

US EPA ARCHIVE DOCUMENT

DATE: 17/MAY/2005

SUBJECT: **PRODUCT CHEMISTRY REVIEW OF TGAI/MP[X] EP[]**
DP BARCODE No.: D304581
File Symbol. No.: 7969-ENU (Transferred to 5481-LEG)
PRODUCT NAME: BAS 670 H Technical
COMPANY: BASF Corporation
PCC: 123009; FOOD USE: **[X]**; Decision #: 211973

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INTRODUCTION

The primary reviews for the technical BAS 670H Technical and the end-use product BAS 670 336SC Herbicide were performed by PMRA. The secondary review for both the products was performed by EPA (See PCR DP290077, dated 09-29-03). The product chemistry data were submitted under MRID Nos. 459021-01 thru 459021-17. The Deficiency letter was written by EPA on January 13, 2004. The registrant responded on April 8, 2004. The following report is the evaluation of the response provided by the BASF Corporation.

SUMMARY OF FINDINGS:

1. ISO common name must be used on the label and the CSF.

Response: The ISO common name will be added to the label as soon as it is approved by the ISO committee. BASF submitted an initial name and there is presently some discussion as to the acceptability by the committee.

There is no difference between "BAS 670H Acid" and the "BAS 670 336 SC free acid" as described on the product labels. The chemical name given by BASF for BAS 670 H is:

[3-(4,5-dihydro-isoxazol)-4-methanesulfonyl-2-methylphenyl]-(5-hydroxy-1-methyl-1H-pyrazol-4-yl)methanone.

2. Five batch analysis for the commercial scale (full scale production) product must be submitted when such samples are available.

Response: Full scale production data for the TGAI is not available. The five batch analysis from the pilot scale was submitted and is representative of expected full scale TGAI production. Upon registration of TGAI, full scale manufacturing will begin and five batch analysis of typical full scale production will be conducted and submitted. The exact date of the data submission is contingent on the date of registration of the TGAI

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3. An analytical grade sample (5 gm) and TGA sample (200 gm) of the new active ingredient must be submitted at the following address: EPA Analytical Laboratory, 701 Mapes Road, Ft. Meade, MD 20755-5350; Attention.: Chuck Stafford.

Response: The requested amount of analytical standard of BAS 670 H has been ordered from Germany and will be sent directly to the listed person in Laboratory Services.

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

CONCLUSIONS:

TRB has evaluated the response of the Deficiency letter and has concluded that:

1. The registrant must submit the product label with correct chemical name of the active ingredient and its nominal concentration which must concur with the nominal concentration of the AI in the CSF.
2. The five batch analysis for BAS 670 H technical produced on commercial scale must be submitted to the Agency. If there are significant changes with respect to nominal concentration of the AI and the impurity profile, a revised CSF must be submitted with correct manufacturing site.
3. Standard sample of the AI must be submitted to the EPA Laboratory, if it has not been done.