Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Proposed Acceptability for Continuing Registration

PACR2005-11

Re-evaluation of 6-Benzylaminopurine

The purpose of this document is to inform registrants, pesticide regulatory officials and the Canadian public that Health Canada's Pest Management Regulatory Agency (PMRA) has re-evaluated 6-benzylaminopurine. The PMRA has determined that 6-benzylaminopurine is acceptable for continued registration with the implementation of additional mitigation measures to further protect workers and the environment. Registrants will be required to submit specified confirmatory data. Upon finalization of the re-evaluation decision, the PMRA will provide registrants of products containing 6-benzylaminopurine with specific direction on how to address these measures and requirements.

This Proposed Acceptability for Continuing Registration (PACR) document provides a rationale for the proposed regulatory decision for 6-benzylaminopurine. 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 at the address below.

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1.0 Background

Health Canada's Pest Management Regulatory Agency (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 details of the re-evaluation activities and program structure.

6-Benzylaminopurine has been re-evaluated by the PMRA under Re-evaluation Program 1 as described in DIR2001-03. Under 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 foreign 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 foreign reviews, 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 6-benzylaminopurine and concluded that, on the basis of health and environmental risk assessments, it was eligible for reregistration with implementation of mitigation measures. These conclusions were published in a 1994 RED document for 6-benzylaminopurine. The USEPA also published a risk assessment to support an exemption from the requirement of tolerances for 6-benzylaminopurine in the Federal Register in 2004. In its re-evaluation of 6-benzylaminopurine, the PMRA based its conclusions on this 1994 RED document and on the 2004 Federal Register, 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 6-Benzylaminopurine

Active substance:	6-Benzylaminopurine
Other names:	6-Benzyladenin, N6-benzyladenine
Chemical name:	N-(phenylmethyl)-1H-purine-6-amine
CAS number:	1214-39-7

In Canada, 6-benzylaminopurine was first registered in 1980. According to current end-use product labels, it is registered in Canada for use as a commercial plant growth regulator on lilies and apples. Currently registered Canadian products containing 6-benzylaminopurine are listed in Appendix I.

Based on the comparison of American and Canadian use patterns, the USEPA assessments described in the RED document for 6-benzylaminopurine and in the 2004 Federal Register are considered to be an adequate basis for the proposed Canadian re-evaluation decision. The details of the assessments conducted by the USEPA are presented in these two documents.

The federal TSMP and Regulatory Directive DIR99-03 were taken into consideration during the review of 6-benzylaminopurine, and it was concluded that 6-benzylaminopurine is not a candidate for Track 1 classification. The technical product is not expected to contain impurities of toxicological concern as identified in Regulatory Directive DIR98-04 or TSMP Track 1 substances as identified in Appendix II of DIR99-03.

3.0 Proposed Re-evaluation Decision

The USEPA published a RED document for 6-benzylaminopurine in 1994 and a risk assessment in support of their proposal to exempt 6-benzylaminopurine from the requirement of tolerances in the 2004 Federal Register. These documents addressed the main science areas that are necessary for Canadian regulatory decisions for 6-benzylaminopurine and addressed uses that are also registered in Canada. The PMRA has determined that 6-benzylaminopurine is acceptable for continued registration with the implementation of the mitigation measures specified in Section 4.0 of this PACR. Registrants will be required to submit the confirmatory data identified in Section 5.0.

All Canadian end-use products are formulated with gibberellin A_4A_7 (GIB), which is currently under re-evaluation. Consequently, 6-benzylaminopurine end-use products will be acceptable for continued registration when the re-evaluation of GIB is also complete. The registrant must implement the most conservative actions resulting from the respective re-evaluation reviews.

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. Registrants of products containing 6-benzylaminopurine should not apply for label amendments or submit the additional data as described in Section 5.0 during this comment period; they will be informed by letter of the specific instructions for addressing label changes and data requirements once the re-evaluation decision has been finalized.

4.0 Proposed Regulatory Actions

Canadian end-use product labels should be amended to include the following statements to further protect workers and the environment.

- A "**PRECAUTIONS**" section must appear on all end-use product labels and must include the following statements:
    - "Wear long pants, a long-sleeved shirt, shoes plus socks, chemical-resistant gloves and goggles or a face shield during mixing, loading, application, clean-up and repair activities."

      The registrant has the option of submitting specific information on the end-use product to support a reduction of the recommended personal protective equipment.
    - "Do not re-enter or allow re-entry into treated areas until 12 hours after application."
- An "**ENVIRONMENTAL HAZARD**" section must appear on all end-use product labels and must include the following statement:
    - "Do not apply directly to aquatic habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs or wetlands) and estuarine/marine habitats. Do not contaminate the above aquatic habitats when cleaning and rinsing spray equipment or containers."
- A "**DIRECTIONS FOR USE**" section must appear on all end-use product labels and must include the following:
    - "Airblast application: Do not direct spray above plants to be treated. Turn off outward pointing nozzles at row ends and outer rows. Do not apply when wind speed is greater than 16 km/h at the application site as measured outside of the treatment area on the upwind side."
    - "Do not apply by air."
    - In the directions for use on apples,
      "Observe a minimum interval to harvest of 28 days after treatment."
    - In the directions for use on lilies, information must indicate whether use on lilies is in greenhouse and/or outdoor.

A submission to request label revisions will be required within 90 days of finalization of the re-evaluation decision.

A revised Statement of Product Specification Form as per Data Code (DACO) 2.12.2, with correct chemical names, is also required for the technical product within 90 days of finalization of the re-evaluation decision.

4.1 Maximum Residue Limits

There are no dietary concerns regarding use of 6-benzylaminopurine on food crops reported in the USEPA RED. This document adequately addresses the Canadian dietary exposure from domestic and imported foods.

6-Benzylaminopurine is currently registered in Canada for use on apple. However, 6-benzylaminopurine may be used on other crops in other countries that are imported into Canada.

Currently, residues of 6-benzylaminopurine in all agricultural commodities, including those approved for treatment in Canada, are regulated by subsection B.15.002(1). Where no specific maximum residue limit (MRL) for a pest control product has been established in the Food and Drug Regulations, subsection B.15.002(1) applies. This requires that residues do not exceed 0.1 ppm and has been considered a general MRL for enforcement purposes. However, changes to this general MRL may be implemented in the future, as indicated in Discussion Document DIS2003-01, *Revocation of the 0.1 ppm General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*. If and when the general MRL is revoked, a transition strategy will be established to allow permanent MRLs to be promulgated.

5.0 Additional Data Requirements

The technical registrant of 6-benzylaminopurine will be required to submit the following within 24 months of finalization of the re-evaluation decision:

- all data (as they relate to the Canadian use pattern) submitted to the USEPA in response to the data call-in prior to the reregistration in the United States and USEPA Data Evaluation Reports (DERs); and

- all data (as they relate to the Canadian use pattern) that were required by the USEPA as a condition of reregistration of 6-benzylaminopurine.

6.0 Supporting Documentation

PMRA documents, such as DIR2001-03, and DACO tables can be found on our website at www.pmra-arla.gc.ca. 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.

The federal TSMP is available through Environment Canada's website at www.ec.gc.ca/toxics.

The USEPA RED document for 6-benzylaminopurine (*N6-Benzyladenine*) is available on the Office of Pesticide Programs' website at www.epa.gov/pesticides/reregistration under Chemical Status.

The risk assessment supporting an exemption from the requirement of tolerances for 6-benzylaminopurine published in the Federal Register on 2 April 2004 (*6-Benzyladenin; Exemption from the Requirement of a Tolerance.* Federal Register. 2004. Volume 69, Number 64. pp. 17304–17308) is available on the Federal Register via the United States Government Printing Office Access (www.access.gpo.gov).

Appendix I Products Containing 6-Benzylaminopurine Registered in Canada as of 31 December 2004

Product Name	Registrant	Registration Number	Guarantee		Class
			6-Benzylaminopurine	Other	
N(6)-Benzyladenine Technical Grade Active Ingredient	Valent Biosciences Corporation	25321	98%	—	Technical
Promalin Plant Growth Regulator Solution	Valent Biosciences Corporation	27137	1.8%	1.8%*	Commercial
Promalin Plant Growth Regulator Solution	Valent Biosciences Corporation	16636	1.8%	1.8%*	Commercial
Fascination Plant Growth Regulator Solution	Valent Biosciences Corporation	27135	1.8%	1.8%*	Commercial
Accel Plant Growth Regulator Solution	Valent Biosciences Corporation	24593	1.8%	0.18%*	Commercial

*Gibberellin A_4A_7