

## Evaluation Report for Category B, Subcategory 2.1, 2.3, 3.1, 3.12, 3.13 Application

**Application Number:** 2008-0053  
**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 IT-4010 DIDP  
**Registration Number:** 30349  
**Active ingredients (a.i.):** 4,5-Dichloro-2-n-octyl-4-isothiazolin-3-one (Kathon 287)  
**PMRA Document Number English PDF:** 2128214

### Purpose of Application

The purpose of this application was to register 2a new commercial product, Vinyzene IT-4010 DIDP, containing 4,5-dichloro-2-N-octyl-3(2H)-isothiazolone (also known as Kathon 287; guarantee 10.1%) as an antimicrobial additive for plastics.

### Chemistry Assessment

Vinyzene IT-4010 DIDP is formulated as a solution 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 0.989 g/cm<sup>3</sup> and pH of 5.87. The chemistry requirements for Vinyzene IT-4010 DIDP are complete.

### Health Assessments

A quantitative health assessment has been conducted to register the new commercial end-use product Vinyzene IT-4010 DIDP, 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 IT-4010 DIDP has low oral and dermal acute toxicity, with LD<sub>50</sub> values above 5000 and 2000 mg/kg bw respectively. It is slightly toxic via the inhalation route based on a LC<sub>50</sub> of 1.90 mg/L in rats. It is a slight eye irritant and a severe skin irritant. It is considered to be a skin sensitizer.

### Environmental Assessment

The active ingredient, Kathon 287, is toxic to aquatic organisms. Direct environmental exposure to Kathon 287 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 IT-4010 DIDP 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 IT-4010 DIDP 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 IT-4010 DIDP and has found the information sufficient to support a full registration for Vinyzene IT-4010 DIDP.

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