Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.1 Application

Application Number: 2023-0620
Application: New End-use Product (Product Chemistry) - Guarantee
Product: MoonBeam 3
Registration Number: 35489
Active ingredient (a.i.): Device using Ultraviolet C (wavelength 100-280 nm)
PMRA Document Number : **3705101**

Purpose of Application

The purpose of this application was to register a commercial-class mobile device, MoonBeam 3, which uses ultraviolet C (254 nm) light to reduce microbial contamination on hard, non-porous surfaces.

Chemistry and Environmental Assessments

Chemistry and environmental assessments were not required for this application.

Health Assessments

Potential sites of exposure to UVC radiation are ocular and dermal. The main acute skin lesion from exposure to ultraviolet radiation (UVR) is erythema or sunburn. Erythema can be induced by ultraviolet light (including UVC), and the wavelength of light, skin type, and skin pigmentation all influence whether it will occur. Other acute skin responses to ultraviolet light include tanning and photosensitivity. Damage to skin cells can increase the rate of aging of the skin or cause skin cancer. The principal acute effects of UVR on the eye are photokeratitis (inflammation of the cornea) and photoconjunctivitis (inflammation of the conjunctiva). The most important cellular target for UVR is DNA, which has an absorption peak in the UVC spectrum at 260 nm. It is generally accepted that UVC radiation is a cause of carcinogenicity in mammals. Chronic UVR exposure is believed to be at least one of the causative factors in the development of cataracts.

The risks to users, bystanders and individuals in residential areas are acceptable when MoonBeam 3 is used according to label directions. Precautionary and directions for use statements on the product label aimed at mitigating user, bystander and residential exposure are considered adequate to protect individuals from any potential risk due to exposure.

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

Value Assessment

The conventional practice of manual cleaning and disinfection of high-touch surfaces can benefit from additional supplemental sanitization. MoonBeam 3 is a mobile ultraviolet C radiation generating device. Laboratory studies demonstrated the device can kill 99.9 – 99.99% of

bacteria, viruses, and select fungi and spores on pre-cleaned hard, non-porous surfaces when used as described on the label. MoonBeam 3 has acceptable value as an antimicrobial device when used as a supplement to, but not a replacement for, conventional cleaning and disinfection products.

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 MoonBeam 3.

References

A. List of Studies/Information Submitted by Registrant

PMRA Document Number	Reference
3436053	2023, Moonbeam 3 Use Description and Scenario, DACO: 5.2
3436054	2023, Safety features on the device that mitigate user or bystander dermal or ocular exposure to UVC rays, DACO: 10.6,5.2
3436055	2019, Electrical Certificate, DACO: 10.6,5.2
3436056	2022, MoonBeam 3 System Block Diagram, DACO: 10.6,5.2 CBI
3436057	2018, Bulb Specifications, DACO: 10.6,5.2 CBI
3436058	2023, Bulb Output, DACO: 10.6,5.2
3436059	2023, Bulb Output Specifications, DACO: 10.6,5.2
3436072	2016, MoonBeam3 Endurance Test Report Ozone Report, DACO: 10.6,5.2
3442854	2020, Test Report IEC 61010-1 Safety requirements for electrical equipment for measurement, control, and laboratory use, DACO: 10.6,5.2
3436060	2023, 10.1 Value Summary Draft, DACO: 10.1,10.2.2,10.3.2,10.4,10.5.1, 10.5.4
3539843	2023, DACO 10.2.3.2. Candida auris, DACO: 10.2.3.2
3539844	2023, DACO 10.2.3.2. Influenza A Virus, DACO: 10.2.3.2
3539845	2023, DACO 10.2.3.2. Poliovirus Type 1, DACO: 10.2.3.2
3539846	2023, DACO 10.2.3.2. Pseudomonas aeruginosa, DACO: 10.2.3.2
3539847	2023, DACO 10.2.3.2. Staphylococcus aureus, DACO: 10.2.3.2
3539848	2023, DACO 10.2.3.2. Mycobacterium terrae, DACO: 10.2.3.2
3539849	2023, DACO 10.2.3.2. Mycobacterium bovis, DACO: 10.2.3.2
3539850	2023, DACO 10.2.3.2. Clostridioides difficile spore, DACO: 10.2.3.2
3539851	2023, DACO 10.2.3.2. Bacillus subtilis, DACO: 10.2.3.2
3574226	2024, NonGLP Report of Supplemental Irradiance Measure of UV Device For Efficacy Testing_v2, DACO: 10.2.3.2
3632667	2024, Influenza A_A39280 - Amended_signed, DACO: 10.2.3.2
3636796	2024, Moonbeam Irradiance Measurement Deviations, DACO: 10.2.3.2

B. Additional Information Considered

Published Information

PMRA Document Number	Reference
2559369	International Commission on Non-ionizing Radiation Protection (ICNIRP), 2007, Protecting Workers from Ultraviolet Radiation, ICNIRP in collaboration with ILO and WHO, ICNIRP 14/2007, DACO: 12.5.4

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