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Proposed Re-evaluation Decision

PRVD2016-16

# Acrolein

*(publié aussi en français)*

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# Overview

## What Is the Proposed Re-evaluation Decision?

After a re-evaluation of the aquatic herbicide and slimicide acrolein, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing continued registration of products containing acrolein for sale and use in Canada.

An evaluation of available scientific information found that currently registered uses of acrolein products do not pose unacceptable risks to human health or the environment when used according to the label directions. As a result of the re-evaluation, the PMRA is proposing to add one label statement to meet current labelling standards.

This proposal follows the interim risk reduction measures for acrolein published in 2011 (Re-evaluation Note REV2011-02, *Acrolein*), and further updated in 2012 (Re-evaluation Note REV2012-12, *Revised Mitigation Measures for Acrolein*). This proposal affects all end-use products containing acrolein registered in Canada. Once the final re-evaluation decision is made, registrants will be instructed on how to address any new requirements.

This Proposed Re-evaluation Decision is a consultation document<sup>1</sup> that summarizes the science evaluation for acrolein and presents the reasons for the proposed re-evaluation decision. This consultation document is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides detailed technical information on the assessment of acrolein.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (please see contact information indicated on the cover page of this document).

## What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards to protect human health and the environment. Acrolein has been re-evaluated under Re-evaluation Program 1 as per Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

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

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian re-evaluation decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

In this proposed decision, the PMRA takes into account the Canadian use pattern and issues (for example, the federal Toxic Substances Management Policy).

Based on the health and environmental risk assessments published in the 2008 RED, the USEPA concluded that acrolein was eligible for re-registration provided that risk reduction measures were adopted. The PMRA compared the American and Canadian use patterns and found the USEPA assessments described in the RED relevant to the Canadian situation.

The PMRA is aware that the USEPA opened their registration review docket for acrolein in October 2015. The USEPA assessment of acrolein is ongoing. Therefore, the status of acrolein as a pest control product in Canada may be revised.

## **What Is Acrolein?**

Acrolein is a herbicide and slimicide registered for control of vegetation in irrigation canals and control of bacteria and fungi in oilfield water injection systems. It acts by binding to organic material, subsequently degrading cellular structures by cross-linking proteins.

## **Health Considerations**

### **Can Approved Uses of Acrolein Affect Human Health?**

**Products containing acrolein are unlikely to affect human health when used according to the label directions.**

People could be exposed to acrolein by working as an applicator, or by entering areas close to treated sites. When assessing health risks, two key factors are considered: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). In the case of acrolein, a human inhalation endpoint was used to establish the dose level to assess risk.

Occupational exposure to acrolein is not of concern for workers handling acrolein for oilfield water injection systems according to the label directions. A potential risk of concern was identified for workers and bystanders when acrolein is used in irrigation canals. As a result, additional risk reduction measures were implemented to minimize exposure to workers and bystanders (REV2011-02, REV2012-12). Dietary exposure to acrolein is not expected based on its use pattern.

Currently registered labels include the required mitigation measures to minimize potential exposure to humans. No additional mitigation measures pertaining to human health exposure are proposed.

## **Environmental**

### **What Happens When Acrolein Is Introduced Into the Environment?**

**Products containing acrolein are unlikely to affect non-target organisms when used according to the label directions.**

Non-target terrestrial and aquatic organisms could be exposed to acrolein in the environment. Risks of concern to non-target organisms were identified from the use in irrigation canals. Therefore, application restrictions were implemented to minimize exposure to non-target organisms (REV2011-02, REV2012-12). No additional mitigation measures pertaining to environmental exposure are proposed.

### **Proposed Measures to Minimize Risk**

Labels of registered pesticide products currently include specific instructions for use. Directions include risk reduction measures to protect human health and the environment. As a result of the re-evaluation of acrolein, the PMRA is proposing to add one label statement to meet current labelling standards (Appendix III).

### **What Additional Scientific Information Is Required?**

There is no additional data requirement proposed under section 12 of the *Pest Control Products Act*.

### **Next Steps**

Before making a final re-evaluation decision on acrolein, the PMRA will consider all comments received from the public in response to this consultation document. A science-based approach will be applied in making a final decision on acrolein. The PMRA will then publish a Re-evaluation Decision<sup>2</sup> that will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA's response to these comments.

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<sup>2</sup> "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.



# Science Evaluation

## 1.0 Introduction

Acrolein is a herbicide and slimicide registered for control of vegetation in irrigation canals and control of bacteria and fungi in oilfield water injection systems.

## 2.0 Use Description of Acrolein

Four products containing acrolein are currently registered in Canada: one technical grade active ingredient, one commercial class product and two restricted class products.

The commercial class product is registered for the control of bacteria and fungi in oilfield water injection systems. It is applied via a closed system, by pumping the pesticide from pressurized containers into closed injection well piping systems.

The restricted class products are registered for the control of submerged and floating weeds and algae in irrigation canals. They are applied through closed system transfer from a cylinder designed to prevent applicator dermal and inhalation exposures. These products are supplied as liquids in pressurized containers with an inert nitrogen blanket above the liquid. Nitrogen is used to press the liquid chemical out of the container and directly into canals below the water's surface through sealed hoses. The applicator must use only specified application equipment built specifically for use with these restricted products. The closed system must be used and maintained in accordance with the manufacturer's written operating instructions. Handlers must wear the personal protective equipment (PPE) specified on the product labels.

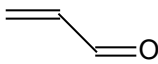
Currently registered products containing acrolein are listed in Appendix I. All current uses are being supported by the technical registrant and were, therefore, considered in the re-evaluation of acrolein.

## 3.0 The Technical Grade Active Ingredient and its Properties

### 3.1 Identity of the Technical Grade Active Ingredient

|  |                          |
|--|--------------------------|
| <b>Common name</b>   | Acrolein                 |
| <b>Function</b>  | Herbicide, Antimicrobial |
| <b>Chemical Family</b>   | Aldehyde                 |
| <b>Chemical name</b>   |                          |
| <b>1 International Union of Pure and Applied Chemistry (IUPAC)</b> | Prop-2-enal              |
| <b>2 Chemical Abstracts Service (CAS)</b>                          | 2-propenal               |



|  |   |
|--|---|
| <b>CAS Registry Number</b>                             | 107-02-8  |
| <b>Molecular Formula</b>                               | C <sub>3</sub> H <sub>4</sub> O   |
| <b>Structural Formula</b>                              |  |
| <b>Molecular Weight</b>                                | 56.1  |
| <b>Purity of the Technical Grade Active Ingredient</b> | 95%   |
| <b>Registration Number</b>                             | 11626   |

Based on the manufacturing process used, impurities of human health or environmental concern as identified in the Canada Gazette, Part II, Vol. 142, No. 13, SI/2008-67 (2008-06-25), including Toxic Substances Management Policy Track 1 substances, are not expected to be present in the product.

### 3.2 Physical and Chemical Properties of the Technical Grade Active Ingredient

| Property                              | Result                              |
|---------------------------------------|-------------------------------------|
| Vapour pressure                       | 29 kPa                              |
| UV/Visible spectrum                   | Not expected to absorb > 300 nm     |
| Solubility in water                   | 208 g/Kg                            |
| n-Octanol–Water partition coefficient | log $K_{ow}$ = 1.08                 |
| Dissociation constant                 | Not applicable, does not dissociate |

## 4.0 Human Health

Toxicology studies describe potential health effects resulting from various levels of exposure to a chemical and identify dose levels at which no effects are observed. When assessing health risks, the PMRA considers two key factors: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers).

### 4.1 Toxicology Summary

Acrolein is acutely toxic via the inhalation, oral and dermal routes. It was determined to be a potent irritant to the mucous membranes. Exposure to acrolein liquids or vapours may cause stinging of the eyes, lacrimation and reddening, ulceration or necrosis of the skin. Acrolein is also a dermal sensitizer.

Acute, chronic and incidental oral exposures to acrolein are not expected based on its use pattern and physical-chemical properties. Dermal exposure to acrolein is also not expected based on its

use pattern and on the current personal protective equipment requirements for workers. Therefore, oral and dermal endpoints were not selected.

The short-term inhalation assessment for acrolein was based on a human inhalation endpoint. Long-term exposure via inhalation is not expected for acrolein based on its use pattern and physical-chemical properties.

The potential carcinogenicity of acrolein was found to be inconclusive; however, no chronic exposure to the parent compound is expected. Glycidol, a metabolite of acrolein in fish, has been identified as a potential human carcinogen and a Q1\* value was established for glycidol residues.

Appendix II provides an overview of the toxicology endpoints selected for acrolein health risk assessments by the PMRA.

## **4.2 Occupational Exposure**

Occupational risk is estimated by comparing potential exposures with the most relevant endpoint from toxicology studies being used to calculate a margin of exposure (MOE). This is compared to a target MOE incorporating uncertainty factors protective of the most sensitive subpopulation. If the calculated MOE is greater than the target MOE, then risk mitigation is not required. If it is less than the target MOE, it does not mean that exposure will result in adverse effects, but mitigation measures to reduce risk would be required.

Workers can be exposed to acrolein during the set up and break down of equipment, as well as during and after application.

### **4.2.1 Oilfield Water Injection Systems**

When used in oilfield water injection systems, acrolein is pumped from pressurized containers into closed injection well piping systems. The closed application system, combined with stringent training and PPE requirements (full-face air-purifying respirator and butyl rubber gloves), is expected to effectively prevent exposures of concern to workers during set up and break down activities. Post-application exposure to workers is also not expected given the product use pattern.

### **4.2.2 Irrigation Canals**

Products containing acrolein for use in irrigation canals are restricted class products. They are applied through closed system transfer from a cylinder designed to prevent applicator exposure.

These products are supplied as liquids in pressurized containers with an inert nitrogen blanket above the liquid. Nitrogen is used to press the liquid chemical out of the container and directly into canals through sealed hoses.

Product application may take from 30 minutes to eight hours. The applicator must use only specified application equipment built specifically for use with these restricted class products. The closed application system, combined with stringent training, certification and PPE requirements (a full-face air-purifying respirator with organic vapor cartridges approved by the NIOSH and

butyl rubber gloves), are expected to effectively prevent exposures of concern to workers during set up and break down activities.

Respiratory protection is not required after set up and prior to break down of equipment. Dermal exposure is not expected after set up and prior to break down of equipment, since products containing acrolein are applied through a closed system, below the water surface. Post-application inhalation exposure to workers may occur from the vaporization of acrolein from the treated water. Exposure would depend on the length of time that a worker remains in the area after application has been completed.

Available air monitoring information (during and after application) indicated that levels of acrolein in the vicinity of treated canals ranged from 1.5 to 63 ppb. Using the air monitoring information, the calculated inhalation (without respirator) MOEs ranged from 1.5 to 60, indicating that exposure may exceed the level of concern. Therefore, in addition to PPE requirements during set up and break down of equipment, the PMRA implemented additional risk reduction measures to minimize use exposure (REV2011-02, REV2012-12), such as:

- Closed system and additional specifications regarding the use of such system;
- Annual training for handlers;
- During application, applicator is required to contact a member of their organization no less than every two hours during the course of the application; and
- All applications must be made during daylight hours.

#### **4.2.3 Residential Bystander Exposure**

There are no residential handler (applicator) uses for acrolein. However, residential bystander exposure can occur through the inhalation pathway if acrolein is applied in irrigation canals located near residential areas. Using air monitoring information, it was estimated that the exposure level may exceed the level of concern. Consequently, the PMRA has implemented additional risk reduction measures to minimize exposure to bystanders (REV2011-02, REV2011-12), such as:

- Applicators must post required warning signs at the site of application and around the application equipment, such as “DO NOT ENTER”, “Pesticide Application in Progress”, “NO SWIMMING”.

#### **4.3 Dietary Exposure and Risk**

##### **Acrolein**

Dietary exposures (acute and chronic) to acrolein are not expected based on its use pattern (no direct applications of acrolein to crops except through irrigation) and available data on plant metabolism. A lettuce metabolism study indicated that acrolein is readily decomposed/ incorporated into natural products, which shows that the only residue of concern is acrolein on the day of application. Risks from drinking water exposures were not assessed. While uncertainties remain regarding the potential for drinking water exposures, it is considered unlikely due to the fact that most, if not all, of any acrolein that could reach a drinking water

source from an irrigation canal would volatilize before and during the aeration stages of the drinking water treatment.

## **Glycidol**

Glycidol is a metabolite of acrolein in some fish. It was identified as a potential human carcinogen. Glycidol was not identified in plant metabolism. Using default assumptions, and the established Q1\* of  $0.16 \text{ mg}^{-1}\text{kg}^{-1}\text{day}^{-1}$ , the cancer risk for glycidol was estimated to be  $1 \times 10^{-6}$  for people who rely heavily on subsistence diets as their food source.

It is concluded that based on the use pattern and physical-chemical properties of acrolein, acute and chronic dietary (food and drinking water) exposures are not expected to be of concern and no mitigation measures are required.

### **4.4 Aggregate Risk Assessment**

Aggregate risk combines the different routes of exposure to acrolein (from food, water and residential exposures). An aggregate risk assessment for acrolein was not conducted based on no anticipated dietary (food and drinking water) exposures to residues of acrolein.

Although a dietary cancer assessment was conducted for glycidol, exposures to glycidol via drinking water, inhalation and dermal pathways are not expected considering that glycidol degrades quickly. Therefore, an aggregate risk assessment was not conducted for glycidol.

### **4.5 Cumulative Effects**

The *Pest Control Products Act* requires that the PMRA consider the cumulative exposure to pesticides with a common mechanism of toxicity. For the current re-evaluation, the PMRA did not identify information indicating that acrolein shares a common mechanism of toxicity with other pest control products. Therefore, there is no requirement for a cumulative assessment at this time.

## **5.0 Environment**

### **5.1 Environmental Fate**

Acrolein is a highly volatile chemical (vapour pressure of 29 kPa), but is very soluble in water. Acrolein is not likely to persist in the environment.

Volatilization, microbial metabolism and binding into plant material were identified as potential major routes of dissipation in an aqueous environment.

Acrolein does not undergo hydrolytic degradation in an aqueous environment, but rather goes into equilibrium with a hydration product, 3-hydroxypropanal. This equilibrium appears to be constant and independent of pH. Based on available data, acrolein appears to degrade by both aerobic and anaerobic metabolism, and the parent compound has an observed DT<sub>50</sub> of approximately one day. Aerobic and anaerobic aquatic metabolism studies suggest that this chemical does not partition into sediment to any significant extent.

Although acrolein is not expected to be persistent in the environment, in fast moving water in irrigation canals, acrolein could move considerable distances in concentrations that would remain a concern for non-target organisms.

## **5.2 Environmental Exposure and Risk Assessment**

For the restricted products, directions for use require that water treated with acrolein be used for irrigation of fields or be held for six days before released into fish bearing waters. Terrestrial organisms may be exposed to acrolein through diet (consumption of treated irrigation water), or through inhalation of volatilized acrolein. Because acrolein is not expected to be persistent, chronic exposure to acrolein is likely to be limited and environmental exposure assessments focussed primarily on acute exposure.

To assess the ecological risk of acrolein to both terrestrial and aquatic non-target plants and animals, estimated environmental concentrations (EECs) were generated based on monitoring data, as well as modelled estimates.

EECs for residues on food and feed items, used to estimate exposures to terrestrial mammals and birds feeding in fields receiving treated irrigation water, were calculated using the maximum concentration of acrolein in irrigation water (15 mg/L), and a foliar dissipation half-life of one day.

EECs from drinking water for birds and mammals were calculated with the assumption that animals drink exclusively from treated canal water and that 100% of the drinking water consumed by an animal in a day contains acrolein at a concentration of 15 mg/L.

The EECs in air were calculated using monitoring data (lower bound) and a modelled estimate (upper bound, based on maximum concentration and Henry's Law Constant value). Acrolein was measured in the air immediately surrounding a treated canal at and just downstream from the application point. Air monitoring levels in the vicinity of treated canals ranged from 1.5 to 63 ppb. An upper bound estimate of the air concentration was generated, based on a maximum treatment concentration of 15 mg a.i./L in the canal water. EECs were then used to calculate vapour inhalation doses for four species (rat, mallard duck, ring-bill gull and songbird).

Aquatic EECs were calculated using the maximum application concentration of acrolein (15 mg a.i./L) and the available monitoring data (highest measured concentration [67 µg/L] from the discharged point of an irrigation canal in Washington State following release after a two-day holding period).

Potential risks of concern were identified for non-target organisms. Therefore, the PMRA implemented additional risk reduction measures in 2011 to further protect the environment (REV2011-02), such as:

- Inclusion of a module on reducing wildlife exposures in the annual training program and in the end-use product application manual;
- Maximum of eight applications per year (minimum of two weeks between applications);
- Advisory label statements regarding acrolein's potential toxicity to non-target organisms.

An additional statement is proposed to meet current labelling standards (Appendix III).

In 2011, additional environmental data were requested (REV2012-12). However, these data requirements are now proposed to be waived as part of this re-evaluation based on the following:

- Acrolein is non-persistent in water, with a half-life of about a day.
- The products used in irrigation canals cannot be applied to waters that will flow into potential drinking water sources.
- Water in treated irrigation canals must be either used for irrigation or retained for 6 days following treatment before being released into fish bearing waters.
- Certified trained professional applicators must apply the products used in irrigation canals and are only permitted to do so after obtaining a provincial permit. The provincial permit includes specifications of measures to prevent treated water for endangering fish in natural water bodies, specifies measures to prevent release of water into dugouts used for domestic and livestock water supplies and requires applicators to notify downstream users of irrigation water and the public of the application.

## **6.0 Value**

Aquatic vegetation can be a serious pest in irrigation canals. Weeds and algae reduce water flow and can cause water level to rise, thus increasing the chance of overflow and canal breaks. Weeds collect silt and debris, necessitating periodic costly cleanouts. Current management practices involve many approaches, including physical removal with harvesters, dredging or by hand, and attempts to push the weeds from canals by increasing water flow. Acrolein is an important tool for chemical control of weeds and algae in irrigation canals, and there are no registered alternative active ingredients.

Acrolein is one of the active ingredients registered to control microorganisms and reduce slime in oilfield water recovery systems.

## **7.0 Pest Control Product Policy Considerations**

### **7.1 Toxic Substances Management Policy Considerations**

The TSMP is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy: persistent (in air, soil, water and/or sediment), bioaccumulative, primarily a result of human activity, and toxic, as defined by the Canadian Environmental Protection Act].

During re-evaluation, acrolein was assessed in accordance with the PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic*

*Substances Management Policy*, and evaluated against the Track 1 criteria. The PMRA has reached the following conclusion:

- The half-life of acrolein in water (~1 day) is below the Track 1 criterion ( $\leq 182$  days).
- The octanol-water partition coefficient of acrolein ( $\log K_{ow} = 1.08$ ) is below the Track 1 criterion ( $\log K_{ow} \geq 5$ ).
- Therefore, acrolein does not meet all TSMP Track-1 criteria, and is not considered a Track 1 substance.

## **7.2 Contaminants and Formulants of Health or Environmental Concern**

Hydroquinone is present in products containing acrolein. Hydroquinone has been included in the Canadian Government's Challenge to Industry arising out of the categorization of the Domestic Substances List, and is also identified as a List 1 formulant by the PMRA. A statement regarding the presence of hydroquinone is currently included on all product labels.

## **8.0 Canadian Environmental Protection Act**

Acrolein has been assessed by the Environment Canada and Health Canada under the *Canadian Environmental Protection Act*. Under this Act, acrolein is considered to be “toxic” for human health. It is not considered to be “toxic” for the environment.

## **9.0 Incident Reports**

Since 26 April 2007, registrants are required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. As of January 26, 2016, there was one incident report in the PMRA database. The incident occurred in the U.S. and was classified as Human Death. The exposure in this incident did not occur under normal use conditions. The exposure was accidental (due to equipment malfunction) and the applicator was not wearing appropriate protective clothing.

## **10.0 Organisation for Economic Co-operation and Development Status of Acrolein**

Canada is part of the Organisation for Economic Co-operation and Development (OECD), which groups member countries and provides a forum in which governments can work together to share experience and seek solutions to common problems.

As part of the re-evaluation of an active ingredient, the PMRA takes into consideration recent developments and new information on the status of an active ingredient in other jurisdictions, including OECD member countries. In particular, decisions by an OECD member to prohibit all uses of an active ingredient for health or environmental reasons are considered for relevance to the Canadian situation.

Acrolein is currently acceptable for use in other OECD member countries, including the United States, Australia and the European Union. As of January 14, 2016, no decision by an OECD

member country to prohibit all uses of acrolein for health or environmental reasons has been identified.

## **11.0 Proposed Re-evaluation Decision**

After a re-evaluation of the aquatic herbicide and slimicide acrolein, Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing continued registration of acrolein and associated end-use products. The labels of Canadian end-use products are proposed to be amended as per Annex III.

There is no additional data requirement proposed under section 12 of the *Pest Control Products Act*. Furthermore, it is proposed that the data requirements outlined in REV2012-12 be waived (see Section 5.2).

## **12.0 Supporting Documentation**

PMRA documents, such as Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, can be found on the Pesticides and Pest Management portion of Health Canada's website at [healthcanada.gc.ca/pmra](http://healthcanada.gc.ca/pmra). PMRA documents are also available through the Pest Management Information Service. Phone: 1-800-267-6315 within Canada or 1-613-736-3799 outside Canada (long distance charges apply); fax: 613-736-3798; e-mail: [pmra.infoserv@hc-sc.gc.ca](mailto:pmra.infoserv@hc-sc.gc.ca).

The federal TSMP is available through Environment Canada's website at [www.ec.gc.ca/toxics](http://www.ec.gc.ca/toxics).

The United States Environmental Protection Agency Reregistration Eligibility Decision document for acrolein is available at [www.regulations.gov](http://www.regulations.gov) (Docket ID: EPA-HQ-OPP-2007-0588).

The USEPA registration review document for acrolein is available at [www.regulations.gov](http://www.regulations.gov) (Docket ID: EPA-HQ-OPP-2015-0571).





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**Appendix I Registered Pest Control Products Containing Acrolein as of  
25 February 2016**

| <b>Registration Number</b> | <b>Marketing Class</b> | <b>Registrant</b>           | <b>Product Name</b>               | <b>Formulation Type</b> | <b>Guarantee (%)</b> |
|----------------------------|------------------------|-----------------------------|-----------------------------------|-------------------------|----------------------|
| 11626                      | Technical              | Baker Petrolite Corporation | Magnacide B Microbicide Technical | Solution                | 95                   |
| 10948                      | Restricted             | Baker Petrolite Corporation | Magnacide H Herbicide             | Solution                | 95                   |
| 27928                      | Commercial             | Baker Petrolite Corporation | Magnacide B Microbicide           | Solution                | 95                   |
| 31001                      | Restricted             | Alligare, LLC               | Alligare Magnacide                | Solution                | 95                   |



## Appendix II Toxicological Endpoints Selected for Acrolein Health Risk Assessments

| Exposure Scenario                                  | Dose (mg/kg bw/day)   | Study  | UF/SF or target MOE  |
|--|---|--|--|
| <b>Acute and Chronic Dietary</b> (all populations) | Acute and chronic oral (dietary and drinking water) exposures are not expected based on the use pattern, physical-chemical properties, and plant metabolism data. Therefore, RfDs are not required and were not selected.   |  |  |
| <b>Incidental Oral</b> (all durations)             | There are no residential uses for acrolein. Therefore, incidental oral exposure endpoints are not required and were not selected for this assessment.   |  |  |
| <b>Dermal</b> (all durations)                      | Worker dermal exposures are not expected based on the use pattern and PPE requirements. There are no residential uses for acrolein. Dermal exposures to residential bystanders are not expected based on the use pattern and physical-chemical properties. Therefore, dermal exposure endpoints are not required and were not selected.   |  |  |
| <b>Short-Term Inhalation</b> (1 – 30 days)         | LOAEL=0.09 ppm (eye irritation)<br><br>LOAEL=0.3 ppm (nasal and throat irritation)  | Human volunteers exposed by inhalation for 60 minutes based on a minimal effect LOAEL of 0.09 ppm for eye irritation. The LOAEL of 0.3 ppm for nasal and throat irritation and decreased respiratory rate is also considered for endpoint selection. | Residential: target MOE = 30<br>Occupational: target MOE = 30<br><br>Eye irritation:<br>UF = 10× (for intraspecies)<br>3x for the lack of a NOAEL<br><br>Nasal and throat irritation:<br>UF = 10×<br>10× for the lack of a NOAEL |
| <b>Cancer</b> (oral, dermal and inhalation)        | The potential carcinogenicity of acrolein is inconclusive; however, exposure to parent acrolein is not expected based on the use pattern.<br><br>Glycidol is a metabolite of acrolein in fish.<br>To quantify the carcinogenic response of glycidol, a multistage model BMD analysis was performed to derive a cancer slope factor of $0.16 \text{ mg}^{-1}\text{kg}^{-1}\text{day}^{-1}$ . |  |  |

|              |   |
|--------------|---|
| UF/SF        | total of uncertainty and/or uncertainty factors for dietary assessments |
| MOE          | desired margin of exposure for occupational or residential assessments  |
| mg/kg bw/day | dose in milligrams per kilogram of bodyweight per day                   |
| RfDs         | reference dose  |
| LOAEL        | lowest observable adverse effect level                                  |
| ppm          | parts per million   |
| NOAEL        | no observable adverse effect level                                      |
| BMD          | Benchmark dose  |



## **Appendix III      Proposed Label Amendment for Products Containing Acrolein**

Appendix III does not include all label requirements for individual end-use products, 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.

### **For Products Used in Irrigation Canals:**

The following statement is proposed to be added under **NOTICE TO USER:**

“The uses of [*Product name*] may be subject to other legislative requirements such as those under the Fisheries Act.”



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## References

### Studies Considered in the Chemistry Assessment

#### LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

| <b>PMRA Document Number</b> | <b>Reference</b>  |
|-----------------------------|---|
| 1179073                     | 1988, Chemical and Physical Properties - Color, Physical State, Odor, Boiling Point, Density/Specific Gravity, Explodability, Corrosion Characteristics, PH, MRID: 40840601, DACO: 2.14.1, 2.14.13, 2.14.2, 2.14.3, 2.14.5, 2.14.6,2.16 CBI |
| 1334281                     | 2006, DACO: 0.1.6003  |
| 1179074                     | 1988, Water Solubility of Acrolein, EM -040-UKA001-1; 88-0300; UKA001, DACO: 2.14.12 CBI  |
| 1260478                     | Chemical and Physical Properties, DACO: 2.14.10, 2.14.12, 2.14.4 CBI  |
| 1260480                     | Exhibit B - Acrolein Process Description, DACO: 2.11.1, 2.11.3 CBI  |
| 1260479                     | Exhibit C - Description of Starting Materials. Material Safety Data Sheets, DACO: 0.9.1, 2.11.2 CBI   |
| 1260481                     | 2003, Exhibit E - Methodology/Validation. Determination of Acrolein and Its Impurities in Five Samples of Acrolein from Baker Petrolite's Acrolein Plant, GLP-0074, DACO: 2.11.4, 2.13.1, 2.13.3 CBI  |

### Studies Considered in the Health and Environmental Risk Assessments

#### ADDITIONAL INFORMATION CONSIDERED

##### Published Information

| <b>PMRA Document Number</b> | <b>Reference</b>   |
|-----------------------------|--|
| 2022903                     | Canada 2011, Re-evaluation Note, Acrolein. REV2011-02                      |
| 2224449<br>REV2012-12       | Canada 2012, Re-evaluation Note, Revised Mitigation Measures for Acrolein. |