Agriculture and Agri-Food Canada
Agriculture et Agro-alimentaire Canada

Food Production and Inspection Branch
Direction générale, Production et inspection des aliments

Plant Industry Directorate
Direction de l'industrie des produits végétaux

Dir93-15

Regulatory Directive

Registration Requirements for Adjuvant Products

The purpose of this Regulatory Directive is to inform registrants, other interested parties and agencies about registration requirements for adjuvant products.

This Regulatory Directive replaces Trade Memorandum T-1-225 dated February 14, 1980.

(publié aussi en français)

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Publications Coordinator
Pest Management Regulatory Agency
Health Canada
2250 Riverside Drive
A.L. 6606D1
Ottawa, Ontario
K1A 0K9

Internet: pmra_publications@hc-sc.gc.ca
www.hc-sc.gc.ca
Facsimile: (613) 736-3798
Information Service:
1-800-267-6315 or (613) 736-3799

Canada

Adjuvants Subject to Registration

Under the authority of Section 2(a) of the *Pest Control Products Act*, a control product includes "any compound or substance that enhances or modifies or is intended to enhance or modify the physical or chemical characteristics of a control product to which it is added". Therefore, non-active ingredients which are (a) components of end-use formulations, or (b) adjuvants which are sold and used separately for in-tank mixing by the end-user, are subject to regulation. The former are considered in the evaluation process for registration of the end-use formulation.

For adjuvants which are sold separately, the requirement for registration will depend on the intended use or label claim. Adjuvants of the "activator or spray modifier" type which are intended to directly improve efficacy or to enhance biological performance of the control product by modifying or enhancing physical or chemical characteristics will be subject to registration provisions of the *PCP Regulations*. "Utility modifier" adjuvants which do not directly improve efficacy, but widen the conditions under which a control product is useful or maintain integrity of the spray diluent, will not be subject to registration. Examples of utility modifier adjuvants are buffering agents, antifoam agents, and pesticide/liquid fertilizer compatibility agents. However, such products with label claims for improved biological performance may require registration.

Labelling Requirements

In addition to the standard labelling requirements for format, precautionary symbols, etc., as outlined in the guidelines for registration, the label must indicate the following:

1) the pesticide product(s)* with which the adjuvant can be mixed;
2) the type of formulation of those products;
3) the crop, area, or animal on which the pesticide/adjuvant combination is to be applied; and
4) any special equipment requirements or restrictions.

* Claims for the use of adjuvants with broad categories of pesticides (e.g., fungicides, herbicides) are not acceptable.

Information Requirements

The information requirements listed below should not be considered final. If further concerns regarding a product arise, or if the information provided is inadequate for full evaluation, a request may be made to the registrant to provide more information in any of the listed areas.

Product Chemistry
For active ingredient(s) of adjuvants not presently found in any registered adjuvant, provide the method of manufacture, composition, specifications and chemical names (see Regulatory Directive Dir93-02). If the active is not a single identifiable chemical, give a detailed description of all the components. This information should be submitted with the Product Chemistry and also entered on the Product Specification Form.

For end-use products, provide information as outlined in Regulatory Directive Dir93-04. The applicant must provide a complete Control Product Specification Form identifying each component, its supplier and percent by weight in the formulation, specific gravity, etc. Formulators and distributors who do not have access to this information may request the basic manufacturers to supply it directly to the Plant Industry Directorate, where it will be regarded as confidential information.

Unlike the traditional pesticides, the technical active ingredient(s) present in an adjuvant product is (are) not required to be registered. The end-use product is registered solely on information available on the product.

Toxicology
Acute toxicology studies of the end-use formulations should be submitted (refer to Trade Memorandum T-1-245). For products with a claim for use on livestock, there may be a requirement for data on safety to the animal.

Residues
There is some possibility that the addition of an adjuvant to a pesticide spray mixture could result in greater residues of the pesticide on the crop or animal product than are allowable under the *Food and Drugs Act*.

Determination of pesticide residues must be carried out on milk, meat, eggs or other representative tissue of any livestock treated with a pesticide/adjuvant mixture.

Determination of pesticide residues in representative samples of crops treated with a pesticide/adjuvant mixture must be carried out if an MRL has been established for the pesticide on the crop. Studies should compare residues from crop treated with pesticide/adjuvant with residues from crop treated with pesticide alone. Studies should be done using maximum rates of both pesticide and adjuvant. Pesticide residue determinations may not be necessary if the pesticide is registered for use on a crop on a negligible residue basis.

Residue data is not required for pesticide/adjuvant mixtures for use in non-crop areas, such as industrial sites, or on ornamentals.

Environmental Impact
Information on environmental impact potential may be required under certain conditions of use, e.g., applications in environmentally sensitive areas.

Efficacy

Adjuvant Rates

Efficacy testing should be conducted using the recommended label rate and preferably also a rate that is higher and one that is lower. If a range of adjuvant rates is recommended, the maximum and minimum rates should be evaluated.

Pesticide Rates

Use recommended label rate. If a range is given on the label, the low-to-medium rates should be tested. Rates approaching the maximum should be used only for the most severe infestations.

Duration, Location, and Number of Trials

Herbicides - For a new adjuvant/pesticide combination, a minimum of five sites per year for two years in representative major commercial use areas.

Fungicides, Insecticides, Acaricides - three to five sites per year for two years in representative geographic locations.

Comparative Treatments

Trials should compare results from the use of the pesticide plus adjuvant against results from the use of:

- pesticide alone;
- untreated control or a control with adjuvant alone; and
- a positive control using the pesticide with a registered adjuvant, if available.

Timing

Follow the instructions on the pesticide label for the timing of application unless the time of application is to be changed with the use of the adjuvant.

Replicates or Total Observations

Experimental design should provide sufficient replication of treatment and check plots to provide sound statistical analyses of results.

Spray Carrier

Volume of spray carrier and water conditions (e.g., pH, hardness) should be reported.

Weather Conditions

A record of weather conditions surrounding all applications should be provided.

Assessment of Merit

Herbicide/Adjuvant

1) improved efficacy determined by standard methods, e.g., weed counts, weed weights, defined visual rating scale and crop yield;
2) increased spectrum of activity; and

3) better reliability.

Insecticide/Adjuvant and Acaricide/Adjuvant

1) improved efficacy determined by standard methods, e.g., insect counts, percentage of crop damaged, crop yield, decrease in number of required repeat applications;
2) increased spectrum of activity; and
3) better reliability.

Fungicide/Adjuvant

1) improved efficacy determined by standard methods, e.g., disease ratings, percentage of crop damaged, crop yield, decrease in number of required repeat applications;
2) increased spectrum of activity; and
3) better reliability.

Phytotoxicity

Observations should be made for crop injury resulting from addition of the adjuvant to the pesticide. Data on crop tolerance is more critical when an adjuvant and a graminicide are used on a cereal crop or an adjuvant and broadleaf weed type of herbicide are used on a broadleaf crop.

Physical Properties

For all pesticide/adjuvant combinations, observations should be made on the following:

1) foaming: does the adjuvant cause excessive foaming and, if so, can use of label directions control the problem;
2) compatibility: does the addition of adjuvant cause sludging, etc.; and
3) mixture stability: when tank mixed in the field, can the mixture be allowed to stand, and are special re-mixing instructions required.

Please direct any inquiries regarding this Regulatory Directive to The Information Service at 1-800-267-6315.