

Evaluation Report for Category B, Subcategories 2.3, 2.4 Application

Application Number: 2023-3799
Application: Changes to End-use Product (Product Chemistry) - Identity of Formulants, Proportion of Formulants
Applicant: International Paint LLC
Product: INTERSPEED 640 ANTIFOULING SERIES (Red, Black)
Registration Number: 22717
Active ingredient (a.i.): Copper (present as cuprous oxide)
PMRA Document Number: 3701314

Purpose of Application

The purpose of this application was to amend the formulations of INTERSPEED 640 ANTIFOULING SERIES (Red, Black). The product is an antifouling protective coating resistant to algae, barnacles, and other marine fouling in fresh, sea, and brackish water on steel boat hulls.

Chemistry Assessment

INTER SPEED 640 ANTIFOULING SERIES (Red, Black) is formulated as a suspension containing copper at 38%, present as cuprous oxide and related copper compounds. This end-use product has a density of 2.20-2.26 g/mL and pH of 5.53-6.75. The required chemistry data for INTER SPEED 640 ANTIFOULING SERIES (Red, Black) have been provided, reviewed and found to be acceptable.

Health Assessments

Under this application, the toxicology profile of the end-use product was re-assessed based on the formulation changes. INTER SPEED 640 ANTIFOULING SERIES (Red, Black) is expected to be of low acute toxicity via the oral and dermal routes of exposure, of high acute toxicity via the inhalation route, severely irritating to the eyes and skin, and a potential sensitizer.

Occupational risk to individuals is acceptable when INTER SPEED 640 ANTIFOULING SERIES (Red, Black) is used according to label directions. Precautionary and personal protective equipment statements on the product label aimed at mitigating user exposure are adequate to protect individuals from any potential risk due to occupational exposure.

Bystander and residential exposure will not result in health risks of concern when the product is used according to label directions. Consequently, the risk to bystanders and individuals in residential areas is acceptable.

There are no food or drinking water exposure concerns when the product is used according to label directions.

Environmental Assessment

The new formulations of INTERSPEED 640 ANTIFOULING SERIES (Red, Black) are similar to the currently registered products containing cuprous oxide as a biocide. The change in formulation is not expected to pose an unacceptable risk to non-target organisms. Therefore, the risk is acceptable when INTERSPEED 640 ANTIFOULING SERIES (Red, Black) is used in accordance with the label, which includes restrictions to mitigate risks to the environment.

Value Assessment

The new formulations for each colour of INTERSPEED 640 ANTIFOULING SERIES (Red, Black) were compared to the registered precedent products. The differences between the formulations for each colour were considered minor, and are unlikely to result in any significant impacts on product performance in term of efficacy. Therefore, INTERSPEED 640 ANTIFOULING SERIES (Red, Black) is expected to have acceptable value as an antifouling paint for use as an antifouling protective coating resistant to algae, barnacles, and other marine fouling in fresh, sea, and brackish water on steel boat hulls when used according to the directions on the label.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to support the registration of the amended formulations of INTERSPEED 640 ANTIFOULING SERIES (Red, Black).

References

A. List of Studies/Information Submitted by Registrant

PMRA Document Number	Reference
3488745	2022, Interspeed 640 (Red, Blue and Black) Antifouling Paint: Evaluation of Physico-Chemical Properties, Including Accelerated Storage Stability; DACO: 3.0 CBI
3488747	2023, Co-formulants Acute/Primary Tox Data and Acute Tox Waiver Request, DACO: 4.6
3488748	2023, OECD 401 Confidential information Acute Oral Tox, DACO: 4.6.1
3488749	2023, Confidential information Acute Oral Tox, DACO: 4.6.1
3488750	2023, Confidential information Acute Oral Tox, DACO: 4.6.1
3488751	2023, Confidential information Acute Oral Tox, DACO: 4.6.1
3488752	2023, Confidential information Acute Oral Tox, DACO: 4.6.1
3488753	2023, Confidential information Acute Oral Tox, DACO: 4.6.1
3488754	2023, Confidential information Acute Oral Tox, DACO: 4.6.1
3488755	2023, Confidential information Acute Oral Tox, DACO: 4.6.1
3488756	2023, Confidential information Acute Dermal Toxicity, DACO: 4.6.2
3488757	2023, Confidential information Acute Dermal Toxicity, DACO: 4.6.2
3488758	2023, Confidential information Acute Dermal Toxicity, DACO: 4.6.2
3488760	2023, Confidential information Acute Dermal Toxicity, DACO: 4.6.2
3488761	2023, Confidential information Acute Dermal Toxicity, DACO: 4.6.2
3488762	2023, Confidential information Acute Dermal Toxicity, DACO: 4.6.2
3488763	2023, Confidential information Acute Dermal Toxicity, DACO: 4.6.2
3488764	2023, Confidential information Acute Dermal Toxicity, DACO: 4.6.2
3488765	2023, Confidential information Acute Inhalation, DACO: 4.6.3
3488766	2023, Confidential information Acute Inhalation Toxicity, DACO: 4.6.3
3488767	2023, Confidential information Acute Inhalation Toxicity, DACO: 4.6.3
3488769	2023, Confidential information Acute Inhalation, DACO: 4.6.3
3488770	2023, Confidential information Acute Inhalation, DACO: 4.6.3
3488771	2023, Confidential information Acute Inhalation, DACO: 4.6.3
3488772	2018, Confidential information Primary Eye & Primary Dermal Irritation and Dermal Sensitization, DACO: 4.6.4,4.6.5,4.6.6
3488773	2023, Confidential information Eye Irritation, DACO: 4.6.4
3488775	2023, Confidential information Primary Eye Irritation, DACO: 4.6.4
3488776	2023, Confidential information Primary Eye Irritation, DACO: 4.6.4
3488777	2023, Confidential information Eye Irritation, DACO: 4.6.4
3488778	2023, Confidential information Primary Eye Irritation, DACO: 4.6.4
3488779	2023, Confidential information Primary Eye Irritation, DACO: 4.6.4
3488780	2023, Confidential information Dermal Irritation, DACO: 4.6.5
3488781	2023, Confidential information Skin Irritation, DACO: 4.6.5
3488783	2023, Confidential information Dermal Irritation, DACO: 4.6.5
3488784	2023, Confidential information Primary Dermal Irritation, DACO: 4.6.5

3488785	2023, Confidential information Dermal Irritation, DACO: 4.6.5
3488786	2023, Confidential information Primary Dermal Irritation, DACO: 4.6.5
3488787	2023, Confidential information Dermal Irritation, DACO: 4.6.5
3488788	2023, Confidential information Skin Sensitization LLNA, DACO: 4.6.6
3488789	2023, Confidential information Dermal Sensitization (non-LLNA), DACO: 4.6.6
3488790	2023, Confidential information Skin Sensitization - LLNA, DACO: 4.6.6
3488792	2023, Confidential information Dermal Sensitization LLNA, DACO: 4.6.6
3488793	2023, Confidential information Skin Sensitization (non-LLNA), DACO: 4.6.6
3488794	2023, Confidential information Skin Sensitization - LLNA, DACO: 4.6.6
3488795	2023, Confidential information Skin sensitization (non-LLNA), DACO: 4.6.6
3488796	2023, Interspeed 640 Use Description Scenario pre and post-application, DACO: 5.2
3704693	2024, Justification for Use of Read-Across Provisions for the Hazard Assessment of Confidential information, DACO: 4.8
3704696	Cosmetic Ingredient Review Expert Panel, 2015, Safety Assessment of Confidential information as Used in Cosmetics, Cosmetic Ingredient Review (CIR), DACO: 4.8
3704697	US Environmental Protection Agency (EPA), 2016, Human Health Risk Assessment and Ecological Effects Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations; Confidential information, DACO: 4.8
3704698	2020, US Environmental Protection Agency (EPA), Risk assessment for CAS # Confidential information, DACO: 4.8
3704699	SIAM 25, US ICCA, 2007, SIDS Initial Assessment Profile Confidential information, DACO: 4.8

B. Additional Information Considered

i) Published Information

PMRA Document Number	Reference
3670853	2023, EU ECHA, Confidential information Acute Inhalation, DACO: 4.6.3
3670854	2023, EU ECHA, Confidential information Primary Eye Irritation, DACO: 4.6.4
3670857	2023, EU ECHA, Confidential information Dermal Sensitization Endpoint Summary, DACO: 4.6.6
3670860	2023, EU ECHA, Confidential information Dermal Sensitization 013 Supporting, DACO: 4.6.6
3670861	2023, EU ECHA, Confidential information Dermal Sensitization 012 Supporting, DACO: 4.6.6
3670862	Karleberg, A.-T., Basketter, D., Goossens, A. and Lepoittevin, J.-P, 1999, Review Article, Regulatory classification of substances oxidized to skin

PMRA Document Number	Reference
	sensitizers on exposure to air, Contact Dermatitis, 40, 183-188, DACO: 4.6.6
3670865	2023, EU ECHA, Confidential information Inhalation, DACO: 4.6.3
3670866	TradeMarkElite, 2024, Confidential information, DACO: 4.8

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