Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.1 Application

Application Number: 2021-3267
Application: New End-Use Product Chemistry - Guarantee
Product: UVD Robot Model C
Registration Number: 34534
Active ingredient (a.i.): Ultraviolet C (Wavelength 280 - 100 nm)
PMRA Document Number: 3358351

Purpose of Application

The purpose of this application was to register a new commercial UV-C device, UVD Robot Model C, a robotic device used to disinfect microorganisms on surfaces for hospital, healthcare and other commercial and public buildings. The UVD Robot Model C is controlled by a trained operator outside of the treatment room or area with the use of a tablet and operates in an autonomous mode to disinfect an empty room or area.

Chemistry and Environmental Assessment

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 carcinogenic to 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 UVD Robot Model C is used according to label directions. Precautionary and direction 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 risk assessments were not required for this application.

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Value Assessment

The UVD Disinfection Robot is an ultraviolet light-emitting device for the control of bacteria on hard non-porous surfaces in public spaces. The laboratory studies provided demonstrated that the device is capable of killing 99.99% of bacteria and 99.99 % of the fungi species *Candida albicans* within 1m of the device, following a five minute exposure.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found it sufficient to support the registration of UVD Robot Model C.

References

A. List of Studies/Information Submitted by Registrant

PMRA Document Number	Reference
3251055	2021, 2021, Use Description, DACO: 5.2
3251057	2018, Philips Lamps Technical Specifications, DACO: 5.2
3251059	2019, Measurement of UV-C Lamps Output, DACO: 5.2
3251061	2021, UVD Robot Model C - Product description, DACO: 5.2
3251062	2021, Functional Safety Report - Autonomous System, DACO: 5.2
3251063	2021, Functional Safety Report - UV System, DACO: 5.2
3251064	2021, UVD Robots - Model C Technical Data, DACO: 5.2
3280210	2021, Registrant Response to 5.2 Follow up questions, DACO: 5.2
3280211	2019, Ozone emission statement, DACO: 5.2
3280212	2021, UVD Robots - Safety System Overview, DACO: 5.2
3280214	2020, Measurement of UV-C Ozone generation, DACO: 5.2
3280216	2021, TuV Certification - Summary Document, DACO: 5.2
3280217	2021, TuV Certification - Attachment 1, DACO: 5.2
3251066	2021, Mode of Action, DACO: 10.2.1
3251067	2020, The UVDR Guide for Healthcare Associated Pathogens, DACO: 10.2.2
3251068	2020, Analysis Report, DACO: 10.2.3.2
3251069	2019, Assessment of UVD Robot Against Reduction of Multi Drug Resistant *Klebsiella pneumoniae*, *Acinetobacter baumanii* and *Clostridium difficile* on Surfaces., DACO: 10.2.3.2
3251071	2020, UVD Robots Clinical Studies: *Candida auris*, DACO: 10.2.3.4(A)

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