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Food Production
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Announcement

**RE-EVALUATION ANNOUNCEMENT
TCMTB, COPPER-8 AND BORAX
ANTISAPSTAIN APPLICATIONS**

PRODUCT MANAGEMENT DIVISION

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TABLE OF CONTENTS

1. RATIONALE	1
2. RESPONSE REQUIRED	2
3. DATA SUBMISSION	2
3.1 Proprietary Data	3
4. CHEMISTRY SPECIFICATIONS	4
5. RELEVANCE OF STUDIES	4
5.1 Toxicology	4
5.2 Environmental Chemistry and Fate	5
5.3 Environmental Toxicology	5
6. INCIDENT DATA	5
7. WORLDWIDE REGULATORY STATUS	5
8. PUBLISHED DATA	5
9. SUBSEQUENT STEPS	6

RE-EVALUATION ANNOUNCEMENT

TCMTB, Copper-8 and Borax

Antisapstain Applications

1. RATIONALE

The purpose of this Announcement document is to formally advise registrants, pesticide regulatory officials and other interested parties that antisapstain applications of products containing 2-(thiocyanomethylthio)benzothiazole (TCMTB), copper-8-quinolinolate (copper-8) and borax are now subject to re-evaluation under the authority of Section 19 of the Pest Control Product Regulations.

An extensive consultation effort on various active ingredients for antisapstain use (both those that were already registered and some that were under evaluation for possible registration) was undertaken late in 1989. A draft Discussion Document on Antisapstain Chemicals, prepared at that time, provided data summaries and status reports on these active ingredients and certain end-use products containing them. Table 1 contains a complete list of the active ingredients, the products and their various names.

TABLE 1 - NAMES OF ANTISAPSTAIN PRODUCTS

PRODUCT	OTHER NAMES
1. Pentachlorophenol	PCP, Penta, Tetra, chlorophenates, sodium pentachlorophenolate, sodium tetrachlorophenolate
2. Azaconazole	Rodewod
3. Copper-8-quinolinolate	Quinolate, Copper-8, Cu-8, Nytek GD, PQ-8, PQ-57, oxine copper, copper salt of 8-hydroxyquinoline
4. Didecyldimethyl ammonium chloride	BARDAC 22 or 2280, DDAC, NP-1
5. 3-iodo-2-propynyl butyl carbamate	Troysan Polyphase, iodocarb, IPBC
6. Borax (+ Sodium Carbonate)	Ecobrite, Ecobrite C, CFST, sodium borate
7. 2-(thiocyanomethylthio) benzothiazole	TCMTB, Busan 30/1030/30 WB

Arising from this consultation was a decision (summarized in Note to CAPCO 90-10) to:

- ! phase out antisapstain uses of pentachlorophenol and related chlorophenates;
- ! register, for the first time, antisapstain end-use products containing the active ingredients didecyldimethyl ammonium chloride (DDAC) and 3-iodo-2-propynyl butyl carbamate (IPBC); and
- ! re-evaluate the previously registered antisapstain uses of TCMTB, copper-8 and borax.

The registrations of the products containing DDAC and IPBC were associated with various terms and conditions including a commitment on the part of the registrants to provide data to fill gaps identified in the Discussion Document. An annual review of the registration status of these products is planned in order to take into consideration the results of data as it is submitted. This approach addresses the concerns of the British Columbia Stakeholder Forum on Sapstain Control, an independent multi-stakeholder forum with representation from the British Columbia government, unions, the forest industry and public interest groups.

An additional end-use product, based on azaconazole, was registered in 1990 with a substantially complete data base (See Note to CAPCO 90-17).

For all currently registered antisapstain active ingredients and end-use products (azaconazole, TCMTB, copper-8, borax, IPBC, DDAC) operator exposure information is needed for the full range of application regimes including spray box, dip tank, etc. By means of this Re-evaluation Announcement this need for operator exposure information is formally recognized for all the antisapstain products. Registrants are being encouraged to explore opportunities for sharing in development of the necessary data in this area in particular.

2. RESPONSE REQUIRED

A written response to this Re-evaluation Announcement is required, within 60 days, from registrants or manufacturers of active ingredients identified in this document if no previous commitment to taking part in the re-evaluation process has been made, e.g., a commitment to submit data. In the response please indicate, by way of an updated index to data (as per section 3.1(2) of this document), what studies have been submitted and what studies (if any) are underway and the planned date of study submission.

3. DATA SUBMISSION

With respect to the re-evaluation of the antisapstain uses of TCMTB, Copper-8 and borax, the preliminary work has already been completed via the preparation of the "Draft Discussion Document on Antisapstain Chemicals". (Copies are available from the Information Division, Pesticides Directorate, Agriculture Canada, Ottawa, Ontario, K1A 0C6 - Phone (613) 9934544, Fax (613) 998-1312).

During the preparation of the Discussion Document, the currently available data were reviewed and gaps in the data bases identified. Registrants were subsequently contacted by letter (October 1, 1990) and requested to consolidate past and current commitments to fill information gaps as identified in the Discussion Document.

For committed data, a table format was requested including the following information:

- ! study name;
- ! anticipated or actual dates for the following:
 - study initiation
 - interim report availability
 - study completion
 - study submission to Agriculture Canada; and
- ! name and address of the laboratory performing the study.

In developing and submitting new data, registrants should take into consideration not only the information in the Discussion Document but also the following general guidelines regarding the development of data and the format for indexing and submitting data. Instructions are also included for carrying out a review of the published literature for each of the active ingredients.

3.1 Proprietary Data

1) 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.

2) Indexes to Data

Each basic manufacturer, registrant and/or data owner should have on file with Agriculture Canada an index to their proprietary studies pertaining to technical borax, copper-8 and/or TCMTB and their major metabolic and transformation products, organized as per T-1-237.

Each registrant and/or data owner should have on file with Agriculture Canada an index to all their proprietary studies pertaining to end-use products containing borax, copper-8 and/or TCMTB, organized as per Trade Memorandum T-1-239.

Indexes should distinguish among studies which:

- a) are being submitted for the first time;
- b) have been submitted since 1980;
- c) are being resubmitted; and
- d) are considered not relevant and are therefore not being submitted.

As data are submitted, indexes should be updated on a regular basis. Five copies of indexes and updates are required. Updated indexes are important in ensuring data protection under the Product Specific Registration policy.

4. CHEMISTRY SPECIFICATIONS

Chemistry specifications formed a part of the review of the data for the Discussion Document. For the most part, the chemistry for these active ingredients from the various sources is acceptable. Some companies are still producing some parts of the information. Agriculture Canada will continue to deal with those registrants on an individual basis until this activity is completed. Registrants are reminded that Agriculture Canada should be notified of any changes that could affect the specifications of the active ingredients and products, e.g., manufacturing processes, as they occur.

5. RELEVANCE OF STUDIES

5.1 Toxicology

In determining relevance of toxicology studies, 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. EPA Pesticide Assessment Guidelines and Standard Evaluation Procedures, and the Organization for Economic Cooperation and Development (OECD) Guidelines for Testing of Chemicals.

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

5.2 Environmental Chemistry and Fate

Current 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). As the sciences of environmental chemistry and fate have been evolving rapidly, all available studies pertaining to these aspects may be considered relevant by Environment Canada, and should be submitted. Studies relating to the movement of these chemicals into aquatic

ecosystems and to the chemistry and fate of these chemicals in fish habitat are of interest to the Department of Fisheries and Oceans and should be submitted. Studies need not conform to the data requirements of T-1-255 in order to be considered.

5.3 Environmental Toxicology

Canadian guidelines regarding data requirements for environmental toxicology have not yet been developed. All studies, especially field studies, regardless of location, may be considered relevant by the Canadian Wildlife Service, and should be submitted. Studies relating to the toxicity of these chemicals to non-target aquatic biota, including aquatic plants, are of interest to the Department of Fisheries and Oceans and should be submitted. Studies need not conform to current guidelines of the U.S. EPA or the OECD in order to be considered. Guidelines for determining phytotoxicity to non-target plants are currently being developed. At this time, Environment Canada and the Department of Fisheries and Oceans would like to receive any existing data which may give information on the susceptibility or non-susceptibility of various plant groups to copper-8, TCMTB and borax.

6. 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 the compounds included in this announcement should be provided.

7. WORLDWIDE REGULATORY STATUS

Basic manufacturers and data owners are requested to provide a summary report of the regulatory status of copper-8, TCMTB and Borax in other countries and any regulatory actions which have been taken.

8. PUBLISHED DATA

Re-evaluation generally includes review of published studies. This aspect may already have been covered during the consideration of data for the Discussion Document. If not, however, the following instructions would apply. The review to be submitted by the registrants would include an examination of a bibliography of published studies accompanied by a description of the data bases and other procedures used to search the published literature. Environment Canada has requested, where possible, that this information be submitted in a DOS readable computerized form. A data base format would be preferred.

The bibliography should be annotated by inclusion of abstracts or summaries provided by the authors or by the basic manufacturer; the source of these annotations (original author or basic manufacturer) should be identified. The bibliography should be arranged according to the eight (8) major parts as described in Trade Memorandum T-1-237. Identification of studies should be made using the numerical system specified in Appendix 1 of T-1-237. There is no

need to list more than one study for each subpart. While each basic manufacturer or data owner is requested to provide such a bibliography, a task force approach is possible to share the cost of bibliography development. Sufficient copies should be provided for distribution to advisor agencies.

9. SUBSEQUENT STEPS

The next steps in the re-evaluation process depend on the commitments for new data development and on the time frames for submission of new data. Some commitments have been received already and are currently under consideration. If these are reasonable and acceptable, and if the data commitments fill the requirements for an adequate data base to support the continued use of products containing borax, copper-8 and TCMTB for control of sapstain, the next step will be review of the new information as it is received and, possibly after further consultation with stakeholders, publication of a Decision Document. Such a Document would outline the final regulatory position for each of the active ingredients and the products containing them.

January 14, 1991

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