

US EPA ARCHIVE DOCUMENT

DP BARCODE No.: D346973 REG. No.: 62719-518(a) PRODUCT NAME: Aminopyralid Technical

DATE: 16 / JAN / 2008

SUBJECT: PRODUCT CHEMISTRY REVIEW OF TGA/MP [X] EP []
DP BARCODE No.: D346973 REG. No.: 62719-518(a)
PRODUCT NAME: Aminopyralid Technical
COMPANY: Dow Agrosciences
PCC: 005100; Decision No.: 386637; ACTION CODE: 345
FOOD USE [X]
INTEGRATED FORMULATION: Yes [X] No []

FROM: Shyam B. Mathur,
Product Chemistry Team Leader
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S B Mathur
01-16-08
DMC

TO: Kathryn Montague / Joanne Miller, RM 23
Herbicide Branch / RD (7505P)

INTRODUCTION

The registrant has submitted an amended CSF for basic formulation (dated 01-15-08) to support the registration of the aminopyralid technical. The previous basic CSF (dated 01-08-07) was accepted by the Agency on April 25, 2007 (see PCR dated 05-25-07; D336048, MRID No. 470294-01). The amended CSF reflects the composition of technical aminopyralid manufactured by using an alternate source of one of the starting materials and no other significant changes were made in original manufacturing process. The 830 series Subgroup A data [excluding 830.1800, enforcement analytical method] have been submitted under MRID No. 472660-01. TRB has been asked to determine whether the data submitted corresponding to guideline 830 series subgroup A support the amended basic CSF (dated 01-15-08) and determine its acceptability. If accepted, the revised basic CSF will supersede the current basic CSF (dated 01-08-07).

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 no variation in the impurity profile for the amended basic & the previously accepted basic CSF. No new impurities have been added and the composition is identical to previous composition with respect to nominal concentrations and certified limits of the active ingredient and the impurities. The nominal concentration (95.3%) of the active ingredient on the amended CSF is unchanged. The product label claim is 95.3%.
3. The registrant has submitted an amended CSF for basic formulation (01-15-08) for the aminopyralid technical product. The average purity of the AI in TGA/MUP is 95.30%, as determined by the five batch analysis. The proposed certified limits for the AI are based on the standard certified limits as set forth in 40CFR§158.350(b) (2), where as the certified limits for the impurities are based on the five batch analysis. The product chemistry data submitted corresponding to guideline reference 830.1550 (product identity & composition) and 830.1750 (certified limits) satisfy the data requirements of 40CFR§158.320 and 158.350 respectively [MRID No. 472660-01].
4. The product chemistry data submitted corresponding to guideline reference 830.1600 (description of material used to produce the product) satisfy the data requirements of 40CFR§ 158.325 [MRID No. 472660-01].

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5. The product chemistry data submitted corresponding to guideline reference 830.1620 (description of production process) satisfy the data requirements for 40CFR§158.330. The aminopyralid technical was manufactured in four step integrated batch process. The product thus obtained was washed, dried & packaged. The details of the production process have been provided which included the amounts of each starting material used in the process, description of the equipment used, the reaction conditions (temperature, pH, etc.) and the yields of the final product and the steps taken to control the quality of the product [MRID No. 472660-01].

6. The product chemistry data submitted corresponding to guideline reference 830.1670 (discussion on the formation of impurities) satisfy the data requirements for 40CFR§158.340. During the production of aminopyralid technical, the registrant discussed and reported the formation of [REDACTED] impurities present at the levels of > 0.1%. All impurities in XDE-750 technical arise from the raw materials or from raw material impurities by carry over into the product or by (side) reactions of raw materials or impurities. The discussion has been provided on theoretical possible impurities and the impurities which are present at levels of < 0.1%. The XDE-750 technical was also analyzed to determine the presence of hexachlorobenzene (HCB, carried over from one of the starting materials). The HCB was not detected in any of the five batches of XDE-750 technical when analyzed by validated gas chromatography and HPLC methods [MRID No. 472660-01].

7. The data submitted corresponding the guideline reference 830.1700 (preliminary analysis) satisfy the data requirements of 40CFR§158.345. The study was conducted under GLP requirements in compliance with 40CFR§160. Five representative batches of the XDE-750 technical were analyzed for percent active ingredient and the impurities. The active ingredient was quantified by HPLC-UV method [DECO GL-AL MD-2003-001967-A1]. A total [REDACTED] impurities were quantified using HPLC method [DECO GL-AL MD-2003-001968-A1]. The five batch analysis supported the amended basic CSF (dated 01-15-08). The analytical methods were validated for accuracy, linearity, and precision [MRID Nos. 472660-01].

CONCLUSIONS

TRB has evaluated the product chemistry data submitted for aminopyralid technical (XDE-750) and has concluded that:

1. All the product chemistry data submitted corresponding to 830 Series Subgroup A are acceptable.
2. The amended CSF for basic formulation (dated 01-15-08) is acceptable and is supported by the five batch analysis. The amended basic CSF (dated 01-15-08) will supersede the current CSF for basic formulation (dated 01-08-07).
3. The hexachlorobenzene was not detected in any of the five batches which were subjected to analysis by validated HPLC, HPLC-MS & GC methods.

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830.1550. Product Identity & composition:

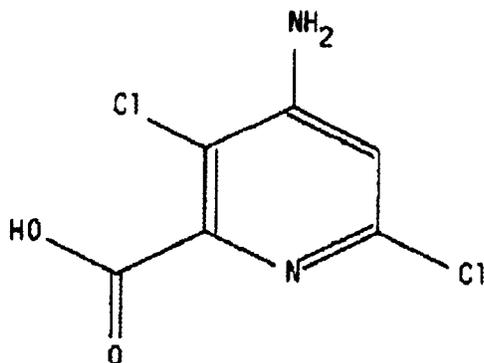
Compound Name: 4-amino-3,6-dichloropyridine-2-carboxylic acid

CAS Name: 2-pyridinecarboxylic acid, 4-amino-3,6-dichloro-

CAS Number: 150114-71-9

Synonyms: aminopyralid, XR-750, XDE-750

II. Empirical and Structural Formulas



Molecular Formula: $C_6 H_4 Cl_2 N_2 O_2$

Molecular Weight: 207.026

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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.
 - 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.
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* 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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