



Evaluation Report for Category B, Subcategory 2.1 Application

Application Number: 2024-3476
Application: New End-use Product (Product Chemistry) - Guarantee
Applicant: Xenex Disinfection Services Inc.
Product: XENEX LIGHTSTRIKE - LSMUV6-SL
Registration Number: 35756
Active ingredient (a.i.): Device, containing ultraviolet C (wavelength 100-280 nm)
PMRA Document Number: 3739546

Purpose of Application

The purpose of this application was to register XENEX LIGHTSTRIKE - LSMUV6-SL, a new commercial device that emits ultraviolet light (UVC), to be used for the control of bacteria on hard non-porous surfaces in public spaces (in unoccupied surgery units and patient rooms following manual cleaning).

Chemistry and Environmental Assessments

Chemistry and environmental assessments were not required for this application.

Health Assessments

Health concerns from potential exposure to ultraviolet radiation (UVR) include effects on the eyes and skin. The main acute skin lesion from exposure to ultraviolet radiation (UVR) is erythema or sunburn. Erythema can be induced by ultraviolet light, 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. 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.

XENEX LIGHTSTRIKE LSMUV6-SL is an ultraviolet radiation-emitting device that uses a Xenon gas lamp to produce pulse germicidal UV radiation. The device is to be used to kill bacteria on hard non-porous surfaces in unoccupied surgery units and patient rooms at the end of the patient stay following manual cleaning. This device is meant to be used as a supplement to regular cleaning practices.

According to International Electrotechnical Commission (IEC) 62471, XENEX LIGHTSTRIKE LSMUV6-SL has been classified as a Risk Group 3 device for actinic and near UV hazards when in operation. The device produces ozone during operation; however, the device is for use in unoccupied rooms with ventilation turned on.

Occupational exposure to UVC is not expected, as workers are to remain outside areas during treatment. The risk due to exposure to individuals is acceptable when the device is used according to label directions.



Access will be restricted to the areas being treated with signage notifying bystanders. The risk due to exposure to bystanders, including the general public, is considered acceptable for the device when used according to label directions.

Value Assessment

XENEX LIGHTSTRIKE - LSMUV6-SL is a ultraviolet radiation-emitting device that uses a Xenon gas lamp to produce pulse germicidal UV light. It is intended to be used to kill bacteria on hard non-porous surfaces. As a mobile non-autonomous device, it can be pushed to the room/area where it will be used. The laboratory studies demonstrated this device is capable of killing 99.9% of bacteria on pre-cleaned hard, non-porous surfaces when either one 4-minute cycle is used at a maximum distance of 1.25 m from the device or two 4-minute cycles are used at a maximum distance of 1.7 m from the device. This device is meant to be used as a supplement to regular cleaning practices.

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 XENEX LIGHTSTRIKE - LSMUV6-SL.

References

PMRA Document Number	Reference
3618831	2024, Health Canada Bench Testing Summary, DACO: 10.2.3.2
3618833	2024, Xenex LightStrike - LSMUV6-SL Raw Data, DACO: 10.2.3.2,10.2.3.3
3636398	2023, Appendix 2 Study Name: Health Canada Simulated Environment Testing, DACO: 10.6
3644384	2023, Study Name: Health Canada Simulated Environment Testing, DACO: 10.6
3644385	2023, Study Name: Health Canada Simulated Environment Testing, DACO: 10.6 CBI
3644393	2024, Study Specific Experimental Data Record, DACO: 10.6
3644394	2024, Study Specific Experimental Data Record, DACO: 10.6 CBI
3618821	2024, DACO 5.2 Use Description/Scenario (Application and Post Application) Xenex LightStrike - LSMUV6-SL, DACO: 5.2
3618822	2024, CSA-UL Xenex LightStrike - LSMUV6-SL, DACO: 10.6, 5.2
3618823	2024, Device Absolute Spectral Irradiance Reference, DACO: 10.6, 5.2
3618824	2024, Justification for use of Device Absolute Spectral Irradiance Reference (Doc. No. DOC-000318) to Address Absolute Spectral Irradiance, DACO: 10.6, 5.2

PMRA Document Number	Reference
3618825	2021, TEST REPORT IEC 61010-1 Safety requirements for electrical equipment for measurement, control, and laboratory use, DACO: 10.6, 5.2
3618826	2020, TEST REPORT IEC 62471 Photobiological safety of lamps and lamp systems, DACO: 10.6, 5.2
3618827	2020, Information on lamps, output power Xenex LightStrike - LSMUV6-SL, DACO: 10.6, 5.2 CBI
3618828	2024, Ozone Datasheet, DACO: 10.6, 5.2
3618829	2021, Ozone Report Xenex LightStrike - LSMUV6-SL, DACO: 10.6, 5.2
3737389	2025, Ozone Data Sheet Health - Canada, DACO: 5.2

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