

DP BARCODE No.: D336048 **REG. No.:** 62719-518 **PRODUCT NAME:** Aminopyralid Technical

DATE: 25 / APR /2007

SUBJECT: FEE.PRODUCT CHEMISTRY REVIEW OF TGA/MP [X] EP []
DP BARCODE No.: D336048 **REG. No.:** 62719-518
PRODUCT NAME: Aminopyralid Technical
COMPANY: Dow Agrosciences
PCC: 005100; **Decision No.:** 373717; **ACTION CODE:** R34
FOOD USE [X]
INTEGRATED FORMULATION: Yes [X] No []

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

S B Mathur
4/25/07
dm

TO: Eugene Wilson / Joanne Miller, RM 23
Herbicide Branch / RD (7505P)

INTRODUCTION

The registrant has submitted a revised CSF for basic formulation (dated 01-08-07) to support the registration of the aminopyralid technical. The previous basic CSF (dated 08-22-05) was based on the pilot plant scale production of technical aminopyralid. As per agreement with the Agency, DAS has updated the basic CSF when the manufacturing process had stabilized and producing the aminopyralid technical with consistent homogeneity. The registrant in support has submitted product chemistry data corresponding to guidelines 830.1700 (five batch analysis) under MRID No. 470294-01. TRB has been asked to determine whether the data submitted corresponding to guideline 830.1700 (five batch analysis) support the basic CSF (dated 01-08-07) and determine its acceptability. If accepted, the revised basic CSF will supersede the current basic CSF (dated 08-22-05).

SUMMARY OF FINDINGS

1. The nominal concentration of the active ingredient aminopyralid technical has not changed and remained consistently at 95.3% as determined by the five batch analysis.
2. There is slight variation in the impurity profile for the revised basic & the previously accepted basic CSF. The registrant has added [REDACTED] new impurities (present at the levels of > 0.1%) in the revised CSF in addition to [REDACTED] impurities listed on the previous CSF. The nominal concentration (95.3%) of the active ingredient on the revised CSF is unchanged. The product label claim is 95.3%.
3. The data submitted corresponding to guideline 830.1700 (preliminary analysis) support the revised basic CSF (dated 01-08-07). The five batches of the aminopyralid produced by DAS in USA, on commercial scale were analyzed by HPLC/UV method for using internal & external standard methods for the active ingredient and the impurities. The identification of the AI & impurities was confirmed by LC-MS and LC-MS-MS. The analytical method was validated for precision, linearity, accuracy, LOD, and LOQ under the experimental parameters.
4. The nominal concentration & the certified limits for the active ingredient mentioned on the revised basic CSF (dated 01-08-07) concur with the experiment analytical data provided under MRID No. 470294-01.

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CONCLUSIONS

TRB has evaluated the product chemistry data submitted for the guideline 830.1700 and has determined that:

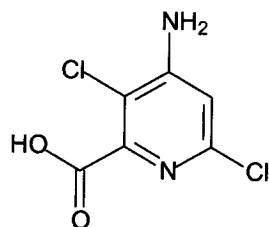
1. The data submitted for five batch analysis support the revised CSF for basic formulation dated January 8, 2007. The revised CSF is acceptable and will supersede the current CSF for basic formulation (dated 08-22-05).
2. TRB has no information on the toxicity of one of the new impurities which is present in the revised basic formulation. For the name of the impurity, please refer to Confidential Appendix.

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830.1550. Product Identity & composition:

	Trade Name	Aminopyralid (DE-750) Technical Herbicide
	Other Name	XDE-750, DE-750, XR-750
	Common Name	Aminopyralid
	IUPAC Chemical Name	4-amino-3,6-dichloropyridine-2-carboxylic acid
	CAS Chemical Name	2-pyridinecarboxylic acid, 4-amino-3,6-dichloro-
	CAS Number	150114-71-9

Structural Formula:



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Pages 4 through 5 are not included in this copy.

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.

 X 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.

 Proprietary information pertaining to the chemical composition of an inert ingredient provided by the source of the ingredient.

 Attorney-Client Privilege.

 Claimed Confidential by submitter upon submission to the Agency.

 Internal Deliberative Information.

* 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.

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Pages 6 through 13 are not included in this copy.

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