

Evaluation Report for Category B, Subcategory 2.1 Application

Application Number: 2021-3369
Application: New End-Use Product Chemistry - Guarantee
Product: CleanSlate UV Sanitizer
Registration Number: 34495
Active ingredient (a.i.): Device with ultraviolet C (wavelength 280 – 100 nm)
PMRA Document Number: 3334332

Purpose of Application

The purpose of this application was to register CleanSlate UV Sanitizer, a new countertop sanitizing UV device that uses an ultraviolet-C (UVC) light with a peak wavelength of 254 nm to inactivate bacteria and viruses on non-critical handheld items with hard, non-porous surfaces.

Chemistry and Environmental Assessments

Chemistry and environmental assessments were not required for this application.

Health Assessments

CleanSlate UV Sanitizer utilizes UVC light (peak wavelength of 254 nm) to inactivate bacteria and viruses on non-critical, hard, non-porous surfaces. Based on information from published scientific literature, acute exposures to UVC can produce irritative effects on the skin (e.g., erythema/sunburn) and the eyes (e.g., photo-keratitis/conjunctivitis). Chronic exposures to ultraviolet light (i.e., typically solar radiation) can cause photoageing of the skin and effects on the eyes (e.g., pterygium, climatic droplet keratopathy, pingueculum, cataracts). Solar ultraviolet light can also suppress immune responses in humans and laboratory animals. Finally, UVC and other wavelengths of ultraviolet light have been demonstrated to be genotoxic *in vitro* and *in vivo*, and IARC has classified UVA, UVB, and UVC *as probably carcinogenic to humans*. For additional information on the health effects of UVC exposure, see PRD2016-15 *Dyson Humidifier*.

Although the UVC generated by the lamps in CleanSlate UV Sanitizer has the potential to cause adverse effects on the skin and the eyes (i.e., likely acute effects), the lamp is completely enclosed within the device and there are a number of design features to ensure that the UVC light is completely contained. Furthermore, the device is to be turned off during all initial set-up, cleaning and maintenance activities. There will be no dermal or ocular exposure to UVC for users, handlers or bystanders during the normal operation, set-up, cleaning or maintenance of CleanSlate UV Sanitizer.

Therefore the risks to these individuals are acceptable when CleanSlate UV Sanitizer is used according to label and operating manual instructions. Precautionary and direction for use statements on the product label and the operating manual are considered adequate to protect individuals from any potential risks due to exposure.

Although the bulbs used in the device contain mercury, the lamp is completely enclosed in the device and the mercury is present in the sealed glass tube of the bulb. Instructions are provided on the safety measures to be taken in the event of a broken bulb.

The bulb material blocks the wavelengths (185 nm) that could generate ozone. Therefore, risks from ozone emissions during the normal operation of the device are not expected to be of concern to users and bystanders.

There is no potential for residential exposure as the product is for commercial use.

Toxicology and dietary exposure assessments were not required for this application.

Value Assessment

The CleanSlate UV Sanitizer is an electromechanical device aimed at sanitizing a range of small personal items. The laboratory studies provided demonstrated that the device is capable of killing 99.99% of bacteria including methicillin-resistant *Staphylococcus aureus* (MRSA) and 99.9% viruses including SARS-CoV-2, the virus that causes COVID-19, on hard non-porous surfaces after one sanitization cycle.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the available information and has found it sufficient to support the registration of CleanSlate UV Sanitizer.

References

PMRA References
Document
Number

A. List of Studies/Information Submitted by Registrant

3266782	2021, Use Description/Scenario, DACO: 5.2
3298186	2021, Device Specifications, DACO: 10.6
3298187	2021, Device Specifications, DACO: 10.6 CBI
3300088	2021, Device Specifications, DACO: 10.6
3300090	2020, Electrical Safety and Radiation Safety Certificates, DACO: 10.6
3266781	2021, Operators Manual, DACO: 10.6
3298180	2020, Electrical Safety and Radiation Safety Certificates, DACO: 10.6
3298181	2020, Electrical Safety and Radiation Safety Certificates, DACO: 10.6 CBI
3266765	2021, Mode of Action (TGAI) and Description of the Product, DACO: 10.2.1
3266766	2021, Description of Pest Problem, DACO: 10.2.2
3266768	2019, Antibacterial Activity and Sanitizing Efficacy of CleanSlate's UV Device, DACO: 10.2.3.2
3266769	2016, Antibacterial Activity and Sanitizing Efficacy of Limestone Labs CleanSlate UV Device, DACO: 10.2.3.2
3266770	2020, Determining Antimicrobial Efficacy of Ultraviolet Germicidal Irradiation Against Microorganisms on Carriers with Simulated Soil, DACO: 10.2.3.2
3266771	2020, Efficacy of Sanitizers Recommended for Inanimate, Hard, Nonporous Non-Food Contact Surfaces Testing of a UVC Disinfection Device, DACO: 10.2.3.2
3266772	2021, Evaluation of the Virucidal Activity of a UV Device for use on Inanimate Environmental Surfaces (Influenza A - H1N1 Virus), DACO: 10.2.3.2
3266773	2020, The Virucidal Efficacy of the CleanSlate UV Against Human Coronavirus 229E, DACO: 10.2.3.2
3266774	2020, Verification of the Effectiveness of the CleanSlate UV-C Device in Decontamination of SARS-CoV-2, DACO: 10.2.3.2
3266775	2021, Small-Scale Studies and Operational Trials, DACO: 10.2.3.3,10.2.3.4
3297101	2021, The CleanSlate UV Device Kills >99.9% of Adenovirus Type 5, DACO: 10.2.3.2
3302239	2021, UVC Exposure Time - Efficacy Studies, DACO: 9.9

B. Additional Information Considered

i) Published Information

3238076	World Health Organization (WHO), 2016, Radiation: Ultraviolet (UV) radiation Q & A, DACO: 4.8
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