

## Evaluation Report for Category B, Subcategory 1.1, 1.3 Application

**Application Number:** 2008-0343  
**Application:** B.1.1 (Changes to TGAI Product chemistry – New source (site) same registrant)  
 B.1.3 (Changes to TGAI product chemistry specifications)  
**Product:** Technical MCPA 2-Ethylhexyl Ester  
**Registration Number:** 19086  
**Active ingredients (a.i.):** MCPA (present as esters) (MAE)  
**PMRA Document Number:** 1749388

### Purpose of Application

Nufarm Agriculture has submitted an application to amend the manufacturing process of the registered source of MCPA 2-ethylhexyl ester and to add two new sources of the active ingredient.

### Chemistry Assessment

Common name: MCPA-2-ethylhexyl  
 IUPAC Chemical name: 2-ethylhexyl 4-chloro-*o*-tolylxyacetate

Technical MCPA 2-Ethylhexyl Ester has the following properties:

Property	Results
Colour and physical state	Brown non-viscous liquid
Nominal concentration	61.5 % (acid equivalent)
Odour	Strong ester odour
Density	1.064 – 1.074 g/mL
Vapour pressure	0.27 – 13 mPa (at 18 – 45°C)
pH	3.5 (saturated in water)
Solubility in water	<0.125 mg/L in pH 5 – 9
n-Octanol/water partition coefficient	log Kow = 6.8

The chemistry requirements for Technical MCPA 2-Ethylhexyl Ester have been completed.

### Health Assessments

The acute toxicology profile of this product is not expected to be altered. Technical grade MCPA 2-ethylhexyl ester produced at all sites is considered chemically equivalent, but not identical, to the precedent registered product. No new toxicology data were required.

Given that the two new sources of MCPA 2-ethylhexyl ester were deemed chemically equivalent to a registered source of MCPA 2-ethylhexyl ester, the food residue chemistry profile is expected to be similar. Accordingly, an increase in exposure to residues of MCPA for each population subgroup is not anticipated.

### **Environmental Assessment**

An environmental assessment is not required for this application.

### **Value Assessment**

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

### **Conclusion**

The PMRA has completed an assessment of available information and has found the information sufficient to support the registration of the two new sources of MCPA 2-ethylhexyl ester as well as the change in the manufacturing process for the registered source of MCPA 2-ethylhexyl ester.

### **References**

#### **Chemistry:**

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- 1542627 1993, MCPA 2EH Ester Determination of Physical Chemical Properties, IRI 351815 9618, MRID: 43129310, DACO: 2.14.1,2.14.12,2.14.2,2.14.3,2.14.5, 2.14.6 **CBI**

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