

Evaluation Report for Category B, Subcategory 1.3 Application

Application Number: 2017-3893

Application: New/Changes TGAI Product Chemistry - Specifications

Product: FOE 5043 Technical Herbicide

Registration Number: 26232 **Active ingredient (a.i.):** Flufenacet **PMRA Document Number:** 2854655

Purpose of Application

The purpose of this application was to amend the specifications of the registered product FOE 5043 Technical Herbicide based on new chemistry data, and to update the label.

Chemistry Assessment

Common Name: Flufenacet

IUPAC* Chemical Name: 4'-fluoro-*N*-isopropyl-2-[5-(trifluoromethyl)-1,3,4-thiadiazol-2-

yloxy]acetanilide

CAS† Chemical Name: N-(4-fluorophenyl)-N-(1-methylethyl)-2-[[5-(trifluoromethyl)-

1,3,4-thiadiazol-2-yl]oxy]acetamide

FOE 5043 Technical Herbicide has the following properties:

Property	Result	
Colour and physical state	Tan solid	
Nominal concentration	97.9%	
Odour	Pungent, mercaptan-like odour	
Density	1.312 g/mL	
Vapour pressure	9×10^{-7} hPa at 20°C 2 × 10 ⁻⁶ hPa at 25°C	
рН	4.49 (1% aqueous slurry)	
Solubility in water (20°C)	<u>pH</u> <u>solubility (mg/L)</u> 4 55.94 7 55.91 9 53.12	



^{*} International Union of Pure and Applied Chemistry

[†] Chemical Abstracts Service

Property	Result
n-Octanol/water partition coefficient	$Log K_{ow} = 3.2 (24^{\circ}C)$

The required chemistry data for FOE 5043 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 the information sufficient to support the amendment of the specifications of FOE 5043 Technical Herbicide.

References

PMRA	Reference
Document	
Number	
1699567	1997, [Privacy INFO Removed] Data Code 2. Chemistry Requirements for the
	Registration of GOE 5043 Technical. Part 2.1-2.15, DACO: 2.1,2.10,2.11.3,
	2.13.2,2.13.3,2.13.4, 2.14.2,2.14.3,2.14.4,2.14.5,2.14.6,2.2,2.3,2.3.1,2.4, 2.5,2.6,
	2.7,2.8,2.9 CBI
1699611	[Privacy INFO Removed] 2.11.1 Manufacturing Summary. DACO 2 - Technical
	Volume 1, Overview of total FOE Process. Filename: A:\FOE.WPD, DACO: 2.11.1
	CBI
1699632	[Privacy INFO Removed] 2.11.4 - Discussion of Formation of Impurities, DACO:
	2.11.4 CBI
1699635	1994, [Privacy INFO Removed] 2.13.1 Methodology / Validation The Composition of
	Technical BAY FOE 5043, DACO: 2.13.1 CBI
1700286	FLT-BCY-1 2.11.2 Description of Starting Materials [Privacy INFO Removed],
	DACO: 2.11.2 CBI
2791229	2017, FOE 5043 (flufenacet) technical herbicide - Part 2 chemistry requirements for
	the registration of a technical grade of active ingredient (TGAI) or an integrated
	system product (ISP), DACO: 2.0,2.1,2.2,2.3,2.3.1,2.4,2.5,2.6,2.7,2.8, 2.9 CBI
2791230	2017, FOE 5043 (flufenacet) technical herbicide - Part 2 chemistry requirements for
	the registration of a technical grade of active ingredient (TGAI) or an integrated
	system product (ISP), DACO: 2.0,2.1,2.2,2.3,2.3.1,2.4,2.5,2.6, 2.7,2.8, 2.9 CBI
2791234	2017, Flufenacet (FOE 5043) - Discussion of the formation of impurities of the
	technical grade active substance for Canada, DACO: 2.11.4 CBI
2791235	2016, Statement regarding the certified limits for flufenacet technical grade active
	substance for USA, DACO: 2.12.1,2.13.3 CBI

PMRA	Reference
Document	
Number	
2791236	2011, Flufenacet - Determination of active substance in technical material HPLC -
	external standard, DACO: 2.13.1 CBI
2791237	2011, Validation of HPLC-method AM015811MP1 - Flufenacet - Determination of
	active substance in technical material [CBI Removed], DACO: 2.13.1 CBI
2791238	2011, Analytical method - Flufenacet- Determination of byproducts in technical
	substance [CBI Removed], DACO: 2.13.1 CBI
2791239	2011, Validation of [CBI Removed] Flufenacet- Determination of byproducts in
	technical substance [CBI Removed], DACO: 2.13.1 CBI
2791240	2012, Flufenacet - Determination of ortho and meta compound in technical substance
	, [CBI Removed], DACO: 2.13.1 CBI
2791241	2012, Validation of HPLC-method AM018212MP1- Determination of ortho and meta
	compound in flufenacet - [CBI Removed], DACO: 2.13.1 CBI
2791242	2012, Spectral data set of flufenacet a.i Reference material, DACO: 2.13.1 CBI
2791243	2001, MT 30 Water; 30.5 Karl Fischer method using pyridine-free reagents, DACO:
	2.13.1
2791244	2012, Amendment no 1 - Material accountability of technical flufenacet (FOE 5043) -
	Five batches of technical flufenacet, DACO: 2.13.3 CBI

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