

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2021-6346
Application: Changes TGAI Product Chemistry - New source (site) same registrant
Product: Reklemel Technical
Registration Number: 34181
Active ingredient (a.i.): Fluazaindolizine
PMRA Document Number : 3426689

Purpose of Application

The purpose of this application was to register a new source (site) for Reklemel Technical.

Chemistry Assessment

Common Name: Fluazaindolizine
IUPAC* Chemical Name: 8-chloro-*N*-[(2-chloro-5-methoxyphenyl)sulfonyl]-6-(trifluoromethyl)imidazo[1,2- α]pyridine-2-carboxamide
CAS† Chemical Name: 8-chloro-*N*-[(2-chloro-5-methoxyphenyl)sulfonyl]-6-(trifluoromethyl)imidazo[1,2- α]pyridine-2-carboxamide

* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

Reklemel Technical has the following properties:

Property	Result
Colour and physical state	Off-white to reddish-brown solid
Nominal concentration	97.3 %
Odour	None
Density	0.515 – 0.85 g/cm ³
Vapour pressure	2.12×10^{-4} mPa
pH	4.44 for 1% w/v aqueous suspension

Property	Result	
Solubility in water	<u>pH</u>	<u>Solubility (g/L)</u>
	distilled water	0.0561
	4.0	0.02210
	7.0	2.1479
	9.0	2.8455
n-Octanol/water partition coefficient	<u>pH</u>	<u>log K_{ow}</u>
	distilled water	0.81
	4.0	2.24
	7.0	-0.16
	9.0	-0.71

The required chemistry data for Reklamel Technical have been provided, reviewed, and found to be acceptable.

Health, Environmental and Value Assessments

Health, environmental and value assessments were not required for this application.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to support the registration of the new source (site) for Reklamel Technical.

Additional Information Being Requested

Since this technical product is manufactured only at pilot scale before registration, five-batch data representing commercial-scale production at the approved manufacturing site will be required as post-market information after registration.

References

PMRA Document Number	Reference
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2958189	2018, Group A-Product identity and composition, description of materials used to produce the product, description of production process, discussion of formation of impurities. Dow AgroSciences LLC, Study ID NAFST-181308 / DuPont-50963
2957839	2018, Analytical method and validation for the determination of impurities in fluazaindolizine (DPX-Q8U80) technical grade material. Crop Protection Product Design and Process R&D, Dow AgroSciences LLC, Study ID DAS-AM-G-180723
3297074	2021, [CBI removed] Reklemel 2020, DACO: 2.13.3

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