



## **Evaluation Report for Category B, Subcategory B.1.1 (New source (site of manufacture) by current registrant) and B.1.3 (Specifications or manufacturing process) Application**

**Application Number:** 2006-0377  
**Application:** Category B, Subcategory B.1.1 and B.1.3.  
**Product:** Kathon 287 Technical Microbiocide  
**Registration Number:** 27418  
**Active ingredients (a.i.):** 4,5-Dichloro-2-n-octyl-4-isothiazolin-3-one [ISZ]  
**PMRA Document Number:** 1396794

### **Background**

The product, Kathon 287 Technical Microbiocide, is a currently fully registered Technical Grade Active Ingredient (TGAI) in Canada under the PCP 27418. This product is used in the manufacture of End use Products (EP) that are used as material preservatives (fully registered status) and in EPs used as antimicrobials in industrial process fluids (temporarily registered status).

### **Purpose of Application**

The purpose of this application is to add a new manufacturing site and to change the specifications of the product - switching the guarantee from minimal to nominal and adding a new impurity to the specifications. The application is classified as a Category B.1.1 and B.1.3.

## Chemistry Assessment

Common Name: N/A  
IUPAC Chemical Name: 4,5-dichloro-2-octylisothiazol-3(2H)-one  
CAS Chemical Name: Isothiazolone, 4,5-dichloro-2-octyl-

Kathon 287 Technical Microbicide has the following properties:

Property	Result
Colour and physical state	pale yellowish solid
Nominal concentration	98.5%
Odour	moderately sweet odour
Density	1.27 g/mL
Vapour pressure	$7.4 \times 10^{-6}$ Torr
pH	N/A
Solubility in water	6.5 ppm
n-Octanol/water partition coefficient	$\text{Log } K_{\text{OW}} = 2.8$ (pH 7)

The chemistry requirements for Kathon 287 Technical Microbicide are complete.

## Health Assessments

The change of guarantee is not considered to be of toxicological concern. The impurity has a well understood origin, is present at low levels and is not considered to be of toxicological concern. The health risks of Kathon 287 Technical Microbicide have been previously assessed and were found to be acceptable. The new source is not expected to be toxicologically different.

The changes in specifications and manufacturing site are not expected to affect worker exposure as the product is still used in the same way. Since this product is not used on any crop or food processing systems, a dietary assessment was not conducted.

## Environmental Assessment

The changes in specifications and manufacturing site are not expected to affect the environmental impact of this product in any significant way. Because of this, an environmental assessment was not performed.

## Value Assessment

The changes in specifications and manufacturing site are not expected to affect the value of this product in any significant way. Because of this, a value assessment was not performed.

## Conclusion

The PMRA has completed an evaluation of the application and has found the information sufficient to amend the registration of Kathon 287 Technical Microbiocide to change the guarantee from minimal to nominal, to add a site of manufacture and to add a new impurity to the specifications.

## References List

### 7.1.1 Studies/Information Provided by Applicant/Registrant

- 1125584 2006, Applicant's and Manufacturers Name and Address, NA, NA, MRID: NA, DACO: 2.1,2.2
- 1125585 Manufacturing Process, Na, NA, MRID: NA, DACO: 2.11.1,2.11.3
- 1125586 Name and Address of Suppliers of Beginning Materials, NA, NA, MRID: NA, DACO: 2.11.2
- 1125587 2006, Discussion of Formulation of Impurities, NA, NA, MRID: NA, DACO: 2.11.4
- 1125588 2006, Establishing Certified Limits, NA, NA, MRID: NA, DACO: 2.12.1
- 1125589 2004, CIS Test Method #04-90-02, NA, NA, MRID: NA, DACO: 2.13.1
- 1125590 2004, Validation of CIS Analytical Method, Rohm and Haas Company, 24P-2004-020, MRID: NA, DACO: 2.13.1
- 1125591 2004, GLP Analysis of Five Batches of Kathon 287 Technical, NA, NA, MRID: NA, DACO: 2.13.2,2.13.3

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