

CANADA GAZETTE, PART II

FOOD AND DRUG REGULATIONS - AMENDMENTS

WILL BE PUBLISHED IN CANADA GAZETTE, PART II OF APRIL 20, 2005

SCHEDULE NO. 1404 (DAMINOZIDE)

P.C. 2005-500 OF APRIL 5, 2005

SOR/2005-94 OF APRIL 5, 2005

Her Excellency the Governor General in Council, on the recommendation of the Minister of Health, pursuant to subsection 30(1)^a of the *Food and Drugs Act*, hereby makes the annexed *Regulations Amending the Food and Drug Regulations (1404 - Daminozide)*.

^a S.C. 1999, c. 33, s. 347

REGULATIONS AMENDING THE FOOD AND DRUG REGULATIONS (1404 - DAMINOZIDE)

AMENDMENT

1. Item D.2A of Table II to Division 15 of Part B of the *Food and Drug Regulations*¹ is replaced by the following:

| Item No. | Common Chemical Name | Chemical Name of Substance | Maximum Residue Limit p.p.m. | Foods |
|----------|----------------------|---|------------------------------|----------------|
| D.2.1 | daminozide | succinic acid mono(2,2-dimethylhydrazide), including the metabolite 1,1-dimethylhydrazine | 0.02 | All food crops |

COMING INTO FORCE

2. These Regulations come into force on the day on which they are registered.

¹ C.R.C., c. 870

REGULATORY IMPACT ANALYSIS STATEMENT
(This statement is not part of the Regulation)

Description

Daminozide (also known as Alar) was registered under the *Pest Control Products Act* as a plant growth regulator for the control of the maturation processes of apples, cherries, grapes, nectarines and peaches. Maximum Residue Limits (MRLs) were established under the *Food and Drugs Act* for residues of daminozide resulting from its use at 55 parts per million (ppm) in sour cherries, 30 ppm in apples and sweet cherries, 25 ppm in peaches/nectarines and 10 ppm in grapes, and at 20 ppm in peanuts and plums, 15 ppm in Brussels sprouts and pears, and 0.5 ppm in tomatoes imported into Canada. By virtue of subsection B.15.002(1) of the *Food and Drug Regulations*, the MRL for other foods is 0.1 ppm.

In June 1990, the registration of all products containing daminozide for use on food crops was cancelled as a result of the review of information generated through new studies indicating that one of the metabolites, unsymmetrical dimethylhydrazine, posed an unacceptable risk to human health. Products containing daminozide for use on ornamentals continue to be registered in Canada and in other countries and could be misused on food crops.

This regulatory amendment will decrease the MRLs for residues of daminozide and its metabolite in all food crops to the limit of quantification of 0.02 ppm for enforcement purposes. This regulatory amendment will also amend the chemical name of daminozide in order to comply with international nomenclature conventions.

This amendment harmonizes with changes proposed by the United States Environmental Protection Agency with respect to MRLs for daminozide.

Alternatives

Under the *Food and Drugs Act*, the sale of food containing residues of pest control products at a level less than or equal to 0.1 ppm is permitted unless a lower MRL has been established in Table II, Division 15, of the *Food and Drug Regulations*. In the case of daminozide, decreasing the MRLs for all food crops is necessary to prevent the import and sale of food with unacceptable residues.

Benefits and Costs

The Canadian public will benefit from this regulatory amendment through the added assurance that detectable residues of daminozide or its metabolite will not be found in food.

There are no additional costs to the agricultural industry as a result

of this regulatory amendment as the use of daminozide on food crops has not been permitted since 1990. Some costs to the government may be incurred related to the analysis of daminozide and its metabolite in all food crops. Resources required are not expected to result in significant costs to the government.

Consultation

Regulatory decisions made by the PMRA are based on internationally recognized risk management principles, which are largely harmonized among member countries of the Organization for Economic Cooperation and Development (OECD). This amendment parallels actions taken by the United States Environmental Protection Agency, the European Union, and other OECD countries.

This schedule of amendment was published in the *Canada Gazette*, Part I, on October 2, 2004. Interested parties were invited to make representations concerning the proposed amendment. One comment was received that stated the MRLs for daminozide have been considerably lowered and that Canada should consider the principle of Special and Differential Treatment of the WTO/SPS Agreement for developing countries and postpone the implementation of these MRLs.

In June 1990, the Canadian registration of all products containing daminozide for use on food crops was cancelled as a result of the review of information generated through new studies indicating that one of the metabolites, unsymmetrical dimethylhydrazine, posed an unacceptable risk to human health. Since daminozide poses an unacceptable health risk, the MRLs for residues of daminozide and its metabolite are being decreased in all food crops to the limit of quantification of 0.02 ppm for enforcement purposes.

Any exporter to Canada who uses a pesticide at application rates and with agricultural practices that would result in residues exceeding a Canadian MRL can petition the PMRA to establish a different MRL so that higher residue levels would be permitted. The petitioner must submit the necessary information, including a description of the use of the pesticide and relevant data on residue chemistry and levels.

Compliance and Enforcement

Compliance will be monitored through ongoing domestic and/or import inspection programs conducted by the Canadian Food Inspection Agency when the MRL for daminozide is adopted.

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