

Evaluation Report for Category B, Subcategory B.2.1,B.2.3,B.2.4,B.3.12,B.3.4 Application

Application Number: 2015-6241
Application: New EP Product Chemistry: Guarantee, Identity of Formulants, Proportion of Formulants;
New Product Labels: New Site or Host, Application Method
Product: Clorox Commercial Solutions Clorox Disinfecting Urine Remover
Registration Number: 32468
Active ingredients (a.i.): hydrogen peroxide
PMRA Document Number: 2680161

Purpose of Application

The purpose of this application was to register a new end-use product, Clorox Commercial Solutions Clorox Disinfecting Urine Remover, intended as a soft surface sanitizer.

Chemistry Assessment

Clorox Commercial Solutions Clorox Disinfecting Urine Remover is formulated as a solution containing hydrogen peroxide at a nominal concentration of 2.20%. This end-use product has a density of 1.0056 g/mL and pH of 2.81. With the exception of the storage stability/corrosion characteristics study, the required chemistry data for Clorox Commercial Solutions Clorox Disinfecting Urine Remover have been provided, reviewed and found to be acceptable.

Health Assessments

Available information indicates that Clorox Commercial Solutions Clorox Disinfecting Urine Remover will be of low acute oral, dermal, and inhalation toxicity, is non-irritating to the skin, and slightly irritating to the eye, and is not expected to be a dermal sensitizer.

There is no occupational concern anticipated from the commercial end-use product's proposed soft surface sanitizer use because of its low toxicity profile and adequate exposure mitigation measures present on the label, which instructs users to avoid breathing spray mists during application and avoid skin contact with treated surfaces until dried. Bystander exposure is not of concern. Post-application exposure is minimized by restricted entry until sprays have dried.

A dietary exposure assessment was not required for this application.

Environmental Assessment

An environmental assessment was not required for this application.

Value Assessment

Several laboratory trials were carried out with three different fabrics types: natural fabrics (cotton), synthetic fabrics (polyester) and a blend of cotton and polyester. Fabric carriers were inoculated with two bacterial strains, dried and treated with the Clorox Commercial Solutions Clorox Disinfecting Urine Remover at room temperature for 3 minutes, as prescribed in the directions for use of the label. These studies demonstrated the capacity of Clorox Commercial Solutions Clorox Disinfecting Urine Remover to kill at least 99.9% of the two bacterial strains representing both Gram positive and Gram negative bacteria. Therefore, Clorox Commercial Solutions Clorox Disinfecting Urine Remover is considered effective for soft surface sanitation.

Conclusion

The PMRA has completed a review of the information available for Clorox Commercial Solutions Clorox Disinfecting Urine Remover and found it sufficient to support registration of the new end-use product.

References

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|----------------------|---|
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| 2583494 | 2015, Chem/Phys, DACO: 3.5.2,3.5.4,3.5.5,3.5.8 CBI |
| 2649319 | 2016, Description of Formulation Process amended, DACO: 3.2.2 CBI |
| 2649320 | 2016, Flow Diagram, DACO: 3.2.2 CBI |
| 2583504 | 2015, Value Summary, DACO: 10.1, 10.2.1, 10.2.2, 10.3.1, 10.3.2, 10.4, 10.5.1, 10.5.3, 10.5.4 |
| 2583505 | 2015, Standard Test Method for Efficacy of Sanitizers Recommended for Soft Non-Food Contact Surfaces (Modification for Spray Product Application) <i>Klebsiella pneumoniae</i> (A TCC 4352), DACO: 10.2.3.2 |
| 2583506 | 2015, Standard Test Method for Efficacy of Sanitizers Recommended for Soft Non-Food Contact Surfaces (Modification for Spray Product Application) <i>Klebsiella pneumoniae</i> (A TCC 4352), DACO: 10.2.3.2 |
| 2583507 | 2015, Standard Test Method for Efficacy of Sanitizers Recommended for Soft Non-Food Contact Surfaces (Modification for Spray Product Application) <i>Klebsiella pneumoniae</i> (A TCC 4352), DACO: 10.2.3.2 |
| 2583508 | 2015, Standard Test Method for Efficacy of Sanitizers Recommended for Soft Non-Food Contact Surfaces (Modification for Spray Product Application) <i>Staphylococcus aureus</i> (ATCC 6538), DACO: 10.2.3.2 |
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| 2583510 | 2015, Standard Test Method for Efficacy of Sanitizers Recommended for Soft Non-Food Contact Surfaces (Modification for Spray Product Application) <i>Staphylococcus aureus</i> (ATCC 6538), DACO: 10.2.3.2 |
| 2583495 | 2015, Toxicology Summary DACO: 4.1 |
| 2583497 | 2015, Acute Oral Toxicity Study (UDP) in Rats, DACO: 4.6.1 |
| 2583498 | 2015, Acute Dermal Toxicity Study in Rabbits, DACO: 4.6.2 |
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| 2583500 | 2015, Acute Eye Irritation Study in Rabbits, DACO: 4.6.4 |
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| 2583502 | 2015, Skin Sensitization:, DACO: 4.6.6 |
| 2583503 | 2015, Part 5: Use Description DACO: 5.2 |

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