Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.1 Application

Application Number: 2022-2364
Application: New End-use Product (Product Chemistry) - Guarantee
Product: ASEPT.2X
Registration Number: 35300
Active ingredient (a.i.): Device using Ultraviolet C (wavelength 100-280 nm)
PMRA Document Number: 3626124

Purpose of Application

The purpose of this application was to register a new commercial-class autonomous device, ASEPT.2X, which uses ultraviolet C (254 nm) light to disinfect 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 ultraviolet C (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 and bystanders are acceptable when the device is used according to label directions. Precautionary and direction for use statements on the product label, as well as the design of the device (i.e., remote control of the device, delayed start, and infrared sensors that trigger deactivation of the device if motion is detected) aimed at mitigating occupational and bystander exposure are considered adequate to protect individuals from any potential risk due to exposure.

The device is for commercial use in health care institutions. However, while there is the potential for residential/general public exposure, including sensitive subpopulations, residential exposure is acceptable as the use pattern does not permit access to the treatment area during use.

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

Value Assessment

ASEPT.2X is an automated mobile UV device intended to be used to kill bacteria on hard, non-porous surfaces in unoccupied rooms. The two laboratory studies provided demonstrated that the device is capable of killing 99.99% of bacteria on hard, non-porous surfaces when used as directed on the product label, as a supplement to normal cleaning and disinfecting protocols.

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 ASEPT.2X.

References

A. List of Studies/Information Submitted by Registrant

PMRA Document Number	Reference
3590739	2024, Sanuvox ASEPT.2X Ozone report v JR_YO, DACO: 5.2
3602135	2024, LSI Spectrograph LMPHGS400, DACO: 5.2
3418330	2022, 10.6 ASEPT.2X-Spec_Sheet-EN-Dec2021, DACO: 10.6,5.2 CBI
3572976	2024, LMPHGS400.pdf, DACO: 5.2
3572975	2024, CE1420-1 - ASEPT.2x CE Test Report.pdf, DACO: 5.2
3572977	2024, Non Ozone Declaration Sanuvox LMPHGS400_400-8.pdf, DACO: 5.2
3511877	2023, 105592479CRT-002 IEC62471_ASEPT.2X, DACO: 5.2 CBI
3434610	2018, 16QPS498_FCC15B, DACO: 10.6,5.2
3434611	2018, TR-0710-501, DACO: 10.6,5.2
3418331	2017, 10.6 CB1420-1 CB test Certificate.pdf, DACO: 10.6,5.2
3418332	2019, 10.6 QPS Certificate of Compliance_CAN_CSA Standard, DACO: 10.6,5.2
3611607	2024, Aeroqual-Gas-Sensor-Specifications, DACO: 5.2
3620449	2024, Measurement Mapping -UV Intensity- ASEPT.2X v2.0, DACO: 5.2 CBI
3583817	2024, Sanuvox Lamps ASEPT units, DACO: 5.2
3418325	2022, 5.2 Use Description Scenario, DACO: 5.2 CBI
3418327	2022, 10.2.3.2 EMSL Test Report 552214369 ASEPT.2X, DACO: 10.2.3.2 CBI
3434612	2023, EMSL Report-Jan-2023, DACO: 10.2.3 CBI
3498515	2020, ASEPT UNITS - Raw Data- Bench sheet, DACO: 10.2.3.2 CBI
3498516	2023, Measurement Mapping -UV Intensity- ASEPT.2X, DACO: 5.2 CBI

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