

Evaluation Report for Category B, Subcategory 1.3 Application

Application Number: 2009-0808
Application: Changes to the TGAI Product Chemistry-Specifications
Product: Sodium Diflufenzopyr Technical Herbicide
Registration Number: 29004
Active ingredients (a.i.): Diflufenzopyr [DFS]
PMRA Document Number: 1897423

Purpose of Application

The purpose of this application was to amend the specifications of Sodium Diflufenzopyr Technical Herbicide (Reg. No. 29004) and withdraw one manufacture site.

Chemistry Assessment

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

Sodium Diflufenzopyr Technical Herbicide has the following properties:

Property	Result												
Colour and physical state	Off-white powder												
Nominal concentration	86.3%												
Odour	Odourless												
Density at 25°C	0.40 g/mL												
Vapour pressure at 25°C	<0.0133 mPa												
pH	10.04 (1% aqueous solution)												
Solubility in water	4.25 g/100 mL												
n-Octanol/water partition coefficient (K_{ow})	<table border="0"> <tr> <td><u>pH</u></td> <td><u>K_{ow}</u></td> <td></td> </tr> <tr> <td>5.0</td> <td>2.76</td> <td></td> </tr> <tr> <td>7.0</td> <td>0.34</td> <td></td> </tr> <tr> <td>9.0</td> <td>0.17</td> <td>0.17</td> </tr> </table>	<u>pH</u>	<u>K_{ow}</u>		5.0	2.76		7.0	0.34		9.0	0.17	0.17
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The chemistry requirements for Sodium Diflufenzopyr Technical Herbicide have been completed.

Health Assessments

The amended Diflufenzopyr Methyl Technical Herbicide is considered toxicologically equivalent to the registered product. Therefore, no new toxicological data were submitted for review.

No new residue data for diflufenzopyr were submitted in support of this application to amend the specification of Sodium Diflufenzopyr Methyl Technical Herbicide. A review of the proposed label and specification form was conducted in the framework of this submission. As this technical active ingredient will be used to formulate registered end-use products within the existing use pattern, from a food residue exposure point of view, no changes in the magnitude of the residues in food and feed crops are expected and therefore, no increase in dietary exposure is anticipated.

Environmental and Value Assessments

Environmental and Value Assessments were not required for this application

Conclusion

The PMRA has conducted a review of the available information for this application and can support the amendments to the product, Sodium Diflufenzopyr Technical Herbicide.

References

Studies/Information Provided by Applicant/Registrant

- 1290769 2006, Manufacturing Summary, DACO: 2.11.1 CBI
- 1290770 1997, SAN 836H Technical, DACO: 2.11.2,2.11.3,2.11.4 CBI
- 1290781 2006, Composition Analysis for Diflufenzopyr Sodium Salt 5-Batch Analysis, DACO: 2.13.1,2.13.3 CBI
- 1727670 2009, DACO 2 Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient (TGAI) or an Integrated System Product, DACO: 2.1,2.2,2.3,2.3.1,2.4,2.5,2.6,2.7,2.8,2.9
- 1727673 2009, Establishing Certified Limits, DACO: 2.12.1 CBI
- 1727674 2005, BAS 654H: Validation of BASF Method AFR0034/01: Reverse-Phase HPLC Method for the Determination of Na-Diflufenzopyr (Reg. No.4080607) as Diflufenzopyr Acid (Reg. No. 362255) in BAS 654 02H and TGAI, DACO: 2.13.1 CBI
- 1727677 2007, Analysis of Five Representative Batches of Sodium Diflufenzopyr Technical Manufactured at [CBI REMOVED], DACO: 2.13.1,2.13.3 CBI
- 1825162 2009, Validation of the analytical method ATM-5024.06 for the determination of impurities of Sodium Diflufenzopyr in technical grade active ingredient by high performace liquid chromatography, DACO: 2.13.1 CBI

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