Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.1 Application

Application Number: 2022-4448
Application: New End-use Product Chemistry - Guarantee
Product: UV002
Registration Number: 35539
Active ingredient (a.i.): Device with ultraviolet C (wavelength 280-100 nm)
PMRA Document Number : 3720815

Purpose of Application

The purpose of this application was to register UV002, a new commercial, germicidal irradiation device that emits ultraviolet light (UVC) to treat SARS-CoV-2 in the air that circulates above indoor, occupied areas.

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.

UV002 is installed by licensed R-Zero technicians in the upper area of a room, at a minimum height of 7 feet. Safety features of the device includes a baffle over the UVC bulbs which projects the UV upwards, away from occupants in the room. As another safeguard, there are two passive infrared (PIR) sensors on the device that trigger the LED bars to power off (for 2 minutes) if motion is detected in the “disinfection zone”.

Thus, the risks to users, bystanders and individuals in residential areas are acceptable when the device 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.

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

Value Assessment

UV002 is a wall-mounted upper room irradiation device intended to treat SARS-CoV-2 in the air that circulates above indoor, occupied areas. Laboratory data demonstrated that the device is able to kill up to 99.99% of SARS-CoV-2 in the air in 30 minutes when used as directed 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 device UV002.

References

PMRA Document Number	References

A. List of Studies/Information Submitted by Registrant

1.0 Human and Animal Health

3385808	2022, Use Description Scenario (Application and Post-application), DACO: 5.2
3497462	2023, Screening Deficiency Response, DACO: 10.6,5.2
3500863	2023, TEST REPORT: Wavelength Verification, DACO: 5.2
3581364	2024, English Manual R-Zero UV002, DACO: 10.6,5.2
3581366	2024, Screening Deficiency Response, DACO: 10.6,5.2
3581367	2024, IEC 62471 Report-R-Zero UV002, DACO: 10.6,5.2
3690776	2025, 2022-4448 5.2 Deficiency Response, DACO: 5.2
3690778	2025, UV002 Specifications, DACO: 5.2
3385800	2022, Ozone-R-Zero UV002, DACO: 10.6,5.2

2.0 Value

3385804	2022, Efficacy of the UR-UVGI Wall Mount Against Aerosolized SARS-CoV-2, DACO: 10.1,10.2.3.2
3497462	2023, Screening Deficiency Response, DACO: 10.6,5.2

B. Additional Information Considered

i) Published Information

1.0 Human and Animal Health

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
3238076 World Health Organization (WHO), 2016, Radiation: Ultraviolet (UV) radiation Q & A, DACO: 4.8
3238072 Government of Canada, 2016, Canadian Centre for Occupational Health (CCOHS) Skin Cancer and Sunlight, DACO: 4.8

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