

Evaluation Report for Category B, Subcategory 1.1, 1.3 Application

Application Number: 2015-7178
Application: New TGAI Product Chemistry – New Source (site) Same Registrant and Specifications
Product: Syngenta Dicamba Technical 2 Herbicide
Registration Number: 32672
Active ingredients (a.i.): Dicamba
PMRA Document Number: 2738664

Purpose of Application

The purpose of this application was to add an alternate manufacturing source to the new source of the active ingredient dicamba registered under 2015-7177.

Chemistry Assessment

Common Name: Dicamba
IUPAC* Chemical Name: 3,6-dichloro-o-anisic acid
 or
 3,6-dichloro-2-methoxybenzoic acid
CAS† Chemical Name: 3,6-dichloro-2-methoxybenzoic acid

* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

Syngenta Dicamba Technical 2 Herbicide has the following properties:

Property	Result
Colour and physical state	Light cream to tan solid
Nominal concentration	98%
Odour	Weak to slightly aromatic and pungent odour
Density	1.5 g/mL
Vapour pressure	1.67 mPa (at 25°C)
pH	2 - 5
Solubility in water	6.6 g/L (pH 1.8) >250 g/L (pH 4.1, pH 6.8, pH 8.2)

Property	Result
n-Octanol/water partition coefficient	Log K _{ow} = -1.9 (pH 8.9) Log K _{ow} = -1.88 (pH 6.8) Log K _{ow} = -0.55 (pH 5.0)

The required chemistry data for Syngenta Dicamba Technical 2 Herbicide have been provided, reviewed, and found to be acceptable.

Health Assessments

Exposure assessments were not required for this application.

Syngenta Dicamba Technical 2 Herbicide was of low toxicity to rats via the oral, dermal, and inhalation routes. It was severely irritating to the isolated chicken eye. It was non-irritating to the skin of rabbits and it was not a dermal sensitizer in mice.

Environmental Assessment

The Dicamba technical from the new source contains contaminants which have been identified in the federal government's Toxic Substances Management Policy (TSMP, 1995) as Track 1 substances. When compared to other registered sources; the use of the new source is not expected to result in an increase in the release of Track-1 contaminants. PMRA's strategy to manage Track 1 contaminants in pest control products is presented in DIR99-03.

Value Assessment

A value assessment was not required for this application.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided and is able to support the alternate manufacturing site for Syngenta Dicamba Technical 2 Herbicide.

References

PMRA Document Number	References
2597137	2003, Dicamba SAN837 - Confirmation of structures of by-products, DACO: 2.12.2, 2.13.4 CBI
2597139	2014, Dicamba Technical SAN837 - Analytical Method and Validation SA-86/1, DACO: 2.13.1 CBI Y
2597138	2015, Dicamba SAN837 - Standards/Certificate of Analysis, DACO: 2.13.3 CBI
2678477	2016, Confidential Business Information - Dicamba Technical 2 Herbicide - Response to deficiency , DACO: 2.12.1 CBI
2656170	2016, Confidential Business Information - Dicamba Technical 2 Herbicide - Clarification Note, DACO: 2.12.1 CBI
2678478	2016, Dicamba - Analysis of Five Representative Batches Produced at [CBI removed] - Final Report, DACO: 2.13.4 CBI
2678479	2016, Dicamba Validation of Analytical Method SBA-86/1 - Final Report, DACO: 2.13.4 CBI
2597325	2015, Dicamba - Acute Oral Toxicity - Up-And-Down Procedure in Rats - Final Report, DACO: 4.2.1
2597326	2015, Dicamba Acute Dermal Toxicity in Rats - Final Report, DACO: 4.2.2
2597327	2015, Dicamba - Acute Inhalation Toxicity in Rats - Final Report, DACO: 4.2.3
2597328	2015, Dicamba - Primary Skin Irritation in Rabbits - Final Report, DACO: 4.2.5
2597329	2015, Dicamba In Vitro Eye Irritation Test in Isolated Chicken Eyes - Final Report, DACO: 4.2.4
2597330	2015, Dicamba - Local Lymph Node Assay (LLNA) in Mice - Final Report, DACO: 4.2.6
2597331	2015, Syngenta Dicamba Technical 2 Herbicide - Summary Toxicology Profile, DACO: 12.7, 4.1, Document M

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