

Evaluation Report for Category B

Application Number: 2006-5091

Application: B.1.1: New Source (site of manufacture) for Same Registrant

B.1.2: Change to Specifications

Product: Diflufenzopyr Technical Herbicide

Registration Number: 25810

Active ingredients (a.i.): Diflufenzopyr PMRA Document Number: 1735268

Purpose of Application

The purpose of this application is to add a new site of manufacture and to change the specifications of diflufenzopyr technical herbicide.

Chemistry Assessment

Common Name: Diflufenzopyr-sodium

Chemical Name: Sodium 2-{(EZ)-1-[4-(3,5-difluorophenyl)semicarbazono]ethyl}

nicotinate

Diflufenzopyr Technical Herbicide has the following properties:

| Property | Result |
|--|--|
| Colour and physical state | Off-white powder |
| Nominal concentration | 87% |
| Odour | Odourless |
| Density at 25°C | 0.40 g/mL |
| Vapour pressure | <1 x 10 ⁻⁷ mmHg (<1.33 x 10 ⁻³ Pa) |
| рН | 10.04 (1% aqueous solution) |
| Solubility in water @25°C | 4.25 g/100mL |
| n-Octanol/water partition coefficient (K _{ow}) | pH K _{ow} 5.0 2.76 7.0 0.34 9.0 0.17 |

The chemistry requirements for diflufenzopyr technical herbicide have been completed.



Health Assessments

The food residue risk profile for the new site of manufacture of diflufenzopyr technical herbicide is expected to be similar to that of the currently registered site of manufacture, therefore, no increase in dietary exposure is anticipated.

The changes in the specifications of diflufenzopyr technical herbicide are not expected to significantly alter the toxicological profile compared to the currently registered specifications of diflufenzopyr technical herbicide, therefore, no toxicological data were required.

Value and Environmental Assessment

Value and environmental assessments were not required for this application.

Conclusion

The new site of manufacture and changes to the specifications of diflufenzopyr technical herbicide are acceptable for registration.

References

A. LIST OF STUDIES/INFORMATION SUBMITTED BY APPLICANT

| 1290768 | 2006, Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient (TGAI) or an Integrated System Product, N/A, MRID: N/A, DACO: 2.1,2.2,2.3,2.3.1,2.4,2.5,2.6,2.7,2.8,2.9 |
|---------|--|
| 1290769 | 2006, Manufacturing Summary, N/A, MRID: N/A, DACO: 2.11.1 CBI |
| 1290770 | 1997, SAN 836H Technical, WL-97-1, MRID: N/A, DACO: 2.11.2,2.11.3,2.11.4 CBI |
| 1290772 | 1997, SAN 836H Techncial: Analysis and Certification of Product Ingredients, TR-04-100-1-97, MRID: N/A, DACO: 2.12.1,2.13.1,2.13.2,2.13.3 CBI |
| 1290777 | 2006, Sodium Diflufenzopyr Production Run Data (Oct. 2001 - Jan. 2002), REvision of Specifications, N/A, MRID: N/A, DACO: 2.12.1,2.13.3 CBI |
| 1290781 | 2006, Composition Analysis for Diflufenzopyr Sodium Salt 5-Batch Analysis, N/A, MRID: N/A, DACO: 2.13.1,2.13.3 CBI |
| 1290782 | 1999, BASF Method F-64 Validation: "GLP Determination of Active Ingredients in TGAIs, PAIs, and Various Formulations Containing Acifluorfen, Atrazine, Bentazon, Dicamba, Diflufenzopyr, Dimethenamid, 2,4-D, Nicosulfuron and/or Quinclorac by HPLC", FR9848, |

| 1290783 | 1997, Color or SAN 836 H, Techncial, 414213-8, MRID: N/A, DACO: 2.14.1 |
|---------|--|
| 1290784 | 1997, Physical State of SAN 836 H, Technical, 414213-7, MRID: N/A, DACO: 2.14.2 |
| 1290785 | 1997, BAS 654 H: Determination of Odor, FR 9725, MRID: N/A, DACO: 2.14.3 |
| 1290786 | 1997, Melting Point of SAN 836 H, Technical, 414213-1, MRID: N/A, DACO: 2.14.4 |
| 1290787 | 2006, Boiling Point, N/A, MRID: N/A, DACO: 2.14.5 |
| 1290788 | 1997, Tap Density of SAN 836 H, Technical, 414213-2, MRID: N/A, DACO: 2.14.6 |
| 1290789 | 1997, Solubility of Technical SAN 836 H in Distilled Water and Organic Solvents, 414213-10, MRID: N/A, DACO: 2.14.7,2.14.8 |
| 1290790 | 1997, Solubility of Technical SAN 836 H in Distilled Water and Organic Solvents, 414213-10, MRID: N/A, DACO: 2.14.7,2.14.8 CBI |
| 1290791 | 2006, Vapor Pressure, N/A, MRID: N/A, DACO: 2.14.9 |
| 1290793 | 2006, Dissociation Constant, N/A, MRID: N/A, DACO: 2.14.10 |
| 1290795 | 2006, Octanol/Water Partition Coefficient, N/A, MRID: N/A, DACO: 2.14.11 |
| 1290798 | 1997, Stability of Technical SAN 836 H, 414213-11, MRID: N/A, DACO: 2.14.13 |
| 1290799 | 1997, Stability of Technical SAN 836 H, 414213-11, MRID: N/A, DACO: 2.14.13 CBI |
| 1290800 | 1997, pH of SAN 836 H, Technical, 414213-3, MRID: N/A, DACO: 2.16 |
| 1310063 | 1996, Vapor Pressure of SAN 835H, 414203, DACO: 2.14.9 CBI |
| 1310064 | 1996, Dissociation Constant of SAN 835H, 414203, DACO: 2.14.10 CBI |
| 1310065 | 1989, Determination of N-Octanol/Water Partition Coefficient for SAN 835H, 414055, DACO: 2.14.11 CBI |

| 1310142 | 1977, Determination of the Ultra-Violet Visible Absorption Spectrum of Diflufenzopyr, 147C-114, DACO: 2.14.12 CBI |
|---------|--|
| 1410508 | 2007, Summary of Validation for 2-acetylnicotinic acid in Technical Grade Sodium Diflufenzopyr (BAS 654 H), N/A, MRID: N/A, DACO: 2.13.1 CBI |

ISSN: 1911-8082

@ Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2010

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.