

## Evaluation Report for Category B, Subcategory 1.2 Application

**Application Number:** 2010-5026  
**Application:** New Source of Technical Grade Active Ingredient by a New Registrant  
**Product:** MANA Fluroxypyr Technical  
**Registration Number:** 30507  
**Active ingredients (a.i.):** Fluroxypyr  
**PMRA Document Number:** 2123823

### Background

The source of fluroxypyr used to determine chemical equivalence was Registration Number 24814.

### Purpose of Application

The purpose of this application was to register a new source of the active ingredient, fluroxypyr, by a different Registrant.

### Chemistry Assessment

Common Name: Fluroxypyr-meptyl  
IUPAC Chemical Name: (*RS*)-1-methylheptyl 4-amino-3,5-dichloro-6-fluoro-2-pyridyloxyacetate  
CAS Chemical Name: 1-methylheptyl [(4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy]acetate

MANA Fluroxypyr Technical has the following properties:

Property	Result	
Colour and physical state	White solid	
Nominal concentration	68.0 % Fluroxypyr, present as 1-methylheptyl ester	
Odour	Organic like and weak sweetish odour	
Density @ 20°C	1.3251 g/cm <sup>3</sup>	
Vapour pressure @ 20°C	1.3 × 10 <sup>-6</sup> Pa	
pH	5.5 (10.65 mg/L solution in 90% methanol/10% water)	
Solubility in water	<u>pH</u>	<u>Solubility (mg/L)</u>
	5	0.0813
	7	0.109
	9	hydrolysis
n-Octanol/water partition coefficient (K <sub>ow</sub> )	Log K <sub>ow</sub> = 4.5 Log K <sub>ow</sub> = 5.61 (pH 7.4)	

The chemistry requirements for MANA Fluroxypyr Technical have been completed.

### Health and Environmental Assessments

As the new source of fluroxypyr 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 MANA Fluroxypyr Technical.

## References

<b>PMRA Document Number</b>	<b>Reference</b>
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1969063	2008, Fluroxypyr-meptyl Manufacturing Process, DACO: 2.11.1, 2.11.3, 2.11.4 CBI
1969065	2010, Discussion on the potential for formation of chlorinated dioxins (CDD), dibenzofurans (CDF) and / or hexachlorobenzene (HCB)., DACO: 2.11.4 CBI
1969068	2010, Fluroxypyr Meptyl Tech Consideration of potential [CBI Removed] formation, DACO: 2.11.4 CBI
1969070	2010, Chemistry-2.11.2-Fluroxypyr TGAI-Starting Materials, DACO: 2.11.2 CBI
1969072	2008, Fluroxypyr Technical 5-Lots Analysis and Method Validation, DACO: 2.13.1, 2.13.2, 2.13.3 CBI
1969074	2008, Fluroxypyr Technical 5-Lots Analysis and Method Validation, DACO: 2.13.1, 2.13.2, 2.13.3 CBI
1969076	2008, Date of production of batches in [CBI Removed], DACO: 2.13.3 CBI
1969078	2009, Date of production of batches in [CBI Removed], DACO: 2.13.3 CBI
1969080	2009, Physical State, Colour and Odour of Fluroxypyr Meptyl Technical, DACO: 2.14.1, 2.14.2, 2.14.3
1969082	2009, Partition Coefficient of Fluroxypyr Meptyl tech. (HPLC), DACO: 2.14.11
1969084	2009, UV/VIS Absorption Spectrum of Fluroxypyr Meptyl tech, DACO: 2.14.12
1969086	2009, Relative Density of Fluroxypyr Meptyl Technical, DACO: 2.14.6
1969089	2009, Solubility of Fluroxypyr Meptyl in Organic Solvents, DACO: 2.14.8
1969091	Anonymous, 1999, EC-Review report for the active substance fluroxypyr, DACO: 2.14.10, 2.14.11, 2.14.4, 2.14.5, 2.14.7, 2.14.8, 2.14.9
2036307	2011, Spec for [CBI Removed], DACO: 2.11.2 CBI
2036309	2011, Spec-[CBI Removed] production, DACO: 2.11.2 CBI
2036310	2011, Spec-[CBI Removed] Production, DACO: 2.11.2 CBI
2036311	2011, [CBI Removed] production, DACO: 2.11.2 CBI
2036312	2011, [CBI Removed] production, DACO: 2.11.2 CBI

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