

## Evaluation Report for Category B, Subcategory 1.1 Application

**Application Number:** 2012-5018  
**Application:** B.1.1 – New Manufacturing Site Same Registrant  
**Product:** Nufarm Bromoxynil Octanoate Technical  
**Registration Number:** 21927  
**Active ingredients (a.i.):** Bromoxynil  
**PMRA Document Number :** 2307391

### Purpose of Application

The purpose of this application was to register a new manufacturing site for Nufarm Bromoxynil Octanoate Technical.

### Chemistry Assessment

**Common Name:** Bromoxynil octanoate  
**IUPAC Chemical Name:** 2,6-dibromo-4-cyanophenyl octanoate  
**CAS Chemical Name:** 2,6-dibromo-4-cyanophenyl octanoate

Nufarm Bromoxynil Octanoate Technical has the following properties:

Property	Result
Colour and physical state	Signal yellow solid
Nominal concentration	65.5 % Bromoxynil (present as octanoate ester)
Odour	Odourless
Density @ 20°C	1.484-1.504 g/mL
Vapour pressure @ 40°C	$< 1 \times 10^{-4}$ mPa
pH	4.4
Solubility in water @ 20°C	1.30 mg/L
n-Octanol/water partition coefficient ( $K_{ow}$ )	$\text{Log } K_{ow} = 6.11$ ( $K_{ow} = 1.29 \times 10^6$ )

The chemistry requirements for Nufarm Bromoxynil Octanoate Technical have been completed.

### Health, Environment and Value Assessments

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

### Conclusion

The PMRA has reviewed the information provided in support of the new manufacturing site. Based on this review, PMRA has determined the new site is acceptable.

## References

- 2249805 2012, Chemistry Summary Document, DACO:  
2.1,2.14.9,2.2,2.3,2.3.1,2.4,2.5,2.6,2.7,2.8,2.9 CBI
- 2249806 2011, Chemical and Physical Characterization of Bromoxynil octanoate TGAI,  
DACO: 2.14.1,2.14.10,2.14.11,2.14.12,2.14.13,2.14.2,2.14.3,2.14.4,2.14.6,2.14.7,  
2.14.8 CBI
- 2249807 2012, Validation of Analytical Methodology for the Assay of 2 Non-Relevant  
Impurities in Bromoxynil Oct. TGAI, DACO: 2.13.1 CBI
- 2249808 2012, Validation of Analytical Methodology for the Assay of 4 Non-Relevant  
Impurities in Bromoxynil Oct. TGAI, DACO: 2.13.1 CBI
- 2249809 2012, Validation of Analytical Methodology for the Assay of [CBI Removed] in  
Bromoxynil Oct. TGAI, DACO: 2.13.1 CBI
- 2249810 2011, Validation of Analytical Methodology for the Assay of Active Ingredient in  
Bromoxynil Oct. TGAI, DACO: 2.13.1 CBI
- 2249811 2012, Preliminary Analysis of Bromoxynil octanoate TGAI, DACO:  
2.13.1,2.13.2,2.13.3 CBI
- 2249813 2012, Preliminary Analysis of Bromoxynil Octanoate TGAI - Confidential  
Attachment, DACO: 2.13.1,2.13.2,2.13.3 CBI
- 2249814 2012, Production Chemistry of Bromoxynil Octanoate, DACO:  
2.11.1,2.11.2,2.11.3,2.11.4 CBI
- 2302978 2012, Production Chemistry of Bromoxynil Octanoate, DACO: 2.11.3 CBI

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