

## Evaluation Report for Category B, Subcategory B.1.2 Application

**Application Number:** 2013-3589  
**Application:** New Source of Technical Grade Active Ingredient by a New Registrant  
**Product:** Preventol IT 14  
**Registration Number:** 31757  
**Active ingredients (a.i.):** 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one  
**PMRA Document Number :** 2508972

### Background

The source of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one used to determine chemical equivalency was Registration Number 21799.

### Purpose of Application

The purpose of this application was to register a new source of the technical grade active ingredients, 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one, by a different Registrant.

### Chemistry Assessment

The Integrated System Product (Preventol IT 14) contains two actives; 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one.

#### **5-chloro-2-methyl-4-isothiazolin-3-one:**

Common Name: 5-chloro-2-methyl-4-isothiazolin-3-one  
IUPAC Chemical Name: 5-chloro-2-methyl-1,2-thiazol-3(2*H*)-one  
CAS Chemical Name: 5-chloro-2-methyl-3(2*H*)-isothiazolone

#### **2-methyl-4-isothiazolin-3-one:**

Common Name: 2-methyl-4-isothiazolin-3-one  
IUPAC Chemical Name: 2-methyl-1,2-thiazol-3(2*H*)-one  
CAS Chemical Name: 2-methyl-3(2*H*)-isothiazolone

Preventol IT 14 has the following properties:

Property	Result
Colour and physical properties	Light amber liquid

Property	Result
Nominal concentration	<ul style="list-style-type: none"> <li>• 5-chloro-2-methyl-4-isothiazolin-3-one.... 11.14%</li> <li>• 2-methyl-4-isothiazolin-3-one.....3.56%</li> </ul>
Odour	Faint
Density at 20°C	1.302 g/mL
Vapour pressure at 20°C	<ul style="list-style-type: none"> <li>• <math>1.8 \times 10^{-2}</math> torr (2.4 Pa) (for 5-chloro-2-methyl-4-isothiazolin-3-one)</li> <li>• <math>6.2 \times 10^{-4}</math> torr (0.083 Pa) (for 2-methyl-4-isothiazolin-3-one)</li> </ul>
pH	4.12 (in 1% solution)
Water solubility at 20°C	Active ingredients are miscible in water
Octanol/water partition coefficient ( $K_{ow}$ )	<ul style="list-style-type: none"> <li>• Log <math>K_{ow}</math> = 0.401, <math>K_{ow}</math> = 2.519 (for 5-chloro-2-methyl-4-isothiazolin-3-one)</li> <li>• Log <math>K_{ow}</math> = -0.486, <math>K_{ow}</math> = 0.326 (for 2-methyl-4-isothiazolin-3-one)</li> </ul>

The chemistry requirements for Preventol IT 14 have been fulfilled.

### Health and Environmental Assessments

As the new source of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one 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 Preventol IT 14.

### References

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