



Proposed Acceptability for Continuing Registration

PACR2003-11

Re-evaluation of Hydramethylnon

The purpose of this document is to inform the registrant, pesticide regulatory officials and the Canadian public that the Pest Management Regulatory Agency (PMRA) has completed a re-evaluation of hydramethylnon. The PMRA has determined that hydramethylnon is acceptable for continued registration provided that the proposed mitigation measures are adopted and the data requirements are addressed.

This Proposed Acceptability for Continuing Registration (PACR) provides a rationale for the proposed regulatory decision for hydramethylnon. 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.

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1.0 General background on re-evaluation

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

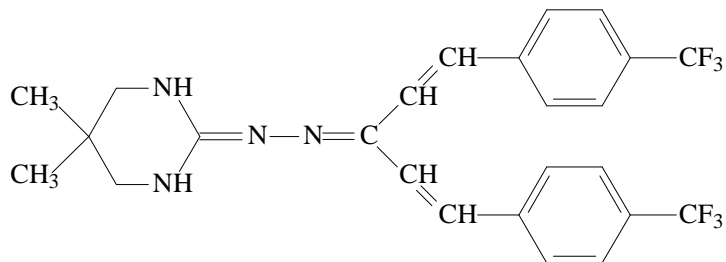
Hydramethylnon has been re-evaluated by the PMRA under Re-evaluation Program 1 as described in DIR2001-03. In Program 1, the PMRA relies as much as possible on foreign reviews to assess Canadian pest control products. For products to be re-evaluated under Program 1, there must exist a suitable foreign review which covers the main science areas that are necessary for Canadian regulatory decisions, which addresses the active ingredient itself and its main formulation types registered in Canada and which is relevant to registered Canadian uses. Based on the outcome of the foreign review, the PMRA will propose, under Program 1, appropriate mitigation measures for Canadian uses of an active ingredient. Program 1 assessments will be used as a starting point for planning and prioritizing future re-evaluation activities for these active ingredients.

The United States Environmental Protection Agency (USEPA) conducted a re-evaluation of the safety of hydramethylnon by examining related health and environmental effects, and recommending measures to mitigate identified risks. PMRA conclusions on the hydramethylnon re-evaluation were based on the Re-registration Eligibility Decision (RED) document (USEPA 1998) for hydramethylnon, with consideration of the Canadian use pattern and Canadian-specific issues (e.g., the Canadian Toxic Substance Management Policy). A review of the chemistry of Canadian products was conducted.

2.0 Re-evaluation of Hydramethylnon

Common name:	Hydramethylnon
Chemical Name: (IUPAC):	5,5-dimethylperhydropyrimidin-2-one 4-trifluoromethyl- α -(4-trifluoromethylstyryl)cinnamylidenehydrazone
(CAS):	Tetrahydro-5,5-dimethyl-2(1H)-pyrimidinone[3-[4-(trifluoromethyl)phenyl]-1-[2-[4-trifluoromethyl)phenyl]ethenyl]-2-propenylidene]hydrazone
CAS Registry Number:	67485-29-4

Structural Formula:



Purity of active: 95.0% (minimum), Registration number 19525

Hydramethylnon was first registered in 1986. Hydramethylnon is an insecticide used to kill cockroaches or ants and acts as a gradual metabolic toxicant that inhibits the formation of ATP. The currently registered technical active ingredient and end-use products containing hydramethylnon in Canada are described in Appendix I.

Canadian registered use sites, application rates, application methods and formulation types are also registered in the U.S.; and the USEPA assessment described in the Re-registration Eligibility Decision (RED)¹ document for hydramethylnon is considered to be an adequate basis for the proposed Canadian re-evaluation decision. The details of the health and environmental risk assessments conducted by the USEPA are outlined in the USEPA RED¹ for hydramethylnon.

The Federal Toxic Substances Management Policy (TSMP)² and Regulatory Directive DIR99-03³ were taken into consideration during the review of hydramethylnon and hydramethylnon is not a TSMP Track-1 substance. The technical product may contain hydrazine, an impurity of toxicological concern as identified in DIR98-04, *Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient or an Integrated System Product*. The technical product is not expected to contain other impurities of toxicological concern or TSMP Track-I substances as identified in DIR99-03 Appendix II.

¹ The USEPA Re-registration Eligibility Decision (RED) document for hydramethylnon is available from the Chemical Status List on the Office Of Pesticide Programs Web page at www.epa.gov/pesticides/reregistration.

² The federal Toxic Substances Management Policy is available through Environment Canada's Web site at: www.ec.gc.ca/toxics.

³ The PMRA'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 1-613-736-3799 outside Canada (long distance charges apply); Fax (613) 736-3798; E-Mail pmra_infoserv@hc-sc.gc.ca or through our Web site at www.hc-sc.gc.ca/pmra-arla.

3.0 Proposed re-evaluation decision

A Re-registration Eligibility Decision (RED) document, addressing the main science areas that are necessary for Canadian regulatory decisions, i.e., human health and the environment, was published for hydramethylnon by the USEPA. This document addressed uses of hydramethylnon that are also registered in Canada. Based on the review of the USEPA RED, and in consideration of the Canadian use pattern, the PMRA has determined that hydramethylnon is acceptable for continued registration provided that the mitigation measures specified below are adopted for Canada and the data requirements outlined in this document are addressed. Acceptable domestic uses of hydramethylnon in Canada are listed in Appendix II and acceptable commercial uses are listed in Appendix III.

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 Proposed regulatory action

For all hydramethylnon end-use products, labels must be modified to include the following statements to protect workers, children and pets (refer to Appendix II and Appendix III for more detailed information regarding use standards):

- All end-use products that are of a gel formulation must include the statement:

“WEAR CHEMICAL-RESISTANT GLOVES DURING APPLICATION”.
- Under DIRECTIONS FOR USE on the box panels, the following statement must appear on the label of all hydramethylnon bait station end-use products:

“Caution should be taken to ensure bait stations are not placed in such a manner that they could be dislodged into sensitive areas i.e., food processing equipment, packaging, aquaria, pet cages and areas frequented by small children”.
- Under PRECAUTIONS on the box panels, the following statement must appear on the label of all hydramethylnon bait station end-use products:

“PLACE BAIT STATIONS IN AREAS NOT ACCESSIBLE TO CHILDREN AND PETS”.

5.0 Additional data requirements

The registrant of technical hydramethylnon is required to submit the following within 90 days of finalization of the re-evaluation decision:

- chemistry data to revise the guarantee for the technical active ingredient to a nominal value;
- all data (as it relates to Canadian use pattern) submitted to the USEPA in response to the U.S. data call-in prior to the U.S. re-registration, USEPA Data Evaluation Reports (DERs), and all data (as it relates to Canadian use pattern) which was required by the USEPA as a condition of re-registration of hydramethylnon.

The registrant of technical hydramethylnon is also required to address any additional Canadian-specific data requirements. These consist of all data outlined in the PMRA's data code (DACO)⁴ tables for use-site category #20 which are not addressed through submission of the data outlined above. The relevant sections of the DACO tables which registrants are required to address are:

USC#20, Structural—TGAI: DACOs 2 through 9, inclusive
USC#20, Structural—EP: DACOs 5 through 9, inclusive

Registrants of technical active ingredients are required to address the Canadian-specific requirements by the next round of re-evaluation. Registrants are required to inform the PMRA of their commitment to address these Canadian-specific requirements.

Additional data may be required if expansion of current uses of hydramethylnon is requested.

⁴ Use-site category DACO tables can be located at the PMRA Web site, <http://www.hc-sc.gc.ca/pmra-arla/>

Appendix I Canadian hydramethylnon products currently registered

Product Name	Class	Guarantee	Registrant	Registration Number
Hydramethylnon Technical Insecticide	Technical	950 g/kg	BASF Canada Inc.	19525
Impact Roach Killing System	Domestic	1.65%	The Clorox Company of Canada Ltd.	19816
Impact Ant Killing System	Domestic	0.9%	The Clorox Company of Canada Ltd.	21274
Combat Roach Killing System	Domestic	1.65%	The Clorox Company of Canada Ltd.	26519
Combat Ant Killing System	Domestic	0.9%	The Clorox Company of Canada Ltd.	26467
Maxforce™ Roach Control System	Commercial	1.65%	Bayer CropScience Inc.	19526
Maxforce® Ant Control System	Commercial	0.9%	Bayer CropScience Inc.	22839
Maxforce® Roach Killer Bait Gel™	Commercial	2.15%	Bayer CropScience Inc.	24239
Maxforce® Roach Killer Bait Gel™	Commercial	2.15%	Bayer CropScience Inc.	24240

Appendix II Use standard for domestic class products containing hydramethylnon

(NOTE: The information in this appendix summarizes the acceptable uses, limitations and precautions for domestic class products containing hydramethylnon, but does not identify all label requirements for such products. Registrants are referred to the PMRA Registration Handbook for further guidance on label requirements for pest control products.)

COMMON NAME: Hydramethylnon

CHEMICAL NAME: 5,5-dimethylperhydropyrimidin-2-one 4-trifluoromethyl- α -(4-trifluoromethylstyryl)cinnamylidenehydrazone

FORMULATION TYPE: SO solid

SITE CATEGORIES: Structural 20

GENERAL LIMITATIONS:

Box panels

Keep out of reach of children.

Place bait stations in areas not accessible to children and pets.

Avoid contamination of food and feed.

Do not place directly over food, utensils, dishes or food preparation surfaces.

Do not remove bait from stations.

May be harmful if swallowed.

Individual package label

Keep out of reach of children.

Place bait stations in areas not accessible to children and pets.

DIRECTIONS FOR USE:

SITES AND PESTS	RATES (AS ACTIVE) AND DIRECTIONS
For use in residential establishments.	
Cockroaches	<ul style="list-style-type: none"> -Use all 12 bait stations. -Use 12 bait stations per 20 m² (200 ft²) of surface area to be treated. Include shelf surfaces when calculating surface area. -Do not remove or puncture labels on bait stations. -Place bait stations wherever you have seen cockroaches. Then place additional bait stations approx. 0.5 metres away. Put remaining bait stations in probable cockroach hiding places. -Caution should be taken to ensure bait stations are not placed in such a manner that they could be dislodged into sensitive areas i.e., food processing equipment, packaging, aquaria, pet cages and areas frequented by small children.
Ants	<ul style="list-style-type: none"> -Use all 3 bait stations. -Do not remove or puncture labels on bait stations. -Place bait stations near trails or where you frequently see ants. Place additional bait anywhere ants may enter your home. -Replace all three bait stations every three months if needed to keep ants under control. -Caution should be taken to ensure bait stations are not placed in such a manner that they could be dislodged into sensitive areas i.e., food processing equipment, packaging, aquaria, pet cages and areas frequented by small children.

Appendix III Use standard for commercial class products containing hydramethylnon

(NOTE: The information in this appendix summarizes the acceptable uses, limitations and precautions for domestic class products containing hydramethylnon, but does not identify all label requirements for such products. Registrants are referred to the PMRA Registration Handbook for further guidance on label requirements for pest control products.)

COMMON NAME: Hydramethylnon

CHEMICAL NAME: 5,5-dimethylperhydropyrimidin-2-one 4-trifluoromethyl- α -(4-trifluoromethylstyryl)cinnamylidenehydrazone

FORMULATION TYPE: SO solid (i.e., bait station)
PA paste (i.e., gel)

SITE CATEGORIES: Structural 20

Bait stations (i.e., solid formulation)

GENERAL LIMITATIONS:

Box panels

Keep out of reach of children.

Place bait stations in areas not accessible to children and pets.

Avoid contamination of food and feed.

Do not remove bait from stations.

May be harmful if swallowed.

Individual package label

Keep out of reach of children.

Place bait stations in areas not accessible to children and pets.

Gel (i.e., paste formulation)

GENERAL LIMITATIONS:

Keep out of reach of children.

Avoid contact with skin, eyes and clothing.

Keep exposed gel away from open foods, food contact surfaces, children and pets.

Do not remove bait from applicator.

May be harmful if swallowed.

PROTECTIVE CLOTHING AND EQUIPMENT:
Wear chemical-resistant gloves during application.

DIRECTIONS FOR USE:

SITES AND PESTS	RATES (AS ACTIVE) AND DIRECTIONS
<p>For use in residential, institutional and commercial establishments</p>	<p>PA formulation: Applications of this product, other than as a crack and crevice treatment, are not permitted.</p>
<p>Cockroaches</p>	<p>SO formulation (i.e., bait station): -Place bait stations in areas not accessible to children, where cockroaches typically harbour. -Never put the bait stations in broad, open areas. -Use 4 to 6 bait stations per 10 m² of surface area including shelf surfaces. -Record number and locations of bait stations. -Replace all bait stations every 2 or 3 months to maintain control. In severe infestations the bait stations should be checked after the first month and replaced as required. -Caution should be taken to ensure bait stations are not placed in such a manner that they could be dislodged into sensitive areas i.e., food processing equipment, packaging, aquaria, pet cages and areas frequented by small children.</p> <p>PA formulation (i.e., bait gel): -Applications of this product, other than as a crack and crevice treatment, are not permitted. -Use bait gel only in areas not accessible to children or pets. -Wear chemical-resistant gloves during application. -Keep exposed gel away from open food and food contact surfaces. -Bait should be applied in cracks and crevices in homes, in NON-FOOD AREAS of restaurants and other food and feed handling establishments. -Reapply when bait is no longer visibly present, according to the remaining level of infestation. -Caution should be taken to ensure bait stations are not placed in such a manner that they could be dislodged into sensitive areas i.e., food processing equipment, packaging, aquaria, pet cages and areas frequented by small children.</p>

SITES AND PESTS	RATES (AS ACTIVE) AND DIRECTIONS
Ants	<p>SO formulation (i.e., bait station):</p> <ul style="list-style-type: none">-Place each bait station indoors immediately next to ant trails or close to areas where ants are numerous.-For normal infestations, you should use 3 bait stations in an average sized room. For heavier infestations, you will need additional bait stations in each room.-Replace all bait stations every 3 months for continuous control of ants.-Caution should be taken to ensure bait stations are not placed in such a manner that they could be dislodged into sensitive areas i.e., food processing equipment, packaging, aquaria, pet cages and areas frequented by small children.

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Ants	<p>SO formulation (i.e., bait station):</p> <ul style="list-style-type: none">-Place each bait station indoors immediately next to ant trails or close to areas where ants are numerous.-For normal infestations, you should use 3 bait stations in an average sized room. For heavier infestations, you will need additional bait stations in each room.-Replace all bait stations every 3 months for continuous control of ants.-Caution should be taken to ensure bait stations are not placed in such a manner that they could be dislodged into sensitive areas i.e., food processing equipment, packaging, aquaria, pet cages and areas frequented by small children.