

US EPA ARCHIVE DOCUMENT

(Aug 27 2003)



Health
Canada

Santé
Canada

Pest
Management

Agence de
régimentation

Tel. / Téléphone: (613) 736-3858
Fax/Télécopieur: (613) 736-3870
E-mail: Bernadette_Boutin-Muma@hc-sc.gc.ca

Regulatory
Agency

de la lutte
antiparasitaire

2720 promenade Riverside Drive
Ottawa, Ontario
K1A 0K9



Your file / Votre référence

August 27, 2003

Memorandum To/Note adressée à: Suzan Matthew
Science Team Lead

From/De: B. Boutin-Muma
Evaluation Officer, CES

Subje Jct/Objet: Sub. No(s): 2003-0839 and 2003-0840
Active Ingredient: MTN-BAZ-31; BAS 670 H
Applicant: BASF Canada INC.

ACTION REQUESTED: Level C1 / Category A Submission

Attached are the deficiencies noted for Parts 2 & 3 of the above-noted submission.

Please note that the review summaries have been saved in the workbook, LS stream under the file name 2003-0839_LS_2_0.wkb and 2003-0840_LS_3_0.wkb

Date: _____
Bernadette Boutin-Muma, Reviewer
Evaluation Officer, CES, PMRA

Date: _____
Yuk Wigfield, Peer Reviewer
Senior Evaluation Officer, CES, PMRA

Date: _____
Karen McCullagh
Division Director, CLSROD, PMRA

Canada

①

PART 2 CHEMISTRY REQUIREMENTS FOR THE REGISTRATION OF A TECHNICAL GRADE OF ACTIVE INGREDIENT (TGAI) OR AN INTEGRATED SYSTEM PRODUCT

DACO 1.0
Title Label

Deficiencies A BASF code "BAS 670 H" is used for the active ingredient instead of the common name.

Required Data: An ISO common name should be used on the label once one is accepted. This issue can be addressed at the level E review stage.

EPA Comments: Agency concurs. The CSF and the product label must have identical chemical or common names.

DACO 2.2
Title Manufacturer's Name and Office Address and
Manufacturing Plant's Name and Address

Deficiencies The manufacturing plant location is listed as "BASF, Research Triangle Park, NC" under DACO 2.2 of the chemistry in the data package and as "BASF, Germany" in box 6 of the SPSF.

Required Data: The applicant is required to confirm the correct plant location where the TGAI is manufactured.

EPA Comments: Agency concurs. In the CSF (Block #6, Country where formulated), the applicant has indicated USA or Germany. The Agency requirements are that for each production facility the applicant must submit alternate formulation CSF along with the supporting data (5 batch analysis). EPA needs CSF's for the TGAI produced in Germany and in USA. A product can have only one basic and various alternate formulations.

DACO 2.13.3
Title Batch data

Deficiencies: The data submitted in support of the specifications of the TGAI, manufactured at the BASF Ludwigshafen, are based on five batches of the TGAI produced in pilot scale.

2

Required Data: Analytical data from five batches of the TGAI from full scale production are required when available, to support the specifications as per the requirements of DIR 98-04.

The requirement of full scale can be addressed at the level E review stage. In the interim, the applicant is required to provide the expected date of such data.

EPA Comments: The Agency concurs. If the full production 5 batch analysis results do not match with previous results submitted, a revised CSF and product label must be submitted for evaluation.

DACO: 2.15
Title: Sample of Chemical Standard

Deficiencies: A 2.5 g analytical standard of the active ingredient was not submitted.

Required Data: As per Dir98-04, a 2.5 g analytical standard of the active ingredient is required. It should be sent directly to:

Laboratory Services
Pest Management Regulatory Agency
Health Canada
Laboratory Services Building, No. 22
Central Experimental Farm
Ottawa, Ontario
K1A 0C6
Attn: Mary O'Neil

EPA Comments: 5 gm analytical grade sample and 200 gm of technical grade sample must be submitted to the Agency at the following address:

EPA Analytical Laboratory
701 Mapes Road, Ft. Meade, MD 20755-5350
Attention: Chuck Stafford (Telf: 410-305-2914)

All the product chemistry data requirements corresponding to 830 Series Subgroup A and Subgroup B have been satisfied for the BAS 670H technical.

3

PART 3 **CHEMISTRY REQUIREMENTS FOR THE REGISTRATION OF A
MANUFACTURING CONCENTRATE (MA) OR AND END-USE
PRODUCT**

DACO 1.0
Title Label

Deficiencies A BASF code "BAS 670 H" is used for the active ingredient instead of the common name.

Required Data: **An ISO common name should be used on the label once one is accepted. This issue can be addressed at the level E review stage.**

EPA Comments: Agency concurs

DACO 3.1.2
Title Formulating Plant's Name and Address

Deficiencies The formulating plant location is listed as "BASF, Research Triangle Park, NC" under DACO 3.1.2 of the Chemistry data package and as "BASF, Germany" in box 6 of the SPSF.

Required Data: **The applicant is required to confirm the correct plant location where the EP is formulated.**

EPA Comments: Agency concurs. CSF must include the correct address where the product is formulated.

DACO 3.5.10
Title Storage stability data

Deficiencies The product is stated to be stable for one year at ambient temperature without supporting data.

Required Data **The applicant is required to provide the results of one year storage stability study as per the requirements of DIR 98-03, if available. If not, it could be provided at the level E review stage. In the interim,**

4

the completion date of such study is required.

CONFIDENTIAL

EPA Comments: The one year storage stability data is required. The registrant is recommended to determine or make observations at 0, 3, 6, 9, and 12 months intervals. The study must be carried out under warehouse conditions with test substance stored in commercial containers. It is recommended that the corrosion characteristics study may be carried out simultaneously.

EPA Comments on the CSF basic formulation:

The CSF for basic formulation (dated 02/05/03) is not acceptable since it contains two food use inert ingredients which are not cleared by the Agency. The applicant must provide the chemical compositions of two food use inert ingredients [REDACTED] and [REDACTED] which must include the chemical names, CAS Nos. and percentages of each component of these food inert ingredients. The MSDS's submitted for these inert ingredients do not include the chemical composition. The composition information must be provided by the manufacturer of the particular inert ingredient.

All other product chemistry data requirements corresponding to 830 Series Subgroup A and B are acceptable.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

INERT INGREDIENT INFORMATION IS NOT INCLUDED

5