

## Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.5, 3.1, 3.12 Application

**Application Number:** 2008-0056  
**Application:** New/Changes EP or MA Product Chemistry (guarantee, identity of form ulants, formulation type)  
New or Changes to Product Labels (application rate increase, new site or host, precautions)  
**Product:** Vinyzene SB-27 K120ND  
**Registration Number:** 30350  
**Active ingredients (a.i.):** 4,5-Dichloro-2-n-octyl-4-isothiazolin-3-one (Kathon 287)  
**PMRA Document Number English PDF:** 2128236

### Purpose of Application

The purpose of this application was to register a new commercial product, Vinyzene SB-27 K120ND, containing 4,5-dichloro-2-N-octyl-3(2H)-isothiazolone (also known as Kathon 287) as an antimicrobial additive for plastics.

### Chemistry Assessment

Vinyzene SB-27 K120ND is formulated as a solid pellet containing 4,5-dichloro-2-n-octyl-3(2H)-isothiazolone at a nominal concentration of 10.0 %. This end-use product has a density of 1.19 g/cm<sup>3</sup>. The chemistry requirements for Vinyzene SB-27 K120ND are complete.

### Health Assessments

A quantitative health assessment has been conducted to register the new commercial end-use product Vinyzene SB-27 K120ND, a material preservative for plastics, containing 4-10% 4,5-dichloro-2N-octyl-3(2H)-isothiazolone. Exposure to mixer/loader/applicators, post-application workers and consumers was determined to be acceptable.

Vinyzene SB-27 K120ND has low oral and dermal acute toxicity, with LD<sub>50</sub> values above 5000 and 2000 mg/kg bw respectively. Due to its physical form, it is not expected to pose an acute toxicity hazard via the inhalation route. It is corrosive to the eye, and is considered to be a skin sensitizer.

A food residue assessment was not required for this submission.

## **Environmental Assessment**

The active ingredient, 4,5-dichloro-2-n-octyl-4-isothiazolin-3-one, is toxic to aquatic organisms. Direct environmental exposure to 4,5-dichloro-2-n-octyl-4-isothiazolin-3-one is not expected, since the product is added to the plastic in indoor commercial facilities and the label does not permit discharge of effluent containing this product into aquatic systems. Depending on the product, the treated plastic is exposed to various indoor and outdoor environments in its normal use. Environmental exposure to material preservatives leaching from treated materials, such as plastics, is considered negligible.

## **Value Assessment**

One laboratory and one outdoor efficacy study was provided to evaluate the ability of Vinyzene SB-27 K120ND to protect flexible vinyl products (PVC) against fungi. The studies were conducted using four different PVC formulations to represent the possible variability of the end-use products. The outdoor study was conducted in South Florida to provide an environment simulating a worst-case scenario of heat and humidity. The data demonstrated that Vinyzene SB-27 K120ND provided effective protection to several PVC formulations against fungi under severe environmental conditions when used at the label rates.

## **Conclusion**

The PMRA has completed an assessment of available information for Vinyzene SB-27 K120ND and has found the information sufficient to support a full registration for Vinyzene SB-27 K120ND.

## **References**

<b>PMRA No</b>	<b>Title</b>
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1532469	2007, Description of Formulation Process, DACO: 3.2.2 CBI
1532470	2007, Discussion of the Formation of Impurities of Toxicological Concern, DACO: 3.2.3 CBI
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- 1767834 1999, Kathon 287 PXE Biocide Acute Inhalation Toxicity Study in Rats, DACO: 4.6.3
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**Additional Information Considered:**

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