

Proposed Re-evaluation Decision

PRVD2025-03

# Carbon Dioxide and Its Associated End-use Products

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Publications Pest Management Regulatory Agency Health Canada 2 Constellation Drive 8<sup>th</sup> floor, A.L. 2608 A Ottawa, Ontario K1A 0K9 Internet: canada.ca/pesticides pmra.publications-arla@hc-sc.gc.ca

Information Service: 1-800-267-6315 pmra.info-arla@hc-sc.gc.ca



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# Proposed re-evaluation decision for carbon dioxide and its associated end-use products

Under the authority of the *Pest Control Products Act*, all registered pesticides must be reevaluated by Health Canada's Pest Management Regulatory Agency (PMRA) to ensure that they continue to meet current health and environmental standards and continue to have value. The reevaluation considers data and information from pesticide registrants, published scientific reports and other regulatory agencies. Health Canada applies internationally accepted risk assessment methods as well as current risk management approaches and policies.

Carbon dioxide is an insecticide and rodenticide fumigant. It is registered for use as a fumigant gas for the control of insects in grain and flour storage areas and for the control of rodents in aircraft fuselage. The shipboard, in-transit ship, and ship hold fumigation uses of carbon dioxide are no longer supported by the registrant and will be removed from the end-use product label. Therefore, these uses are not considered as part of this re-evaluation. Carbon dioxide is applied using pressurized containers and fumigation equipment suitable for dispensing gas. Currently, there is one technical grade active ingredient and one restricted-class end-use product containing carbon dioxide registered in Canada. These products can be found in the <u>Pesticide Product</u> Information Database and in Appendix I. Appendix II lists all uses for which carbon dioxide is presently registered that are supported by the registrant.

The registered restricted-class end-use product containing carbon dioxide is only to be used by individuals holding an appropriate pesticide applicator certificate or license recognized by the provincial/territorial pesticide agency where the application occurs.

This document presents the proposed re-evaluation decision for carbon dioxide, including the proposed amendments (risk mitigation measures) to protect human health and the environment, as well as the science evaluation on which the proposed decision is based. For the human health review, Health Canada considered information from other regulatory agencies, such as the United States Environmental Protection Agency (USEPA), the European Union (EU)/European Food Safety Authority (EFSA), and California Department of Pesticide Regulation (CalDPR). All products containing carbon dioxide as the active ingredient that are registered in Canada are subject to this proposed re-evaluation decision. This document is subject to a 90-day public consultation period<sup>1</sup>, during which the public (including the registrant and stakeholders) may submit written comments and additional information to <u>PMRA Publications</u>. The final re-evaluation decision will be published after taking into consideration the comments received during the consultation period.

### Proposed re-evaluation decision for carbon dioxide

Health Canada, under the authority of the *Pest Control Products Act*, has conducted all evaluations considered necessary with respect to the health and environmental risks and value of carbon dioxide based on available scientific information in accordance with subsection 16(6) of the *Pest Control Products Act*. Based on these evaluations, Health Canada is proposing for

<sup>&</sup>lt;sup>1</sup> "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

public consultation, pursuant to section 28 of the *Pest Control Products Act*, the continued registration of the following uses of carbon dioxide and the associated end-use product registered for sale and use in Canada under section 21 of the *Pest Control Products Act*:

- Fumigation of grain and flour storage areas for control of grain insects.
- Aircraft fuselage fumigation for control of rodents.

The registered shipboard, in-transit ship, and ship hold fumigation uses of carbon dioxide are no longer supported for continued registration by the registrant; therefore, these uses of carbon dioxide will be removed from the end-use product label.

With respect to human health, risks are considered to be acceptable when carbon dioxide is used according to the proposed conditions of registration, which include the implementation of the proposed mitigation and label amendments outlined below and in Appendix III.

For environment, based on the current use pattern for carbon dioxide, risk to non-target organisms is considered acceptable. Label amendments outlined below and in Appendix III are proposed to meet current standards.

Carbon dioxide and its end-use product have acceptable value with the proposed label amendments outlined below and in Appendix III.

#### **Risk mitigation measures**

Registered pesticide product labels include specific directions for use. Directions include risk mitigation measures to protect human health and the environment and must be followed by law. The proposed label amendments including any revised/updated label statements and/or mitigation measures, as a result of the re-evaluation of carbon dioxide, are summarized below. Refer to Appendix III for details. Additional revisions to the carbon dioxide labels are also proposed to meet the current labelling standards.

#### Human health

Risk mitigation:

The following risk mitigation measures are proposed to reduce potential exposure and risk to human health.

To protect workers from carbon dioxide exposure, the following risk-reduction measures are proposed (details are included in Appendix III):

• Personal protective equipment (PPE) requirements and precautionary statements to bring the product labels up to current standards, including statements requiring applicators and other fumigation handlers to wear a long-sleeved shirt, long pants, shoes, and socks and protective eyewear, such as a full-face shield or goggles, when handling liquid, if full-face respiratory protection is not being used.

- Higher levels of respiratory protection for applicators when conducting fumigation treatment (in other words, requiring self-contained breathing apparatus (SCBA) and supplied air respirators to be operated in positive pressure mode.
- Requirements for air monitoring and gas detection equipment.
- Establishment of treatment and aeration buffer zones based on real-time air monitoring, with a minimum distance of 3 meters required during the treatment period.
- A site-specific fumigation management plan must be completed prior to each fumigation application.
- Updated instructions for aeration and re-entry.
- Mandatory training must be completed annually by all employees working in the fumigation facility.

Label amendments to meet current standards:

- Updated placarding statements for treatment areas and buffer zone perimeters.
- Updated spill and leak procedures.
- Updated instructions for disposal.
- As part of the updates to label text related to fumigation of grain storage areas. Add "Warning: contains the allergen sulfites".

#### Environment

Label amendments to meet current standards:

- Updated instructions for disposal/decontamination.
- Add instructions for management of any emission resulting from the use of carbon dioxide.

#### Value

Label amendments to meet current standards:

- Removal of all label texts related to shipboard, in-transit ship or ship hold fumigation.
- Updated instructions for direction for use.

With the proposed risk-reduction measures and label amendments, potential risks to human health and the environment are considered to be acceptable for carbon dioxide and its end-use product when used as a space and commodity fumigant to treat grain and flour storage areas and aircraft fuselages, and the products have acceptable value.

### **International context**

Carbon dioxide is currently acceptable for use in other Organisation for Economic Co-operation and Development (OECD) member countries, including the European Union, Australia, New Zealand, Japan, and the United States. Internationally and within the available information, no evidence of a ban as of 9 October 2024 to prohibit all uses of carbon dioxide for health or environmental reasons has been identified.

### Next steps

Upon publication of this proposed re-evaluation decision, the public, including the registrant and stakeholders, are encouraged to submit comments and additional information during the 90-day public consultation period.

Health Canada will accept written comments on this proposal up to 90 days from the date of publication of this document (by 29 May 2025). Comments on the proposed decision can be submitted during the consultation period to the PMRA through <u>PMRA Publications</u>, or the <u>Public Engagement Portal</u> (Public Engagement Forms - Consultation Comment). For more information or if you have questions, contact the PMRA's <u>Pest Management Information</u> <u>Service</u>.

Before making a re-evaluation decision on carbon dioxide under section 21 of the *Pest Control Products Act*, the comments received during the consultation period will be taken into consideration in preparation of the final re-evaluation decision document. A science-based approach will be applied in making a final decision on carbon dioxide. In accordance with subsection 28(5) of the *Pest Control Products Act*, Health Canada will then publish a final re-evaluation decision document, which will include the decision, the reasons for it, a summary of the comments received on the proposed re-evaluation decision during the consultation period, and Health Canada's response to these comments.

Refer to Appendix I for details on specific products impacted by this proposed decision.

#### **Other information**

The relevant confidential test data on which the proposed decision is based (as listed in the References Section of this document) are available for public inspection, upon application, in PMRA's Reading Room. For more information, please contact the <u>Pest Management Information Service</u>.

#### Additional scientific information

No additional scientific data are being requested.

# **Science evaluation**

Carbon dioxide (CO<sub>2</sub>) is an insecticide and rodenticide fumigant. Currently, there is one technical grade active ingredient (liquid) and one restricted-class end-use product (gas) registered in Canada. The registered restricted-class end-use product containing carbon dioxide is applied as a gas using pressurized containers and fumigation equipment suitable for dispensing gas (for example, gas cylinders and pressure regulators). It is only to be used by individuals holding an appropriate pesticide applicator certificate or license recognized by the provincial/territorial pesticide agency where the application occurs.

### **1.0** Human health assessment

Carbon dioxide is registered in Canada only for grain storage fumigation (bins, silos, railcars, flour operations and elevators) and aircraft fuselage fumigation. These fumigation sites are well-controlled and are non-residential sites. This risk assessment considers people that could be exposed to carbon dioxide while working at the fumigation site (in other words, "workers" which includes both certified/licensed applicators and other workers present in the facility during product use).

#### **Toxicology summary**

Oral or dermal exposure to liquid carbon dioxide can result in severe burns and frostbite. Excessive inhalation of the gas may result in cardiovascular, respiratory, and neurological effects. Symptoms of exposure to carbon dioxide as a gas may range from headaches and dizziness at 20 000 - 50 000 ppm to coma and death at concentrations exceeding 170 000 ppm. Exposure to the high concentration of carbon dioxide gas used during fumigation may result in suffocation or death.

#### **Occupational exposure summary**

Health Canada proposes additional risk mitigation measures to protect workers by reducing potential exposure and risks to human health. Additional mitigation and label updates are also proposed to bring the carbon dioxide end-use product label up to current standards and to comply with the mandatory training requirements for restricted-class products and fumigants in Canada.

The proposed mitigation measures and label updates (Appendix III) include: a higher level of respiratory protection for applicators when conducting fumigation treatment (in other words, requiring self-contained breathing apparatus and supplied air respirators to be operated in positive pressure mode during fumigation); detailed requirements for air monitoring and detection equipment; and site-specific fumigation management plans.

The proposed mitigation measures also include the need for both treatment and aeration buffer zones to protect workers and to ensure carbon dioxide levels are below the occupational exposure limit of 5000 ppm<sup>2</sup> currently included in the label. Health Canada is proposing establishment of both treatment and aeration buffer zones based on real-time air monitoring, with a minimum treatment buffer zone of 3 meters during the treatment period. The buffer zones are established and monitored by a certified/licensed applicator to ensure the carbon dioxide levels are below the occupational exposure limit of 5000 ppm, with the potential to expand/adjust the buffer zone based on air monitoring results. The procedures of establishing the buffer zone must be predetermined (as proposed as part of label amendments) and specified in the fumigation management plan before fumigation. Buffer zones are effective in mitigating potential worker exposure and risks from fumigants and have been considered to mitigate potential risks resulted from other commodity fumigations in Canada. Establishing a minimum distance and buffer zones by air monitoring is consistent with the buffer zone requirements for commodity fumigants and USEPA's and CalDPR's requirements for commodity fumigants.

#### Dietary and non-occupational exposure summary

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Carbon dioxide is a gas that disperses into the atmosphere after fumigation and does not leave significant residues on food or drinking water higher than the background levels of carbon dioxide (in other words, carbon dioxide in the atmosphere). For that reason, dietary exposure resulting from the fumigation uses of carbon dioxide is also not expected.

Residential exposures are not expected based on the registered use pattern. The fumigation sites are well-controlled and are non-residential sites. In addition, carbon dioxide products are classified as restricted use, which requires that they be used by applicators who are trained in its use and are knowledgeable regarding the use directions, detector devices, and emergency procedures. They are also trained to minimize exposures and must monitor air concentration and maintain a restrictive buffer zone until all levels are at an acceptable level.

The National Institute for Occupational Safety and Health (NIOSH) and the American Conference of Governmental Industrial Hygienists (ACGIH®) recommended the following occupational exposure limits for carbon dioxide, which are also adopted by the Canadian Centre for Occupational Health and Safety (CCOHS):

Threshold Limit Value (TLV) - Time-Weighted Average (TWA): 5000 ppm

Threshold Limit Value (TLV) - Short-term Exposure Limit (STEL): 30 000 ppm

The National Institute for Occupational Safety and Health (NIOSH): Carbon dioxide. October 30, 2019. https://www.cdc.gov/niosh/npg/npgd0103.html

The American Conference of Governmental Industrial Hygienists (ACGIH®): Carbon dioxide. https://www.acgih.org/carbon-dioxide/

The Canadian Centre for Occupational Health and Safety: Carbon dioxide. https://www.ccohs.ca/oshanswers/chemicals/chem\_profiles/carbon\_dioxide.html

#### Aggregate and cumulative exposure summary

Health Canada aggregates exposure for a single pesticide active ingredient by combining potential dietary exposures from all food residues and drinking water, as well as exposure from residential activities, when applicable. Health Canada also considers the cumulative non-occupational exposure to pesticides with a common mechanism of toxicity, based on the likelihood that people may be exposed to more than one of these pesticides at the same time.

Since non-occupational exposures are not expected from the fumigation uses of carbon dioxide, aggregate and cumulative assessments are not required at this time.

In conclusion, based on the above, potential risk to human health, from the use of carbon dioxide restricted-class end-use product is considered acceptable, when used according to the proposed conditions of registration, which include the implementation of the proposed mitigation and label amendments outlined in Appendix III.

No additional scientific data are being requested at this time.

#### 2.0 Environmental assessment

Carbon dioxide is a naturally occurring substance in the environment and its fate and behaviour are well understood. Carbon dioxide is present in the atmosphere at a concentration of 0.04%. It is taken up by plants during photosynthesis and is a by-product of all aerobic respiration by living organisms. Under ambient conditions, carbon dioxide is found in a stable gaseous state.

Based on the current use pattern for carbon dioxide, exposure to non-target organisms is expected to be negligible compared to the carbon dioxide usually present in air including the naturally occurring carbon dioxide and that coming from other anthropogenic activity. Considering this, and the current use pattern, risk to non-target organisms is considered negligible and is considered acceptable. No additional risk mitigation measures are proposed.

However, label amendments to meet current standards are proposed (Appendix III). In accordance with the PMRA Regulatory Directive DIR99-03<sup>3</sup>, the assessment of carbon dioxide against Track 1 criteria of Toxic Substances Management Policy (TSMP) under *Canadian Environmental Protection Act* was conducted. Health Canada has reached the conclusions that carbon dioxide does not meet all Track 1 criteria and is not considered a Track 1 substance.

Carbon dioxide does not form any transformation products that meet all Track 1 criteria.

No additional scientific data are being requested at this time.

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DIR99-03, The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy.

### 3.0 Incident reports

As of 8 August 2024, no human, domestic animal or environmental incidents involving carbon dioxide have been reported to Health Canada.

#### 4.0 Value assessment

Carbon dioxide is applied as a gas to the sealed structure. Efficacy is temperature sensitive for control of insects. Treatment duration increases as temperatures decrease. Efficacy is not temperature sensitive for rodents.

Carbon dioxide is an alternative to methyl bromide, phosphine and sulfuryl fluoride fumigants for use in structures and transport vehicles (railcars).

Carbon dioxide and its end-use product have acceptable value with the proposed label amendments (Appendix III).

### List of abbreviations

% ACGIH® CalDPR CCOHS	percent American Conference of Governmental Industrial Hygienists California Department of Pesticide Registration Canadian Centre for Occupational Health and Safety
cm	centimeters
$CO_2$	Carbon dioxide
DIR	Regulatory Directive
EU	European Union
EFSA	European Food Safety Authority
FMP	Fumigation Management Plan
hrs	hours
IDLH	Immediately Dangerous to Life or Health
kg	kilogram
m	metre
m <sup>3</sup>	cubic metre
MSHA	Mining Safety and Health Administration
NIOSH	National Institutes for Occupational Safety and Health
OECD	Organisation for Economic Co-operation and Development
OSHA	Occupational Safety and Health Administration
PMRA	Pest Management Regulatory Agency of Health Canada
PPE	Personal Protective Equipment
ppm	Parts per million
PRVD	Proposed Re-evaluation Decision
SCBA	Self-Contained Breathing Apparatus
SDS	Safety Data Sheets
STEL	Short-term Exposure Limit
TLV	Threshold Limit Value
TSMP	Toxic Substances Management Policy
TWA	Time-Weighted Average
USEPA	United States Environmental Protection Agency

## Appendix I Registered products containing carbon dioxide in Canada

 Table 1 Products containing carbon dioxide subject to proposed label amendments<sup>1</sup>

Registration number	Marketing class	Registrant	Product name	Formulation type	Active ingredient (%)
27221	Technical	Linde Canada Inc.	Carbon Dioxide Technical	Pressurized Product – Liquid	99.8
20088	Restricted	Linde Canada Inc.	Carbon Dioxide Fumigant	Pressurized Product – Gas	99.8

<sup>1</sup>As of 7 October 2024, excluding discontinued products or products with a submission for discontinuation.

# Appendix II Registered uses of carbon dioxide in Canada

Sites	Pests	Formulation type	Application method	Application rate
Grain and flour storage areas (bins, grain elevators, silos, rail cars, flour operations)	Grain insects	Pressurized	Fumigation	600 000–900 000 ppm (60–90% labelled, temperature sensitive duration)
Aircraft fuselage	Rodents	product - Gas		918 600 ppm (91.86% or 1.78 kg/m <sup>3</sup> labelled)

 Table 1
 Registered commercial uses of carbon dioxide in Canada<sup>1</sup>

<sup>1</sup> As of 7 October 2024, excluding the uses not supported for re-evaluation by the registrant.

# Appendix III Proposed label amendments for products containing carbon dioxide

The proposed label amendments presented below do not include all label requirements, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the label statements below.

#### I. Label amendments for carbon dioxide technical product (Registration No. 27221):

i. On the principal display panel,

**Replace:** "GUARANTEE: Liquid Carbon Dioxide......99.8%"

With: "ACTIVE INGREDIENT: Liquid Carbon Dioxide.......99.8%"

Add: "Warning, contains the allergen sulfites"

- ii. On the principal display panel, NET CONTENTS: **specify** "number" of tonnes.
- iii. Under DISPOSAL/DECONTAMINATION:

**Replace:** "Canadian formulators using this product should dispose of unwanted active ingredient and containers in accordance with the municipal or provincial regulations. For information on disposal of unused, unwanted product, call the manufacturer or the provincial regulatory agency. Contact the manufacturer and the provincial regulatory agency in case of a spill, and for cleanup of spills."

**With:** "Canadian registrant must dispose of unwanted active ingredients and containers in accordance with municipal and provincial/territorial regulations. For additional details and cleanup of spills, contact the registrant and the provincial/territorial regulatory agency."

# **II.** Label amendments for carbon dioxide restricted-class end-use product (Registration No. 20088):

i. On the principal display panel,

Add: Warning, contains the allergen sulfites,

Add: NET CONTENTS: "number" of tonnes

ii. Above "PRECAUTIONS" section, remove "NET CONTENTS: tonnes"

# Proposed amendments and additional risk mitigation measures relating to the human health assessment:

#### Label brochure

1. Add a "TERMS USED IN THIS LABEL" section containing the following:

Aeration Buffer Zone: An area that extends from the point of carbon dioxide emission from the treatment area (e.g., structure or aircraft edge) to a distance determined by this label where access is limited. Entry by any person except the fumigation handlers is prohibited except as provided in the "EXCEPTIONS TO TREATMENT AND AERATION BUFFER ZONE ENTRY RESTRICTIONS" section of the label. The aeration buffer zone begins when aeration begins and ends when the air concentration of carbon dioxide in the breathing zone of the treatment area for structural fumigation, or in the air space immediately around the treated commodity, is 5000 ppm or less.

Aeration Period: The period of time starting at the initiation of aeration and ending when the concentration of carbon dioxide is 5000 ppm or less, as measured according to the directions in the "MONITORING AND GAS DETECTION EQUIPMENT" section of the label.

Breathing Zone: Areas where individuals typically stand, sit or lie down while performing work functions.

Fumigation Site: The location at which fumigation activities will be conducted, at a minimum encompassing the treatment area, and treatment and aeration buffer zones.

Fumigation Handlers: Persons at the Fumigation Site involved in the fumigation, including the certified/licensed applicator and persons who are trained in accordance with the label by the certified/licensed applicator and work under direct supervision and in the physical presence of the certified/licensed applicators. Fumigation handlers must be trained and equipped to use PPE according to label requirements. Does not include persons who do not enter the treatment area, and treatment and aeration buffer zones.

Person in Charge of the Facility or Agricultural Establishment (i.e., "Owner"): Any person or company who has a present possessory interest (including leasehold, rental, or other) in the commodity or space being fumigated.

Personnel: All employees (i.e., all individuals such as, workers, contractors, farmers, and farm workers) present in the facility during product use.

Release: When control and responsibility for the commodity or structure is passed to the owner of the commodity or structure, responsible site manager, or another person designated by the owner.

Remote Monitoring: Monitoring conducted remotely is performed using a system set up in a treatment area or structure prior to the introduction of carbon dioxide which allows the fumigation handler to check concentrations from outside the treatment area and without opening the treatment area. Inserting a hand-held device into the treatment area through a port or seam is not considered remote monitoring.

Treatment Area: The structure, area or space which is, or was, enclosed or sealed to contain carbon dioxide during the fumigation and continuing until the commodity or structure is moved or released.

Treatment Buffer Zone: An area surrounding a treatment area during the treatment period where access is limited. The treatment buffer zone extends from the perimeter of the treatment area to a distance determined by this label. Entry by any person except the certified/licensed applicator and fumigation handlers under their direct supervision is prohibited except as provided in the "EXCEPTIONS TO TREATMENT AND AERATION BUFFER ZONE ENTRY RESTRICTIONS" section of the label. The treatment buffer zone begins when the fumigant is introduced into the fumigation enclosure and ends when aeration begins.

Treatment Period: This period starts at the application time and ends at the exposure duration (holding period) specified on the product label; however, it may be extended depending on on-site conditions to achieve the desired efficacy in pest control.

Start of the Fumigation: The point in time at which carbon dioxide is first introduced/delivered/dispensed into the air of the treatment area.

#### 2. Under **PRECAUTIONS**:

**Add:** All persons working with Carbon Dioxide Fumigant must be trained or licensed in the use of this product and be knowledgeable regarding the proper use of personal protective equipment, air detection equipment and emergency procedures.

# 3. Add a "**PERSONAL PROTECTIVE EQUIPMENT** (**PPE**)" section containing the following:

#### PERSONAL PROTECTIVE CLOTHING

Applicators and other fumigation handlers must wear:

- Long-sleeved shirt and long pants.
- Shoes and socks.
- Protective eyewear, such as a full-face shield or goggles, when handling liquid if full face respiratory protection is not being used.

#### RESPIRATORY PROTECTION REQUIREMENTS

The current label text requires handlers to wear a "National Institutes for Occupational Safety and Health/Mining Safety and Health Administration (NIOSH/MSHA) approved supplied air respirator, or a NIOSH/MSHA approved self-contained breathing apparatus (SCBA) with a full-face shield."

Update the current label text of respiratory protection requirements for handlers with the following:

Licensed fumigation applicators and fumigation handlers under their direct supervision must wear a NIOSH-approved self-contained breathing apparatus (SCBA) (NIOSH approval number prefix TC-13F) that has a full-face shield and is operated in a pressure demand or other positive mode, OR a NIOSH-approved supplied-air respirator (NIOSH approval number prefix TC-19C) that has a full-face shield and is operated in a pressure-demand or other positive-pressure mode in combination with an auxiliary self-contained positivepressure breathing apparatus, when conducting any activity during the treatment period in the treatment area, initiating aeration and handling spills and leaks.

Once carbon dioxide has been introduced into the treatment area, fumigation handlers conducting air monitoring, or entering the treatment area, a treatment or aeration buffer zone must wear either a supplied air respirator (NIOSH approval number prefix TC-19C) or a self-contained breathing apparatus (SCBA) (NIOSH approval number prefix TC-13F) according to the concentrations as specified in the current label.

In addition, add the following:

The respiratory protection must fit properly; any obstruction to a proper fit should be removed (e.g., beard, long sideburns).

- 4. Under "DIRECTIONS FOR USE" section, update with the following:
  - 1) Add a section of "GENERAL" including the following:

**NOTICE TO USER:** This is a **Restricted Use Pesticide** and can be used only in accordance with the directions on the label. This fumigant is a highly hazardous material and may be used only by individuals trained in its proper use. Before using, read and follow all label precautions and directions. All persons working with this fumigant must be knowledgeable about the hazards and trained in the use of required respirator equipment and detector/monitoring devices, emergency procedures, and proper use of the fumigant. It is an offence under the *Pest Control Products Act* to use this product in a way that is inconsistent with the directions on the label. The user assumes the risk to persons or property that arises from any such use of this product.

#### NATURE OF RESTRICTIONS:

This product is for sale ONLY to a certified/licensed applicator, who is holding an appropriate pesticide applicator certificate or license recognized by the provincial/territorial pesticide regulatory agency where the pesticide application occurs. This product is to be used by a certified/licensed applicator or by persons who are trained in accordance with the label by the

certified/licensed applicator and working under direct supervision and in the physical presence of the certified/licensed applicator(s). Physical presence means "on site" or "on the premises". Certified/licensed applicator must maintain training records for fumigation handlers who have received training in accordance with the label, ensuring the records are available to Health Canada upon request for a minimum of two years.

**THIS PRODUCT IS TO BE USED** for control of listed insect pests in grain and flour storage areas and rodents in aircraft fuselages ONLY. **DO NOT USE THIS PRODUCT IN** residential structures or in public food service facilities (such as public restaurants). All parts of the label are equally important for safe and effective use of this product. If you have any questions about the proper use of this product, contact the registrant before using this product.

In facilities where this product is used, all employees MUST complete mandatory annual training as outlined in "MANDATORY ANNUAL TRAINING" section. Training includes information on the hazards of this product, the use of safety equipment (i.e., respiratory protection and personal monitors), and the exposure limit of 5000 ppm. It is the responsibility of the certified/licensed applicator to inform person in charge of the facility, where the fumigation will take place, of the requirement for the mandatory training.

**APPLICATION RESTRICTIONS:** At least two persons, a certified/licensed applicator, and a person trained in accordance with the label working under direct supervision of the certified/licensed applicator, must be present during the treatment period, at the initiation of aeration, and when testing for re-entry to the treatment area. All fumigation handlers must be under direct on-site supervision of the certified/licensed applicator at the start of the fumigation, at the initiation of aeration, when testing for re-entry into the treatment area, until the commodity/structure is fully aerated (carbon dioxide concentrations are < 5000 ppm). Only one fumigation handler needs to be present if monitoring is conducted remotely (from outside the treatment area).

The site to be fumigated must first be inspected to determine if it can be made sufficiently gas tight. Then a **Fumigation Management Plan** must be developed prior to actual fumigation to provide for safe and efficient application of the fumigant, to include emergency procedures, etc. and to decide how monitoring should be conducted to prevent excessive exposures (refer to "SITE SPECIFIC FUMIGATION MANAGEMENT PLAN" section).

Exposure to carbon dioxide gas must never exceed 5000 ppm without following the requirements in the "RESPIRATORY PROTECTION REQUIREMENTS" section. Only if necessary, should workers be present in the treatment buffer and aeration buffer zones. All workers present in the buffer zones during the fumigation or aeration periods MUST wear appropriate respiratory protection, as outlined in the "RESPIRATORY PROTECTION REQUIREMENTS" section.

Treatment and aeration buffer zones must be established for all fumigated sites as per the instructions outlined under the "TREATMENT & AERATION BUFFER ZONE REQUIREMENTS" section. Post warning placards around both the fumigated area and the treatment and aeration buffer zone perimeter as per instructions in the "PLACARDING INSTRUCTIONS" section.

Monitoring must be conducted for selection of respiratory protection, establishing and maintaining buffer zones and efficacy, according to the requirements specified in "MONITORING AND GAS DETECTION EQUIPMENT" section.

For emergency use/or to escape from conditions which are Immediately Dangerous to Life or Health (IDLH), keep an adequate number of appropriate escape-type, NIOSH approved self-contained breathing apparatus for use by all workers. Notify appropriate company employees prior to the fumigation and provide relevant safety information to local officials (fire department, police, etc.) for use in the event of emergency. Observe all provincial pesticide regulations. Refer to "EMERGENCY RESPONDER PROTECTION" section.

2) Add a section title of "USES AND APPLICATION RATES".

Remove all label texts related to shipboard, in transit ship or ship hold fumigation.

For aircraft fuselage fumigation,

Replace:

"Introduce Carbon Dioxide Fumigant as described in the Applicable Aircraft Maintenance Manual."

#### With:

"Carbon dioxide is introduced through a high-level opening in the cockpit and properly secured to the base of the seat frame. The  $CO_2$  is vented through a low level partially opened cargo bay door to purge the air."

3) Add a "**TREATMENT & AERATION BUFFER ZONE REQUIREMENTS**" section, including the following:

#### ESTABLISHMENT OF TREATMENT & AERATION BUFFER ZONES

Treatment Buffer Zones

- Before starting the fumigation treatment, an initial treatment buffer zone must be predetermined and established by a certified/licensed applicator taking into consideration site characteristics and environmental conditions, as specified in the Fumigation Management Plan (FMP). The initial treatment buffer zone MUST NOT be less than 3 meters but may be larger.
- 2. An air monitoring procedure and schedule is determined by the certified/licensed applicator based on site characteristics and environmental conditions, as specified in the FMP.

- 3. The certified/licensed applicator in charge of the fumigation (or workers under their supervision) must post warning placards around both the treatment area and the treatment buffer zone perimeter before the actual fumigation treatment (See "PLACARDING INSTRUCTIONS" section).
- 4. Throughout the fumigation period (i.e., from the beginning of the fumigant application until the beginning of aeration), a supervising fumigant applicator/handler or trained personnel designated by the certified/licensed applicator must periodically monitor carbon dioxide levels at various points along the treatment buffer zone perimeters, according to the designated schedule, adapting as necessary to site conditions.
- 5. If at any time during monitoring, carbon dioxide levels exceed 5000 ppm, all individuals without appropriate respiratory protection must immediately evacuate the area. The treatment buffer zone must be expanded until carbon dioxide levels are at or below 5000 ppm along the perimeter. If expanding the buffer zone is impractical, corrective actions such as halting product application or sealing leaks must be implemented until carbon dioxide levels are compliant along the fumigation zone perimeter. Once levels are safe, fumigation activities can resume.
- 6. The buffer zone may be adjusted/reduced based on air monitoring during the fumigation period; however, the minimum treatment buffer zone distance MUST NOT be reduced to less than 3 meters.

#### Aeration Buffer Zones

- 1. Before starting the aeration, an initial aeration buffer zone must be pre-determined and established by a certified/licensed applicator taking into consideration site characteristics and environmental conditions, as specified in the Fumigation Management Plan (FMP). The initial aeration buffer zone may be larger than the treatment buffer zone at that time when the treatment is halted, due to the potential for a sudden and significant release of fumigant gas. This can lead to a higher concentration of the gas in the surrounding area, necessitating a larger buffer zone to ensure safety.
- 2. An air monitoring procedure and schedule is determined by the certified/licensed applicator based on site characteristics and environmental conditions, as specified in the FMP.
- 3. The certified/licensed applicator in charge of the fumigation (or workers under their supervision) must maintain warning placards around both the treatment area and the aeration buffer zone perimeter before the initiate the aeration (See "PLACARDING INSTRUCTIONS" section).
- 4. Throughout the aeration period (i.e., from the beginning of aeration until the carbon dioxide level is at or below 5000 ppm), a supervising fumigant applicator/handler or trained personnel designated by the certified/licensed applicator must periodically monitor carbon dioxide levels at various points along the aeration buffer zone perimeters, according to the designated schedule, adapting as necessary to site conditions.
- 5. If at any time during monitoring, carbon dioxide levels exceed 5000 ppm, all individuals without appropriate respiratory protection must immediately evacuate the area. The buffer zone must be expanded until carbon dioxide levels are at or below 5000 ppm along the perimeter. If expanding the buffer zone is impractical, corrective actions such as adjusting aeration or sealing leaks must be implemented until carbon dioxide levels are

compliant along the fumigation zone perimeter. Once levels are safe, aeration activities can resume.

6. The buffer zone may be adjusted/reduced based on air monitoring during the aeration period.

# EXCEPTIONS TO TREATMENT AND AERATION BUFFER ZONE ENTRY RESTRICTIONS

Only if necessary, should pesticide applicators/handlers or workers be present in the treatment or aeration buffer zones. All workers in the buffer zones, MUST wear respiratory protection as outlined in the "RESPIRATORY PROTECTION REQUIREMENTS" section.

There are two exceptions for entry into the treatment buffer zones and aeration buffer zones:

- 1. Occupied Structure Exception: Occupants of a structure in the facility that is within the treatment/aeration buffer zone may remain in the structure, provided continuous real-time monitoring indicates that carbon dioxide concentrations are 5000 ppm or less within the occupied structure and the exposure time will be less than 8 hours. Fumigation handlers must monitor the air concentrations. This exception only applies to structures occupied by workers. To use this exception, the FMP must state the distance of the occupied structure to the treatment area, the method of conducting the real time monitoring for carbon dioxide during the period when the treatment buffer zone and aeration buffer zone are in force, and specific procedures for immediate intervention, such as cessation of aeration, evacuation of building, or other procedures if the concentration of carbon dioxide exceeds 5000 ppm at any time.
- 2. Transit Exception: Limited transit through treatment and aeration buffer zones is allowed if brief and unavoidable. Routine or repeated work-related tasks are prohibited in the treatment and aeration buffer zones. No person is allowed to transit through a treatment or aeration buffer zone unless the person is protected by respiratory protection as outlined in the section of RESPIRATORY PROTECTION REQUIREMENTS, or the carbon dioxide levels are less than 30 000 ppm, and the transit time is less than 15 minutes.

#### PLACARDING INSTRUCTIONS

Replace the current label texts with the following:

"Requirements for placarding the treatment area and treatment & aeration buffer zones include:

- The certified/licensed applicator in charge of the fumigation (or someone under their supervision) must post warning placards around both the treatment area and the treatment buffer zone perimeter before the actual fumigation treatment. The certified/licensed applicator must placard or post warning signs at all usual points of entry, all entrances to the fumigated area, and along other likely routes of approach where people not under the operator's control may be in close proximity to the fumigated site and the treatment buffer zone. These signs must be posted at eye level and must be visible from all visible points of entry to the fumigation site. Each separate treated area (i.e., bins, silos, railcars, flour operations, grain elevators, and aircraft) must be posted or placarded with these signs. Placards should be placed in advance of the fumigation to keep unauthorized persons away.
- 2. Posting of warning signs for the treatment and aeration buffer zone perimeter is required. Once the fumigation treatment is complete, the warning placards MUST be relocated to

establish the aeration zone perimeter. Such signs must only be removed when aeration has occurred and when the air concentration of carbon dioxide is monitored as described in this label and indicates that carbon dioxide levels are 5000 ppm or less. The warning signs at entrances to fumigated structures and around the buffer zone perimeters MUST only be removed by the certified/licensed applicator in charge of the fumigation (or someone under their supervision).

- 3. Signs must be legible during the entire posting period. Placards must be at least 35 centimeters (cm) long and 25 cm wide and made of substantial material that can be expected to withstand adverse weather conditions. They must bear the following information in both English and French:
  - a. The signal word **DANGER** in letters at least 7 cm high and the skull and crossbones symbol in red.
  - b. The "DO NOT WALK" symbol.
  - c. The statement, "Area and/or commodity under fumigation, "DO NOT ENTER".
  - d. "Carbon Dioxide Fumigant in Use"
  - e. The date and time when the fumigation begins and the date and time when aeration can begin.
  - f. The name of the fumigant and the product used.
  - g. Contact information: name address, and telephone number of the certified/licensed applicator supervising the fumigation.
  - h. Placards must bear a 24-hour emergency response telephone number.
- 4. For railroad hopper cars, placards must be placed on both sides of the car near the ladders and next to the top hatches into which the fumigant is introduced.
- 5. Do not enter or allow entry by anyone other than the fumigation handlers following the "Respirator Requirements" into the treatment area, treatment buffer zone, or aeration buffer zone until the signs are removed except as provided in the "EXCEPTIONS TO TREATMENT AND AERATION BUFFER ZONE ENTRY RESTRICTIONS" section of the label."

#### MONITORING AND GAS DETECTION EQUIPMENT

Add the following label texts:

#### MONITORING FOR SAFETY

Monitoring for Selection of Respiratory Protection

From the start of the fumigant application until the end of the aeration period, certified/licensed applicators and fumigation handlers under their direct supervision must measure carbon dioxide levels to select the appropriate respiratory protection before entering areas with potential carbon dioxide exposure. Measures should be made in the worker's breathing zone. Breathing zones are defined as areas where individuals typically stand, sit or lie down while performing work functions. The monitoring must be recorded in the FMP.

Monitoring for Establishing and Maintaining Buffer Zones

At each site undergoing fumigation, ambient air monitoring must be conducted according to a procedure specified in the fumigation management plan (FMP) to establish and maintain buffer

zones. The procedure is determined by the certified/licensed applicator, taking into account site characteristics and environmental conditions. Carbon dioxide levels must be checked in all areas around the fumigation area during both fumigation and aeration, including workspaces under and adjacent to the treatment area to determine where exposures may occur. The buffer zone perimeter is then determined to prevent exposure of unprotected workers to concentrations of carbon dioxide > 5000 ppm. Note: the minimum treatment buffer zone is 3 meters but may be larger based on air monitoring results.

To maintain, expand or adjust the treatment and aeration buffer zones, scheduled ambient air monitoring of carbon dioxide concentrations must be conducted, downwind, along the buffer zone perimeters to prevent exposure of unprotected workers to concentrations of carbon dioxide greater than 5000 ppm. It may be necessary to monitor gas levels in other areas as well. Monitor (and record) the wind direction and adjust the carbon dioxide monitoring if wind direction changes over the fumigation/aeration period.

Keep a log or manual of monitoring records for each fumigated site and the treatment and aeration buffer zones. This log must, at a minimum, contain the timing, number of readings taken and level of concentrations found in each location. Document any carbon dioxide level even if it is present below the exposure limit of 5000 ppm.

#### MONITORING FOR EFFICACY

Carbon dioxide readings should be taken from within the fumigated area/structure to ensure proper gas concentrations, along with temperature and relative humidity readings. Readings must be taken according to a schedule specified in the fumigation management plan (FMP). At least two persons, a certified/licensed applicator and a person trained in accordance with the label working under direct supervision of the certified/licensed applicator, must be present when testing carbon dioxide concentrations in the treatment area. Two persons do not need to be present if monitoring is conducted remotely (outside of the area being fumigated).

#### RECOMMENDATIONS FOR GAS DETECTION EQUIPMENT AND SENSITIVITIES

For efficacy, during fumigations, the concentration of carbon dioxide in the treatment area should be monitored to ensure application rates are met and to evaluate efficacy, using gas detection equipment with measuring range that covers the application rates.

For safety, such as establishing buffer zones and determining respiratory protection and safe reentry, concentrations of carbon dioxide must be measured using either:

- A continuous real-time detection device, e.g., a stationary monitor with an alarm set at the exposure limit of 5000 ppm. OR
- A direct reading detection device that is capable of accurately measuring carbon dioxide levels with an alarm set at the exposure limit of 5000 ppm.

Information on carbon dioxide detection equipment may be obtained from your distributor.

Create a section "AERATION AND RE-ENTRY" and add the following texts:

#### **AERATION AND RE-ENTRY**

After fumigation, aerate treated areas until the level of CO<sub>2</sub> is below 5000 ppm before unprotected persons may be in the area.

Before aeration is complete, entry into the treatment and aeration buffer zones is prohibited for any person other than the certified/licensed applicator supervising the fumigation or individuals under their direct supervision. Workers who enter the treatment or aeration buffer zones must follow the personal protective equipment requirements specified for fumigation handlers in this label.

Only if necessary, should workers be present in the treatment or aeration buffer zone. All workers (including certified/licensed applicators and workers who are trained in accordance with the label by the certified/licensed applicator and working under their direct supervision) in the buffer zone during fumigation and until the fumigated site has been aerated and the carbon dioxide level is at or below 5000 ppm in the buffer zone, MUST wear respiratory protection as outlined in the "RESPIRATORY PROTECTION REQUIREMENTS" section OR a personal carbon dioxide monitor with an alarm set at 5000 ppm. Each unprotected worker in the buffer zone must know how to operate the personal carbon dioxide monitor and be informed of procedures required if the levels of carbon dioxide exceed 5000 ppm. If at any time carbon dioxide levels exceed 5000 ppm, all individuals who are not wearing respiratory protection as outlined in "RESPIRATORY PROTECTION REQUIREMENTS" section MUST vacate the area until carbon dioxide levels are at or below 5000 ppm."

5. Under "SPILL AND LEAK PROCEDURES" section, update with the following:

Evacuate the immediate area where the leak has occurred. A spill, other than incidental to application or normal handling, may produce high levels of carbon dioxide; and therefore, attending personnel/all workers present must wear appropriate respiratory protection and personal protective equipment as specified in the "PERSONAL PROTECTIVE EQUIPMENT" section for entry into the affected area to correct the problem. A buffer zone must be established by the certified/licensed applicator around the location of the spill site taking into consideration site characteristics and environmental conditions, to prevent exposure of unprotected workers to concentrations of carbon dioxide > 5000 ppm.

Delete all texts related to cargo/vessel fumigation.

6. Under "DISPOSAL" section, add the following:

The flow rates of venting are maintained through site-specific atmospheric monitoring to ensure the  $CO_2$  concentration level is below the 5000 ppm threshold for personnel exposure.

While disposing of carbon dioxide, if carbon dioxide levels are unknown or above 5000 ppm, appropriate respiratory protection must be worn. Appropriate respiratory protection, as outlined in the "RESPIRATORY PROTECTION REQUIREMENTS" section MUST be worn. A buffer zone must be established by the certified/licensed applicator around the location of the spill site taking into consideration site characteristics and environmental

conditions.

# 7. Add an **"EMERGENCY RESPONDER PROTECTION"** section, including the following:

Wear a NIOSH-approved self-contained breathing apparatus (SCBA) with full facepiece and operated in a pressure demand or other positive-pressure mode OR a NIOSH-approved airline respirator with a full-facepiece operated in a pressure-demand or other positive-pressure mode combined with an auxiliary self-contained positive-pressure breathing apparatus when the concentration of carbon dioxide is unknown. If the concentration is known, other appropriate respiratory protection must be worn as specified in "RESPIRATORY PROTECTION REQUIREMENTS" section.

Cylinders, Containers & Tanks, Transportation operates a 24-hour Emergency Response and Incident Management System. Phone: 1-800-363–0042 (24 hrs).

#### 8. Add a "MANDATORY TRAINING ELEMENTS" section, including the following:

#### **RESPONSIBLE PARTIES**

Certified/Licensed Applicator: Responsible for informing the person in charge of the facility, the employer or their representative of the requirement for the mandatory training and maintenance of training records, and directing the person in charge of the facility, the employer or their representative on how to obtain a copy of the product-specific training material from the registrant. The certified/licensed applicator is also responsible for developing and maintaining the Fumigation Management Plan.

Registrant: Responsible for developing product-specific training material (in both English and French) and having the product-specific training material readily available upon request.

The person in charge of the facility or agricultural establishment or the employer or his/her representative is responsible for:

- Developing site-specific training material in conjunction with the FMP and collaborating with certified/licensed applicators to develop these training materials.
- Providing both product-specific and site-specific training to workers.
- Maintaining training records for their employees/workers for a minimum of two years and available to Health Canada upon request.

Personnel: All employees (i.e., all individuals such as, workers, contractors, farmers, and farm workers) present in the facility during product use.

In facilities where this product is used, all employees who are present in the facility during product use, MUST complete mandatory annual training using product-specific training material supplied by the registrant, and additional site-specific training information developed by the employer or their representative, before the fumigation is conducted.

#### MANDATORY TRAINING ELEMENTS

The site- and product-specific training material MUST contain the following information:

Safety Data Sheets (SDS): Summary documents that provide information about the hazards of a product and advice about safety precautions.

Hazards of carbon dioxide: Information on the acute toxicity of carbon dioxide must be included in the mandatory training. Carbon dioxide products are classified as restricted-class products due to exposure in fumigation may cause suffocation and death.

Symptoms: Headache, dizziness, restlessness, paresthesia; dyspnea (breathing difficulty); sweating, malaise (vague feeling of discomfort); increased heart rate, cardiac output, blood pressure; coma; asphyxia; convulsions; frostbite (liquid, dry ice). (https://www.cdc.gov/niosh/npg/npgd0103.html)

The 5000-ppm Exposure Limit: Information on the 5000-ppm exposure limit and that it is time-dependent, with specific time limits when a respirator is not required must be included in the mandatory training. The training should also specify that frequent exposure to concentrations above permissible levels over a period of days or weeks could cause poisoning.

How to use Gas Detection Equipment and Personal Protective Equipment: Information on facility-specific equipment (e.g., how to use gas detection equipment and how to properly fit respirators), must be included in the mandatory annual training. In addition, information on when respiratory protection should be used must be included.

Procedures when Levels of Carbon Dioxide Exceed 5000 ppm: Facility-specific details on what to do when carbon dioxide levels exceed 5000 ppm, where workers are to go, who they should contact, the personal protective equipment to wear, and where the personal protective equipment is located must be included in the mandatory annual training.

Establishing Treatment Buffer Zone and Aeration Buffer Zone: Guidance for establishing appropriate treatment buffer zone and aeration buffer zone distances based on air monitoring provided in the "TREATMENT & AERATION BUFFER ZONE REQUIREMENTS", "PLACARDING INSTRUCTIONS" and "MONITORING AND GAS DETECTION EQUIPMENT" sections of the label must be included in the mandatory annual training.

Aeration and Re-entry: Guidance for how to determine safe re-entry to the treated area provided in "AERATION AND RE-ENTRY" section of the label must be included in the mandatory annual training.

9. Add a "Fumigation Management Plans (FMPs)" section, including the following:

# A FUMIGATION MANAGEMENT PLAN MUST BE WRITTEN FOR ALL FUMIGATIONS PRIOR TO ACTUAL TREATMENT

Prior to fumigating, the certified/licensed applicator supervising the fumigation must verify that a site-specific fumigation management plan (FMP) exists. The FMP is intended to

ensure a safe and effective fumigation and must be devised to cover the application and exposure period, aeration, and disposal of the fumigant in order to keep any human exposures to carbon dioxide to a minimum and help ensure the adequate control of pests. The certified/licensed applicator in charge of the fumigation is responsible for working with the Person in Charge of the Facility or Agricultural Establishment ("owners") and/or responsible employees of the site to be fumigated to develop a site-specific FMP. The certified/licensed applicator supervising the fumigation must ensure that the FMP is up-to-date and applicable to the fumigation before it takes place.

Before the start of any fumigation, the certified/licensed applicator supervising the fumigation must verify in writing (sign and date) that the FMP reflects current site conditions and that it addresses all elements identified in this label.

For situations where an initial FMP is developed and certain elements do not change for the fumigation, only elements that have changed need to be updated in the site-specific FMP provided that the certified/licensed applicator supervising the application has verified that those elements are current and applicable to the fumigation site before the fumigation begins, and record-keeping requirements are followed for the entire FMP (including elements that do not change).

The FMP must document the characteristics of the site, the treatment and aeration buffer zones, include appropriate monitoring and notification requirements, and include a record that the following have been completed:

- 1. Inform the person in charge of the facility where the fumigation will take place that all workers must complete mandatory annual training as outlined in the label "MANDATORY ANNUAL TRAINING" section. Training includes information on the hazards of the product, the use of safety equipment (i.e., respiratory protection and monitoring equipment), and the exposure limit of **5000 ppm**.
- 2. Certified/licensed applicators, or workers who are trained in accordance with the label by the certified/licensed applicator and working under direct supervision of the certified/licensed applicators under their supervision, must inspect the site to determine its suitability for fumigation. The application site consists of the treatment area and any structure that the treatment area is inside of.
- 3. Before fumigating, the certified/licensed applicators, or workers who are trained in accordance with the label by the certified/licensed applicator and working under direct supervision of the certified/licensed applicators, must assess the application site for any changes since the last application that could affect the efficacy or safety of the fumigation. This assessment must include a review of the most recent fumigation log from the application site and the most recent monitoring data from adjacent, occupied buildings, where such documents are available. In addition, the certified/licensed applicators, or workers under their supervision, must consult the site manager regarding changes to the application site monthly, or if no fumigation has occurred at the application site for a month or more, upon resumption of fumigation activities.

If the certified/licensed applicator determines, based on the assessment, that modifications

to the application site are required to ensure efficacy or safety, the basis for this conclusion, and confirmation that the modifications were made prior to fumigation, shall be recorded.

When sealing is required, the certified/licensed applicator must consult previous records for any changes to the site/structure, seal leaks, and monitor any occupied adjacent buildings to ensure safety.

- 4. Certified/licensed applicators, or workers under their supervision, prior to each fumigation must review existing FMPs, Safety Data Sheets (SDS), carbon dioxide label, mandatory training materials, and other relevant safety procedures for the specific location or site and consult with owners (whose structure or commodity is fumigated) and appropriate employees, if available.
- 5. Certified/licensed applicators, or workers under their supervision, must consult company officials in the development of procedures and appropriate safety measures for nearby workers that will be in and around the area during application and aeration.
- 6. Certified/licensed applicators, or workers under their supervision, must consult with company officials to ensure that an appropriate monitoring plan will be in place to confirm that nearby workers will not be exposed to levels above the allowed carbon dioxide safety limit (i.e., **5000 ppm**) during application, fumigation and aeration. This plan must consider all of the treatment and aeration buffer zone requirements.
- 7. Certified/licensed applicators, or workers under their supervision, must develop an appropriate exterior monitoring plan that will conform with the requirements of the treatment and aeration buffer zones to ensure that nearby workers are not exposed to levels above the allowed limits during fumigation and aeration and consult with owners, or site managers, if available.
- 8. Certified/licensed applicators, or workers under their supervision, must determine the proper treatment and aeration buffer zones, according to the carbon dioxide product label and record the dosage, fumigated volume, and other parameters used to determine treatment and aeration buffer zone distances.
- 9. Certified/licensed applicators, or workers under their supervision, must develop procedures for notification of local emergency responders in the event of an emergency ("Emergency Response Plan") and consult with owners or site managers, if available. The Emergency Response Plan must comply with all requirements established by local emergency responders while remaining consistent with label requirements.

If local emergency responders have not established any requirements, or if requirements are minimal or contradict the label, then the plan shall still include, at a minimum, instructions on the persons or entities to contact if: (1) there is a spill, leak, equipment failure, or other emergency at the application site during a fumigation that presents a risks to humans; or (2) anyone at the application site is experiencing symptoms of exposure.

Certified/licensed applicators, or workers under their supervision, must consult with local emergency responders at least annually to confirm the Emergency Response Plan conforms

to their requirements, or, in the absence of such requirements, that the Emergency Response Plan contains the correct contact information.

- 10. Certified/licensed applicators, or workers under their supervision, must confirm the placement of warning placards around the fumigation site as described on the label. Placards should be placed to secure entrances and placed along other routes of approach into any site under fumigation and along the treatment and aeration buffer zone perimeters.
- 11. Certified/licensed applicators, or workers under their supervision, must document the following:
  - a. Credentials of the certified/licensed applicator in charge when the fumigant was introduced and when final clearance testing was completed (if different)
  - b. Credentials and/or names and contact information of all personnel members part of the fumigation/aeration prior to the induction of the fumigant and at the time the commodity is aerated (if different)
  - c. The commodity or structure being fumigated
  - d. The target pest (if known)
  - e. The amount of fumigant introduced into the treatment area
  - f. Date and time of the fumigant introduction
  - g. Date and time final clearance testing completed
  - h. Monitoring specifications and results as noted in the "MONITORING AND GAS DETECTION EQUIPMENT" section of this label.

This information may be documented on a form designated for this purpose or on supplemental documents such as those identified below, provided that each data point is documented in at least one location.

12. Certified/licensed applicators, or workers under their supervision, must confirm the required safety and monitoring/clearance equipment (including equipment required for entry into an area under fumigation) is in place and the necessary, trained fumigation handlers are available to complete a safe, effective fumigation.

It is important to note that some Fumigation Management Plans will be more comprehensive than others. All Fumigation Management Plans should reflect the experience and expertise of the certified/licensed applicator and circumstances at and around the site/structure and the treatment and aeration buffer zones. Elements of the FMP may be fulfilled through the use of supplemental documents such as fumigation logs, service reports, pesticide application records, facility maps, facility emergency plans, provincial or federally required forms, and other supplemental documents prepared for or used during the actual fumigation.

In addition to the development of the Fumigation Management Plan, the certified/licensed applicator must read the entire label and follow its directions carefully. If the certified/licensed applicator has any questions about the development of a Fumigation Management Plan, contact the product registrant for further assistance.

#### RECORDKEEPING

The certified/licensed applicator's employer or the certified/licensed applicator supervising the fumigation must maintain all records required under the provisions of this label including the FMP and supplemental documents used to fulfill FMP requirements, information on incidents and complaints, and all air monitoring results for two years from the date of the fumigation. Certified/licensed applicator must maintain training records for fumigation handlers who have received training in accordance with the label, ensuring the records are available to Health Canada upon request for a minimum of two years. During the two-year period following a fumigation, these records must be made available upon request to any provincial, municipal, or federal pesticide enforcement personnel.

During the treatment and aeration buffer zone periods, the certified/licensed applicator must make a copy of the FMP and the associated safety data sheet (SDS) available for viewing by all fumigation handlers. The certified/licensed applicator must ensure the FMP is available upon request at the fumigation site while the treatment and aeration buffer zones are in effect.

Records of air monitoring results must include:

- Date of fumigation,
- Monitoring equipment used,
- Location and time of each required sample, and
- Concentration of carbon dioxide found for each required sample.

Records of spills, equipment failures and other emergencies must include:

- Description of what happened
- Emergency procedures followed
- Whether the incident was reported to the provincial lead agency or other agency.

Records of complaints related to the fumigation received by the applicator during or after the fumigation must include:

- Contact information for the person filing the complaint
- Description of control measures or emergency procedures followed after the complaint, if any.

Records must be maintained and made available to Health Canada upon request. A copy of the records must be sent to the registrant at the end of the calendar year. These will be summarized (minus personal information such as name and location) and sent to the PMRA on annual basis.

#### GUIDANCE FOR PREPARATION OF A FUMIGATION MANAGEMENT PLAN

A Fumigation Management Plan (FMP) is an organized, written description of the required steps involved to help ensure a safe, legal and effective fumigation. It will also assist you and others in complying with pesticide product label requirements. The guidance that follows is designed to help assist you in addressing all the necessary factors involved in preparing for and fumigating a structure and/or area.

This guidance is intended to help you organize any fumigation that you might perform,

PRIOR TO ACTUAL FUMIGATION. It is meant to be somewhat prescriptive, yet flexible enough to allow the experience and expertise of the fumigator to make changes based on circumstances which may exist in the field. By following a step-by-step procedure, yet allowing for flexibility, a safe and effective fumigation can be performed.

Before any fumigation begins, carefully read and review the product label. This information must also be given to the appropriate company officials (supervisors, foreman, safety officer, etc.) in charge of the site. Preparation is the key to any successful fumigation. If you do not find specific instructions for the type of fumigation that you are to perform listed in this Guidance Document, you will want to construct a similar set of procedures using this document as your guide or contact LINDE CANADA INC for assistance. Finally, before any fumigation begins, you must be familiar with and comply with all applicable federal, provincial and municipal laws and regulations. The success of the fumigation is not only dependent on your ability to do your job but also upon carefully following all rules, regulations and procedures required by governmental agencies.

#### CHECKLIST GUIDE FOR A FUMIGATION MANAGEMENT PLAN

This checklist is provided to help you take into account factors that must be addressed prior to performing all fumigations. It emphasizes safety steps to protect people and property. The checklist is general in nature and cannot be expected to apply to all types of fumigation situations. It is to be used as a guide to prepare the required Fumigation Management Plan. Each item must be included if it is applicable to the fumigation. However, it is understood that each fumigation is different and not all items will be necessary for each fumigation site.

#### A. PRELIMINARY PLANNING AND PREPARATION

- 1) Determine the purpose of the fumigation and ensure the application is to control the pests listed on the product label.
- 2) Determine the type of fumigation. For example:
  - a. grain and flour storage areas;
  - b. vehicle railcar;
  - c. aircraft fuselage fumigation.
- 3) Fully acquaint yourself with the site and commodity to be fumigated, including:
  - a. The general structure layout, construction (materials, design, age, maintenance), of the structure, fire or combustibility hazards, connecting structures and escape routes, above and below ground, and other unique hazards or structural characteristics. Prepare, with the owner/operator/person in charge, a drawing or sketch of structure to be fumigated, delineating features, hazards, and other structural characteristics.
  - b. The number and identification of persons who routinely enter the area to be fumigated (i.e., employees)
  - c. The specific commodity to be fumigated, its mode of storage, and its condition.
  - d. The previous fumigation/treatment history of the commodity, if available.
  - e. Accessibility of utility service connections
  - f. Nearest telephone or other means of communication. Mark the location of these items on the drawing/sketch.

- g. Emergency shut-off stations for electricity, water and gas. Mark the location of these items on the drawing/sketch.
- h. Current emergency telephone numbers of local health, fire, police, hospital and physician responders.
- i. Name and phone number (both day and night) of appropriate company officials.
- j. Check, mark and prepare the points of fumigant application locations if the job involves entry into the structure for fumigation.
- k. Location of command centre
- 1. Exposure time considerations:
  - (1) Product to be used
  - (2) Minimum treatment period, as defined and described by the label use directions.
  - (3) Down time required to be available
  - (4) Aeration requirements
  - (5) Clean-up requirements, including dry or wet deactivation methods, equipment, and personnel needs, if necessary.
  - (6) Measured and recorded commodity temperature and moisture
- m. Determination of dosage:
  - (1) Cubic footage or other appropriate space/location calculations
  - (2) Structure sealing capability and methods
  - (3) Label recommendations
  - (4) Temperature, humidity, wind
  - (5) Commodity/space volume
  - (6) Past history of fumigation of the site/structure
  - (7) Exposure time
  - (8) Amount of fumigant used
  - (9) Actual concentration achieved
- n. Distance to other on-site structures or areas where workers may be exposed.
- o. Site of aeration vent(s) to be opened to aerate site/structure.
- p. Treatment and aeration buffer zone requirements, including provisions for areas not under the control of the owner/operator of the application site (e.g. agricultural areas, roads and rights of way, publicly owned and/or operated areas.

#### **B. PERSONNEL**

- 1. Confirm in writing that all personnel in and around the site to be fumigated have been notified prior to application of the fumigant. Consider using a checklist that each employee initials indicating they have been notified.
- 2. Instruct all fumigation personnel to read the label concerning the hazards that may be encountered, and about the selection of personal protection devices, including sufficiently sensitive detection equipment.
- 3. Confirm that all personnel are aware of and know how to proceed in case of an emergency situation.

- 4. Instruct all personnel on how to report any accident and/or incidents related to fumigant exposure. Provide a telephone number for emergency response reporting.
- 5. Instruct all personnel to report to proper authorities any theft of fumigant and/or equipment related to fumigation.
- 6. Establish a meeting area for all personnel in case of an emergency.

#### **C. MONITORING**

- 1. Safety
  - a. Scheduled ambient air monitoring of carbon dioxide concentrations must be conducted, downwind, along the treatment and aeration buffer zone perimeters to prevent exposure of unprotected workers to concentrations of carbon dioxide greater than 5000 ppm\*\*\* and to determine where exposures may occur. It may be necessary to monitor gas levels in other areas as well. Document where monitoring will occur.
  - b. Monitor (and record) the wind direction and adjust the carbon dioxide monitoring if wind direction changes over the fumigation/aeration period.
    - Keep a log or manual of monitoring records for each fumigated site and the treatment and aeration buffer zones. This log must, at a minimum, contain the monitoring equipment used, location and timing of each sample, number of readings taken and level of concentrations found in each location.
  - c. When monitoring, document any carbon dioxide level even if it is present at or below the limit of detection.
  - d. From the beginning of the fumigant application and until the end of the treatment period, the certified/licensed applicator supervising the fumigation and/or workers under their supervision must periodically monitor (i.e., according to a schedule made by the certified/licensed applicator as per site characteristics and environmental conditions as stated in the **Fumigation Management Plan**) carbon dioxide levels at several locations along the treatment and aeration buffer zone perimeters. During aeration, the certified/licensed applicator must also periodically monitor (i.e., according to a schedule made by the certified/licensed applicator as per site characteristics and environmental conditions as stated in the **Fumigation Management Plan**) carbon dioxide levels at several locations and environmental conditions as stated in the **Fumigation Management Plan**) carbon dioxide levels at several locations and environmental conditions as stated in the **Fumigation Management Plan**) carbon dioxide levels at several locations and environmental conditions as stated in the **Fumigation Management Plan**) carbon dioxide levels at several locations along the treatment and aeration buffer zone perimeters.

Only if necessary, should workers be present in the treatment and aeration buffer zones. All workers present in the buffer zones during the fumigation or aeration periods MUST follow the requirements, as outlined in the label – "RESPIRATORY PROTECTION REQUIREMENTS" section.

\*\*\***NOTE: An evacuation action may be necessary when carbon dioxide levels exceed 5000 ppm.** To determine carbon dioxide levels, readings may be taken using a real-time detection device or a direct reading detection device.

#### **D. NOTIFICATION**

Confirm all the appropriate local authorities (fire departments, police departments, etc.) have been notified as per label instructions, local ordinances, or instructions of the client.

Prepare written procedure ("Emergency Response Plan"), which contains explicit instructions, names, and telephone numbers so as to be able to notify local authorities if carbon dioxide levels are exceeded in an area that is outside the facility/not under the control of the facility owner and could be dangerous to bystanders and/or domestic animals.

#### **E. SEALING PROCEDURES**

- 1. Sealing must be adequate to control the pests. Care should be taken to ensure that sealing materials will remain intact until the fumigation is complete.
- 2. If the site has been fumigated before, review the previous Fumigation Management Plan for previous sealing information.
- 3. Make sure that construction/remodeling has not changed the site/structure in a manner that will affect the fumigation.
- 4. Warning placards must be placed to secure any entrance into the fumigated site and along other likely routes of approach.

#### F. APPLICATION PROCEDURES AND TREATMENT PERIOD

- 1. Plan carefully and apply the product in accordance with the label requirements.
- 2. At least two persons, a certified/licensed applicator and a person trained in accordance with the label working under the direct supervision of the certified/licensed applicator, must be present during fumigation of structures when entry into the structure for application of the fumigant is required. Appropriate respiratory protection, as outlined in the "RESPIRATORY PROTECTION REQUIREMENTS" section MUST be worn during delivery/dispensing of product, while attending to spills and leaks and while monitoring carbon dioxide levels.

Apply fumigant from the outside when and where appropriate. Large-scale fumigations may require the posting of a police officer or guard to prevent entry into the site under fumigation and the treatment and aeration buffer zones. Refer to provincial pesticide regulations.

- 3. When entering sites/structures, always follow applicable provincial legislation for confined spaces.
- 4. Document that the receiver of transport vehicles shipped piggyback by rail and/or shipping containers fumigated in-transit has been notified.
- 5. Turn off any electric lights in the fumigated site and/or structure, as well as all nonessential electrical motors.

#### G. POST-APPLICATION OPERATIONS

- 1. Large-scale fumigations may require the posting of a police officer or guard to prevent entry into the site under fumigation and the treatment and aeration buffer zones. Refer to provincial pesticide regulations.
- 2. Ventilate and aerate the fumigated site in accordance with site and/or structural limitations and nearby occupied areas in order to minimize exposure.
- 3. Turn on ventilating or aeration fans, where appropriate.
- 4. Determine carbon dioxide concentration in the fumigated environment from outside if possible. As much as possible limit exposure, for example, by using monitoring equipment that measures indoor concentrations and displays results outside of the fumigated site. Use a sufficiently sensitive gas detector before entry into a fumigated site and/or structure to determine fumigant concentration.
- 5. During aeration, monitor gas levels periodically (i.e., according to a schedule made by the certified/licensed applicator as per site characteristics and environmental conditions as stated in the **Fumigation Management Plan**) until the fumigated site and/or structure is ready for entry.
- 6. Keep written records of monitoring to document completion of aeration.
- 7. Consider temperature when aerating.
- 8. Ensure that aeration is complete before moving treated transport vehicles onto public roads.
- 9. The warning signs/placards may only be removed by the certified/licensed applicator (or someone under their supervision) only after aeration of the fumigated site is complete and the carbon dioxide level is at or below 5000 ppm in the fumigated site and the aeration buffer zone as determined by using a detection device.
- 10. Inform business/client that employees/other persons may return to work or otherwise be allowed to enter the aerated site.

#### Proposed label updates relating to the environment assessment:

Under "NOTICE TO USER":

#### Add:

"Use of carbon dioxide and management of any resulting emission, storage, transportation, and disposal must also be in accordance with any other applicable federal, provincial /territorial acts or regulations, such as the Canadian Environmental Protection Act, the Greenhouse Gas Pollution Pricing Act, the Canada Shipping Act, the Cargo, Fumigation and Tackle Regulations, etc. Consult with local regulatory authorities on any requirements for use of this product and management of any resulting emission containing this product."

#### Proposed label updates relating to the value assessment:

#### a) Under "DIRECTIONS FOR USE":

#### Replace:

#### GRAIN AND FLOUR STORAGE AREAS

- 1. Storage silos should be airtight and adequately sealed.
- 2. Purge silo to 90% CO2 atmosphere and maintain the temperature at 25 degrees C. We recommend one day (24 hours) treatment for the adult kill: 2 days (48 hours) for other stages.

**NOTE:** If silo cannot be totally sealed, and/or temperature cannot be maintained at 25 degrees C or above, longer exposure will be necessary to obtain 100% kill of all stages.

- between 20 degrees C and 25 degrees C with a minimum of 60% concentration, 4 days (96 hours) are recommended.
- between 15 degrees C and 20 degrees C with a minimum of 60% concentration, 6 days (144 hours) are recommended.
- below 15 degrees C much longer exposure time will be required.

#### Consult Linde Canada Inc.

#### FUMIGATION DIRECTIONS:

#### A. GRAIN and FLOUR STORAGE AREAS

(bins, silos, railcars, flour operations and elevators)

- For the fumigation of grain insects such as: 1) Granary weevil (Sitophilus granarius)
  - Cranary weevil (Shophilus granarius)
     Rusty grain weevil (Cryptolestes ferrugineus)
  - Red flour beetle (Tribolium castaneum)
  - 4) Confused flour beetle (Tribolium confusum)
  - 5) American black flour beetle (Tribolium audax)
  - 6) Black flour beetle (Tribolium maden)

#### With:

"For the control of the following grain and flour insects:

- 1. Granary weevil (*Sitophilus granarius*)
- 2. Rusty grain weevil (*Cryptolestes ferrugineus*)
- 3. Red flour beetle (*Tribolium castaneum*)
- 4. Confused flour beetle (*Tribolium confusum*)
- 5. American black flour beetle (*Tribolium audax*)
- 6. Black flour beetle (*Tribolium maden*)

#### FUMIGATION IN GRAIN and FLOUR STORAGE AREAS

(bins, silos, railcars, flour operations and grain elevators)

1. Storage areas should be airtight and adequately sealed.

2. Purge storage areas to 90% CO2 atmosphere and maintain the temperature at 25 degrees C. We recommend one day (24 hours) treatment for the adult kill: 2 days (48 hours) for other stages.

**NOTE:** If storage areas cannot be totally sealed, and/or temperature cannot be maintained at 25 degrees C or above, longer exposure will be necessary to obtain 100% kill of all stages.

- between 20 degrees C and 25 degrees C with a minimum of 60% concentration, 4 days (96 hours) are recommended.
- between 15 degrees C and 20 degrees C with a minimum of 60% concentration, 6 days (144 hours) are recommended.
- below 15 degrees C much longer exposure time will be required."
- b) Replace "C. AIRCRAFT FUSELAGE FUMIGATION" with "FUMIGATION IN AIRCRAFT FUSELAGE" and above this line add "For the control of rats and mice."
- c) Replace "DIRECTIONS FOR USE for the control of rodents:" with "METHOD OF APPLICATION:"

## References

#### Additional information considered

#### A. Published information

PMRA Document Number	Reference
844013	Canada, 2004. Proposed Acceptability for Continuing Registration, Re-evaluation of Carbon Dioxide. PACR2004-31. August 6, 2004.
1057742	Canada, 2005. Re-evaluation Decision Document RRD2005-10, Carbon Dioxide. July 22, 2005.
1840666	Canada, 2010. Proposed Registration Decision PRD2010-06, Liquid Carbon Dioxide: Cryonite. April 7, 2010.
2053083	Canada, 2011. Registration Decision RD2011-08, Liquid Carbon Dioxide: Cryonite. May 11, 2011.
3571080	Canada, 2024. Proposed Re-evaluation Decision PRVD2024-03, Methyl bromide and its associated end-use products.
3461582	Canada, 2021. Residential Indoor Air Quality Guidelines: Carbon Dioxide. March 2021.
715356	US EPA, 1991. Reregistration Eligibility Document (RED): Carbon and Carbon Dioxide. September 1991.
3461583	US EPA, 2008. Carbon and Carbon Dioxide Summary Document. EPA-HQ-OPP-2007-0705-0002. March 19, 2008.
3461584	US EPA, 2014. Carbon and Carbon Dioxide Proposed Interim Registration Review Decision Case Number 4019. EPA-HQ-OPP-2007-0705-0044. May 30, 2014.
3461585	US EPA, 2015. Carbon and Carbon Dioxide Interim Registration Review Decision Case Number 4019. EPA-HQ-OPP-2007-0705-0059. September 30, 2015.
3461586	European Commission 2019a. Draft Renewal Assessment Report Prepared by Rapporteur Member State France and Co-Rapporteur Member State Austria according to Regulation (EC) No 1107/2009 and Published for Public Consultation on the Active Substance Carbon Dioxide. Volume 1. February 19, 2020.
3609313	European Commission, 2019b. Draft Renewal Assessment Report prepared according to Regulation (EC) N° 1107/2009. CARBON DIOXIDE Volume 3 – B.6 (PPP) – Carbo Kohlensäure.
3609324	European Commission, 2019c. Draft Renewal Assessment Report prepared according to Regulation (EC) N° 1107/2009. CARBON DIOXIDE Volume 3 – B.8 (PPP) – ALIGAL-2.
3461587	EFSA 2021. Peer Review of the Pesticide Risk Assessment of the Active Substance Carbon Dioxide. https://doi.org/10.2903/j.efsa.2021.6605. April 30, 2021.
3461588	European Commission 2022. Final Renewal Report for the Active Substance Carbon Dioxide Finalised by the Standing Committee on Plants, Animals, Food and Feed in view of the Renewal of the Approval of Carbon Dioxide in accordance with Regulation (EC) No 1107/2009. SANTE/10824/2021 Rev 2. January 28, 2022
3609339	Germany, 2023. REGISTRATION REPORT, Part A, Risk Management Product code: CAK-10001-A1-0-GA, Product name: Organic CARBOxid Chemical active substance: Carbon dioxide, 999 g/kg. Interzonal Zonal Rapporteur Member State: Germany. NATIONAL ASSESSMENT Germany (authorisation) Applicant: CARBO Kohlensäurewerke GmbH & Co. KG Submission date: 22/07 /2021. MS finalisation date: 03/08/2023.

PMRA	Reference		
Document			
Number			
3609373	California Department of Pesticide Regulation. 2021. Pesticide Use Enforcement		
	Program Standards Compendium Volume 3, Appendix G, Commodity Fumigation		
	(https://www.cdpr.ca.gov/docs/enforce/compend/vol 3/append g.pdf, last accessed		
	on July 3 <sup>rd</sup> , 2024)		
3609390	Occupational Safety and Health Administration (OSHA). 2024. Technical data sheet		
	for "Carbon Dioxide in Workplace Atmospheres".		
	(https://www.osha.gov/sites/default/files/methods/osha-id172.pdf; accessed on June		
	30, 2024).		

# **B.** Unpublished information

PMRA Document	Reference		
Number			
3603068	Transport Canada, 2023. Response from Transport Canada on CO2 use on aircraft 2023-08-08		
3609308	EFSA, 2024. EFSA's response to a Request Number: 00011138, Subject: The requirement of a 30-meter buffer zone for fumigation using carbon dioxide. Dated 2024-03-07		
3609312	German Federal Institute for Risk Assessment (BfR), 2024. BfR's response to the requirement of a 30-meter buffer zone for fumigation using carbon dioxide. Dated 2024-03-10		