



Evaluation Report for Category B, Subcategory 1.3 Application

Application Number: 2013-2635
Application: New / Changes TGAI or ISP Prod Chemistry-Specifications
Product: Hexazinone Technical Herbicide
Registration Number: 19544
Active ingredients (a.i.): Hexazinone
PMRA Document Number : 2417004

Purpose of Application

The purpose of this application was to include a new impurity from a new manufacturing process and to amend the product chemistry specifications of the currently registered product Hexazinone Technical Herbicide.

Chemistry Assessment

Common Name: Hexazinone
IUPAC* Chemical Name: 3-cyclohexyl-6-(dimethylamino)-1-methyl-1,3,5-triazine-2,4(1*H*,3*H*)-dione
CAS† Chemical Name: 3-cyclohexyl-6-(dimethylamino)-1-methyl-1,3,5-triazine-2,4(1*H*,3*H*)-dione

* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

Hexazinone Technical Herbicide has the following properties:

Property	Result
Colour and physical state	Colourless crystals
Nominal concentration	98.7%
Odour	Odourless
Specific gravity	1.25
Vapour pressure	0.03 mPa (25 °C) 8.5 mPa (86 °C)
pH	7.5 (in 1% water)
Solubility in water	29.8 g/L (pH 7)
n-Octanol/water partition coefficient	LogK _{ow} = 1.2 (pH 7)

The chemistry requirements for Hexazinone Technical Herbicide have been fulfilled.

Health Assessments

The addition of a new manufacturing process as well as amending the product chemistry by inclusion of a new impurity results in a product that is chemically equivalent to the registered one are minor changes and not expected to impact the toxicological profile. Consequently no toxicological data was submitted or required.

Environmental and Value Assessments

Environmental and value assessments were not required for this application.

Conclusion

The PMRA has completed an assessment of the information provided and is able to support the registration of Hexazinone Technical Herbicide.

References

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- 2303157 2012, Hexazinone (DPX-A3674) Identity, composition, and certified limits-non-confidential, DACO: 2.12,2.12.1,2.13.2
- 2303158 2011, Hexazinone (DPX-A3674) Technical: Confirmation of impurity identification in the active ingredient by HPLC/UV Spectroscopy, DACO: 2.13.3 CBI
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- 2303166 2011, Description and validation of the analytical methods for determination of impurities in technical grade hexazinone (DPX-A3674) - confidential, DACO: 2.13.1 CBI
- 2303167 2011, Description and validation of the analytical methods for determination of impurities in technical grade hexazinone (DPX-A3674) - non-confidential, DACO: 2.13.1
- 2303168 2011, Quantitation of Active Ingredient and [CBI Removed] in hexazinone (DPX)A3674) toxicological samples and batches of technical material, DACO: 2.13.3 CBI

- 2461273 2014, determination of [CBI Removed] in batch analysis of hexazinone technical material, DACO: 2.13.4
- 2461276 2014, batch data for [CBI Removed], DACO: 2.13.3
- 2461279 2014, batch data for [CBI Removed], DACO: 2.13.3
- 2463431 2011, Batch analysis of hexazinone (DPX-A3674) Technical, DACO: 2.13.3

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