



Agriculture Canada

Food Production
and Inspection Branch

Pesticides Directorate

Direction générale,
Production et inspection des aliments

Direction des pesticides

Announcement

A92-02

RE-EVALUATION OF HEAVY DUTY WOOD PRESERVATIVES

The purpose of this Announcement is to notify registrants, pesticide regulatory officials and other interested parties that the active ingredients in pest control products used for heavy duty wood preservation are now subject to re-evaluation under the authority of Section 19 of the Pest Control Product Regulations.

PRODUCT MANAGEMENT
DIVISION
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1. ACTIVE INGREDIENTS IN HEAVY DUTY WOOD PRESERVATIVES

Heavy duty wood preservatives include those products which are applied under pressure or are applied thermally, i.e., wood is dipped into the heated preservative. Pressure-treated wood is used for railroad ties, lumber, timber and plywood, pilings, posts, cross arms, and poles. Active ingredients subject to this re-evaluation belong to the following groups:

arsenic pentoxide, chromic acid and cupric oxide (as components of copper/chromium/arsenic = CCA type preservatives)	ARP CRO CUO
Creosote (including coal tars)	CRT
pentachlorophenol and related chlorophenols	PCP
disodium octaborate tetrahydrate	BOC*
copper, elemental, present as copper naphthenate	CUN
copper-8-quinolinolate	CUQ*
zinc, elemental, present as zinc naphthenate	ZNN

Only the uses of these active ingredients as heavy duty wood preservatives will be re-evaluated.

* used in antisapstain wood preservatives

2. RATIONALE

The decision to re-evaluate heavy duty wood preservatives was made after considering the following factors:

- a) This re-evaluation is a continuation of the current re-evaluation of wood preservative uses for pentachlorophenol (see cluster number A-5 in Memorandum to Registrants R-1-226, May 20, 1986).
- b) The age, completeness and overall quality of the data base do not meet present standards.
- c) Inorganic arsenic, chromium salts, creosote, coal tar, and pentachlorophenol or some of their conversion products, by-products or contaminants may be capable of causing tumors.
- d) These wood preservatives, and wood treated with them are widely used.
- e) These active ingredients and their metabolic and transformation products are considered to be persistent in the environment.
- f) Heavy duty wood preservatives are ranked sixth and ninth in the re-evaluation scheme proposed in Memorandum to Registrants R-1-226.

3. RESPONSE REQUIRED

Registrants of control products and manufacturers of active ingredients identified in this document must respond within 60 days of the date of this Re-evaluation Announcement indicating intent to participate in the re-evaluation process.

4. DATA SUBMISSION

Data and information requirements described in this announcement have been determined in consultation with Agriculture Canada's advisors.

4.1 Data Requirements

a) Organization of Data

All data submitted must be organized as per Agriculture Canada Trade Memorandum T-1-237 (October 1, 1983) for the technical active ingredient and its major metabolic and transformation products, and Trade Memorandum T-1-239 (October 1, 1983) for end-use products. Three copies of all studies, reports and other information will be required.

b) Studies Relevant to this Review

i. Animal Toxicology and Effects on Humans

In determining the relevance of toxicology studies to this data call-in, companies should consider conformity of studies to contemporary standards regarding protocols and reporting criteria. For guidance concerning toxicology protocols, consult Agriculture Canada Trade Memorandum T-1-245, U.S. Environmental Protection Agency (EPA) Pesticide Assessment Guidelines and Standard Evaluation Procedures, and the OECD Guidelines for Testing of Chemicals.

Current requirements for toxicology studies in support of the registration of pest control products are listed in Agriculture Canada Trade Memorandum T-1-245 (Guidelines for Developing a Pesticide Toxicology Database, September 19, 1984). Please note that Health and Welfare Canada now considers human exposure studies necessary for the evaluation of occupational and bystander risk.

Copies of published or unpublished case reports, clinical studies, morbidity, mortality, reproduction, teratology or other health or epidemiologic studies on humans which could be relevant to this re-evaluation should also be submitted.

ii. Environmental Chemistry and Fate

Data requirements for environmental chemistry and fate are listed in Agriculture Canada Trade Memorandum T-1-255 (Guidelines for Determining Environmental Chemistry and Fate of Pesticides, October 30, 1987).

iii. Environmental Toxicology

Canadian guidelines regarding data requirements for environmental

toxicology have not yet been developed. All pertinent studies may be considered relevant by Environment Canada, and should be submitted. Studies need not conform to current guidelines of the U.S. EPA or the OECD in order to be considered, but experiments and reports must be done and presented according to rigorous scientific principles.

iv. Benefits

The value or benefits data will be organized to include information related to product performance as well as an examination of the relative value of alternative products and technologies.

c) Initial Requirements for Re-evaluation of Technical Active Ingredients

i. Index

Each basic manufacturer and/or data owner is asked to submit, within six months of the date of this announcement, an index to all studies pertaining to an active ingredient and its major metabolic and transformation products, organized as per T-1-237. Where possible, the index should distinguish among studies which:

- 1) are being submitted for the first time;
- 2) have been submitted since 1980;
- 3) are being resubmitted; and
- 4) are considered not relevant and are therefore not being submitted at this time.

ii. Studies

Each basic manufacturer and/or data owner is asked to submit, within 6 months of the date of this announcement, all available relevant studies, except those which have been submitted since 1980 (see "Resubmission of Studies" below).

iii. Chemistry Specifications

Each basic manufacturer is asked to submit all required chemistry data as prescribed in Trade Memorandum T-1-238 (October 1, 1983) for current production of their active ingredient.

d) Initial Requirements for Proprietary Data - Formulations (End-use Products)

i. Index

Each registrant and basic manufacturer is asked to submit, within six months of the date of this announcement, an index to all studies pertaining to heavy duty end-use products, organized as per Trade Memorandum T-1-239.

Where possible, the index should distinguish among studies which:

- 1) are being submitted for the first time;
- 2) have been submitted since 1980;
- 3) are being resubmitted; and
- 4) are considered not relevant and are therefore not being submitted at this time.

ii. Studies

Each registrant is asked to submit, within six months of the date of this announcement, all available relevant data (other than efficacy data), except those which have been submitted since 1980 (see "Resubmission of Studies" below).

e) Resubmission of Studies

Data submitted prior to 1980 may not be considered unless resubmitted. Companies should resubmit older relevant data which they wish to have considered; companies may be asked to resubmit particular studies at a later point in the re-evaluation process. Resubmission of data received after 1980 and organized according to T-1-237 and T-1-239 will not be necessary.

4.2 Incident Data

Incident records, or unpublished reports regarding poisonings, user or bystander overexposure or any other health hazards, water supply contamination, spills, accidents and/or wildlife problems associated with heavy duty wood preservative active ingredients which have come to the attention of registrants should be provided if available.

4.3 Worldwide Regulatory Status

Basic manufacturers and data owners are requested to provide a summary report of the regulatory status of a heavy duty wood preservative active ingredient in other countries and any regulatory actions which have been taken.

4.4 Published Data

This re-evaluation will include a review of published studies pertaining to the active ingredients and their by-products, contaminants, conversion products or metabolites. This review will begin with an examination of a bibliography of published studies pertaining to actives on page 1 of this document (technical, end-use products and major metabolic and transformation products) accompanied by a description of the data bases and procedures used to search the published literature.

The bibliography should be annotated in a separate indexed document listing the abstracts or summaries, (indicate whether they were provided by the authors or by the basic manufacturer) and the source of these annotations (original author or basic manufacturer). The bibliography should be arranged according to the major parts (not subparts) described in Trade Memorandum T-1-237 and cross-referenced so that there is no duplication. While each basic manufacturer or data owner is requested to provide such a bibliography within six months of the date of this announcement, industry may wish to consider a task force approach in order to share the cost of bibliography development. Sufficient copies should be provided for distribution to advisor agencies. Environment Canada has requested, where possible, that the bibliographic review be submitted in a DOS readable computerized data base format.

Note: Published studies generally play the role of providing supplementary support to proprietary studies. Published studies will be accepted if they are accompanied by the details of the study. They provide supplementary information and do not replace the need for a registrant to supply complete scientific data.

5. INTERNATIONAL REGULATORY ASPECTS

5.1 U.S. - Special Review of Pentachlorophenol, Creosote and Inorganic Arsenicals

EPA officials completed a Special Review of certain heavy duty wood preservatives in 1984. Health and safety concerns surrounding the use of creosote, inorganic arsenicals and pentachlorophenol, prompted a review of the risks and benefits associated with their use.

The following regulatory decisions were made to reduce the risk associated with the use of these products:

- a) cancelling and denying registrations of spray formulations of pentachlorophenol containing less than 5% PCP.
- b) prohibiting indoor applications of wood preservatives.
- c) prohibiting most indoor uses of treated wood and uses of wood preservatives likely to contaminate food, feed or drinking water.
- d) required use of certain personal protection measures (e.g., clothing and equipment) during application.
- e) improved industrial hygiene.
- f) classifying all three chemicals for Restricted Use only by certified applicators (except for brush-on treatments of the inorganic arsenicals).

- g) requirement for a teratogenicity/fetotoxicity warning on pentachlorophenol labels.

The EPA determined that "there will be no unreasonable adverse effects posed to man or the environment if registrants amend their registrations of the three wood preservatives to include these requirements".

5.2 U.S. Re-registration (equivalent to Canadian re-evaluation)

Heavy duty wood preservatives are currently undergoing a more complete re-assessment called Re-registration. A re-assessment of registered uses will be part of this initiative. The EPA has estimated that their review of existing data and subsequent Data Call-In will be completed by late 1992. Regulatory decisions will emerge after newly submitted data has been reviewed.

Note: In Canada, the remaining uses for certain actives such as pentachlorophenol (PCP) represent a narrower range of uses than are registered in U.S. Specifically, PCP is currently registered in Canada only for heavy duty wood preservation, whereas in the U.S. pentachlorophenol continues to be registered as a pulp and paper biocide, cooling tower biocide and in all wood preservative applications (antisapstain, heavy duty, joinery/millwork).

6. PRIORITY SUBSTANCE LIST - CANADIAN ENVIRONMENTAL PROTECTION ACT

Arsenic and chromium (components of copper chromated arsenate) and creosote impregnated waste materials (CIWM) are currently the subject of a priority substance list review by Environment Canada. This review is not part of the re-evaluation of the wood preservative use, but could have a bearing on the re-evaluation process.

7. RE-EVALUATION PROCEDURES

Submitted data will be reviewed by Agriculture Canada and advisory agencies.

Registrants will be notified if data gaps and information gaps are identified.

Registrants may be requested to provide additional information, or replacement studies to fill identified data gaps, or to supplement or replace studies found to be incomplete, invalid or inadequate.

All basic manufacturers of the technical active ingredients listed above and registrants of pertinent end-use products are responsible for development and provision of data packages in support of their registered product. Industry may wish to consider a task force approach in order to share the cost of data development.

As part of the consultative process, registrants, user and public interest groups, and other interested parties will be invited to comment on any proposed revisions to the regulatory status of products containing the technical ingredients listed above, before such changes are implemented.

Please address your comments to:

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