigation, and failure to comply with fumigant product labeling. Additionally, EPA believes that providing safety information to other fumigant handlers will help them understand and adhere to practices that will help handlers protect themselves from risks of exposure.

It is important to note that training developed and provided by registrants as required by this RED is separate and distinct from state certification programs. EPA encourages registrants, in developing their training proposals, to work with states where their products are used to identify opportunities to build on and complement state programs. However, the training programs required as part of this decision will be separate from the state certification process and will be developed and administered by registrants. Individual state regulatory agencies have the option of working with registrants on these activities, but are not required to do so. It is important to note that some fumigant registrants have already developed product-specific training that will serve as a good basis for this expanded effort.

Training for Applicators Supervising Fumigations

Registrants will be required to develop and implement training programs for applicators in charge of soil fumigations on the proper use of and GAPs for soil fumigants. EPA is requiring registrants to submit proposals for these programs as data requirements in the Data Call-In that will accompany this RED. The training programs must address, at minimum, the following elements: how to correctly apply the fumigant; how to protect handlers and bystanders; how to determine buffer zone distances; how to develop a FMP and complete the post fumigation application summary; how to determine when weather and other site-specific factors are not favorable for fumigant application; how to comply with required GAPs and document compliance in the FMP. The training program must be made available to applicators at least annually. The registrant shall provide documentation, such as a card or certificate, to each applicator who successfully completes the training. This documentation shall include the applicator's name, address, license number, and the date of completion.

The registrant must be able to provide to federal, state, or local enforcement personnel, upon request, the names, addresses, and certified applicator license numbers of persons who successfully completed the training program, as well as the date of completion. Applicators supervising fumigations must have successfully completed the program within the preceding 12 months and must document when and where the training program was completed in the FMP. The registrants will be required to (1) develop a database to track which certified applicators have successfully completed the training and (2) make this database available to state and/or federal enforcement entities upon request. In addition, the applicator must provide to Federal, State, or local enforcement personnel, upon request, documentation that verifies completion of the appropriate training program(s).

Product labels will state that before applying the product, the certified applicator supervising the application must have successfully completed, within the preceding 12 months, a dazomet training program made available by the registrant, and that the FMP must document when and where the training program was completed.

EPA encourages registrants to include in their proposals additional stewardship elements such as technical support information and resources for certified applicators and/or handlers; hotlines to answer technical questions from applicators about product use, emergency preparedness and response; and equipment verification programs to assist applicators with calibration and testing of soil fumigation equipment. The Agency is soliciting input during the post-RED comment period from states, user groups, registrants, and other stakeholders on content and how best to implement training programs and other stewardship elements.

Training Materials for Handlers

EPA has determined that registrants must prepare and disseminate training information and materials for other fumigant handlers, i.e., those working under the supervision of the certified applicator in charge of fumigations. EPA is requiring registrants to submit proposals for these materials as data requirements in the Data Call-Ins that will accompany this RED. The training materials must address, at minimum, the following elements: (1) what fumigants are and how they work, (2) safe application and handling of soil fumigants, (3) air monitoring and respiratory protection requirements for handlers, (4) early signs and symptoms of exposure, (5) appropriate steps to take to mitigate exposures, (6) what to do in case of an emergency, and (7) how to report incidents. Registrants must provide this training information through channels open to the public (e.g., via a website). Pesticide labels will require that applicators supervising fumigations provide this training information to handlers under their supervision before they perform any fumigant handling task, or they must ensure that handlers have been provided the required information within the preceding 12 months. The label will also require that the training information be provided in a manner that the handler can understand. Applicators supervising fumigations must ensure the FMP includes how and when the required training information was provided to the handlers under their supervision.

"The certified applicator must provide fumigant safe handling information to each handler involved in the application or confirm that each handler participating in the application has received fumigant safe handling information in the past 12 months."

Soil Fumigation Training Considerations

In comments on fumigant risk management options, stakeholders were broadly supportive of additional training for applicators and handlers. During the most recent comment period, the vast majority of stakeholders, including growers, community groups, farm workers, states, and registrants expressed strong support for increased training for applicators and other handlers. Several comments noted that fumigant incidents affecting both fumigant workers and bystanders could have been prevented or mitigated if applicators had better training about correct practices and procedures.

The Agency agrees that additional training and technical support for fumigant applicators and handlers will help educate and inform these workers, thus decreasing the likelihood of both incidents and noncompliance. EPA believes fumigant-specific training for applicators and handlers also will help reduce the magnitude and frequency of exposure incidents and, coupled with the other mitigation measures described in this decision, will address risks of unreasonable adverse effects from the use of soil fumigants.

As noted above, several states have high-quality certification programs for fumigators which include exams to test the competency of fumigators. EPA recognized that for applicators to become certified in those states, they must acquire the knowledge and skill necessary to pass the exam. But several stakeholders commented that training opportunities are varied across the country, and the scope and detail of information provided in available training is not consistent. EPA is also concerned that information in existing programs will need to be updated as a result of new requirements associated with this decision and the label changes which will result. Although the federal program will be revised eventually and will establish a consistent standard, EPA believes that registrants must play a central role in developing and delivering training in the interim.

EPA stresses that registrant training programs will be separate from the state certification process and will be developed and administered by registrants in coordination with EPA. EPA will, however, work with state organizations and training experts to explore opportunities for the registrant programs to supplement state programs to provide additional training opportunities for fumigators. EPA will work with registrants in reviewing training program proposals and in developing the content for the programs and materials. EPA will also work with states to identify ways in which registrant training programs can be tailored to complement existing state programs. EPA's goal in requiring registrant training is to add to training resources. EPA is aware of the need to coordinate carefully with states to ensure that new training does not become a burden on state agencies. EPA specifically requests comments from States on the best implementation approaches to meet these goals, and plans to meet with states during and after the public comment period to discuss options.

The Agency also expects that FMPs will serve as tools with which fumigant users can maintain records of their compliance with training requirements in addition to the other measures described in this document. Thus, FMPs would serve as an additional tool for verification state enforcement personnel to verify compliance.

7. Community Outreach and Education Programs

EPA understands from public comments, site visits, and stakeholder meetings, conducted as part of the soil fumigant review, that there is often a fundamental lack of information and communication within communities where soil fumigation occurs, which has raised health and safety concerns among community members. This lack of information and communication has led to inappropriate responses in cases where fumigants have moved off site and into communities. This also has led in some cases to unwarranted concern and anxiety among communities about the risks associated with the use of fumigants. The Agency believes that outreach and education to communities where soil fumigation occurs is an important component of the overall package of measures to address bystander risk. This outreach and education will address the risk of acute bystander exposure by educating community members in high-use areas about buffer zones and their characteristics and purpose; the importance of not entering these zones; how to recognize early signs of fumigant exposure, and how to respond appropriately in case of an incident. The first responder training discussed above is a significant part of this program.

Therefore, the Agency is requiring registrants to develop and implement community outreach and education programs, including programs for first responders, to address these needs. EPA encourages registrants' proposals to work with existing community resources, such as community health networks, for dissemination of information and implementation of their programs. Registrants' proposals must also include criteria and a plan for identifying and selecting the communities that will be receive outreach programs.

Community outreach and education programs must include the following elements, at minimum: (1) what soil fumigants are and how they work, (2) what buffer zones are, (3) early signs and symptoms of exposure, (4) appropriate steps to take to mitigate exposures, (5) what to do in case of an emergency, and (6) how to report an incident.

EPA expects registrants' proposals for the first responder programs described above will also be designed to integrate with existing local first-response and emergency preparedness networks.

The community outreach and education proposal and supporting materials for communities and first responders, as well as a plan for evaluating the effectiveness of the programs, will be included as data requirements in the Data Call-In that will accompany this RED.

As with the training for fumigant applicators and handlers, the community outreach and education program that the Agency is requiring is intended to be part of the registrants' long term

product stewardship. State governments are not required to participate in the program, but have the option of working with EPA and registrants to develop and track this and any other stewardship components which the registrants may include in their proposals.

iii. Environmental Risk Management

As mentioned in Section III.D, the Agency is concerned about both aquatic and terrestrial risks. The Agency believes that mitigation measures detailed in the Human Health Risk Mitigation Section will also reduce ecological risks. Although buffer zones and GAPs do not directly reduce the potential risk to ecological organisms, they do provide an incentive to reduce fumigant application rates and individual treatment areas which in turn will contribute to lower exposure and risks for non-target organisms.

Exposure to terrestrial organisms such as birds and mammals could occur two ways, as either oral exposure to dazomet granules or by the inhalation route of exposure to the breakdown product of MITC. Potential exposure to aquatic organisms may occur from surface runoff/leaching and drift (wind) of MITC.

The risk assessment identified potential acute risks of concern for birds and mammals, since it is assumed they could be exposed to unincorporated dazomet granules. There are uncertainties about the aquatic risks since there are no toxicity data available. Additional ecotoxicity data are required for both dazomet and MITC.

Since dazomet is applied as a granular and watering in is required in order to activate the product, the amount of dazomet granular left on the soil surface to which birds and mammals could have access is not estimated in this assessment. It is likely the amount of dazomet available to birds and mammals is less than assumed in the risk assessment due to watering in.

In addition, the registrants will lower the maximum rate for dazomet from 530 to 425 lbs a.i./A for all use sites, except for golf-course renovation. This rate reduction will also reduce the potential for effects on non-target organisms. In addition, the structure of the buffer zones required in this decision encourages growers to use the lowest rate and block size feasible in order to establish the smallest possible buffer zone distance for an application. Although this mitigation measure does not directly reduce the potential risk to ecological organisms, it does provide an incentive to reduce fumigant application rates and individual treatment areas which in turn will contribute to lower exposure and risks for non-target organisms.

Based on the fate parameters of MITC, it should not persist in terrestrial environments because of volatilization and degradation and the available non-targeted monitoring data does not detect MITC in the ground- water samples within the U.S.A. However, MITC is highly soluble in water and has a low adsorption to soil which suggests that there is a potential of leaching to shallow groundwater under flooded and saturated conditions. Also, if intense rainfall or continuous irrigation occurs there is potential for MITC to move to surface water. The Agency recognizes that managing soil moisture is important factor that may be used to reduce peak emissions, and the requirements related to soil moisture described in the GAP section on page 50

will not result in the leaching of MITC into ground or surface water. Language is required for both tarped and non-tarped dazomet applications to minimize potential for leaching or runoff. The specific label statements can be found in the dazomet label table, Table 4.

b. Dazomet Antimicrobial Uses

A summary of the risk mitigation measures for the antimicrobial uses of dazomet is presented below; for further information on the antimicrobial risk assessment and mitigation, please see these documents in the dazomet docket:

- *Dazomet: Revised Occupational and Residential Exposure Assessment of Antimicrobial Uses for the Reregistration Eligibility Decision (RED) Document.* (Walls, C., Dated June 4, 2008)
- *Risk Mitigation Measures and Updated Label Language for the Antimicrobial Uses of Dazomet (PC Code 035602) for the Reregistration Eligibility Decision Document.* (Garvie, H., Dated June 2 2008)

All of the dazomet antimicrobial uses are for occupational applications. These uses include: 1) a treatment during the production of pulp and paper; 2) a materials preservative treatment for coatings, adhesives, epoxy flooring compounds, slurries, and high viscous suspensions; 3) a biocide treatment used during petroleum operations; 4) a biocide treatment used in recirculating cooling water systems; and 5) a remedial wood treatment to utility poles.

Risks of Concern

All of the occupational handler inhalation, dermal and total MOEs were above the target MOE of 100 (short-term and intermediate-term) except for the following scenarios:

- Intermediate-term dermal exposure resulting from the preservation of epoxy flooring compounds via solid open pour methods: MOE = 58
- Intermediate-term total exposure resulting from the preservation of epoxy flooring compounds via solid open pour methods: MOE = 55
- Intermediate-term dermal exposure resulting from pulp and paper slimicide use via solid open pour methods: MOE = 79
- Intermediate-term total exposure resulting from pulp and paper slimicide use via solid open pour methods: MOE = 74
- Intermediate-term inhalation exposure resulting from the maintenance dose of microbe control in large water cooling system via metering pump: MOE = 98
- Intermediate-term total exposure resulting from the maintenance dose of microbe control in large water cooling system via metering pump: MOE = 55

Risk Mitigation Measures

1. For epoxy flooring open pour scenario- labeling language must state that the product is not to exceed 3,500 ppm (maximum application rate of .35%) by weight of material treated.
2. For the pulp and paper solid open pour scenario – update PPE language to state that long sleeve coveralls will be required in addition to wearing long sleeved shirt, long pants, shoes, socks, goggles or face shield and chemical resistant gloves.
3. For the cooling tower use: update personal protective equipment (PPE) language to state that chemical resistant gloves are necessary, in addition to goggles or face shield.
4. For all scenarios that use metering pumps, chemical resistant gloves must be used.
5. Additional label instructions for pole treatment use requiring that pre-drilled holes are plugged immediately after application and instructions that holes are not to be drilled through seasoning checks.

The data requirements for dazomet’s antimicrobial use and label changes are found in Section V, beginning on page 69.

2. Endocrine Disruptor Effects

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) *“may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate.”* Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there were scientific bases for including, as part of the program, androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC’s recommendation that the Program include evaluations of potential effects in wildlife. When the appropriate screening and/or testing protocols being considered under the Agency’s Endocrine Disrupter Screening Program (EDSP) have been developed and vetted, dazomet may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

3. Endangered Species Considerations

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species and to implement mitigation measures that address these impacts. The Endangered Species Act (ESA) requires federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. To analyze the potential of registered pesticide uses that may affect any particular species, EPA uses basic toxicity and exposure data and considers ecological parameters, pesticide use information, geographic relationship between specific pesticide uses and species locations, and biological requirements and behavioral aspects of the

particular species. When conducted, these analyses take into consideration any regulatory changes recommended in this RED being implemented at that time.

The ecological assessment that EPA conducted for this RED does not, in itself, constitute a determination as to whether specific species or critical habitat may be harmed by the pesticide. Rather, this assessment serves as a screen to determine the need for any species-specific assessment that will evaluate whether exposure may be at levels that could cause harm to specific listed species and their critical habitat. The species-specific assessment refines the screening-level assessment to take into account information such as the geographic area of pesticide use in relation to the listed species and the habits and habitat requirements of the listed species. If the Agency's specific assessments for the pesticidal use of dazomet result in the need to modify use of the pesticide, any geographically specific changes to the pesticide's registration will be implemented through the process described in the Agency's *Federal Register* Notice (54 FR 27984) regarding implementation of the Endangered Species Protection Program.

Risk findings are based solely on EPA's qualitative assessment for dazomet and do not constitute "may affect" findings under the ESA. A determination that there is a likelihood of potential effects to a listed species may result in limitations on the use of the pesticide, other measures to mitigate any potential effects, and/or consultations with the Fish and Wildlife Service or National Marine Fisheries Service, as necessary. If the Agency determines use of dazomet "may affect" listed species or their designated critical habitat, EPA will employ the provisions in the Services regulations (50 CFR Part 402). EPA plans to begin the Registration Review process for dazomet and the other soil fumigants in 2013, which will include a comprehensive endangered species assessment. Once that endangered species assessment is completed, further changes to dazomet registrations may be necessary.

D. Conclusion

In this document, the Agency has described a package of mitigation measures with elements that are designed to work together to reduce risk to human health and the environment. The Agency believes that all of the mitigation measures required by this decision will mitigate risks so that dazomet use will result in no unreasonable adverse effects.

Stakeholder comments and Agency analyses indicate that mitigation may impact the benefits of fumigant use. One analysis the Agency completed quantifies the potential impact of buffer zones.¹² The Agency believes that some impact will occur in order to protect human health and the environment from unreasonable adverse effects. EPA believes that impacts have been minimized because the mitigation package incorporates flexibility which allows users to make choices that minimize potential impacts. For example a current application practice might require a large buffer that a user is not able to implement. However, instead of setting a fixed buffer for all applications regardless of application-specific parameters, this decision allows

¹² Review of Stakeholder Submitted Impact Assessments of Proposed Fumigant Buffers, Comments on Initial Buffer Zone Proposal, and Case Studies of the Impact of a Flexible Buffer System for Managing By-Stander Risks of Fumigants

growers the flexibility to modify their practices to achieve smaller buffers; for example treat smaller application blocks, or switch to a lower emission application method. Also, the buffer zone reduction credits allow users to take advantage of site conditions (e.g., soil conditions) to lessen the impact. In addition the Agency believes that flexibility decreases the impacts associated with respiratory protection mitigation. Instead of requiring respirators for all handling tasks, the monitoring scheme indicates when respiratory protection is needed. This mitigation is protective of handlers while not increasing the burden to users by mandating respirators that may hinder communication or could potentially cause heat stress.

When dazomet is used as an antimicrobial chemical the Agency believes that the required mitigation is protective and anticipates that it will have minimal impact on the benefits. Taking into consideration the risk and benefit assessments and stakeholder comments, the Agency believes the mitigation required by this document will be protective and minimize impacts.

V. What Registrants Need to Do

The Agency has determined that the products containing dazomet are eligible for reregistration provided that the mitigation measures and label changes identified in this RED are implemented. EPA recognizes that the extent of the mitigation needed for dazomet will require continued coordination among state regulatory agencies, the Agency, registrants, growers and other stakeholders to ensure that all provisions of the RED are understood, that data are developed and evaluated expeditiously, and that bystander and worker protection measures are implemented as soon as practicable. EPA also acknowledges that certain provisions of the RED, such as the worker training programs and community education, will take time to develop in terms of both the content of the program as well as a strategy for implementation.

EPA envisions the following approximate schedule for implementation of the dazomet RED:

July 2008	Dazomet RED issued
Fall 2008	Comment period closes
Early 2009	EPA responds to comments, amends RED if appropriate
Mid 2009	EPA issues product and generic DCIs
Mid 2009	Registrants submit revised labels to EPA
Late 2009	EPA reviews/approves new labeling
During 2009	Registrants develop worker and community training and education plans and submits to EPA
Early 2010	Products bearing new labels enter the market; training and education programs ramp up.
2009-2012	Registrants develop data per DCI
2013	EPA begins Registration Review for dazomet and other fumigants

The Agency is issuing this decision document for dazomet, as announced in a Notice of Availability published in the Federal Register. Due to the broad scope of the decision for the soil fumigant group, there will be a 60-day public comment period for this document to allow stakeholders the opportunity to review and provide comments on issues related to the

implementation of the risk mitigation measures. After considering public comment, the Agency will issue a public determination as to whether modifications to this decision are appropriate.

Labeling

Registrants will need to amend their product labeling to incorporate the label statements set forth in the Label Changes Summary Tables 4 and 5. The Agency will consider post-RED comments prior to finalizing labeling. The Agency anticipates that label amendments will need to be submitted approximately 1 year from the issuance of the RED.

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of dazomet for the eligible uses has been reviewed and determined to be substantially complete. However, data to characterize the hazard of MITC, the degradate of dazomet, are not available and are necessary to confirm the reregistration eligibility decision documented in this RED.

Data requirements for all dazomet uses

OPPTS Guideline Number	Data Requirement	Study type
870.6200	Neurotoxicity Screening Battery – Inhalation (MITC)	TOX
870.3550	Developmental Toxicity Screening Test – Inhalation (MITC)	TOX
870.3800	Reproduction and Fertility Effects – Inhalation (MITC)	TOX
870.5550	Unscheduled DNA Synthesis in Mammalian Cells in Culture (MITC)	TOX
870.4200	Chronic/Carcinogenicity Rats – Inhalation (MITC)	TOX
870.4200	Chronic/Carcinogenicity Mice – Inhalation (MITC)	TOX

870.6200 - Neurotoxicity Screening Battery

Acute neurotoxicity study in rat via the inhalation route with pathological evaluation of the complete respiratory tract. The Agency is using single day, acute exposures in its consideration of buffer zones following applications of dazomet. The toxicology data available to inform this decision are limited to an eye irritation study in human subjects and an acute

inhalation study in rats. The purpose of the acute study in rats was to determine the LC50, not for use in hazard identification for human health risk assessment. The Agency can not evaluate the dose response relationship of irritation and systemic effects to the nose and lungs using these studies. This information on the respiratory tract is critical for the risk assessment as the relative sensitivity of eye irritation and more serious health outcomes is unknown. The Agency is open to discussing MITC-specific changes to the standard neurotoxicity screening battery to ensure that the appropriate target organs are evaluated and that relevant dose-response data would be generated.

870.3550 - Developmental Toxicity Screening Test - Inhalation

This inhalation developmental toxicity study in rat is being requested to further characterize the toxicity profile of this compound via the inhalation route. MITC has been shown to travel off fields to residential areas. As such, it is appropriate to evaluate the effects of MITC on pregnant females and their fetuses.

870.3800 - Reproduction and Fertility Effects

Two generation reproduction study in rats via inhalation with pathological evaluation of the complete respiratory tract in offspring is needed for MITC. This inhalation reproductive toxicity study is being requested to further characterize the toxicity profile of this compound via the inhalation route. MITC has been shown to travel off fields to residential areas. As such, it is appropriate to evaluate the effects of MITC on reproductive performance and to pups directly exposed to MITC via the inhalation route. The Agency is open to discussing with the registrant the potential for performing the new enhanced 1-generation reproductive study instead of the standard 2-generation study.

870.5550 - Unscheduled DNA Synthesis in Mammalian Cells in Culture

This study is required to complete the genetic toxicity testing battery for MITC.

870.4200 - Chronic/Carcinogenicity Rats

870.4200 - Chronic/Carcinogenicity Mice

Carcinogenicity studies for MITC per se are not available; therefore, the carcinogenic potential of MITC cannot be determined at this time. Although there are not expected to be exposures of six months or longer in duration in a given year, since the same fields are often treated every year, there is potential for exposure to occur annually for many years. Moreover, metaplasia of the respiratory epithelium, a lesion often associated cancer, was observed after only 28 days of exposure in the subchronic inhalation study in rats with MITC. As such EPA is requiring inhalation carcinogenicity studies with MITC in rats and mice.

Data requirements for dazomet's soil uses

OPPTS Guideline Number	Data Requirement	Study type
835.8100	Field Volatility from Soil	ORE
Special	Avian Acute Inhalation, MITC	ECO
850.2300	Avian Reproduction, Dazomet (bobwhite quail and mallard)	ECO
850.1075	Acute Marine/Estuarine Fish, MITC	ECO
850.1025	Acute Marine/Estuarine Mollusk, MITC	ECO
850.1035	Acute Marine/Estuarine Shrimp, MITC	ECO
850.4225	Seedling Emergence – Tier II, MITC.	ECO
850.4250	Vegetative Vigor – Tier II, MITC	ECO
850.4400	Aquatic Plant Growth – Tier II, MITC (3 remaining species)	ECO
850.3020	Honeybee Acute Contact, MITC	ECO
Special	Community Outreach and Education Program	Special
Special	Training for Applicators Supervising Fumigations	Special
Special	Training Materials for Handlers	Special

835.8100 - Field Volatility from Soil

Volatility studies are required for dazomet's soil uses to determine flux for modeling purposes of the breakdown products of dazomet, including formaldehyde.

Special - Avian Acute Inhalation, MITC

The current estimate of avian risk is based largely on the mammal assessment. This study will enable an inhalation risk assessment specific to birds. This is critical, since avian exposure to MITC is expected to be largely via inhalation.

850.2300 - Avian Reproduction (bobwhite quail and mallard duck), Dazomet

These studies are needed to assess potential reproductive effects in birds from exposure to the parent dazomet in the granular formulation. Neither of the existing studies is able to provide an overall NOAEL/LOAEL needed for risk assessment. There were problems with mixing of the diet in both studies and the mallard study had unacceptably high embryo mortality in the controls between day 21 and hatch. The studies indicate the possibility of severe reproductive effects, particularly in the mallard study, which included effects prior to those identified in the controls.

850.1075 - Acute Marine/Estuarine Fish, MITC

The aquatic risk assessment of dazomet use is based on exposure to MITC. Given the use patterns evaluated, marine/estuarine species could also be exposed. This study will enable a risk assessment for marine/estuarine species exposure.

850.1025 - Acute Marine/Estuarine Mollusk, MITC

The aquatic risk assessment of dazomet use is based on exposure to MITC. Given the use patterns evaluated, marine/estuarine species could also be exposed. This study will enable a risk assessment for marine/estuarine species exposure. It will also improve certainty with the endangered species risk assessment, as this test species may be more representative of endangered freshwater mussels than the freshwater *Daphnia*.

850.1035 - Acute Marine/Estuarine Shrimp, MITC

The aquatic risk assessment of dazomet use is based on exposure to MITC. Given the use patterns evaluated, marine/estuarine species could also be exposed. This study will enable a risk assessment for marine/estuarine species exposure.

850.4225 - Seedling Emergence – Tier II, MITC

Dazomet is used in part due to the phytotoxicity of MITC at the application site. This study will enable the assessment of risk to non-target terrestrial plants off-site. The protocol should be modified to test using air concentrations of MITC.

850.4250 - Vegetative Vigor – Tier II, MITC

Dazomet is used in part due to the phytotoxicity of MITC at the application site. This study will enable the assessment of risk to non-target terrestrial plants off-site. The protocol should be modified to test using air concentrations of MITC.

850.4400 - Aquatic Plant Growth – Tier II, MITC

Only one of five tests currently available (on duckweed) is considered to be Acceptable (Core) (MRID #45919422). The submission of data for remaining test species under this guideline will reduce uncertainty and improve the assessment of risk to aquatic plants. For example, the blue-green alga and green alga studies are 72-hour OECD studies that are only accepted as Tier I screening studies.

850.3020 – Honeybee Acute Contact, MITC

Although there is honeybee data for dazomet indicating that it is relatively non-toxic to honey bees, there is a concern that MITC could be more toxic to bees. Therefore, honeybee acute contact data is required for MITC.

Special Study - Community Outreach and Education Program

The Agency is requiring registrants to develop and implement community outreach and education programs, including programs for first responders, to address these needs. Community outreach and education programs must include the following elements, at minimum: (1) what soil fumigants are and how they work, (2) what buffer zones are, (3) early signs and symptoms of exposure, (4) appropriate steps to take to mitigate exposures, (5) what to do in case of an emergency, and (6) how to report an incident. EPA expects registrants' proposals for the first responder programs described in Section IV will also be designed to integrate with existing local first-response and emergency preparedness networks.

Special Study - Training for Applicators Supervising Fumigations

EPA has determined that training, developed and implemented by registrants to foster product stewardship, will help reduce potential risks associated with failure to adequately manage the complexities of fumigation, and ensure compliance with fumigant product labeling. Additionally, EPA believes that providing safety information to other fumigant handlers will help them understand and adhere to practices that will help handlers protect themselves from fumigant exposure.

Registrants are required to develop and implement training programs for applicators in charge of soil fumigations on the proper use of and GAPs for soil fumigants. EPA is requiring registrants to submit proposals for these programs. The training programs must address, at minimum, the following elements: how to correctly apply the fumigant; how to protect handlers and bystanders; how to determine buffer zone distances; how to develop a FMP and complete the post fumigation application summary; how to determine when weather and other site-specific factors are not favorable for fumigant application; how to comply with required GAPs and document compliance in the FMP. The training program must be made available to applicators at least annually. The registrant shall provide documentation, such as a card or certificate, to each applicator who successfully completes the training. This documentation shall include the applicator's name, address, license number, and the date of completion.

The registrant must be able to provide to federal, state, or local enforcement personnel, upon request, the names, addresses, and certified applicator license numbers of persons who successfully completed the training program, as well as the date of completion. Applicators supervising fumigations must have successfully completed the program within the preceding 12 months and must document when and where the training program was completed in the FMP. The registrants will be required to (1) develop a database to track which certified applicators have successfully completed the training and (2) make this database available to state and/or federal enforcement entities upon request. In addition, the applicator must provide to Federal, State, or local enforcement personnel, upon request, documentation that verifies completion of the appropriate training program(s).

Special Study - Training Materials for Handlers

EPA has determined that registrants must prepare and disseminate training information and materials for other fumigant handlers, i.e., those working under the supervision of the certified applicator in charge of fumigations. The training materials must address, at minimum, the following elements: (1) what fumigants are and how they work, (2) safe application and handling of soil fumigants, (3) air monitoring and respiratory protection requirements for handlers, (4) early signs and symptoms of exposure, (5) appropriate steps to take to mitigate exposures, (6) what to do in case of an emergency, and (7) how to report incidents. Registrants must provide this training information through channels open to the public (e.g., via a website). Pesticide labels will require that applicators supervising fumigations provide this training information to handlers under their supervision before they perform any fumigant handling task, or they must ensure that handlers have been provided the required information within the preceding 12 months. The label will also require that the training information be provided in a manner that the handler can understand. Applicators supervising fumigations must ensure the FMP includes how and when the required training information was provided to the handlers under their supervision.

Data requirements for dazomet's antimicrobial uses

Chemical Manufactures Association (CMA) unit exposure data to be called in:

- GLN 875.1200 – dermal indoor exposure
- GLN 875.1400 – inhalation indoor exposure
- GLN 875.1600 – applicator exposure monitoring data reporting
- GLN 875.1700 – product use information

Because dazomet degrades into MITC, the Agency needs MITC air concentration monitoring data for all enclosed facilities that utilize dazomet. The guideline numbers are as follows:

- GLN 875.2500 – inhalation exposure study
- GLN 875.2700 – product use information
- GLN 875.2800 – description of human activity
- GLN 875.2900 – post-application data reporting and calculations

Residue data are needed to support the dazomet antimicrobial use in pulp and paper manufacturing. The purpose of this confirmatory study is to demonstrate that the paper manufacturing processes remove any residual dazomet and MITC - GLN 860.1520

Avian acute oral LD₅₀ data using technical MITC to bobwhite quail or mallard duck – GLN 850.2100

Acute estuarine fish LC₅₀ data using technical MITC – GLN 850.1075

Acute mysid shrimp using technical MITC – GLN 850.1035

Acute bivalve embryo larvae using technical MITC to Eastern oyster – GLN 850.1055

2. Labeling for Manufacturing-Use Products

To ensure compliance with FIFRA, manufacturing use product (MUP) labeling must be revised to comply with all current EPA regulations, PR Notices, and applicable policies. The MUP labeling must bear the labeling contained in Tables 4 and 5.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The Registrant must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers must be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product. The Agency intends to issue a separate product-specific data call-in (PDCI), outlining specific data requirements.

2. Labeling for End-Use Products

In order to be eligible for reregistration, registrants must amend all product labels to incorporate the risk mitigation measures outlined in Section IV. Tables 4 and 5 describe how language on the labels should be amended.

Labeling Changes Summary Table

In order to be eligible for reregistration, amend all product labels to incorporate the risk mitigation measures outlined in Section IV. The following table describes how language on the labels should be amended.

Table 4: Summary of Labeling Changes for Dazomet Soil Uses		
Description	Amended Labeling Language for Manufacturing Use Products	Placement on Label
Manufacturing Use Products		
For all Manufacturing Use Products	“Only for formulation into a fumigant for the following use(s) [fill blank only with those uses that are being supported by MP registrant].” “Use in greenhouses is prohibited. Application with handheld equipment is prohibited. End use products with directions for use for soil fumigation must specifically prohibit these uses and all references to such applications must be removed.” “Dazomet cannot be formulated into end-use products labeled for pre-plant or pre-transplant uses unless the registrant makes available to certified applicators who purchase or apply the end-use product a training program that provides information on how to correctly apply the fumigant including how to protect themselves, other handlers and bystanders, how to determine buffer zone distances, how to develop a Fumigant Management Plan, and how to determine when weather and other site-specific factors are not favorable for fumigant application. The training program must be made available to the certified applicators at least annually and the registrant must be able to provide, upon request, the names, addresses, and certified applicator license number of persons who successfully complete the training program. “Dazomet cannot be formulated into end-use products labeled for pre-plant or pre-transplant uses unless the registrant assures warning signs suitable for posting buffer zones are available to end-use product users at the point of sale. The buffer zone sign must meet the following standards: - o Signs must remain legible during entire posting period. - o The size and type of the buffer zone signs must follow the requirements in the Worker Protection Standard for Agricultural Pesticides for treated area posting.	Directions for Use

	Contents of Sign  -- "DO NOT ENTER/NO ENTRE," -- "[Name of fumigant] Fumigant BUFFER ZONE," -- a space for the date and time of fumigation, -- a space for the date and time buffer zone restrictions are lifted (i.e., buffer zone period expires) -- brand name of this product, and -- a space for the name, address, and telephone number of the certified applicator in charge of the fumigation	
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	"This product is toxic to fish and aquatic invertebrates. 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		
Restricted Use Requirement for all products that contain soil use	“Restricted Use Pesticide due to acute inhalation toxicity to humans. For retail sale to and use by certified applicators or persons under their direct supervision and only for those uses covered by the certified applicator’s certification.”	Top of the front panel
Certified applicator must complete annual training program	“The certified applicator supervising that application must successfully complete a dazomet training program made available by the registrant within the last 12 months. The Fumigant Management Plan (see details elsewhere on this label) must document when and where the training program was completed.”	Directions for Use
Supervision of handlers	“The certified applicator supervising the application must be at the fumigant application site and able to maintain visual contact with every handler participating in the application starting when the fumigant is first introduced into the soil and ending after the fumigant has stopped being delivered/dispensed to the soil and the soil is sealed. The certified applicator must provide fumigant safe handling information to each handler involved in the application or confirm that each handler participating in the application has received fumigant safe handling information in the past 12 months. For all other fumigant handling tasks (as defined on this label), at least two WPS-trained handlers must be present to monitor one another.”	Directions for Use Under the section “protection for handlers”
Fumigation Handlers	“Persons engaged in any of the following activities are defined as fumigant handlers: • Persons participating in the application as supervisors, loaders, drivers, tractor co-pilots, shovelers, or as other direct application participants (application starts when the fumigant is first introduced into the soil and ends after the fumigant has stopped being delivered/dispensed to the soil); • Persons taking air samples to monitor fumigant air concentrations; • Persons cleaning up product spills; • Persons handling or disposing of product containers; • Persons cleaning, handling, adjusting, or repairing the parts of fumigation equipment that may contain product residues; • Persons installing, repairing, operating irrigation equipment in the fumigant application block or surrounding buffer zone during the buffer zone period; • Persons entering the application site or surrounding buffer zone during the buffer zone period to perform scouting or crop advising tasks;	In the Precautionary Use Section

	- Persons installing, perforating (cutting, punching, slicing, poking), removing, repairing, or monitoring tarps-until: > After tarps are perforated and removed if tarp removal is completed less than 14 days after application, or > 14 days after application is complete if tarps are not perforated and removed during those 14 days, or > 48 hours after tarps are perforated if they will not be removed prior to planting. NOTE: see Tarp Perforation and Removal section on this labeling for requirements about when tarps are allowed to be perforated.”	
Exclusion of Non Handlers from Application Block and Buffer Zone	“The certified applicator supervising the application and the owner/operator of the establishment where the fumigation is taking place must make sure that all persons who are not trained and PPE-equipped and who are not performing one of the handling tasks defined in this labeling are: - excluded from application block during the entry prohibition period, and - excluded from the buffer zone during the buffer zone period.”	Directions for Use Under the section “protection for handlers”
Providing, cleaning, and maintaining PPE	“The employer of the fumigant handlers must make sure that all handlers in the application block and the surrounding buffer zone are provided and correctly wear the required PPE. The PPE must be cleaned and maintained as required by the Worker Protection Standard for Agricultural Pesticides.”	Directions for Use Under the section “protection for handlers”
Respirator Availability	“In case of emergency or the need for immediate respiratory protection, the fumigation handler employer must make sure that the following PPE are immediately available to all persons performing fumigant handling activities: unless an air-purifying respirator is being worn by each person performing a handling task at the site, enough air-purifying respirators and face-sealing goggles (if the respirator is a half-face style) of the type specified in the PPE section of this labeling must be immediately available at the site for each handler.”	Directions for Use Under the section “protection for handlers”
PPE Requirements Established by the RED for dermal protection	“Personal Protective Equipment (PPE) for skin protection 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.”	Immediately following/below Precautionary Statements: Hazards to

	“All loaders, applicators and other handlers must wear at a minimum: • coveralls over short-sleeved shirt and short pants, • chemicals resistant gloves, and • shoes plus socks. IMPORTANT: see Personal Protective Equipment (PPE) for eye and lung protection on this labeling for more requirements.”	Humans and Domestic Animals
PPE Requirements Established by the RED for all Eye and Lung Protection	“Personal Protective Equipment (PPE) for eye and lung protection All handlers required on this label to wear a respirator and eye protection must wear: > a NIOSH-approved half-face, full-face, or helmet/hood style respirator with either: -- 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)., and > face-sealing goggles if a half-face respirator is worn. Handlers must wear the required respirator and eye protection when: • loading the fumigant, or • repairing equipment when exposure to liquid spray is possible, or • activating irrigation equipment when in the application block or surrounding buffer zone, or • repairing unperforated tarp within 14 days after the end of application, or • performing a handling task that is too short-term for air monitoring (described below) at hourly intervals to be feasible, or • fumigant air monitoring (described below) indicates that a respirator and eye protection are necessary. Fumigant Air Monitoring: The following air monitoring procedures must be followed to determine whether a respirator and eye protection are required for persons performing a fumigant handling task as defined in this labeling. • Air monitoring samples for MITC must be collected in the breathing zone of a handler performing a representative handling task starting approximately 30 minutes from the handler’s initial exposure and at least once every 1 hour thereafter. • A direct reading detection device, such as a Draeger device, with sensitivity of at least 100 ppb for	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

	MITC must be used to monitor air concentration levels of MITC. • If at any time (1) MITC concentrations are greater than or equal to 100 ppb, OR (2) any handler experiences sensory irritation, then a respirator and eye protection as specified in this section must be worn by every handler in the application block and surrounding buffer zone, • If two consecutive breathing zone samples taken at least 15 minutes apart, show levels have decreased to less than 100 ppb for MITC, then handlers may remove the respirators and eye protection. • If at any time (1) a handler experiences any sensory irritation when wearing a respirator, or (2) any air sample is greater than or equal to 1000 ppb (1 ppm) for MITC, then all handler activities must cease and handlers must be removed from the application block and surrounding buffer zone until corrective action has been taken. • During the corrective actions a respirator and eye protection must be worn. • In order to resume work activities: > Two consecutive air samples for MITC taken at the handling site at least 15 minutes apart must be less than 1000 ppb (1 ppm) for MITC. > During the collection of air samples a respirator and eye protection must be worn by the handler taking air samples. > If MITC concentrations are greater than or equal to 100 ppb, then handlers resuming their handler activities must wear a respirator and eye protection. See engineering controls section for more options.”	
Engineering Controls	“Engineering Controls for Motorized Ground Equipment with an Enclosed Cab: Applicators using an enclosed cab that meets the definition in the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(5)] may: -- wear long-sleeve shirt, long pants, shoes, and socks; -- if a respirator and eye protection are triggered by MITC air monitoring <i>either</i> wear the respirator and eye protection required in the PPE section for respirator and eye protection or use an enclosed cab that is declared in writing by the manufacturer or by a government agency to provide at least as much respiratory protection as this type of respirator; -- be provided, have immediately available for use, and wear in an emergency when they must exit the cab in the application block or surrounding buffer zone: coveralls and chemical-resistant gloves plus – if not already using one – the eye protection and respirator specified in the PPE section for respirator and eye	

	protection -- take off any PPE that was worn before reentering the cab, and -- store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab.”	
User Safety Recommendations	“User Safety Recommendations Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing.”	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)
User Safety Requirements	“Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.” “Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product’s concentrate. Do not reuse them.”	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements
PPE Requirements Established by the RED ¹ For all Formulations	“Respirator fit testing, medical qualification, and training Employers must ensure that all fumigant handlers are: • Fit-tested and fit-checked using a program that conforms to OSHA’s requirements (see 29CFR Part 1910.134) • Trained using a program that confirms to OSHA’s requirements (see 29CFR Part 1910.134) • Examined by a qualified medical practitioner to ensure physical ability to safely wear the style of respirator to be worn. A qualified medical practitioner is a physician or other licensed health care	Directions for Use Under the section “Protection for Handlers”

	professional who will evaluate the ability of a worker to wear a respirator. The initial evaluation consists of a questionnaire that asks about medical conditions (such as a heart condition) that would be problematic for respirator use. If concerns are identified, then additional evaluations, such as a physical exam, might be necessary. The initial evaluation must be done before respirator use begins. Handlers must be reexamined by a qualified medical practitioner if their health status or respirator style or use-conditions change.”	
Application Requirements, when tarps are used: Tarp Perforation and/or Removal <i>Note to Registrant:</i> Dazomet is not typically used with a tarp. However, if a dazomet label contains directions for use with tarps, then all sections of this label table that pertain to tarps must be added.	“Tarp Perforation and/or Removal IMPORTANT: Persons perforating, repairing, removing, and/or monitoring tarps are defined, within certain time limitations, as fumigant handlers (see definition of fumigant handlers in this labeling) and must be provided the PPE and other protections for handlers as required on this labeling and in the Worker Protection Standard for Agricultural Pesticides. Tarps used for fumigations must be perforated (cut, punched, poked, or sliced) only by mechanical methods. Perforation by hand or with hand-held tools is prohibited. Each tarp panel used for broadcast fumigation must be perforated using a lengthwise cut. Tarps cannot be perforated until a minimum of 5 days (120 hours) have elapsed after the fumigant injection into the soil is complete (e.g. after injection of the fumigant product and tarps -- if used -- have been laid or after drip lines have been purged and tarps have been laid), unless an adverse weather condition exists for broadcast applications. See below. If tarps will be removed after perforation, tarp removal cannot begin until at least 24 hours after tarp perforation is complete. If tarps will NOT be removed after perforation, planting or transplanting cannot begin until at least 48 hours after the tarp perforation is complete If tarps are left intact for a minimum of 14 days after fumigant injection into the soil is complete, planting or transplanting can take place while the tarps are being perforated. Adverse Weather Conditions Exception for broadcast applications only:	Direction For Use

	Tarps may be removed before the required 5 days (120 hours) if adverse conditions will compromise the integrity of the tarp, provided that: • At least 48 hours have passed after the fumigant injection into the soil is complete, • The buffer zone period is extended until 24 hours after tarp removal is complete, • Subsequent fumigations of untreated areas within the application block do not occur for at least 24-hours after tarp removal is complete, and • Appropriate PPE, respiratory protection, air monitoring and other requirements for the protection of handlers are met.	
Monitoring Air Concentration Levels	“MONITORING AIR CONCENTRATION LEVELS Monitoring Air Concentrations in the Buffer Zone Areas: When air concentration levels must be monitored (i.e., as specified in the general buffer zone requirements section), use a direct reading detection device, such as a Draeger device, with a sensitivity of at least 100 ppb for MITC (a breakdown product of dazomet).”	Directions for Use under the heading “General Buffer Zone Requirements”
Agriculture Use Requirements box	“Agricultural Use Requirements After the standard paragraphs for the Agricultural Use Requirements box, substituted the following text for the standard restricted-entry interval and double notification requirements: “For entry prohibition and notification requirements, see the “<i>Application Block Entry Prohibition and Notification</i>” section of this labeling.”	Agricultural Use Requirements box
Application Block Entry Prohibitions	“Entry Prohibitions Entry (including early entry that would otherwise be permitted under the WPS) by any person – other than a correctly trained and PPE-equipped handler who is performing a handling task listed on this labeling – is PROHIBITED -from the start of the application until: ➤ 5 days (120 hours) after application is complete if tarps are not perforated and removed for at least 14 days following application, or ➤ 5 days (120 hours) after application has ended for untarped applications., or	Directions for Use under the heading “heading “Application Block Entry Prohibition and Notification”

	➤ 48 hours after tarps are perforated if they will not be removed within 14 days following application, or ➤ tarp removal is completed if tarps are both perforated and removed less than 14 days after application. NOTE: see Tarp Perforation and Removal section on this labeling for requirements about when tarps are allowed to be perforated.”	
Application Block Notification Requirement	“NOTIFICATION: Notify workers of the application by warning them orally and by posting fumigant warning signs. The signs must bear the skull and crossbones symbol and state: -- "DANGER/PELIGRO," -- "Area under fumigation, DO NOT ENTER/NO ENTRE," -- "[Name of fumigant] Fumigant in USE," -- the date and time of fumigation, -- the date and time entry prohibition period is over, -- Name of this product, and -- name, address, and telephone number of the certified applicator in charge of the fumigation. Post the fumigant warning sign instead of the WPS sign for this application but follow all WPS requirements pertaining to location, legibility, size, and timing of posting and removal. Post the fumigant warning signs at all entrances to the application block.(i.e., the field or portion of a field treated with a fumigant in any 24-hour period)”	Direction for Use under the heading “Application Block Entry Prohibition and Notification”
Mandatory Good Agricultural Practices for all formulations	“Mandatory Good Agricultural Practices (GAPs) The following GAPs must be followed during all fumigant applications. All measurements and other documentation planned to ensure that the mandatory GAPs are achieved must be recorded in the FMP and/or the post application summary report. Weather Conditions • Prior to fumigation the weather forecast for the day of the application and the 48-hour period following the fumigant application must be checked. • Do not apply fumigant if ground-level winds are less than 2 mph. • Applications must not occur during a temperature inversion or when temperature inversions are	Directions for Use under “Mandatory Good Agricultural Practices”

	forecasted to persist for more than 6 consecutive hours for the 36-hour period after application. ○ <i>The application must not occur if the following visual features exist at the time of the application, misty conditions (for day or night applications) or clear skies where stars are visible (for nighttime applications).</i> • Detailed local forecasts for sky conditions, weather conditions, wind speed, and forecasted temperature inversions may be obtained on-line at http://www.nws.noaa.gov. • For further guidance, contact the local National Weather Service Forecasting Office.” The following requirements may already be on dazomet end use product labels. All of these label statements are required: • “Do not use dazomet when the soil temperature is extremely high (over 90 deg F, 2”deep). • Do not apply within 3-4 feet of growing plants or closer than the drop line of trees and large shrubs. If slopes are treated with this product, take precautions to prevent the chemical from washing downward to growing plants. • The area intended for treatment should be in seedbed condition with a fine tilth, free of clods. Do not apply dazomet to dry or improperly tilled soil. Repeated cultivation before treating will improve control of perennial weeds. Ditching around the site will prevent weed seeds, nematodes, and fungi from washing into the treated area and contaminating it. • For optimal effect, the soil to be fumigated must have sufficient moisture for good plant growth (at least 50% field capacity) for 5-14 days (depending on temperature) before the treatment. • Do not apply dazomet if ambient air temperature exceeds 103 degrees F. (I’m not sure if this is for efficacy or risk?) • After application, the soil must be kept uniformly moist for 5-7 days. As soon as possible after incorporation, the soil should be sealed to retain the concentration of gases in the soil which can be achieved by: ○ Compacting the soil surface after incorporation with a roller attached behind the compacting implement. ○ Moistening the surface after incorporation so a crust forms. ○ Lightly moistening the soil on the third and fourth days after treatment in case the weather dries out the soil surface to avoid surface cracks. ○ In difficult situations best results may be obtained by tarping the treated area. • Do not store dazomet in an open spreader overnight. • Do not apply dazomet when wind may cause granules to drift from target area.	
--	--	--

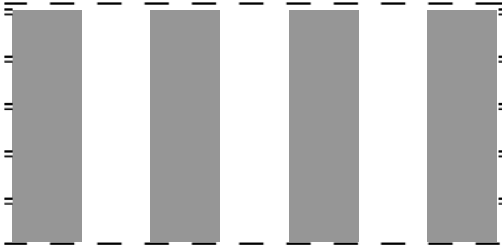
	- Do not apply dazomet through any type of irrigation equipment. - Before using dazomet be aware that the three most critical factors for a successful fumigation program are: soil preparation, soil temperature, and soil moisture.”	
Site-Specific Fumigation Management Plans for all dazomet end-use products containing directions for use for soil fumigation	“Site-Specific Fumigation Management Plan (FMP) Prior to the start of fumigation, the certified applicator supervising the application must verify that a site-specific fumigation management plan (FMP) exists for each application block (i.e., a greenhouse or field or portion of a field treated with a fumigant in any 24-hour period). The FMP may be prepared by the certified applicator, the site owner/operator, registrant, or other party. The certified applicator must verify in writing the site-specific FMPs reflects current site conditions before the start of fumigation. Each site specific FMP must contain the following elements: ❖ General site information ➤ Site address, ➤ Site operator/owner’s name, address, and, phone number ➤ Map, aerial photo, or detailed sketch showing field location, dimensions, buffer zones, property lines, public roads, bus stops, water bodies, wells, rights-of-ways inside buffers, nearby application blocks, surrounding structures (occupied and non-occupied), locations of posted signs for buffers, and sites requiring ¼ mile buffer zones (e.g., prisons, schools, hospitals, state licensed day care centers) with distances from the application site labeled ❖ Applicator information (license #, address, phone, contact information for person supervising the fumigation) ❖ Authorized on-site personnel (Names of all handlers and the tasks they are authorized and trained to perform) ❖ Application procedures ➤ Fumigation window (target application date, earliest and latest possible date of fumigation, duration of fumigation) ➤ Product information (brand name, registration number) ➤ Type of fumigation (e.g., shank, broadcast, drip, raised bed, strip, etc.) ➤ Target application rate and application block size ❖ Good Agricultural Practices (GAPs) ➤ Description of applicable mandatory GAPs (registrants may also include optional GAPs) ➤ Measurements and other documentation planned to ensure GAPs are achieved (e.g. measurement of soil and other site conditions; tarp repair/cutting/removal plans; etc.)	In the Directions for Use for Pre-plant soil fumigation under the heading “Site-Specific Fumigation Management Plan (FMP)”

	❖ Buffer zones ➤ Calculations and rationale for buffer zones distances (e.g. specify table from label that distances based on, rate and block size, applicable credits applied) ➤ Start and stop times for buffer zones ❖ Respirators and other personal protective equipment (PPE) for handlers (respirator type, respirator cartridge, and other PPE selection; verification that respirator training/fit-testing/medical exams is current; and maintenance/storage procedures) ❖ Air monitoring ➤ Type of samples that will be collected (e.g., occupational, in occupied structures, outside buffer zone if fumigation site monitoring is conducted, etc.) ➤ When and where samples will be collected ➤ Duration of samples ➤ Sampling methods ➤ Name, address, and, phone number of person taking samples ❖ Posting (names of persons who will post signs, location of posting signs, procedures for posting and sign removal) ❖ Site specific response and management ➤ Fumigation site monitoring ▪ Description of who, when, where, and procedures for monitoring buffer zone perimeter ➤ Response information for neighbors ▪ List of residences and businesses informed (neighboring property owners) ▪ Method of sharing information ❖ State and tribal lead agency notification ➤ Include information that is sent to the lead agency ❖ Plan describing how communication will take place between applicator, land owner/operator, and other on-site handlers (tarp cutters/removers, irrigators, etc.) ❖ Record keeping procedures ❖ Emergency procedures (evacuation routes, locations of telephones, contact information for first responders, local/state/federal contacts, key personnel and emergency procedures/responsibilities in case of an incident, equipment/tarp/seal failure, odor complaints or elevated air concentration levels outside buffer zone suggesting potential problems, or other emergencies). ❖ Hazard communication (product labels, material safety data sheets, etc.) For situations where an initial FMP is developed and certain elements do not change for multiple fumigation	
--	---	--

	sites (e.g. applicator information, authorized on-site personnel, record keeping procedures, emergency procedures, etc.) only elements that have changed need to be updated in the site-specific FMP provided the following: • The certified applicator supervising the application has verified that those elements are current and applicable to the application block before it is fumigated and has documented the verification in the site-specific FMP. • Recordkeeping requirements are followed for the entire FMP (including elements that do not change) Once the application begins, the certified applicator and owner/operator of the application block must provide a copy of the FMP to handlers who are involved in the fumigation, workers in adjacent areas to the application block, and Federal/State/local enforcement personnel, upon request. The certified applicator supervising the fumigation and the owner/operator of the agricultural establishment where the fumigation is taking place must, upon request, make the FMP available to any Federal, state, tribal, or local enforcement personnel. Within 30 days of completing the application portion of the fumigation process, the certified applicator supervising the application must complete a post fumigation application summary that describes any deviations from FMP that have occurred, measurements taken to comply with GAPs as well as any complaints and/or incidents that have been reported to him/her. The summary must include the actual date of the application, application rate, and size of application block fumigated. The certified applicator who supervised the fumigation and the owner/operator of the agricultural establishment where the fumigation took place must keep a signed copy of the site-specific FMPs and the post-application summary record for at least 2 years following the application and must make them available, upon request, to Federal, state, tribal, and/or local enforcement personnel.”	
Information Exchange	“When the certified applicator supervising the application leaves the application site after the application portion of the fumigation process is complete and other persons will be performing handler tasks (see the handling activities listed elsewhere in this labeling), the certified applicator must communicate in writing all of the requirements on this labeling with respect to the fumigation process and protection of handlers to the owner/operator of the agricultural establishment where the fumigation is taking place.	

	IMPORTANT: this requirement does not override the requirements in the Worker Protection Standard for Agricultural Pesticides for information exchange between owners/operators of agricultural establishments and commercial pesticide applicators.”	
General Buffer Zones requirements for all formulations	“General Buffer Zone Requirements A “buffer zone” must be established for every fumigant application • “Buffer zone” is an area established around the perimeter of each application block where a soil fumigant is applied. The buffer zone must extend from the edge of the application block equally in all directions. • All non-handlers including field workers, nearby residents, pedestrians, and other bystanders, must be excluded from the buffer zone during the entire buffer zone period except for certain exemptions for persons transiting through the buffer zone (see transit exemptions below). • An “application block” is a greenhouse or field or portion of a field treated with a fumigant in any 24-hour period. • The “buffer zone period” starts when the fumigant is first introduced into the soil within the application block and lasts for a minimum of 48 hrs after injection of the fumigant product has stopped and tarps have been laid, and after any the hot gas drip lines have purged of fumigant. • "Roadway" means that portion of a street or highway improved, designed, or ordinarily used for vehicular travel. “Roadway” does not include any sidewalk or shoulder even if the sidewalk or shoulder is used by persons riding bicycles. In the event a highway includes two or more separated roadways, the term "roadway" shall refer to any such roadway separately. <u>Buffer zone distances</u> • Minimum buffer zone distances must be based on look-up tables in the “Buffer Zone Distance” section of this label (25 feet is smallest buffer zone distance regardless of site-specific application parameters). <u>Authorized entry to buffer zones</u> • Only trained and PPE-equipped handlers performing a fumigant handling tasks listed in this labeling are allowed in the buffer zone during the buffer zone period. All non-handlers including field workers, nearby residents, pedestrians, and other bystanders, must be excluded from the buffer zone during the buffer zone period except for certain persons in transit (see exemptions section). <u>Buffer zone proximity</u>	In the Directions for Use for Pre-plant soil fumigation under the heading “General Buffer Zone Requirements”

	• Buffer zones from multiple application blocks may not overlap (including blocks fumigated by adjacent property owners, (see below for exemptions for areas not under the control of owner/operator of application block). • No fumigant applications will be permitted within 0.25 (one-quarter) mile of schools, state licensed daycare centers or preschools, nursing homes, assisted living facilities, elder care facilities, hospitals, in-patient clinics and prisons if these facilities will be occupied during the buffer zone period. <u>Exemptions for transit within buffer zones (Posting and site specific response and management requirements in this labeling must be complied with.)</u> • Vehicular and bicycle traffic on public and private roadways within the buffer zone is permitted. • Bus stops or other locations where persons wait for public transit are not permitted with in the buffer zone. <u>Structures under the control of owner/operator of the application block (Posting and site specific response and management requirements in this labeling must be complied with.)</u> • Buffer zones may not include buildings used for storage such as sheds, barns, garages, etc., UNLESS, 1. The storage buildings are not occupied during the buffer zone period, and 2. The storage buildings do not share a common wall with an occupied structure. <u>Areas not under the control of owner/operator of the application block (Posting and site specific response and management requirements in this labeling must be complied with).</u> • Buffer zones may not include residential areas (including employee housing, private property, buildings, commercial, industrial, and other areas that people may occupy or outdoor residential areas, such as lawns, gardens, or play areas, UNLESS, 1. The occupants provide written agreement that they will voluntarily vacate the buffer zone during the entire buffer zone period, and 2. Reentry by occupants and other non-handlers must not occur until ▪ The buffer zone period has ended, and ▪ Two consecutive air samples for MITC taken in the structure at least 30 minutes apart must indicate less than 100 ppb MITC is present. • Buffer zones may not include agricultural areas owned/operated by persons other than the owner/operator of the application block, UNLESS, 1. The owner/operator can ensure that the buffer zone will not overlap with a buffer zone from any adjacent property owners, and	
--	---	--

	2. The owner/operator of the areas that are not under their control provides written agreement to the certified applicator supervising the fumigant application that they, their employees, and other persons under their jurisdiction will not enter or remain in the buffer zone during the entire buffer zone period. • Buffer zones may not include publicly owned and/or operated areas (e.g., parks, rights-of-way, sidewalks, walking paths, playgrounds, athletic fields, etc), UNLESS, 1. The area is not occupied during the entire buffer zone period, 2. Entry by any person, except a trained and PPE-equipped handler performing a handling task listing in this labeling, is prohibited during the buffer zone period, and • Written permission to include the public area in the buffer zone is granted by the appropriate state and/or local authorities responsible for management and operation of the area.”	
Buffer Zone Distances for all formulations	“Buffer Zone Distances Buffer zone distances must be calculated using the application rate and the size of the application block.  Figure 1. Broadcast Application  Figure 2. Bedded Application In Figures 1 and 2, the dashed line represents the perimeter of the field, the shaded area is the portion of the field that is treated, and the un-shaded area is the area of the field that is untreated. Assuming both fields are 10 acres, and only 50% of field in figure 2 is fumigated, the <i>labeled rate per treated acre</i> is 400 lbs ai/A for both Figure 1 and 2. The <i>broadcast rate</i> for figure 1 is 400 lb ai/A but the <i>effective broadcast equivalent rate</i> for Figure 2 is 200 lbs ai/A. The minimum buffer zone distances must be based on the broadcast or effective broadcast equivalent rates.” Note to registrant: Labels may express rates as lbs per treated acre under the application instructions but they must identify buffer zone distances based on the broadcast or effective broadcast equivalent rates.	In the Directions for Use for Pre-plant soil fumigation under the heading “Buffer Zone Distances”

“For all dazomet soil applications, the following tables must be used to determine the minimum buffer distances. Round-up to the nearest rate and block size, where applicable.”

Buffer zone distances (in feet) for all dazomet soil applications																			
Block Size (acres)	Application Rates for either surface or incorporated applications (lbs ai/acre)																		
	530	400	390	380	370	360	350	340	330	320	310	300	290	280	270	265	260	250	240
1 or less	200	75	72	69	66	63	60	57	54	51	48	45	42	39	36	33	30	25	25
2	200	100	96	92	88	84	80	76	72	68	64	60	56	52	48	44	40	36	32
5	200	150	147	144	141	138	135	132	128	124	120	116	112	108	104	100	89	78	67
10	350	239	233	226	219	213	207	201	194	187	179	172	164	158	156	152	141	130	119
15	500	329	318	308	298	287	278	269	259	250	237	227	216	208	208	204	193	182	170
20	650	440	426	412	398	384	370	356	343	330	317	305	288	275	260	250	245	234	223
30	812	599	582	565	548	531	514	496	480	460	446	430	411	400	383	369	360	345	330
40	1080	770	750	730	710	690	670	650	630	610	590	565	545	524	505	500	490	471	452
Block Size (acres)	Application Rates for either surface or incorporated applications (lbs ai/acre)																		
	230	220	210	200	190	180	170	160	150	140	132	130	120	110	100	90	80	70	66
1 or less	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25
2	28	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25
5	56	46	36	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25
10	108	98	87	79	76	74	71	68	65	62	58	58	53	48	43	38	33	28	25
15	160	149	139	133	128	122	117	111	105	99	92	92	82	72	62	52	42	32	25
20	212	201	190	187	179	171	163	154	145	136	125	125	110	95	80	65	50	35	25
30	323	308	293	281	268	255	242	229	215	202	188	188	164	141	117	94	70	47	25
40	433	414	395	375	357	339	321	303	285	267	250	250	218	186	154	122	90	58	25

Buffer Zone Credits

“Buffer Zone Credits

The buffer zone distances for dazomet applications may be reduced by the percentages listed below. Credits may be added, to a total of 20%. Also the minimum buffer zone distance is 25 feet regardless of buffer zone credits available.

- 10% reduction in buffer zone distance, IF the organic content of soil in the application block is greater

In the Directions for Use for Pre-plant soil fumigation under the heading “Buffer Zone

	than 3%. Record the measurements taken to verify the organic content in the FMP. 10% reduction in buffer zone distance, IF the clay content of the soil in the application block is greater than 27%. Record the measurements taken to verify the clay content in the FMP. Example of credit calculation For example, if the buffer zone is 50 feet and the application qualifies for a buffer zone reduction credit since the soil organic content is greater than 3%. Then the buffer zone can be reduced by 10%, i.e., reduced by 5 feet based on the following calculation: 50 feet – (50 feet x 10%) = 45 feet”	Credits”
Posting of Buffer Zones	“Posting Fumigant Buffer Zones - Posting all entrances to the application block (i.e., the greenhouse or field or portion of a field treated with a fumigant in any 24-hour period) is required for all soil fumigants and use sites. The posting requirements for the application block are listed elsewhere in this labeling. - Posting of the fumigation buffer zone is required, <u>except</u> when one of the following conditions exist: (1) if there is a physical barrier that prevents access into the buffer zone, such as a fence or wall, that separates the edge of the buffer zone from workers or bystanders, or (2) if the area within 300 feet of the edge of the buffer zone is entirely controlled by owner/operator of the application block (i.e., the greenhouse or field or portion of a field treated with a fumigant in any 24-hour period); however this exception does not apply to any area under the control of the owner/operator that may be used as housing for workers or other employees. IMPORTANT: if there is public land or any land under someone else’s control within 300 feet from the edge of the buffer zone, the buffer zone must be posted. - If the buffer zone must be posted, signs must be placed at all usual points of entry and along likely routes of approach from areas where people not under the control of the application block’s owner/operator may approach the buffer zone. - Some examples of points of entry include, but are not limited to, roadways, sidewalks, paths, and bike trails. - When there are no usual points of entry, signs must be posted in the corners of the buffer zone, between the corners of the buffer zone, and along sides so that one sign can be viewed (not read) from the previous one. - The buffer zone posting signs must remain posted at least until the end of the buffer zone period and must be removed within 3 days after the end of the buffer zone period.	In the Directions for Use for Pre-plant soil fumigation under the heading “Posting”

	▪ Contiguous Application Blocks Exception: If multiple contiguous application blocks are fumigated within a 14-day period, a buffer zone may be established starting from the outer edge of the contiguous application blocks. This buffer zone is in effect from the beginning of the first application until the buffer zone period for the last application block has expired. The periphery of the buffer zone must be posted during this entire period. Signs may remain posted until 3 days after the buffer zone period for the last application block has expired. • The buffer zone posting should meet the following standards: ○ The printed side of the sign must face away from the buffer zone. ○ Signs must remain legible during entire posting period. ○ The signs at entrances to buffer zones must be removed by the certified applicator in charge of the fumigation (or someone under his/her supervision). ○ The general standards for size and type of signs for the buffer zone signs must follow the requirements in the Worker Protection Standard for Agricultural Pesticides for treated area posting. ○ The signs must remain visible and legible during the time they are posted.” Contents of Signs The treated area sign must state the following: -- Skull and crossbones symbol  -- "DANGER/PELIGRO," -- "Area under fumigation, DO NOT ENTER/NO ENTRE," -- "[Name of fumigant] Fumigant in USE," -- the date and time of fumigation, -- the date and time entry prohibition is lifted -- brand name of this product, and -- name, address, and telephone number of the certified applicator in charge of the fumigation. The buffer zone sign must state the following: -- Do not walk sign  -- "DO NOT ENTER/NO ENTRE," -- "[Name of fumigant] Fumigant BUFFER ZONE," -- the date and time of fumigation, -- the date and time buffer zone restrictions are lifted (i.e., buffer zone period expires) -- brand name of this product, and -- name, address, and telephone number of the certified applicator in charge of the fumigation	
Site specific response	“Site Specific Response and Management	In the Directions

and management	The certified applicator must either follow the directions under the “fumigant site monitoring” section or follow the directions under the “response information for neighbors” section. Fumigation Site Monitoring From the beginning of the fumigant application until the buffer zone period expires, a certified applicator or someone under his/her supervision must monitor the air concentration levels of the fumigant in the area between the buffer zone and any residences or businesses that trigger the ‘response information for neighbors’ requirement. • The person monitoring the air concentration levels must take readings starting approximately 30 minutes from the start of application and at least once each hour during the entire application and buffer zone period. • A direct reading detection device, such as a Draeger device with a sensitivity of at least 100 ppb for MITC must be used to monitor the air concentration levels of MITC. • If at any time (1) MITC concentrations are greater than or equal to 100 ppb OR (2) the person monitoring the air concentrations experiences sensory irritation, then the emergency response plan stated in the FMP must be immediately implemented by the person monitoring the air concentrations • If other problems occur, such as a tarp coming loose, then the appropriate control plan must be activated. • The results of the air concentration monitoring must be recorded in the FMP. • Informing the appropriate federal, state or tribal lead agencies is still required. Response Information for Neighbors The certified applicator (or someone under his/her supervision) supervising the fumigation must ensure that residences and owners/operators of businesses that meet the criteria below have been provided the emergency response information at least 48 hours before fumigation occurs. The information provided may include application dates that range for no more than 2 weeks. After 2 weeks, the information must be delivered again. Criteria for providing response information for neighbors: • If the buffer zone is less than or equal to 100 feet, then residences and businesses within 50 feet from the edge of the buffer zone must be informed.	for Use for Pre-plant soil fumigation under the heading “Site specific response and management”
----------------	--	---

	• If the buffer zone is greater than 100 feet but less than or equal to 200 feet, then residences and businesses within 100 feet from the edge of the buffer zone must be informed. • If the buffer zone is greater than 200 feet but less than or equal to 300 feet, then residences and businesses within 200 feet from the edge of the buffer zone must be informed. • If the buffer zone is greater than 300 feet, then residences and businesses within 300 feet from the edge of the buffer zone must be informed. Information that must be included: • Location of the application block and surrounding buffer zone • Fumigant(s) applied including EPA Registration # • Applicator and property owner/operator contact information • Time period that fumigation may occur (must not range more than 2 weeks) • Duration of buffer zone • The information must also include: ○ information on what is being applied, ○ signs and symptoms of exposure to the fumigant, ○ what to do and who to call if you believe you are being exposed (911 in most cases). • The method used to share the response information for neighbors must be described in the FMP and may be accomplished through mail, door hangers, or through other methods that will effectively inform people in residences and businesses within the required distance from the edge of the buffer zone.”	
Notice to State and Tribal Lead Agencies	“Notice to State and Tribal Lead Agencies The state and tribal lead agency information must be provided to the appropriate state or tribal lead agency in a written format prior to the application. The information that must be provided to state and tribal lead agencies includes the following: ○ Location of the application block and surrounding buffer zone, ○ Fumigant(s) applied including EPA Registration #, ○ Applicator and property owner/operator contact information, ○ Time period that fumigation may occur (must not range more than 2 weeks),	Directions for Use under “Notice to State and Tribal Lead Agencies”

	o Duration of buffer zone.”	
Pre-plant Application Restrictions	Maximum incorporated rate for all uses, except for golf course renovation, is 425 lbs ai/A. The maximum rate for golf course renovation, with the incorporated application method is 530 lbs ai/A “Use in greenhouses is prohibited.” “Application with handheld equipment is prohibited.”	In the Directions for Use for Pre-plant soil fumigation under the heading “Maximum Application Rates for Pre-Plant Soil Fumigation” within its own box
Environmental Hazards	“This pesticide is toxic to fish and aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate.”	Precautionary Statements immediately following the User Safety Recommendations
Surface and Ground Water Advisory	“While dazomet and its major degradate MITC have certain properties and characteristics in common with chemicals that have been detected in groundwater (MITC is highly soluble in water and has low adsorption to soil), volatilization is this chemical's most important route of dissipation. To reduce the potential for leaching to groundwater, especially in soils with shallow groundwater, for broadcast, tarped applications, the tarps must be perforated (cut, punched, etc.) before noon and only when rainfall is not expected within 12 hours. For raised-bed, tarped applications, rainfall is not a factor since planting occurs with the tarp in place. For untarped applications of dazomet, potential leaching into groundwater and runoff into surface water can be reduced by avoiding applications when heavy rainfall is forecasted to occur within 24 hours.”	Precautionary Statements immediately following the User Safety Recommendations
General Application Restrictions	“Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.”	Place in the Direction for Use

		directly above the Agricultural Use Box.
--	--	--

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.

The label changes required for dazomet products with antimicrobial uses are listed below in Table 5.

Table 5: Labeling Changes Summary Table for the Antimicrobial Uses of Dazomet		
Description	Amended Labeling Language	Placement on Label
For remedial treatment of wooden poles/timbers	Add language clarifying application methods 1. Plug the pre-drilled holes immediately after applications; 2. Do not treat structures/beams indoors; 3. Do not drill an application hole through seasoning checks to apply product. If the hole intersects a check, plug the hole and drill another. If more than 2 treatment holes intersect an internal void or rot pocket, re-drill the holes farther up the pole into relatively solid wood.	Directions for Use
Additional label language for registrations that use dazomet as a materials preservative or in industrial processes and water systems	“This pesticide is toxic to fish and aquatic invertebrates.”	Environmental Hazards
Additional Label Language for all oil field uses	“This pesticide is toxic to fish, aquatic invertebrates, oysters, and shrimp.”	Environmental Hazards
For wood preservation uses, the label must state	“This pesticide is toxic to fish and aquatic invertebrates”; and “This pesticide is expected to be toxic when in contact with terrestrial or aquatic plants.”	Environmental Hazards
For all scenarios that use metering pumps:	“Gloves must be worn when handling the product.”	Personal Protective Equipment (PPE)

Additional PPE language for the cooling water system use	“Appropriate PPE (long pants, long-sleeved shirts, chemical resistant gloves, and goggles or face shield) must be used when applying the product.”	Personal Protective Equipment (PPE)

Appendix A

Appendix A(1): Dazomet (PC Code 035602) Soil Fumigant Uses Eligible for Reregistration

Use Site	Formulation	Method of Application	Maximum Application Rate	Use Limitations
Soil				
Nonbearing crops (such as orchard crops, berries, and flower bulbs), ornamental sites (establishing or renovating), field nurseries (establishing or renovating), compost piles, potting soils, and strawberries and tomatoes in California only	Granular	Tractor drawn spreader	425 lbs ai/A for incorporated applications. 265 lbs ai/A for surface applications.	Application with hand-held applications is prohibited. Labels must prohibit use in greenhouses. See the label table in Section V for additional use restrictions.
Golf greens/tees, turf sites (establishing or renovating),	Granular	Tractor drawn spreader	530 lbs ai/A for incorporated applications. 265 lbs ai/A for surface applications.	Application with hand-held applications is prohibited. Labels must prohibit use in greenhouses. See the label table in Section V for additional use restrictions.

Appendix A(2): Dazomet (PC Code 035602) Antimicrobial Uses Eligible for Reregistration

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Materials Preservatives				
Clay slurries, adhesives, coatings and high viscosity suspensions	Ready to use 1448-103 1448-395 1706-193	Pump or Gravity feed.	Add 0.03-0.50% by weight based on the total formulation. Actual use levels should be determined by a test of the system.	Product should be added at a point in the system where there will be sufficient time and agitation for good mixing and dispersion.

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	9386-3 9386-28 <i>Formulation Intermediate:</i> 1448-98 <i>Technical chemical:</i> 9386-10			
	Soluble concentrate 1448-104 1706-195 9386-13 33753-25	Pump or Gravity feed.	Add 0.01-0.11% by weight based on the total formulation. Actual use levels should be determined by a test of the system.	Product should be added at a point in the system where there will be sufficient time and agitation for good mixing and dispersion.
	Flowable concentrate 67869-25	Pump or Gravity feed.	Add 0.5-2.5% by weight of the suspension or dispersion. Actual use levels should be determined by a test of the system.	Product should be added at a point in the system where there will be sufficient time and agitation for good mixing and dispersion.
	Ready to use 74655-1	Pump or Gravity feed.	Add 1.67-2.5 pounds per 1000 gallons of material to be preserved. Actual use levels should be determined by a test of the system.	Product should be added at a point in the system where there will be sufficient time and agitation for good mixing and dispersion.

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Paper and pulp mill Slime control	Ready to use 1448-103 1448-395 9386-3 9386-28	Pump or Gravity feed.	Intermittent method: Add 12-20 oz per ton (dry basis) of pulp or paper for two hours every 8 hours.	Badly fouled systems may require cleaning before initial treatment.
			Continuous method: Add 5-15 oz per ton (dry basis) of pulp or paper on a continuous basis.	
	Ready to use 1706-193	Pump or Gravity feed.	Add 5-36 oz per ton of finished product on a continuous basis. Actual use levels should be determined by a test of the system.	Shock dosages are to be avoided. Badly fouled systems may require cleaning before initial treatment.
	Ready to use 1706-195	Pump or Gravity feed.	0.083-0.415 lbs. per 1000 gallons of treated water. Actual use levels should be determined by a test of the system.	
	Flowable concentrate 67869-25	Pump or Gravity feed.	Add 0.5-2.5% by weight of the suspension or dispersion. Actual use levels should be determined by a test of the system.	Badly fouled systems may require cleaning before initial treatment.

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	Ready to use 74655-1	Pump or Gravity feed.	If system is noticeably fouled, add product at the rate of 0.5 to 3.0 pounds per ton of pulp or paper product. Additions to additive system should be made directly at the rate of 0.2 to 4.0 pounds (24 to 480ppm) per 1000 gallons. Add product at the rate of 0.5-2.0 pounds per ton of pulp or paper produced. Treat the system as needed to maintain control. Additions to the additive system may be reduced to 0.2 to 2.0 pounds (24 to 240 ppm) per 1000 gallons.	Badly fouled systems may require cleaning before initial treatment.
Leather tanning	Soluble concentrate: 67869-46	Immersion	Apply directly at a concentration of 1000 to 8000ppm into pickle solution	
Metal working fluids and lubricants	Soluble concentrate: 67869-46	Incorporation	Apply directly at a concentration of 1000 to 10,000 ppm, can be added or metered into the final cutting fluid either prior to its addition to the system or after the system has been filled	
Construction Products: Caulking material, Concrete additives, concrete and	Soluble concentrate: 67869-46	Incorporation	Can be fed at concentration of 250 to 6000 ppm either directly to the finished	

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
masonry additives			product or to one of the raw materials	
Paints/coatings/inks/dyes	Soluble concentrate: 67869-46	Incorporation	Add at concentrations of 250 to 4000 ppm into the makeup water during the grind during the manufacturing process	
Polymer dispersion/emulsions	Soluble concentrate: 67869-46	Incorporation	Add using moderate agitation immediately following the cool down process at concentrations of 250 to 4000 ppm	
Industrial Processes and Water Systems				
Recirculating cooling water systems	Ready to use 1448-103 1448-395 9386-3 9386-28	Pump or Gravity feed.	Add 3.25-6.5 ounces of product to 1000 gallons of water to produce a 30-60ppm concentration initially. Add 0.5-3.25 ounces of product to 1000 gallons of water to produce a 5-30ppm concentration to maintain control.	
	Soluble concentrate 1448-104	Pump or Gravity feed.	Add 16 ounces of product per each 5,000-16,000 gallons of water in system initially to produce a concentration of 7.5-15ppm. Add 16 ounces of product per each 15,000-96,000 gallons of water in system to produce a concentration of 1.25-7.5ppm	

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
			to maintain control.	
	Crystalline 9386-13	Open pour	Add 9.5 to 18.9 ounces of product per 10,000 gallons of water in the system initially. Add 1.5-9.5 ounces of product per 10,000 gallons of water to maintain control.	
Oilfield water treatment and water floods	Ready to use 1448-103 1448-395 9386-3 9386-28	Open Pour	Add 2.1 pounds of product to 1000 gallons of drilling fluid to produce a 2500ppm concentration initially. Add 0.30 pounds of product to 1000 gallons of drilling fluid to produce a 350ppm concentration to maintain control.	
Oilfield water treatment and water floods	Soluble concentrate 1448-104	Open Pour	Add 5.22 pounds of product to 1000 gallons of drilling fluid to produce a 625ppm concentration initially. Add 0.73 pounds of product to 1000 gallons of drilling fluid to produce an 88ppm concentration to maintain control. For water soluble packaging: One pound per 191 gallons initially then one pound per	

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	Soluble concentrate 33753-25		1363 gallons to maintain control. Add 1.67 pounds of product to 1000 gallons of drilling fluid to produce a 200ppm concentration initially. Add 1.25 pounds of product to 1000 gallons of drilling fluid to produce a 150ppm concentration to maintain control.	
Oilfield Drilling Muds and work over or completion fluids	Soluble concentrate 1448-104 9386-13 33753-25	Open Pour	Add 175-182 pounds of product to 1000 barrels of drilling fluid to produce a 500-520ppm concentration. For best results add product in a thin stream to the pit while drilling fluid is circulating.	
	Ready to use 1448-103 9386-3	Open Pour	Add 75 pounds of product to 1000 barrels of drilling fluid to produce a 2080-2500ppm concentration. For best results add product in a thin stream to the pit while drilling fluid is circulating.	

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	Ready to use 1448-395 9386-28		Add 75 pounds of product to 1000 barrels of drilling fluid to produce a 2080ppm concentration. For best results add product in a thin stream to the pit while drilling fluid is circulating.	
Wood Preservatives				
Utility Poles, pilings, timbers, solid and laminated wood products.	Pelleted solid 7969-162 71406-5 <i>Technical Chemical:</i> 7969-16	Applied in treatment holes drilled into wood product to be treated.	Drill three 7/8 in. diameter by 14 in. long holes at a steep angle (45 deg or greater) in a spiral patten starting at ground line. Apply 70 grams of end use product into each hole. Do not overfill treatment hole. Add liquid accelerant if desired to treatment hole. Plug treatment hole with a tight fitting treated wooden dowel, removable plastic plug or other suitable cap.	For wood in ground contact, the first hole should start at or slightly below ground line and should be arranged in a spiral pattern covering the treatment zone with about 6” to 12” vertically between holes. An accelerant of a 1% solution of copper naphthenate in mineral spirits may be added to treatment holes after application of the product and is designed to speed up the decomposition and release of the active fumigant inside the wood product. Keep accelerant away from product except when in treatment holes, which should be plugged immediately after they combine. Not to be used indoors or underneath indoor structures.

Appendix B. Table of Generic Data Requirements and Studies Used to Make the Reregistration Decision

This section is currently not available.

Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in room S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA 22202. It is open Monday through Friday, excluding legal holidays, from 8:30 am to 4 pm.

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site: <http://www.regulations.gov>
These documents include:

Health Effects Support Documents

Dazomet: Updated Final Revised HED Chapter of the Reregistration Eligibility Decision Document (RED). Smith, C. et al.; D354014; June 24, 2008.

Mode of Action, Eye Irritation, and the Intra-Species Factor: Comparison of Chloropicrin and MITC. Lowitt, A. and Reaves, E.; D293356; TXR 0054860; June 25, 2008.

The Health Effects Division's Response to Comments on EPA's Phase 5 Reregistration Eligibility Decision Document for Dazomet. Smith, C.; D306858; June 18, 2008.

Environmental Fate and Ecological Effects Support Documents

Revised Environmental Fate and Ecological Risk Assessment For Dazomet. Khan, F. and Felkel, J.; D306855; April 8, 2008.

Response to Phase 5 Public Comments on the Phase 4 Dazomet Environmental Fate and Ecological Risk Assessment. Khan, F., and Felkel, J.; D306854; April 2, 2008.

Biological and Economical Analysis Support Documents

Assessment of the Benefits Soil Fumigants (Methyl Bromide, Chloropicrin, Metam-Sodium, Dazomet) Used by Forest Tree Seedling Nurseries. (Chiri, D. and Donaldson, D. Dated April 19, 2007) EPA-HQ-OPP-2005-0125-0044

Assessment of the Benefits of Soil Fumigation with Methyl Bromide, Chloropicrin, Dazomet, Metam Potassium and Metam Sodium for Use in Raspberry Nurseries, Fruit and Nut Deciduous Tree Nurseries, and Rose Bush Nurseries in California. (Faulkner, J., and Yourman, L., Dated April 20, 2007) EPA-HQ-OPP-2005-0125-0045

Assessment of the Benefits of Soil Fumigation with Chloropicrin, Methyl Bromide, Metam-sodium, and Dazomet In Strawberry Nursery Runner Production. (Yourman, L., and Smearman, S., Dated April 19, 2007) EPA-HQ-OPP-2005-0125-0054

Assessment of the Benefits of Soil Fumigation with Chloropicrin, Methyl Bromide, Metam Sodium and Dazomet in Ornamental Production. (Chiri, A., and Wyatt, T., Dated April 18, 2007) EPA-HQ-OPP-2005-0128-0060

Response to Phase 5 BEAD Related Public Comments Received on the Reregistration of Chloropicrin, Dazomet, Metam Potassium, Metam Sodium, and Methyl Bromide. (Donaldson, D. et al., Dated June 2008)

Review of Stakeholder Submitted Impact Assessments of Proposed Fumigant Buffers, Comments on Initial Buffer Zone Proposal, and Case Studies of the Impact of a Flexible Buffer System for Managing By-Stander Risks of Fumigants. (Wyatt. T., et al, Dated June 2008)

Antimicrobial Assessment Support Documents

Dazomet Antimicrobial Risk Mitigation Paper. Garvie, H., Dated June 2, 2008.

Dazomet: Revised Occupational and Residential Exposure Assessment of Antimicrobial Uses for the Reregistration Eligibility Decision (RED) Document. Walls, C.; D Dated June 2008.

Phase 6 Response to Substantive Public Comments on Antimicrobials Division's Occupational and Residential Assessments for the Reregistration Eligibility Decision (RED) Documents for the following chemicals: Methylisothiocyanate (MITC), Metam Sodium, Dazomet, and Chloropicrin. Walls, C.; February 14, 2008.

Buffer Zone Credits Support Document

Factors Which Impact Soil Fumigant Emissions - Evaluation for Use in Soil Fumigant Buffer Zone Credit Factor Approach. Dawson, J. and Smith, C.; D306857; June 9, 2008.

Risk Management Support Documents

SRRD's Response to Phase 5 Public Comments for the Soil Fumigants. Rice, M. and McNally, R.; July 2008.

Risk Mitigation Options to Address Bystander and Occupational Exposures from Soil Fumigant Applications. EPA-HQ-OPP-2005-0128-0031.