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Pest
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Agence de
réglementation
de la lutte
antiparasitaire

2720 promenade Riverside Drive
Ottawa, Ontario
K1A 0K9

Telephone/Téléphone:
Fax/Télécopieur:

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Memorandum To/Note adressée All Registrants, applicants and their representatives
à:

Subject/Objet: Implementation of the Formulants Program

Purpose

The purpose of this memo is to provide industry with an update on changes being made to the formulants requirements, prior to the publication of the revised Formulants Policy Directive. (In order to be consistent with departmental practice, the term “program” is being replaced by “policy” in the name of the revised directive.) This memo also provides practical guidance on the implementation of those requirements that will soon be in effect. It covers allergen and formulation preservative disclosure labelling and clarifies labelling deadline dates as well as recently announced changes to List 2 formulant requirements.

Background

The Regulatory Directive [DIR 2004-01](#), *Formulants Program*, was published in January 2004 and outlines how formulants are regulated in Canada. The directive is being revised for publication this summer. Policy changes are limited and pertain mostly to List 2 formulant label disclosure. The PMRA was intending to publish a separate guidance document for industry to aid in the implementation of the formulants program. However, because the Formulants Program Directive requires revision, it was decided to include guidance on implementation in the revised directive. The revised directive will contain two parts. Part 1 will describe the formulants policy (previously described as formulants program) and will be very similar to the current directive in both format and content. Part II will provide practical guidance to applicants and registrants on implementation of the policy.

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LIST 2 FORMULANTS

Label disclosure of List 2 formulants will not be required for any List 2 formulants. The PMRA will be advising registrants who have already disclosed List 2 formulants on their label text that the List 2 statement can be removed through notification. Upon notification by the registrant, the PMRA will remove the List 2 label text from the PMRA web label.

Although label disclosure of List 2 formulants will not be required, reassessment of List 2 formulants remains a priority. Registrants are still encouraged to remove List 2 Formulants, replace them with formulants from List 3 or 4, or provide data/information to support a risk assessment.

IMPLEMENTATION OF ALLERGEN AND FORMULATION PRESERVATIVE REQUIREMENTS

Labelling Disclosure Deadlines for Allergens and Formulation Preservatives

The implementation deadline date (9 July 2005) listed in the Formulants Program Regulatory Directive (DIR 2004-01) for disclosure labelling of allergens and formulation preservatives applies to the label text version of the product label. Registrants of products containing allergens and/or formulation preservatives must take action to amend the label text version of the product labels by 9 July 2005, using the options described in this memorandum. A four month grace period will be given to registrants before the PMRA considers taking any action for failure to meet this deadline. In order to provide registrants with additional time to prepare for marketplace label implementation, only pest control product containers labelled after 9 July **2006**, i.e., 12 months after the implementation deadline date, are required to have the appropriate disclosure statements.

Label Disclosure for Products with Multiple Formulations

Multiple formulations are defined as more than one formulation acceptable under the same registration number where the formulations differ with respect to the proportions and/or identity and composition of formulation ingredients. When a product is registered with multiple formulations that have differing label disclosure requirements, all formulants subject to disclosure as well as formulation preservatives will be required to be declared on the label text version of the label. However, the marketplace labels must only disclose the formulant(s) or formulation preservative(s) (as required by the Formulants Program) found in the particular formulation being labelled for sale in the marketplace. An example would be as follows: A registered product has two formulations. Formulation 1 contains an allergen (wheat) that is required to be disclosed on the product label. Formulation 2 does not contain wheat; however, it does contain a formulation preservative (formaldehyde). On the label text version of the product label, both wheat and formaldehyde would be disclosed. The marketplace label for Formulation 1 would contain only the disclosure statement for wheat

and not for formaldehyde. Similarly, the marketplace label for Formulation 2 would contain only the disclosure statement for formaldehyde and not for wheat.

ALLERGENS

Allergen Label Disclosure

Labels of products containing formulants, which are common allergenic substances known to cause anaphylactic type reactions, (i.e., milk, eggs, fish, crustaceans [naming the crustacean]), shellfish (naming the shellfish), peanuts, soy, tree nuts (naming the tree nut) or their shells, sesame seeds, wheat or any protein-containing derivative of these substances (including hydrolyzed plant protein, starch and lecithin) as well as sulphites must carry the following statement:

“Warning, contains the allergen, (insert name of allergen e.g., sulphites)”

This statement must be placed in proximity to, on the same label panel as, and in a type and font size comparable to, the guarantee statement.

Allergens found in currently registered pest control products are flagged on the Regulatory Directive [REG 2005-01](#), *PMRA List of Formulants*. When the allergenic formulant is a derivative, it is acceptable to include only the name of the allergen source (e.g., in the case of soya lecithin it would be sufficient to indicate “contains the allergen, soy” on the product label.) If the derivative’s name does not indicate the allergen source and a registrant wishes to disclose the derivative, the allergen source must also be included in brackets after the name of the derivative, [e.g., “contains the allergen, casein (milk)”].

Label Amendment Submission Timelines

By 9 July 2005, the label text version of the product label for all registered products that contain allergens must be revised to include the required disclosure statement. Addition of this label statement must be documented via:

1. the notification process, i.e., through the submission of a letter in which the registrant attests that the statement provided above has been added to the label as required. The letter of notification must be submitted by 9 July 2005 and must identify the exact statement that is being added and specify the location of the statement as it will appear on the marketplace label, OR
2. an application to amend or renew the registration when the submission is being completed before 9 July 2005. In this case, the registrant may opt to include the statement at the final stage of the registration process.

Applications Received Before 9 July 2005

Applications received before 9 July 2005, for which the certificate of registration/amended registration is issued after this date, will require label disclosure i.e., the allergen statement must be on the approved text label before the certificate is issued.

Applications Received After 9 July 2005

All applications to register products containing allergens or amendments involving the addition of allergens, received after 9 July 2005 must comply with the allergen label disclosure requirement.

FORMULATION PRESERVATIVES

A formulation preservative added to a pest control product to protect the formulation from degradation or denaturation by pests is itself by definition a pest control product active ingredient under the *Pest Control Products Act* (PCPA). Since formulation preservatives are by definition active ingredients, they will no longer be described as formulants.

Formulation preservatives do not contribute to the intended effect of the control product to which they are added. For example, insecticides added to rodenticide baits to prevent feeding by insects are considered formulation preservatives, and antimicrobial and antifungal agents added in small amounts to pesticide formulations to prevent bacterial and fungal growth within the container are also considered formulation preservatives.

Formulation preservatives are added to pest control products either directly as a single ingredient or by way of a formulated product that itself contains formulants in addition to the formulation preservative active ingredient(s). Formulation preservative labelling requirements pertain to the formulation preservative active ingredient. When the formulation preservative itself is a formulated product, both the formulation preservative product and its active ingredient(s) must be declared on the statement of product specifications form (SPSF).

Please note that substances regulated as food additive preservatives under the *Canadian Food and Drugs Act* that do not meet the definition of active ingredient, (e.g., antioxidants), would not be subject to the formulation preservative requirements as described below.

Formulation Preservative Disclosure on the SPSF and Label

Any formulation preservative as described above must be identified as a formulation preservative on the SPSF under purpose in the formulation and on the pest control product label. The following statement must be placed on the label in proximity to, on the same label panel as, and in a type and font size comparable to, the guarantee statement:

“Contains (insert name of formulation preservative active ingredient) at (insert percent weight/weight) % as a preservative.”

This labelling requirement applies to all formulation preservatives used in pest control products including those preservatives that contain registered active ingredients and those that contain formulation preservative active ingredients that are not registered. Please note that the name of the formulation preservative active ingredient (common or chemical name) and not the tradename of the preservative product is to appear in the disclosure statement.

An exception to the preservative labelling requirement is being made for microbial products. For these products label identification of the formulation preservative(s) will not be required. The addition of formulation preservatives, often a complex system of multiple preservatives, is critical to protecting the viability of the active ingredient (microorganism) itself rather than to preserving the formulation.

Label and SPSF Amendment Submission Timelines

Products (containing formulation preservatives) Registered Before 9 July 2005:

The Formulants Program Directive indicates that registrants of products containing formulation preservatives are required to submit applications to amend product labels and SPSFs as well as to provide letters of confirmation of source of supply (LOCs), by 9 July 2005, to address the formulation preservative requirements. In order to reduce the burden associated with this approach to addressing the preservative requirements, registrants may instead choose to address the formulation preservative requirements in two phases as outlined below:

Phase 1—Label Disclosure

In the first phase, formulation preservative active ingredients must be disclosed on product labels (label text version). Label disclosure may be documented through notification and the letter of notification must be submitted by 9 July 2005. The letter must include the exact statement being added to the label text as well as specifying the location of the statement as it will appear on the marketplace label.

When the formulation preservative(s) has been added to a pest control product (e.g., XYZ Insecticide) by way of a formulated product (e.g., ABC Microbiocide), the name and guarantee of the formulation preservative active ingredient must be listed on the label of the pest control product (XYZ Insecticide). The identity and concentrations of the formulants found in the preservative product (ABC Microbiocide) are not to be disclosed on the label for XYZ Insecticide. In the case of ABC Microbiocide, the active ingredients, e.g., 5-chloro-2-methyl-4-isothiazolin-3-one, and 2-methyl-4-isothiazolin-3-one and their guarantees in XYZ Insecticide would be listed on the XYZ Insecticide label.

Phase 2—SPSF Disclosure

In the second phase, revision of SPSFs, if necessary, and submission of LOCs, where applicable, will be done after 9 July 2005 through the next amendment application or at registration renewal (beginning with renewal 2006, i.e., products expiring 31 December 2006), whichever comes first. A revised SPSF is required if the formulation preservative active ingredient is not currently disclosed as a preservative under the purpose in the formulation and/or the guarantee of the preservative active ingredient is not disclosed appropriately.

When the formulation preservative(s) has been added to a pest control product (e.g., XYZ Insecticide) by way of a formulated product (e.g., ABC Microbiocide), the name and guarantee of the formulation preservative active ingredient(s) must be listed on the SPSF for the pest control product (XYZ Insecticide) in addition to the name and amount (% w/w) of the formulation preservative product (ABC Microbiocide). (Please refer to the attached two SPSF examples.) The guarantee of the formulation preservative should be expressed in terms of nominal or minimal concentration as appropriate. The identity and concentrations of the formulants found in the preservative product (ABC Microbiocide) are not to be disclosed on the SPSF for XYZ Insecticide. In the case of ABC Microbiocide, the active ingredients, 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one and their guarantees in XYZ Insecticide would be listed on the SPSF for XYZ Insecticide. ABC Microbiocide and its % w/w in the pest control product would also be listed on the SPSF for XYZ Insecticide.

A Letter of Confirmation of Source of Supply from the supplier/registrator of the formulation preservative must be included with the application when the formulation preservative added to a pest control product is itself registered in Canada as a pest control product. This applies to cases when the formulation preservative is added directly as a single ingredient that is registered (e.g., malathion; Reg. No. XXXX) and where it is added by way of a formulated product that is registered (e.g., ABC Microbiocide; Reg. No. YYYY).

Applications Received Before 9 July 2005

Applications received before 9 July 2005, for which the certificate of registration/amended registration is issued after this date, will require label disclosure i.e., the preservative statement must be on the approved text label before the certificate is issued. Revised SPSFs and LOCs will not be required to be submitted in order to complete registration. However, if applicants wish to use such applications to incorporate all formulation preservative requirements, they should first contact the PMRA Information Service.

Applications Received After 9 July 2005

All applications to register products containing formulation preservatives and amendments involving the addition of formulation preservatives, received after 9 July 2005 must comply with the formulation preservative requirements.

Registration Renewal—SPSF Amendments Involving Identification of Formulation Preservatives

Amendments to the SPSF which involve only identification of formulation preservatives already contained in pest control products and/or the submission of LOCs for registered formulation preservative products, will be accepted as part of the renewal process as noted in the section describing Phase 2 above.

Should you have any questions or require clarification on the contents of this memorandum, please contact the PMRA Information Service for more details by email at: pmra_infoserv@hc-sc.gc.ca or by calling 1 800 267-6315 (from within Canada) or (613) 736-3799 (from outside Canada).

Attachment

Sample SPSF for Disclosing a Formulation Preservative Added by Way of a Formulated Product

Product Name: XYZ Insecticide

12. Product Component	13. Supplier	14. %w/w	15. Certified Limits		16. Purpose in Product
			a. Lower	b. Upper	
LMN Permethrin Technical Insecticide (98.25%) (nominal) Reg. No. xxxxx	[insert supplier]	25	N = 24.6		Active ingredient
			23.9	25.3	
ABC Microbiocide (minimal) Reg. No. yyyy that contains:	[inert supplier]	1.0	N=		Formulation preservative
5-Chloro-2-methyl-4-isothiazolin-3-one (1.0%)			N=		Formulation preservative
			0.01		
2-Methyl-4-isothiazolin-3-one (0.4%)			N=		Formulation preservative
			0.004		
Formulant A	[insert supplier]	74			Solvent
			71.8	76.2	
TOTAL % W/W (sum of column 14)		100%			

Sample SPSF for Disclosing a Formulation Preservative Added as a Single Ingredient

Product Name: XYZ Insecticide

12. Product Component	13. Supplier	14. %w/w	15. Certified Limits		16. Purpose in Product
			a. Lower	b. Upper	
LMN Permethrin Technical (98.25%) (nominal) Reg. No. xxxxx	[insert supplier]	25	N = 24.6		Active ingredient
			23.9	25.3	
Formaldehyde (100%)	[insert supplier]	0.1			Formulation preservative
			0.1		
Formulant A	[insert supplier]	74.9	N=		Solvent
			72.7	77.1	
TOTAL % W/W (sum of column 14)		100%			