

# **Evaluation Report for Category B, Subcategory 1.2 Application**

**Application Number:** 2014-2164

**Application:** New Source of Technical Grade Active Ingredient by a New

Registrant

**Product:** Sharda Fenoxaprop-P-Ethyl Technical Herbicide

**Registration Number:** 32191

**Active ingredients (a.i.):** fenoxaprop-P-ethyl

PMRA Document Number: 2604928

## **Purpose of Application**

The purpose of this application was to register a new source of the active ingredient, fenoxaprop-P-ethyl, by a different Registrant.

## **Chemistry Assessment**

Common Name: Fenoxaprop-P-ethyl

IUPAC\* Chemical Name: ethyl (2*R*)-2-{4-[(6-chloro-1,3-benzoxazol-2-yl)oxy]phenoxy}

propanoate

CAS† Chemical Name: ethyl (2*R*)-2-[4-[(6-chloro-2-benzoxazolyl)oxy]phenoxy]

propanoate

Sharda Fenoxaprop-P-ethyl Technical Herbicide has the following properties:

Property	Result
Colour and physical state	White solid
Nominal concentration	97.10%
Odour	Weak aromatic
Specific Gravity at 20°C	1.3215
Vapour pressure at 20°C	$6.97 \times 10^{-4}  \text{mPa}$
pН	6.37
Solubility in water	57.1μg/L (22°C)
n-Octanol/water partition coefficient	$Log K_{ow} = 4.18$



<sup>\*</sup> International Union of Pure and Applied Chemistry

<sup>†</sup> Chemical Abstracts Service

The required chemistry data for Sharda Fenoxaprop-P-ethyl Technical Herbicide have been provided, reviewed, and found to be acceptable.

#### **Health and Environmental Assessment**

As the new source of fenoxaprop-P-ethyl is chemically equivalent to the registered source, the health and environmental risk profiles are expected to be similar to that of the product used to determine chemical equivalence. No additional assessments were required.

#### **Value Assessment**

A value assessment is not required for technical grade active ingredient products.

#### Conclusion

The PMRA has completed an evaluation of the subject application and has determined that it can support the registration of Sharda Fenoxaprop-P-Ethyl Technical Herbicide.

#### References

PMRA Document	
Number	Reference
2434424	2014, Applicant's Name and Office Address, Formulating Plant and address, and
	Stability (Temperature, Metals) for Sharda Fenoxaprop-P-Ethyl Technical Herbicide, DACO: 2.1,2.14.13,2.2
2434425	2014, Applicant's Name and Office Address, Formulating Plant and address for
	Sharda Fenoxaprop P Ethyl Technical Herbicide, DACO: 2.1,2.14.13,2.2 CBI
2434427	2010, Fenoxaprop-p-Ethyl Technical Manufacturing and control (CMC) document, DACO: 2.11.1,2.11.2,2.11.3,2.11.4
2434428	2010, Enforcement Analytical Method: Validation of Analytical Method for the
	Determination of Fenoxaprop-P-Ethyl Technical Grade Active Ingredient (TGAI) to
	Determine % Fenoxaprop-P-Ethyl Active Ingredient and its Associated Impurities,
	DACO: 2.13.1,2.13.4 CBI
2434429	2011, Determination of [CBI removed] in Five Representative Production Batches of
	Fenoxaprop-P-Ethyl Technical Grade Active Ingredient (TGAI) by HPLC, DACO:
	2.13.3 CBI
2434430	2010, Determination of [CBI Removed] in Five Representative Production Batches of
	Fenoxaprop-P-Ethyl Technical Grade Active Ingredient (TGAI) by HPLC, DACO:
	2.13.3 CBI
2434431	2010, Preliminary Analyses of Five Representative Production Batches of
	Fenoxaprop-P-Ethyl Technical Grade Active Ingredient (TGAI) to Determine %
	Fenoxaprop-P-Ethyl and to Quantify its Associated Impurities, DACO:
	2.12.1,2.13.1,2.13.2,2.13.3,2.13.4 CBI
2434433	2011, Fenoxaprop-P-Ethyl Technical: Determination of the Colour, Odour and
	Physical State, DACO: 2.14.1,2.14.2,2.14.3,2.4,2.5,2.6,2.7,2.8,2.9

2434434 2011, Fenoxaprop-P-Ethyl Technical: Determination of the Dissociation Constant in Water, DACO: 2.14.10 2011, Fenoxaprop-P-Ethyl Technical: Determination of the Partition Coefficient (n-2434435 Octanol/Water), DACO: 2.14.11 2011, Fenoxaprop-P-Ethyl Technical: UV/Vis, IR, MS and NMR Spectra, DACO: 2434436 2.14.12 2434437 2011, Fenoxaprop-P-Ethyl Technical: Determination of the Accelerated Storage Stability and Corrosion Characteristics, DACO: 2.14.14,2.16 2011, Fenoxaprop-P-Ethyl Technical: Determination of the pH Value and Acidity or 2434438 Alkalinity, DACO: 2.14.15,830.7000 2011, Fenoxaprop-P-Ethyl Technical: Determination of the Melting Point, DACO: 2434439 2.14.4 2434440 2011, Fenoxaprop-P-Ethyl Technical: Determination of the Boiling Point, DACO: 2.14.5 2434441 2011, Fenoxaprop-P-Ethyl Technical: Determination of the Relative Density, DACO: 2.14.6 2011, Fenoxaprop-P-Ethyl Technical: Determination of the Water Solubility, DACO: 2434442 2.14.7 2434443 2011, Fenoxaprop-P-Ethyl Technical: Determination of the Solubility in Organic Solvents, DACO: 2.14.8 2434444 2011, Fenoxaprop-P-Ethyl Technical: Determination of the Vapour Pressure, DACO: 2011, Fenoxaprop-P-Ethyl Technical: Determination of the Oxidizing Properties, 2434445 DACO: 2.16 2011, Fenoxaprop-P-Ethyl Technical: Determination of the abiotic degradation 2434446 hydrolysis as a function of the pH, DACO: 2.16 2434447 2011, Fenoxaprop-P-ethyl Technical Explosive Properties, DACO: 2.16 2011, Fenoxaprop-P-Ethyl Technical: Determination of the Flammability, DACO: 2434448 2.16 2011, Fenoxaprop-P-Ethyl Technical: Determination of the Chemical Compatibility 2434449 (Corrosion Test), DACO: 2.14.13,2.16 2011, Fenoxaprop-P-Ethyl Technical: Determination of the Direct 2434450 Phototransformation, DACO: 2.16 2434451 2011, Fenoxaprop-P-Ethyl Technical: Determination of the Surface Tension, DACO: 2014, Letter Confirming Source of Technical used in 5 Batch Analysis, DACO: 2471179 2.13.3 CBI 2471180 2004, MATERIAL SAFETY DATA SHEET [CBI Removed], DACO: 2.11.2 CBI 2471181 2002, MATERIAL SAFETY DATA SHEET [CBI Removed], DACO: 2.11.2 CBI 2471182 2009, MATERIAL SAFETY DATA SHEET [CBI Removed], DACO: 2.11.2 CBI 2471183 2000, MATERIAL SAFETY DATA SHEET [CBI Removed], DACO: 2.11.2 CBI 2471184 2005, MATERIAL SAFETY DATA SHEET [CBI Removed], DACO: 2.11.2 CBI 2471185 2005, MATERIAL SAFETY DATA SHEET [CBI Removed], DACO: 2.11.2 CBI 2471186 2013, MATERIAL SAFETY DATA SHEET [CBI Removed], DACO: 2.11.2 CBI 2471187 2006, MATERIAL SAFETY DATA SHEET [CBI Removed], DACO: 2.11.2 CBI

1994, MATERIAL SAFETY DATA SHEET [CBI Removed], DACO: 2.11.2 CBI

2471188

0.471100	
2471189	2012, MATERIAL SAFETY DATA SHEET [CBI Removed], DACO: 2.11.2 CBI
2471190	1996, MATERIAL SAFETY DATA SHEET [CBI Removed], DACO: 2.11.2 CBI
2471192	2000, MATERIAL SAFETY DATA SHEET [CBI Removed], DACO: 2.11.2 CBI
2471194	2008, MATERIAL SAFETY DATA SHEET [CBI Removed], DACO: 2.11.2 CBI
2471197	2009, MATERIAL SAFETY DATA SHEET [CBI Removed], DACO: 2.11.2 CBI
2471199	2010, Chromatograms from: Preliminary Analysis of Five Representative Production
	Batches of Fenoxaprop-p-ethyl Technical Grade Active Ingredient (TGAI) to
	Determine % Fenoxaprop-p-ethyl and to Quantify its Associated Impurities, DACO:
	2.13.2 CBI
2471200	2014, Response to Notice of Deficiencies for Sharda Fenoxaprop-P-ethyl Technical
	Herbicide Submission Number: 2014-2164, DACO: 2.11.2,2.13.2,2.13.3,2.13.4
2486490	2014, The Analysis of Polychlorinated Dioxins and Furans, in Five Batches of
	Fenoxaprop-p-Ethyl Technical, (CAS No: 71283-80-2)., DACO: 2.13.4 CBI
2544652	2006, MSDS for [CBI Removed], DACO: 2.11.2 CBI
2544654	2015, Description of Starting Materials in Sharda Fenoxaprop-P-ethyl Technical,
	DACO: 2.11.2 CBI
2544656	2015, Manufacturing Method Sharda Fenoxaprop-P-ethyl Technical - Revised,
	DACO: 2.11.1,2.11.2,2.11.3,2.11.4 CBI
2544657	n/a, 2008, Fenoxaprop-P-ethyl 484, CIPAC book M B13, DACO: 2.13.1,2.13.3
2544658	n/a, 2008, CIPAC Method Fenoxaprop-P-ethyl 484, DACO: 2.13.1,2.13.3
2544659	2015, The Analysis of Polychlorinated Dioxins and Furans, in Five Batches of
	Fenoxaprop-p-Ethyl Technical, (CAS No: 71283-80-2), DACO: 2.13.4 CBI
2544661	2015, The Analysis of Polychlorinated Dioxins and Furans, in Five Batches of
	Fenoxaprop-p-Ethyl Technical, (CAS No: 71283-80-2), DACO: 2.13.4 CBI
2544663	2015, The Analysis of Polychlorinated Dioxins and Furans, in Five Batches of
	Fenoxaprop-p-Ethyl Technical, (CAS No: 71283-80-2), DACO: 2.13.4 CBI
2544667	2015, The Analysis of Polychlorinated Dioxins and Furans, in Five Batches of
	Fenoxaprop-p-Ethyl Technical, (CAS No: 71283-80-2), DACO: 2.13.4 CBI
2544669	2015, The Analysis of Polychlorinated Dioxins and Furans, in Five Batches of
	Fenoxaprop-p-Ethyl Technical, (CAS No: 71283-80-2), DACO: 2.13.4 CBI
2544671	2015, The Analysis of Polychlorinated Dioxins and Furans, in Five Batches of
	Fenoxaprop-p-Ethyl Technical, (CAS No: 71283-80-2), DACO: 2.13.4 CBI
2544673	2015, The Analysis of Polychlorinated Dioxins and Furans, in Five Batches of
	Fenoxaprop-p-Ethyl Technical, (CAS No: 71283-80-2), DACO: 2.13.4 CBI
2544675	2015, The Analysis of Polychlorinated Dioxins and Furans, in Five Batches of
	Fenoxaprop-p-Ethyl Technical, (CAS No: 71283-80-2), DACO: 2.13.4 CBI
2544677	2015, PMRA Clarification Questions and Responses for harda Fenoxaprop-P-ethyl
	Technical Herbicide, Sub. No. 2014-2164, DACO:
<b></b>	1.1.1,2.11.2,2.11.3,2.11.4,2.13.1,2.13.2,2.13.3 CBI
2547680	2015, Response to clarifications for Sharda Fenoxaprop-P-ethyl Technical Herbicide,
	submission 2014-2164, DACO: 2.12.1 CBI

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