Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 1.1, 1.3 Application

Application Number: 2014-1322
Application: B.1.1 - New Source Same Registrant
B.1.3 - Change Product Specifications
Product: Sencor Technical
Registration Number: 20537
Active ingredients (a.i.): Metribuzin
PMRA Document Number : **2537512**

Purpose of Application

The purpose of this application was to register a new source by the same registrant and to register an additional alternate manufacturing process for Sencor Technical for this site.

Chemistry Assessment

Common Name: Metribuzin
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
CAS Chemical Name: 4-amino-6-(1,1-dimethylethyl)-3-(methylthio)-1,2,4-triazin-5(4*H*)-one

Sencor Technical has the following properties:

Property	Result
Colour and Physical state	white to light grey
Nominal guarantee	Metribuzin at 95.4%
Odour	Characteristic, slight musty
Density at 20°C	1.27 g/mL
Vapour pressure	0.058 mPa at 20ºC
Dissociation constant (pK_a)	1.0 ± 0.1
Octanol/water partition coefficient (K_{ow})	$\underline{\log K_{ow}}$ = 1.60
pH	5.5

The chemistry requirements for Metribuzin have been fulfilled.

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Health Assessments

The new manufacturing process results in a product that is toxicologically equivalent to the currently registered product. No toxicological data were required.

Environmental and Value Assessments

Environmental and value assessments were not required.

Conclusion

PMRA has reviewed information provided in support of the amendments as described above. Based on this review, the amendments to the subject product are acceptable for registration.

References

2415072	2013, Metribuzin (AE F055208) - Description of the manufacturing process of the technical grade active substance, DACO: 2.11.1,2.11.2,2.11.3,2.11.4,IIA 1.8.1,IIA 1.8.2 CBI
2415074	2014, MSDS booklet of starting materials, DACO: 2.11.2,IIA 1.8.2 CBI
2415075	2013, Material accountability of technical Metribuzin (AE F055208) - Five batches of technical Metribuzin, DACO: 2.13.3,IIA 1.11.1,IIA 2.5.1,IIA 2.5.2 CBI
2415076	2013, Material accountability of technical Metribuzin (AE F055208) - Five batches of technical Metribuzin, DACO: 2.13.3,IIA 1.11.1,IIA 2.5.1,IIA 2.5.2 CBI
2415080	2013, Determination of metribuzin (AE F055208) in technical grade and pure active substance by gas chromatography, DACO: 2.13.1,IIA 4.2.1 CBI
2415081	2013, Validation of the GC analytical method AM036112FP1 - Determination of metribuzin (AE F055208) in technical grade and pure active substance by gas chromatography, DACO: 2.13.1,IIA 4.2.1 CBI
2415082	2013, Determination of by-products metribuzin (AE F055208) in technical grade metribuzin (AE F055208) and pure active substance by gas chromatography, DACO: 2.13.4,IIA 4.2.3 CBI
2415084	2013, Analytical method - Determination of solvents methanol (AE F130989) and toluene (AE F125577) in technical grade and pure metribuzin (AE F055208) by gas chromatography (GC), DACO: 2.13.4,IIA 4.2.3 CBI
2415085	2013, Validation of the GC analytical method AM036012FP1 Determination of by-products in technical grade and pure Metribuzin (AE F055208) by gas chromatography, DACO: 2.13.4,IIA 4.2.3 CBI
2415087	2013, Validation of the GC analytical method AM037313FP1 - Determination of the solvents methanol (AE F130989) and toluene (AE F125577) in technical grade and pure metribuzin (AE F055208) by gas chromatography (GC), DACO: 2.13.4,IIA 4.2.3 CBI

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