

US EPA ARCHIVE DOCUMENT

DATE: 29/SEPT/2003

SUBJECT: SECONDARY PRODUCT CHEMISTRY REVIEW OF TGAI/MP[] EP[X]
DP BARCODE No.: D290069
File Symbol. No.: 7969-ENL
PRODUCT NAME: BAS 670 336SC Herbicide
COMPANY: BASF Corporation
PCC: 029806; FOOD USE: [X]; Decision #: 211978

FROM: Shyam E. Mathur,
Team Leader
Product Chemistry Team
Technical Review Branch/RD (7505C)

Shyam E. Mathur
9/29/03
DM: AGL

TO: Joanne Miller/James Stone, PM 23
Herbicide Branch/RD(7505C)

INTRODUCTION

The primary reviews for the technical BAS 670H Technical and the end-use product BAS 670 336SC Herbicide were performed by PMRA. This report contains the secondary review for both the products. The product chemistry data have been submitted under MRID Nos. 459018-01 thru 459018-06.

SUMMARY OF FINDINGS & CONCLUSIONS:

1. ISO common name must be used on the label and the CSF.
2. The correct address for formulation process facility must be provided on the CSF.
3. One year storage stability (830.6317) 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 the test substance stored in commercial containers. It is recommended that corrosion characteristics study (830.6320) may be carried out simultaneously.
4. The CSF for basic formulation is not acceptable since two food use inert ingredients present in the formulation are not cleared by the Agency. The registrant must submit the chemical composition of these two food use inert ingredients. The chemical composition must include the chemical names, CAS numbers, and percentages of

DP BARCODE No.:D290069 File Symbol. No.:7969-ENL PRODUCT NAME:BAS 670 336SC Herbicide

each component present in the formulation. The information must come from the manufacturer of these inert ingredients. The MSDS's submitted do not contain the required information. For the names please refer to Confidential Appendix.

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

6. The registration of the end-use product is subject to the approval and registration of the BAS 670H Technical (7969-ENU).

②

CONFIDENTIAL APPENDIX

DP BARCODE No.:D290069 File Symbol. No.:7969-ENL PRODUCT NAME:BAS
670 336SC Herbicide

Names of the food use inert ingredients not cleared by the Agency
are:



Chemistry data review for the registration of a manufacturing concentrate (MA) or an end-use product (EP).

Product Name: BAS 670 336SC Herbicide

Submission Number / DP Bar Code: 2003-0840

Registration Number: EPA: 7969-ENL

Source Code(s) / PC Code: MTN-BAZ-31 / 029806

Applicant's / Registrant's Name and Address:

BASF Canada Inc.
345 Carlingview Drive
Toronto, Ontario
M9W 6N9
Phone: 416-674-3611

Formulating Plant's Name and Address:

BASF Corporation
Agricultural Products Group
P.O. Box 13528
Research Triangle Park, NC
27709-3528
Phone: 919-547-2000

TGAI(s) in EP: BAS 670H Technical containing ([3-(4,5-Dihydro-isoxazol-3-yl)-4-methansulfonyl-2-methylphenyl]-(5-hydroxy-1-methyl-1 H-pyrazol-4-yl)-methanone at 99.2% nominal, sub. #2003-0839, currently under review.

Guarantee: On the label:
BAS 670 H..... 336 g/L

On the SPSF:
BAS 670H ([3-(4,5-Dihydro-isoxazol-3-yl)-4-methansulfonyl-2-methylphenyl]-(5-hydroxy-1-methyl-1 H-pyrazol-4-yl)-methanone 336 g/L (325 -345 g/L)

Reviewer: B. Boutin-Muma

Good Laboratory Practices Compliance Statement:

The studies contained within this report were conducted in accordance with the Good Laboratory Practice Standards as specified in 40 CFR 160 or equivalent.

yes [x] no []

OECD Principles of Good Laboratory practice and the GLP Principles of the German "Chemikaliengesetz"(Chemicals Act).

INTRODUCTION:

The purpose of this submission Category A submission is to register a new commercial herbicide containing BAS 670 H as the active ingredient. In support of the registration, a hard copy of Part 0-Index, Part 1- label, the Product Statement of Specification Form and the electronic version of Part 3 Chemistry data, in V:\Subs-E-Info\2003 subs\2003-0840\BAS H, 2nd set, have been submitted.

SUMMARY OF FINDINGS:

BAS 670 336SC Herbicide is an end use product prepared by a simple blending of the active ingredient, emulsifiers, and diluent. The formulation process does not involve any chemical reactions and no impurities are expected to occur.

The product is guaranteed to contain the active ingredient at a nominal concentration of 336 g/L with the lower and upper certified limits of 325 and 345 g/l respectively. The certified limits are within the standard limits. The calculated guarantee is consistent with the guarantee on the label and on the specification form

The active ingredient was determined by HPLC with UV detection. Full validation data as well as all relevant chromatograms were submitted in support of the method. The method was assessed to be specific, precise and accurate for use as an enforcement analytical method.

Impurities of toxicological concern as identified in section 2.13.4 of DIR 98-04 and TSMP track substances as per Appendix II of DIR 99-05 are not expected to be present in the raw materials or formed as a result of the formulation process. The product does not contain any EPA inert List 1 or 2 formulators.

Chemical and physical properties were provided where applicable.

CONCLUSIONS:

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.

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.

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.

Table 1. Chemical & Physical Properties				
DACO # / GLN	Title	MRID / Report #	Status ¹	Result ² or Deficiency
¹ A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not applicable. ² For example, "brown" for 830.6302; "1.021" for 830.7300.				
3.5.1 / 830.6302	Colour		A	Light beige
3.5.2 / 830.6303	Physical State		A	Liquid
3.5.3 / 830.6304	Odour		A	Aromatic
3.5.4	Formulation Type		A	Suspension concentrate
3.5.5	Container Material and Description		A	Stainless steel or HDPE containers
3.5.6 / 830.7300	Density or Specific Gravity		A	1.13 g/cm ³ at 20°C
3.5.7 / 830.7000	pH		A	3.9
3.5.8 / 830.6314	Oxidizing or Reducing Action			No reaction with reducer Reaction with oxidizer
3.5.9 / 830.7100	Viscosity		A	65.7 mPa·s at 20°C
3.5.10 / 830.6317	Storage Stability Data		N	Stable (54°C, 14 d). The applicant claimed that the interim results from a two years study at 20°C show that the EUP is stable for the first 12 months. No supporting data were provided. Data requested.
3.5.11 / 830.6315	Flammability		A	Not flammable
3.5.12 / 830.6316	Explosibility		A	Not explosive
3.5.13 / 830.6319	Miscibility		N/A	BAS 670 336 SC Herbicide is a suspension concentrate.
3.5.14 / 830.6320	Corrosion Characteristics		N/A	The commercial containers will not react with the product.
3.5.15 / 830.6321	Dielectric Breakdown Voltage		N/A	BAS 670 336 SC Herbicide is not a conductant liquid and is not designed for use around electrical equipment.

Data Submitted: See Table 2.

Table 2. Data Submitted for the BAS 670 336SC Herbicide				
DACO # / GLN	Title	MRID / Report #	Status ¹	Details and/or Deficiency ²
3.2.1 / 830.1600	Description of Starting Material		A	No deficiencies
3.2.2 / 830.1620 830.1650	Production / Formulation Process		A	No deficiencies
3.2.3 / 830.1670	Discussion of Impurities		A	No deficiencies
3.3.2 / 830.1550	Control Product Specification Form / Confidential Statement of Formula		A	No deficiencies
3.3.1 / 830.1750	Certification of Limits		A	No deficiencies
830.17	Preliminary Analysis			<i>For EP containing non-registered TGAI or for EP which is an ISP only.</i>
3.4.1 / 830.1800	Enforcement Analytical Method		A	No deficiencies
¹ A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not applicable. ² Refer to CBI Appendix A for details				

ATTACHMENT: CONFIDENTIAL APPENDIX

Secondary Product

Chem. Bureau ZPTG/II/MP DP Brevé D290069 (42403)

Page is not included in this copy.

Pages 9 through 11 are not included.

The material not included contains the following type of information:

- Identity of product inert ingredients.
- Identity of product impurities.
- Description of the product manufacturing process.
- Description of quality control procedures.
- Identity of the source of product ingredients.
- Sales or other commercial/financial information.
- A draft product label.
- The product confidential statement of formula.
- Information about a pending registration action.
- FIFRA registration data.
- The document is a duplicate of page(s) .
- The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

Summary written by: B. Boutin-Muma
Date written: 03/07/23
Peer reviewed by: Y. Wigfield
Date peer reviewed: S. Mathur
Last update date: 10-6-03
Review Retrievability: The file was last saved in PMRA database under workbook\2003-0840_LS_3_0_492860.wkb on 2003/08/29.



Health Canada / Santé Canada

Pest Management / Agence de réglementation

Regulatory Agency / de la lutte antiparasitaire

2720 promenade Riverside Drive
Ottawa, Ontario
K1A 0K9

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



Your file / Votre référence

August 27, 2003

Memorandum To/Note Suzan Matthew
adressée à: 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

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.

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.

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, the completion date of such study is required.**

CONFIDENTIAL

INERT INGREDIENT INFORMATION IS NOT INCLUDED

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 components 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.