

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2011-5429
Application: B.1.1 (Product chemistry - new source, same registrant)
Product: Pyroxsulam Technical Herbicide
Registration Number: 28886
Active ingredients (a.i.): Pyroxsulam (JUA)
PMRA Document Number : 2188754

Purpose of Application

The purpose of this application was to register an alternate manufacturing source by the same registrant of Pyroxsulam Technical Herbicide.

Chemistry Assessment

Common Name: pyroxsulam
IUPAC Name: *N*-(5,7-dimethoxy[1,2,4]triazolo[1,5-*a*]pyrimidin-2-yl)-2-methoxy-4-(trifluoromethyl)pyridine-3-sulfonamide
CAS Name: *N*-(5,7-dimethoxy[1,2,4]triazolo[1,5-*a*]pyrimidin-2-yl)-2-methoxy-4-(trifluoromethyl)-3-pyridinesulfonamide

Pyroxsulam Technical has the following properties:

Property	Result										
Colour and physical state	Off-white solid										
Nominal concentration	99.0%										
Odour	Spicy odour										
Density	1.618 g/cm ³ at 20°C										
Vapour pressure	< 1 × 10 ⁻⁷ Pa at 20°C										
pH	4.06 (1% aqueous solution)										
Solubility in water at 20°C	<table border="0"> <tr> <td><u>pH</u></td> <td><u>Solubility (g/L)</u></td> </tr> <tr> <td>purified water</td> <td>0.0626</td> </tr> <tr> <td>4</td> <td>0.0164</td> </tr> <tr> <td>7</td> <td>3.20</td> </tr> <tr> <td>9</td> <td>13.7</td> </tr> </table>	<u>pH</u>	<u>Solubility (g/L)</u>	purified water	0.0626	4	0.0164	7	3.20	9	13.7
	<u>pH</u>	<u>Solubility (g/L)</u>									
	purified water	0.0626									
	4	0.0164									
7	3.20										
9	13.7										
n-Octanol/water partition coefficient (K _{ow})	<table border="0"> <tr> <td><u>pH</u></td> <td><u>log K_{ow}</u></td> </tr> <tr> <td>4</td> <td>1.08</td> </tr> <tr> <td>7</td> <td>-1.01</td> </tr> <tr> <td>9</td> <td>-1.60</td> </tr> </table>	<u>pH</u>	<u>log K_{ow}</u>	4	1.08	7	-1.01	9	-1.60		
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With the exception of commercial-scale batch data which will be submitted once available, the chemistry requirements for Pyroxsulam Technical Herbicide have been completed.

Health Assessments

The proposed source of Pyroxsulam Technical Herbicide results in a product chemically equivalent to that of a previously registered source. Subsequently, no new toxicological data were submitted or are required.

Environmental and Value Assessments

Environmental and value assessments were not required for this application.

Conclusion

The PMRA has completed an assessment of the available information and is able to support the registration of an alternate manufacturing source of Pyroxsulam Technical Herbicide.

References

PMRA Document Number	References
1283060	2006, Group A - Product Identity and Composition, Description of Materials to Produce the Product, Description of the Production Process, Discussion of Formation of Impurities, Preliminary Analysis, Certified Limits, and Enforcement Analytical Method for XDE-742 Technical
1283061	2005, Analytical Method and Validation for the Determination of Active Ingredient and Process Impurities in XDE-742 Technical by Liquid Chromatography, DACO: 2.13.1 CBI
1283063	2005, Analytical Method and Validation for the Determination of Residual Solvent in XDE-742 Technical by Gas Chromatography, DACO: 2.13.1 CBI
2128094	2011, Pyroxsulam TGAI [CBI removed], DACO: 2.1,2.2,2.3,2.4,2.5,2.6,2.7, 2.8,2.9 CBI
2128095	2011, Group A - Product Identity and Composition, Description of Materials Used to Produce the Product, Description of the Production Process, Discussion of Formation of Impurities, Preliminary Analysis, Certified Limits, and Enforcement Analytical Methods of Pyroxsulam

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