



## Evaluation Report for Category B Subcategory 2.1, 2.3, 2.4, 3.1, 3.12 Application

**Application Number:** 2008-4123  
**Application:** New product chemistry: guarantee, identity of formulants, proportion of formulants; New product label: application rate increase, new site or host  
**Product:** Nuosept W  
**Registration Number:** 29948  
**Active ingredients (a.i.):** Bronopol, 2-methyl-4-isothiazolin-3-one, and 5-chloro-2-methyl-4-isothiazolin-3-one  
**PMRA Document Number:** 1991049

### Purpose of Application

The purpose of this application was to register a new commercial liquid in-can preservative to be added to paints, coatings and pigment slurries.

### Chemistry Assessment

Nuosept W is formulated as a solution containing 5-chloro-2-methyl-4-isothiazolin-3-one at a nominal concentration of 0.75% and 2-methyl-4-isothiazolin-3-one at a nominal concentration of 0.25%. This end-use product has a density between 1.0481 and 1.0563 g/cm<sup>3</sup> and a pH between 1.9-4.5. The chemistry requirements for Nuosept W are complete.

### Health Assessments

Nuosept W is considered to be of moderate toxicity via the oral route, low toxicity via the dermal route, slightly irritating to the skin and a potential skin sensitizer. A risk assessment was not performed as the proposed use pattern fits within the existing use profile for the three active ingredients. The potential exposure to mixers, loaders, applicator and post-applicators is not expected to exceed that of other registered uses of the three active ingredients.

### Environmental Assessment

An environmental assessment was not required.

### Value Assessment

Laboratory studies were conducted to evaluate the ability of Nuosept W to protect in-can paints, coatings and pigment slurries against bacteria and fungi. The studies were conducted in paint and slurries containers to simulate in-can conditions. The data demonstrated that Nuosept W is effective against bacteria and fungi growth under representative use conditions.

## **Conclusion**

The PMRA conducted an evaluation of the subject application and determined there was sufficient information to support full registration of Nuosept W.

## **References**

PMRA Document Number: 1651189

Reference: 2008, Efficacy discussion for Nuosept W in paints and similar matrices (adhesives, caulks, grouts, pigment slurries, etc.), Data Numbering Code: 10.2, 10.2.3.2

PMRA Document Number: 1651240

Reference: 2008, Nuosept W Concentrate product chemistry, Data Numbering Code: 3.0 Confidential Business Information

PMRA Document Number: 1651241

Reference: Nuosept W Concentrate starting materials, Data Numbering Code: 3.2.1 Confidential Business Information

PMRA Document Number: 1651242

Reference: Nuosept W Concentrate analytical method, Data Numbering Code: 3.4.1 Confidential Business Information

PMRA Document Number: 1651243

Reference: Nuosept W Concentrate physical-chemical properties, Data Numbering Code: 3.5 Confidential Business Information

PMRA Document Number: 1651244

Reference: 2007, Nuosept W conc: acute oral toxicity study in the rat (up and down procedure), Data Numbering Code: 4.6.1

PMRA Document Number: 1651247

Reference: 2007, Nuosept W conc: acute dermal toxicity study in rats, Data Numbering Code: 4.6.2

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Reference: 2008, Nuosept W conc: 4-hour acute inhalation toxicity study in rats, Data Numbering Code: 4.6.3

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Reference: 2007, Nuosept W conc: primary skin irritation study in rabbits (4-hour semi-occlusive application), Data Numbering Code: 4.6.5

PMRA Document Number: 1651252

Reference: 2007, Nuosept W conc: local lymph node assay (LLNA) in mice (identification of contact allergens), Data Numbering Code: 4.6.6

PMRA Document Number: 1844192

Reference: 2009, Analysis of BN, MIT & CIT in: Nuosept W, Nuosept W Conc & CF-FI-17 intermediates by gradient RP-C8-HPLC-UV-ESTD, Data Numbering Code: 3.4.1 Confidential Business Information

PMRA Document Number: 1844193

Reference: 2009, Storage Stability GLP Study Letter, Data Numbering Code: 3.5.10 Confidential Business Information

PMRA Document Number: 1844194

Reference: 2009, Corrosion Characteristics - Submission Date, Data Numbering Code: 3.5.14 Confidential Business Information

PMRA Document Number: 1844195

Reference: 2009, Rationale for waiver of dielectric voltage breakdown test, Data Numbering Code: 3.5.15 Confidential Business Information

PMRA Document Number: 1868549

Reference: 2010, Validation of a modified analytical method for the determination of the active ingredients in the formulation of Nuosept W conc, Data Numbering Code: 3.4.1 Confidential Business Information

PMRA Document Number: 1868550

Reference: 2010, Storage stability and corrosion characteristics of Nuosept W conc, Data Numbering Code: 3.5.10, 3.5.14 Confidential Business Information

ISSN: 1911-8082

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