Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.1, 2.3, 3.12 Application

Application Number: 2007-8096
Application: New/Changes EP or MA Product Chemistry (guarantee, identity of formulants, formulation type)
New or Changes to Product Labels (application rate increase, new site or host, precaustions)
Product: Vinyzene IT-4000 DIDP
Registration Number: 30347
Active ingredients (a.i.): 4,5-Dichloro-2-n-octyl-4-isothiazolin-3-one [Kathon 287]
PMRA Document Number English PDF: 2128169

Purpose of Application

The purpose of this application was to register a new commercial product, Vinyzene IT-4000 DIDP, containing 4,5-dichloro-2-N-octyl-3(2H)-isothiazolone (also known as Kathon 287; guarantee 4.02%) as an antimicrobial liquid additive for plastics.

Chemistry Assessment

Vinyzene IT-4000 DIDP is formulated as a solution containing 4,5-dichloro-2-n-octyl-3(2H)-isothiazolone at a nominal concentration of 4.0 %. This end-use product has a density of 0.974 g/cm^3 and pH of 5.35. The chemistry requirements for Vinyzene IT-4000 DIDP are complete.

Health Assessments

A quantitative health assessment has been conducted to register a new commercial end-use product, Vinyzene IT-4000 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-4000 DIDP has low oral and dermal acute toxicity, with LD_{50} values above 5000 and 2000 mg/kg bw respectively. It is slightly toxic via the inhalation route based on a LC_{50} of 1.90 mg/L in rats. It is a moderate eye irritant and a severe skin irritant. It is considered to be a skin sensitizer.

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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 were provided to evaluate the ability of Vinyzene IT-4000 DIDP to protect flexible vinyl products (PVC) against fungi. The studies were conducted using four different PVC formulations to represents 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-4000 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-4000 DIDP and has found the information sufficient to support a full registration for Vinyzene IT-4000 DIDP.

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