Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 2.5, 2.6, 3.12 Application

Application Number: 2022-3407
Application: New End-Use Product (Product Chemistry) – Guarantee, Identity and Proportion of Formulants, Formulation Type, New combination of Technical Grade Active Ingredients; New Product Labels - New Site or Host
Product: Intace B-6773
Registration Number: 35257
Active ingredients (a.i.): Diodofon, chlorothalonil
PMRA Document Number: 3613412

Purpose of Application

The purpose of this application was to register a new commercial end-use product Intace B-6773, for use as a surface coating treatment on paper and paperboard products used for the packaging of bar soap products.

Chemistry Assessment

Intace B-6773 is formulated as a solution containing chlorothalonil at a concentration of 28.30% and diodofon at a concentration of 12.08%. This end-use product has a density of 1.218 g/mL and pH of 5.96. The required chemistry data for Intace B-6773 have been provided, reviewed and found to be acceptable.

Health Assessments

Intace B-6773 is of low acute toxicity via the oral and dermal routes, and of slight acute toxicity via the inhalation route. It is considered to be severely irritating to the eyes, non-irritating to the skin, and a potential dermal sensitizer.

The use of Intace B-6773 on paper and paperboard is not expected to result in potential occupational, postapplication or bystander exposure over the registered use of chlorothalonil and diodofon. No health risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label.

A dietary exposure assessment was not required for this application.

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Environmental Assessment

The use of Intace B-6773 as a material preservative applied as a surface coating on paper and paperboard used for packaging bar soap is within the currently registered use pattern for both diodofon and chlorothalonil. Therefore, the risk is acceptable when Intace B-6773 is used in accordance with the label, which includes statements to mitigate risks to the environment.

Value Assessment

A study was submitted to support the efficacy of Intace B-6773 in controlling fungal growth on soapbox paper. Results demonstrated that the product controls fungal growth on paper at active ingredient concentrations from 1000-2000 ppm (dry paper weight basis). Therefore, it has been demonstrated that Intace B-6773 has acceptable value for controlling fungal growth in paper and paperboard products.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to register the new end-use product Intace B-6773.

References

PMRA Document Number	Reference
3374099	2022, Microbiological Fungal Resistance Report for: Intace B-6773 in Soap Box Paper, DACO 10.2.3.2(E)
3374106	2002, Acute Oral Toxicity Study in Rats - Limit Test, DACO: 4.6.1
3374107	2002, Acute Dermal Toxicity Study in Rats - Limit Test, DACO: 4.6.2
3374108	2002, Acute Inhalation Toxicity Study in Rats, DACO: 4.6.3
3374109	2001, Primary Eye Irritation Study in Rabbits, DACO: 4.6.4
3374110	2001, Primary Skin Irritation Study in Rabbits, DACO: 4.6.5
3374111	2001, Dermal Sensitization Study in Guinea Pigs (Buehler Method), DACO: 4.6.6
3374100	2022, Intace B-6773 Product Chemistry Supplement to Support PMRA Registration, DACO: 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.2.1, 3.2.2, 3.2.3, 3.3.1, 3.5.4, 3.5.5 CBI
3374102	2014, Enforcement Analytical Method: Determination of Active Ingredients by HPLC Analysis, DACO: 3.4.1
3374103	2022, Intace B-6773 Product Chemistry Waiver Requests to Support PMRA Registration, DACO: 3.5.1, 3.5.11, 3.5.12, 3.5.13, 3.5.15, 3.5.3
3374105	2012, Physical and Chemical Characteristics of Intace Fungicide B-6773: Physical State, Oxidation/Reduction, pH, Viscosity and Relative Density, DACO: 3.5.2, 3.5.6, 3.5.7, 3.5.8, 3.5.9
3531323	2023, Test Method # 23-245-02, DACO: 3.4.1
3531324	2023, GLP Validation of Test Method# 23-245-01 for Reverse Phase HPLC Analysis of Intace B- 6773 Formulation for Active Ingredients, DACO: 3.4.1
3531325	2023, Intace B-6773: Determination of Accelerated Storage Stability, DACO: 3.5.10, 3.5.14