

Evaluation Report for Category B, Subcategory 1.1, 1.3 Application

Application Number: 2009-1196
Application: New/Changes to the technical grade active ingredient: changes in product chemistry specifications and new source (site) by the same registrant
Product: AC 9000001 Technical Herbicide
Registration Number: 27290
Active ingredients (a.i.): Picolinafen
PMRA Document Number: 1947749

Purpose of Application

The purpose of this application was to add a new manufacturing site and change the specifications of the currently registered technical grade active ingredient AC 9000001 Technical Herbicide, Registration Number 27290.

Chemistry Assessment

Common Name: Picolinafen
Chemical Name: 4'-fluoro-6-(α , α , α -trifluoro-m-tolyloxy)pyridine-2-carboxanilide

AC 900001 Technical Herbicide has the following properties:

Property	Result
Colour and physical state	White crystalline solid
Nominal concentration	99.4%
Odour	Musty, phenolic
Density	1.42 g/mL at 20°C
Vapour pressure	1.66×10^{-7} mPa at 20°C
pH	Not applicable
Solubility in water	3.9×10^{-5} g/L at 20°C
n-Octanol/water partition coefficient	$\log K_{ow} = 5.37$

The chemistry requirements for AC 900001 Technical Herbicide have been completed.

Health Assessments

The toxicity profile of the product from the new manufacturing site of picolinafen is not expected to be significantly different from the currently registered source as a result, no toxicological data were required.

No new residue data for picolinafen were submitted in support the application to add a new manufacturing site and amend the specification form for AC 900001 Technical Herbicide, (Registration Number 27290). A review of the TGAI manufactured at the proposed new site was conducted in the framework of this applicaiton. From a food residue exposure perspective, no changes in the magnitude of the residues in food and feed crops are expected and therefore, no increase in dietary exposure is expected.

Environmental and Value Assessments

Environmental and value assessments were not required as part of this application.

Conclusion

The PMRA has conducted a review of the available information for this application and has concluded that the addition of a new source for the production of AC 900001 Technical Herbicide and the changes in the product specifications are acceptable.

References

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- 1739614 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
- 1739617 2009, Daco 2.11 - Manufacturing Methods for the TGAI, DACO: 2.11.1, 2.11.2, 2.11.3 CBI
- 1739619 2008, Compositional Analysis of Picolinafen (BAS 700 H) Technical Grade Active Ingredient Manufactured at [CBI removed], [CBI Removed], in Support of Registration with World-Wide Regulatory Authorities, DACO: 2.12.1 CBI
- 1739624 2003, Validation of method M-3437_1 (Determination of the by-compounds Reg.No. 4 110 462 and Reg.No. 4 110 467 in Picolinafen (TGAI)), DACO: 2.13.1 CBI
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- 1739628 2001, Compositional analysis of Picolinafen (BAS 700 H) technical grade active ingredient manufactured at [CBI Removed] in support of registration with world-wide regulatory authorities, DACO: 2.13.
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ISSN: 1911-8082

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