

## Evaluation Report for Category B, Subcategory 1.3 Application

**Application Number:** 2012-3992  
**Application:** B.1.3 – Change in Specifications  
**Product:** Trinexpac-ethyl Technical  
**Registration Number:** 26988  
**Active ingredients (a.i.):** Trinexpac-ethyl  
**PMRA Document Number :** **2300847**

### Purpose of Application

The purpose of this application was to update the specifications of the product based on updated manufacturing process with the manufacturing site remaining the same.

### Chemistry Assessment

**Common Name:** Trinexpac-ethyl  
**IUPAC Chemical Name:** Ethyl (*RS*)-4-cyclopropyl(hydroxy)methylene-3,5-dioxocyclohexanecarboxylate  
**CAS Chemical Name:** Ethyl 4-(cyclopropylhydroxymethylene)-3,5-dioxocyclohexanecarboxylate

Trinexpac-Ethyl Technical has the following properties:

Property	Result										
Colour and physical state	Yellow to red-brown liquid or crystals										
Nominal concentration	97 %										
Odour	Slightly sweet										
Density at 20°C	1.215 g/mL										
Vapour pressure	$2.16 \times 10^{-3}$ Pa at 25°C (by extrapolation of curve from 38.0 - 170.2°C).										
pH	3 – 4 (1% in water)										
Water solubility at 25°C	<table style="width: 100%; border: none;"> <tr> <td style="text-align: left;"><u>pH</u></td> <td style="text-align: right;"><u>Solubility (g/L)</u></td> </tr> <tr> <td>3.5 (distilled water)</td> <td style="text-align: right;">1.1</td> </tr> <tr> <td>4.9 (buffer)</td> <td style="text-align: right;">2.8</td> </tr> <tr> <td>5.5 (buffer)</td> <td style="text-align: right;">10.2</td> </tr> <tr> <td>8.2 (buffer)</td> <td style="text-align: right;">21.2</td> </tr> </table>	<u>pH</u>	<u>Solubility (g/L)</u>	3.5 (distilled water)	1.1	4.9 (buffer)	2.8	5.5 (buffer)	10.2	8.2 (buffer)	21.2
	<u>pH</u>	<u>Solubility (g/L)</u>									
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	4.9 (buffer)	2.8									
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8.2 (buffer)	21.2										
n-Octanol/water partition coefficient ( $K_{ow}$ ) at 25°C	<table style="width: 100%; border: none;"> <tr> <td style="text-align: left;"><u>pH</u></td> <td style="text-align: right;"><u>log K<sub>ow</sub></u></td> </tr> <tr> <td>5.3</td> <td style="text-align: right;"><math>1.60 \pm 0.22</math></td> </tr> </table>	<u>pH</u>	<u>log K<sub>ow</sub></u>	5.3	$1.60 \pm 0.22$						
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5.3	$1.60 \pm 0.22$										

The chemistry requirements for Trinexpac-Ethyl Technical have been completed.

## **Health Assessments**

The changes to the manufacturing process result do not result in a product which is toxicological different from the currently registered product. Subsequently, no toxicological data were submitted or are required.

## **Environmental and Value Assessments**

Environmental and value assessments were not required for this application.

## **Conclusion**

PMRA has reviewed the information provided to support the change to the specifications of the subject product. PMRA has determined the changes to the specifications are acceptable.

## **References**

- 2227139 Description of Production Process, DACO: 2.11.1,2.11.3 CBI
- 2227140 Description of Starting Materials, DACO: 2.11.2 CBI
- 2227141 Discussion of Formation of Impurities, DACO: 2.11.4 CBI
- 2227142 Composition and Certified Limits, DACO: 2.12.1 CBI
- 2227145 2000, Confirmation of structures of by-products for CGA 163935 by mass spectroscopy, DACO: 2.13.1 CBI
- 2227146 2001, TRINEXAPAC-ETHYL Analysis of five representative batches, DACO: 2.13.3 CBI

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