



Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2020-1585
Application: New TGAI Product Chemistry, New Source Same Registrant
Product: DE-570 Technical Herbicide
Registration Number: 26888
Active ingredient (a.i.): Florasulam
PMRA Document Number: 3236236

Purpose of Application

The purpose of this application was to add a new manufacturing site for the technical product, DE-570 Technical Herbicide.

Chemistry Assessment

Common Name: Florasulam
IUPAC* Chemical Name: 2',6',8-trifluoro-5-methoxy[1,2,4]triazolo[1,5-c]pyrimidine-2-sulfonamide
CAS† Chemical Name: *N*-(2,6-difluorophenyl)-8-fluoro-5-methoxy[1,2,4]triazolo[1,5-c]pyrimidine-2-sulfonamide

* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

DE-570 Technical Herbicide has the following properties:

Property	Result
Colour and physical state	Off-white solid
Nominal concentration	99.2%
Odour	No odour
Specific gravity	1.53
Vapour pressure	0.01 mPa at 25°C
pH	5.0
Solubility in water	6.360 g/L (pH 7.0)
n-Octanol/water partition coefficient	Log K _{ow} = -1.22 (pH 7.0)

The required chemistry data for DE-570 Technical Herbicide 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 it sufficient to support the addition of the new manufacturing site for DE-570 Technical Herbicide.

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
3115424	2020, Deccan - Group A - Product Identity and Composition, Description of Materials Used to Produce the Product, Description of Production Process, Discussion of Formation of Impurities, Preliminary Analysis, Certified Limits, and Enforcement Analytical Method for Florasulam, DACO: 2.11,2.12,2.13.1,2.13.2
3115426	2020, Florasulam Technical Grade Active Ingredient Specification Justification, DACO: 2.11.4
3115427	2020, Batch Analysis Study for Florasulam (CBI Removed), DACO: 2.13.3
3216013	2021, Quality Control Data for Five Representative Batches of Florasulam Technical, DACO: 2.11.3,2.13 CBI
3221070	2021, DACO 2.13.3 and 2.12.4 (CBI Removed) Raw Pilot Batch Data, DACO: 2.13.3,2.13.4 CBI
3234795	2021, DACO 2.11 (CBI Removed) Manufacturing Process and Raw Material – (CBI Removed), DACO: 2.11 CBI

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