



## Evaluation Report for Category B, Subcategory 1.2 Application

**Application Number:** 2013-3010  
**Application:** New Source of Technical Grade Active Ingredient by a New Registrant  
**Product:** Isocil  
**Registration Number:** 31764  
**Active ingredients (a.i.):** 2-methyl-4-isothiazolin-3-one and 5-chloro-2-methyl-4-isothiazolin-3-one  
**PMRA Document Number :** 2507589

### Background

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

### Purpose of Application

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

### Chemistry Assessment

**Common Name:** No ISO approved common name. The PMRA accepted names are:  
2-methyl-4-isothiazolin-3-one  
and  
5-chloro-2-methyl-4-isothiazolin-3-one

**IUPAC Chemical Name:** 2-methylisothiazol-3(2H)-one  
and  
5-chloro-2-methylisothiazol-3(2H)-one

**CAS Chemical Name:** 2-methyl-3(2H)-isothiazolone  
and  
5-chloro-2-methyl-3(2H)-isothiazolone

ISOCIL has the following properties:

Property	Result
Colour and physical state	Golden yellow liquid

Property	Result
Nominal concentration	5-chloro-2-methyl-4-isothiazolione at 10.80% 2-methyl-4-isothiazolin-3-one at 3.83%
Odour	Pungent aromatic
Density at 25°C	1.2 g/cm <sup>3</sup>
Vapour pressure at 25°C	$1.8 \times 10^{-2}$ torr (2.4 Pa) (for 5-chloro-2-methyl-4-isothiazolin-3-one); $6.2 \times 10^{-4}$ torr (0.083 Pa) (for 2-methyl-4-isothiazolin-3-one)
pH	2.0-4.0
Solubility in water	Both actives are completely soluble in water
n-Octanol/water partition coefficient	$K_{ow} = 2.519$ (for 5-chloro-2-methyl-4-isothiazolin-3-one); $K_{ow} = 0.326$ (for 2-methyl-4-isothiazolin-3-one)

The chemistry requirements for ISOCIL have been fulfilled.

### Health and Environmental Assessments

As the new source of the active ingredients, 2-methyl-4-isothiazolin-3-one and 5-chloro-2-methyl-4-isothiazolin-3-one is acceptable, the health and environmental risk profiles are expected to be similar to that of the product used to determine 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 Isocil.

### References

PMRA Document Number	Reference
2325816	2009, Isocil: Alternate Manufacturing Process and Impurity Discussion, DACO: 2.11.1, 2.11.3
2325817	2009, Isocil: Alternate Manufacturing Process and Impurity Discussion - CONFIDENTIAL ATTACHMENT, DACO: 2.11.1,2.11.3 CBI
2325818	1995, Discussion of Formations of Impurities, DACO: 2.11.4 CBI
2325819	2013, UV/Visible Absorption Spectra, DACO: 2.14.12 CBI

2325820	EPI Suite Results, DACO: 2.14.10, 2.14.11 ,2.14.5, 2.14.9 CBI
2326527	DACO: 2.0
2337415	ISOCIL - Certificate of Analysis 5 Lots, DACO: 2.13.3 CBI
2466220	1995, Isocil Manufacturing Use product Registration Requirements Product Identity and Composition, DACO: 2.11.3,2.11.4 CBI
2466221	2011, Preliminary Analysis, DACO: 2.13.1,2.13.2,2.13.3,2.13.4 CBI
2466224	1997, One Year Storage Stability of Isocil MG, DACO: 2.14.14 CBI
2475143	2009, 102-06B10MITCMIT: Storage Stability and Corrosion Characteristics of Arch, DACO: 2.14.14 CBI

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