

CANADA GAZETTE, PART II

FOOD AND DRUG REGULATIONS - AMENDMENTS

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SCHEDULE NO. 1322 (S-METHOPRENE)

P.C. 2004-256 OF MARCH 23, 2004

SOR/2004-47 OF MARCH 23, 2004

Her Excellency the Governor General in Council, on the recommendation of the Minister of Health, pursuant to subsection 30(1)<sup>a</sup> of the *Food and Drugs Act*, hereby makes the annexed *Regulations Amending the Food and Drug Regulations (1322 — (S)-methoprene)*.

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<sup>a</sup> S.C. 1999, c. 33, s. 347

REGULATIONS AMENDING THE FOOD AND DRUG REGULATIONS (1322 — (S)-  
METHOPRENE)

AMENDMENT

1. Table II to Division 15 of Part B of the *Food and Drug Regulations*<sup>1</sup> is amended by adding the following after item M.6:

I	II	III	IV	
Item No.	Common Chemical Name	Chemical Name of Substance	Maximum Residue Limit p.p.m.	Foods
M.6.1	(S)-methoprene	1-methylethyl ( <i>E,E</i> )-11-methoxy- 3,7,11-trimethyl- 2,4- dodecadienoate	0.05	Mushrooms

COMING INTO FORCE

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

<sup>1</sup> C.R.C., c. 870

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

**Description**

Methoprene is registered under the *Pest Control Products Act* (PCPA) as an insect growth regulator for the control of sciarid flies on mushrooms. (S)-methoprene, a formulation with a higher concentration of the biologically active S-isomer of methoprene, is registered under the PCPA as an insect growth regulator for the control of various insects on pets and in commercial buildings and indoor dwellings.

The Pest Management Regulatory Agency (PMRA), of Health Canada, has recently approved an application to allow the use of (S)-methoprene for the control of sciarid flies on mushrooms. This regulatory amendment will establish a Maximum Residue Limit (MRL) for residues of (S)-methoprene resulting from this use in mushrooms, in order to permit the sale of food containing these residues.

Before making a registration decision regarding a new use of a pest control product, the PMRA conducts the appropriate assessment of the risks and value of the product specific to its proposed use. The registration of the pest control product will be amended if: the data requirements for assessing value and safety have been adequately addressed; the evaluation indicates that the product has merit and value; and the human health and environmental risks associated with its proposed use are acceptable.

The human health risk assessment includes an assessment of dietary risks posed by expected residues of the pest control product, as determined through extensive toxicological studies. An acceptable daily intake (ADI) and/or acute reference dose (ARD) is calculated by applying a safety factor to a no observable adverse effect level or, in appropriate cases, by applying a risk factor which is calculated based on a linear low-dose extrapolation. The potential daily intake (PDI) is calculated from the amount of residue that remains on each food when the pest control product is used according to the proposed label and the intake of that food from both domestic and imported sources in the diet. PDIs are established for various Canadian subpopulations and age groups, including infants, toddlers, children, adolescents and adults. Provided the PDI does not exceed the ADI or ARD for any subpopulation or age group, and the lifetime risk is acceptable, the expected residue levels are established as MRLs under the *Food and Drugs Act* to prevent the sale of food with higher residue levels. Since, in most cases, the PDI is well below the ADI and lifetime risks are very low when MRLs are originally established, additional MRLs for the pest control product may be added in the future.

After the review of all available data, the PMRA has determined that an MRL for (S)-methoprene of 0.05 parts per million (ppm) in mushrooms would not pose an unacceptable health risk to the public.

### **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 (S)-methoprene, establishment of an MRL for mushrooms is necessary to support the additional use of a pest control product which has been shown to be both safe and effective, while at the same time preventing the sale of food with unacceptable residues.

### **Benefits and Costs**

The use of (S)-methoprene on mushrooms will provide joint benefits to consumers and the agricultural industry as a result of improved management of pests. In addition, this regulatory amendment will contribute to a safe, abundant and affordable food supply by allowing the importation and sale of food commodities containing acceptable levels of pesticide residues.

Some costs may be incurred related to the implementation of analytical methods for analysis of (S)-methoprene in the food mentioned above. Resources required are not expected to result in significant costs to the government.

### **Consultation**

Registration decisions, including dietary risk assessments, 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. Individual safety evaluations conducted by the PMRA include a review of the assessments conducted at the international level as part of the Joint Food and Agriculture Organization of the United Nations/World Health Organization Food Standards Programme in support of the Codex Alimentarius Commission, as well as MRLs adopted by other national health/regulatory agencies.

This schedule of amendment was published in the *Canada Gazette*, Part I, on September 28, 2002. Interested parties were invited to make representations concerning the proposed amendment. One comment was received requesting that a higher MRL be established to harmonize with the Codex MRL of 0.2 ppm, the MRL of 0.2 ppm in Japan or the MRL of 1.0 ppm in the United States.

The MRL of 0.05 ppm being established through this regulatory amendment is based on approved application rates for (S)-methoprene in Canada. 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. To date, no such petition has been received.

The comments also requested the data and risk assessment methodology used to establish the MRL in Canada. The confidential test data cannot be provided, as they are protected from disclosure under the *Access to Information Act*. Risk assessment methodology used by the PMRA is described in the document Science Policy Notice SPN2000-01, *A Decision Framework for Risk Assessment and Risk Management in the Pest Management Regulatory Agency*, which is available on the PMRA web site ([www.hc-sc.gc.ca/pmra-arla/english/pdf/spn/spn2000-01-e.pdf](http://www.hc-sc.gc.ca/pmra-arla/english/pdf/spn/spn2000-01-e.pdf)).

### **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 (S)-methoprene is adopted.

### **Contact**

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