Health Canada Santé Canada

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Evaluation Report for Category B, Subcategory 1.2 Application

Application Number: 2014-0547
Application: New Source of Technical Grade Active Ingredient by a New Registrant
Product: Sharda Metribuzin Technical
Registration Number: 32098
Active ingredients (a.i.): Metribuzin
PMRA Document Number : 2577664

Purpose of Application

The purpose of this application was to register a new source of the active ingredient, metribuzin, by a different Registrant.

Chemistry Assessment

Common Name: metribuzin
CAS Chemical Name: 4-amino-6-(1,1-dimethylethyl)-3-(methylthio)-1,2,4-triazin-5(4*H*)-one
IUPAC Chemical Name: 4-amino-6-*tert*-butyl-4,5-dihydro-3-methylthio-1,2,4-triazin-5-one
Or
4-amino-6-*tert*-butyl-3-methylthio-1,2,4-triazin-5(4*H*)-one
PIN: 4-amino-6-*tert*-butyl-3-(methylsulfanyl)-1,2,4-triazin-5(4*H*)-one

Sharda Metribuzin Technical has the following properties:

Property	Result
Colour and physical state	White solid
Nominal concentration	98.51%
Odour	characteristic
Specific gravity	1.2614 at 20°C
Vapour pressure	1.11×10^{-4} Pa at 40°C 7.83×10^{-5} Pa at 32°C 4.45×10^{-5} Pa at 20°C (calculated)

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Property	Result
pH	6.95
Solubility in water	1.22 g/L in unbuffered water (pH 6.7)
n-Octanol/water partition coefficient (K_{ow})	Log K_{ow} = 1.70 (pH 7.1)

The chemistry requirements for Sharda Metribuzin Technical have been fulfilled.

Health and Environmental Assessment

As the new source of metribuzin is chemically equivalent to the registered source, the health and environmental risk profiles are expected to be similar to that of the product used to determine chemical equivalence. No additional assessments were required.

Value Assessment

A value assessment is not required for technical grade active ingredient products.

Conclusion

The PMRA has completed an evaluation of the subject application and has determined that it can support the registration of Sharda Metribuzin Technical.

References

PMRA Document Number	**Reference**
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2392712	2012, Analysis of 5 Batches of Metribuzin Technical Material to Determine the Content of the Active Ingredient and Specified Impurities with the Associated Validation in Complicance with Good Laboratory Practice, DACO: 2.13.1,2.13.2,2.13.3,2.4,2.5,2.6,2.7 CBI
2392713	2012, Appendix I to III, DACO: 2.13.1,2.13.2,2.13.3 CBI
2392716	2012, Appendix VI-IX, DACO: 2.13.1,2.13.2,2.13.3 CBI
2392717	2012, Metribuzin Technical: Determination of the Colour, Odor and Physical State, DACO: 2.14.1,2.14.2,2.14.3
2392720	2012, Metribuzin Technical: Determination of the Partition Co-efficient (n-octanol/water), DACO: 2.14.11
2392721	2012, Metribuzin Technical: UV vis, IR, MS and NMR Spectra, DACO: 2.14.12
2392722	2012, Metribuzin Technical: Determination of the Accelerated Storage Stability and Corrosion Charateristics, DACO: 2.14.13

PMRA Document Number	Reference
2392723	2012, Metribuzin Technical: Determination of the Chemical Compatibility, DACO: 2.14.13
2392724	2012, Metribuzin Technical: Determination of the Melting Point, DACO: 2.14.4
2392725	2013, Metribuzin Technical: Determination of the Boiling Point, DACO: 2.14.5
2392726	2012, Metribuzin Technical: Determination of the Relative Density, DACO: 2.14.6
2392727	2012, Metribuzin Technical: Determination of the Water Solubility, DACO: 2.14.7
2392728	2012, Metribuzin Technical: Determination of Solubility in Organic Solvents, DACO: 2.14.8
2392729	2012, Metribuzin Technical: Determination of the Vapour Pressure, DACO: 2.14.9
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ISSN: 1911-8082