



# Proposed Acceptability for Continuing Registration

**PACR2004-20**

## **Re-evaluation of Sodium Monofluoroacetate**

The purpose of this document is to inform registrants, pesticide regulatory officials and the Canadian public that the Pest Management Regulatory Agency (PMRA) has completed a re-evaluation of sodium monofluoroacetate. The PMRA has determined that sodium monofluoroacetate is acceptable for continued registration.

This Proposed Acceptability for Continuing Registration (PACR) document provides a rationale for the proposed regulatory decision for sodium monofluoroacetate. 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 the Publications Coordinator at the address below.

*(publié aussi en français)*

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## 1.0 Background

The PMRA is re-evaluating all pesticides, both active ingredients and formulated end-use products, that were registered prior to 31 December 1994 to ensure that their continued acceptability is examined using current scientific approaches. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the re-evaluation activities and program structure.

Sodium monofluoroacetate has been re-evaluated by the PMRA under Re-evaluation Program 1 as described in DIR2001-03. In Program 1, the PMRA relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents, to assess Canadian pest control products. For products to be re-evaluated under Program 1, there must exist a suitable USEPA review that meets the following conditions:

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

Based on the outcome of the USEPA review, the PMRA will propose, under Program 1, a regulatory decision and appropriate mitigation measures for Canadian uses of an active ingredient.

The USEPA conducted a re-evaluation of sodium monofluoroacetate and concluded, on the basis of a health and environmental risk assessment, that it was eligible for reregistration with implementation of mitigation measures. These conclusions were published in a 1995 RED<sup>1</sup> document for sodium monofluoroacetate. In its re-evaluation of sodium monofluoroacetate, the PMRA based its conclusions on this 1995 RED document, taking into account the Canadian use pattern and Canadian issues (e.g., the federal Toxic Substances Management Policy [TSMP]). A review of the chemistry of Canadian products was also conducted.

## 2.0 Re-evaluation of sodium monofluoroacetate

Sodium monofluoroacetate was first registered in 1984. It is a predicide for wolves and coyotes and is formulated as a solution inside livestock protection collars or as tablets. As

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<sup>1</sup> The USEPA RED document for sodium monofluoroacetate (EPA 738-R-95-025, September 1995) is available from the Chemical Status List on the Office of Pesticide Programs webpage at [www.epa.gov/pesticides/reregistration](http://www.epa.gov/pesticides/reregistration)

of 31 December 2003, there are three end-use products registered in Canada; these are listed in Appendix I.

## 2.1 Chemical identification

Active substance: Sodium fluoroacetate

Common name: Sodium monofluoroacetate or compound 1080

Chemical names:

IUPAC: Sodium fluoroacetate

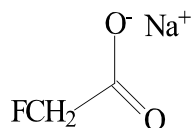
CAS: Fluoroacetic acid, sodium salt

CAS number: 62-74-8

Molecular formula:  $C_2H_2FNaO_2$

Molecular weight: 100.02

Structural formula:



## 2.2 Description of uses

In Canada, sodium monofluoroacetate has a restricted use status as an animal toxicant for vertebrate pest control. It is registered for use in the provinces of Alberta and Saskatchewan for coyote and wolf control. It is formulated as a solution inside livestock protection collars or as tablets.

Collars are attached to goats and sheep. When a predator attacks livestock wearing a collar, the collar is punctured and the predator is killed by ingesting the liquid. Toxic collars can only be transported and used by provincial government staff in the province of Alberta.

Tablets are placed in small drop baits (usually meat, viscera or chicken heads) and buried beneath snow, leaves, or soil in order to minimize non-target exposure. They are used by trained personnel from the Saskatchewan or Alberta provincial government. Single dose or multi-dose baits can be used for coyotes and small or large bait can be used for wolves. The landholder must approve its use and the tablets must be used at a distance of 400 m from a residence (except that of the landholder) as well as at least 800 m from the town boundary. Warning signs must be posted at all normal entry points to the land where

sodium monofluoroacetate is in use. Baits must be regularly inspected, at least every seven days. Complete records for the use of the product must be maintained. The baits must be stored under lock and key. The baits must be removed and destroyed within 15–90 days of initial placement, which is dependent upon the time of the year when livestock predation is occurring.

## **2.3 Effects having relevance to human health**

Although only collar uses of sodium monofluoroacetate are registered in the United States, the human health assessment described in the USEPA RED for sodium monofluoroacetate was considered to be an adequate basis for the proposed Canadian re-evaluation decision.

Based on the USEPA RED conclusions, the primary health concern with any formulation of sodium monofluoroacetate is its acute toxicity to humans. The risk of acute toxicity to applicators is adequately mitigated by the use of gloves during application and the current restriction that it is to be used by trained and certified personnel only. Based on the above label restrictions, bystander exposure is expected to be minimal. There are no food/feed uses for sodium monofluoroacetate. Dietary exposure through food or drinking water is expected to be minimal.

## **2.4 Environmental assessment**

This review is based on data from USEPA RED for sodium fluoroacetate. In characterizing the environmental risk of sodium monofluoroacetate, the PMRA utilized a deterministic approach that characterizes the risk by quotient method, in which a risk quotient (RQ) is calculated as the ratio of the estimated environmental concentration (EEC) to the effects endpoint of concern. RQs less than one are considered as a low risk to non-target organisms, whereas RQs greater than one indicate some degree of risk.

In the assessment, EECs for aquatic and terrestrial ecosystems were based on label rates and one application/season. Toxicity endpoints (acute and/or chronic) were chosen for the most sensitive species and used as surrogates for the range of species that can potentially be exposed following treatment with rodenticides.

### **2.4.1 Environmental fate**

The limited available data suggest that transformation by biologically mediated processes is the major route of dissipation. Non-validated data suggest that sodium monofluoroacetate does not transform substantially in sterile soil for 27 days.

Sodium monofluoroacetate is very soluble in water. Based on solubility in water, untransformed monofluoroacetate may tend to leach. However, the potential for leaching may be reduced in some soils by adsorption to organic matter and clay particles and absorption by plants.

Based on published articles, the stability of sodium monofluoroacetate in water and saline solutions was determined for a period of approximately 6 months. An immediate loss of fluorine was detected in both water and saline solutions. A progressive loss of fluorine was reported in the water after the initial loss.

#### **2.4.2 Environmental toxicology<sup>2</sup>**

Sodium monofluoroacetate is highly to very highly toxic to avian species on an acute oral basis ( $LD_{50} = 1.0\text{--}15$  mg a.i./kg) and highly toxic ( $LC_{50} = 230\text{--}486$  mg a.i./kg diet) to avian species on a dietary basis. It is also highly to very highly toxic ( $LD_{50} = 0.1\text{--}41.6$  mg a.i./kg) to mammals on an acute basis. It may also be a cause of secondary toxicity to predator/scavenger birds and mammals.

Sodium monofluoroacetate is practically non-toxic to aquatic invertebrates ( $EC_{50} = 350$  mg a.i./L) and slightly to practically non-toxic to fish ( $LC_{50} = 54\text{--}970$  mg a.i./L).

#### **2.4.3 Terrestrial assessment**

The results of this screening assessment identified various levels of risk to non-target terrestrial organisms exposed to sodium monofluoroacetate.

The potential for exposure of avian and mammalian scavengers to food baits exists primarily from unprotected bait. As the acute toxicity of sodium monofluoroacetate is very high to birds and mammals, there is a high risk for these animals when they are exposed to unprotected bait. However, the primary method for delivering sodium monofluoroacetate in Canada is in small baits, which are buried, and therefore may not be accessible to avian scavengers.

There is also the potential of a secondary hazard coming from carcasses and vomitus (the chemical has emetic properties) of poisoned target animals. The data suggest that the secondary hazard to animals that may feed on a contaminated coyote carcass is ordinarily not substantial. However, it is possible that carcasses will occasionally contain enough sodium monofluoroacetate to kill a scavenger.

#### **2.4.4 Aquatic assessment**

Based on the low toxicity of sodium monofluoroacetate to aquatic organisms and a use pattern with low potential for exposure, the risk to the aquatic environment would be minimal.

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<sup>2</sup> a.i. (active ingredient);  $LD_{50}$  (lethal dose 50%);  $LC_{50}$  (lethal concentration 50%);  $EC_{50}$  (effective concentration 50%); kg (kilogram); mg (milligram); L (litre)

## 2.4.5 Environmental assessment conclusions

The potential for exposure of avian and mammalian scavengers to food baits exists primarily from unprotected bait. As the acute toxicity of sodium monofluoroacetate is very high to birds and mammals, there is a high risk for these animals when they are exposed to unprotected bait. However, the product is restricted for use by certain authorized personnel of the provinces of Alberta and Saskatchewan. Thus, the use pattern indicates that the exposure to non-target birds and mammals would be minimal.

## 2.5 Other assessment considerations

The federal TSMP<sup>3</sup> and Regulatory Directive DIR99-03<sup>4</sup> were taken into consideration during the PMRA re-evaluation of sodium monofluoroacetate. However, due to the lack of data, it is not possible to determine if sodium monofluoroacetate or its transformation products do or do not meet the TSMP Track 1 criteria.

## 3.0 Proposed re-evaluation decision

Based on the USEPA RED and in consideration of the Canadian use pattern, the PMRA has determined that sodium monofluoroacetate is acceptable for continued registration. Additional data requirements are outlined in Section 4.0.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document to allow interested parties an opportunity to provide input into the proposed re-evaluation decision for these products.

## 4.0 Data requirements

A request to register a technical source for each end-use product is required.

Additional data may be required if the expansion of current uses of sodium monofluoroacetate is requested.

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<sup>3</sup> The federal Toxic Substances Management Policy is available through Environment Canada's website at [www.ec.gc.ca/toxics](http://www.ec.gc.ca/toxics)

<sup>4</sup> *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, DIR99-03, is available through the Pest Management Information Service. Phone: 1 800 267-6315 within Canada or (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); or through our website at [www.hc-sc.gc.ca/pmra-arla/](http://www.hc-sc.gc.ca/pmra-arla/)

**Appendix I Currently registered sodium monofluoroacetate products in  
Canada (as of 31 December 2003)**

<b>Product name</b>	<b>Formulation type</b>	<b>Class</b>	<b>Guarantee</b>	<b>Registrant</b>	<b>Registration number</b>
Sodium Monofluoroacetate Predacide	Tablet	Restricted	5 mg a.i. per tablet	Alberta Department of Agriculture Food and Rural Development	18300
Sodium Monofluoroacetate Predacide (compound 1080)	Tablet	Restricted	0.45% 5 mg a.i. per tablet	Fish and Wildlife Branch, Saskatchewan Environment and Resource Management	25857
Sodium Monofluoroacetate Restricted Toxic Collar	Liquid filled collar	Restricted	10 mg/ml solution	Alberta Department of Agriculture Food and Rural Development	24512