Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 2.5, 3.1, 3.12 Application

Application Number: 2008-4862
Application: B.2.1 (Product chemistry - guarantee)
B.2.3 (Product chemistry - identity of formulants)
B.2.4 (Product chemistry - proportion of formulants)
B.2.5 (Product chemistry - formulation type)
B.3.1 (Product labels - application rate increase)
B.3.11 (Product labels - new site)
Product: WT Smart Balls
Registration Number: 30117
Active ingredients (a.i.): 1-alkyl-1,3-aminopropane (AAM)
PMRA Document Number English PDF: 2055568

Purpose of Application

The purpose of this application was to register a new end-use product, WT Smart Balls, by a new registrant, to protect water in petroleum/gas storage tanks, pipelines or natural gas wells from bacterial contamination.

Chemistry Assessment

WT Smart Balls is a solid (pellets) containing the active ingredient 1-alkyl-1,3-aminopropane at a minimum concentration of 13.0 %. This product has a density of 1.068 g/mL at 20°C and pH of 10.20 for a 1% solution in water. The chemistry requirements for WT Smart Balls have been completed.

Health Assessments

In rats, WT Smart Balls is of slight toxicity by the oral route (LD_{50} = 1750 mg/kg), of low acute toxicity by the dermal route (LD_{50} > 5000 mg/kg), and of moderate toxicity by the inhalation route (LC_{50} = 0.14 – 0.58 mg/L). It is extremely irritating to the skin of rabbits and extremely corrosive or irritating to the eye. It is a dermal sensitizer in guinea pigs.

The use of WT Smart Balls fits within the existing use pattern of the active ingredient, 1-alkyl-1,3-aminopropane. No unacceptable risk is expected when workers follow the label directions and wear the required personal protective equipment (PPE).

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Environmental Assessment

As the technical grade active ingredient, 1-alkyl-1,3-aminopropane, is registered for use in Industrial Process Fluids (USC 17), no additional environmental data were required to support the registration of this product. An environmental assessment was not conducted as there is no potential increase in the environmental exposure and impact from that of the currently registered uses. Environmental concerns are mitigated with label statements.

Value Assessment

Laboratory and field studies were conducted to evaluate the efficacy of WT Smart Balls to protect water in petroleum/gas storage tanks, pipelines or natural gas wells from bacterial contamination. The laboratory studies were conducted with real contaminated water samples from storage tanks, representing real-life contamination possibilities. The field studies were conducted in a water storage tank and in a pipeline with contamination already present. The data demonstrated that WT Smart Balls are effective against bacterial growth under representative use conditions. Laboratory studies have also been conducted in different solvents to show that WT Smart Balls were not soluble in petroleum solvents, which supported the application rate of the product. This product represents a new option for water treatment in storage tank as it is a solid ball shaped product, which sinks to the bottom of the tank and dissolves only in water. Liquid spills can also be avoided when using this product. The two products currently registered with this active ingredient are liquid products.

Conclusion

The PMRA has assessed the available information and is able to support the full registration of WT Smart Balls to protect water in petroleum/gas storage tanks, pipelines or natural gas wells from bacterial contamination.

References

PMRA Number	Reference
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1662611	2008, Formulating Plants Name and Office Address, DACO: 3.1.2
1662612	2008, Trade Name, DACO: 3.1.3
1662613	2008, Other Name, DACO: 3.1.4
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1662615	2008, Product Chemistry of WT Smart Ball, DACO: 3.2,3.3.1,3.4,3.5 CBI
1748586	2009, Storage Stability and Corrosion characteristics, DACO: 3.5.10,3.5.14

1921067 2010, Solubility of WT Smart Ball in Petroleum Solvents, DACO 3.5

1933527 Solubility of WT Smart Ball in Hexane, DACO: 3.5

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1662617 2008, Acute Dermal Toxicity Study in Rats - Limit Test, DACO: 4.6.2

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