

Evaluation Report for Category B, Subcategory 2.1 Application

Application Number: 2022-1739
Application: New End-use Product Chemistry-Guarantee
Product: Aero HygenX SPARX UVC Device
Registration Number: 34927
Active ingredient (a.i.): Ultraviolet C (wavelength 100-280nm) Device
PMRA Document Number : 3479703

Purpose of Application

The purpose of this application was to register a portable ultraviolet C device, Aero HygenX SPARX UVC Device, which emits ultraviolet C light to disinfect both non-porous and porous surfaces.

Chemistry Assessment

A chemistry assessment was 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 radiation (including UVC) and the wavelength, 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 Aero HygenX SPARX UVC 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.

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

Environmental Assessment

An environmental assessment was not required for this application.

Value Assessment

The Aero HygenX SPARX UVC Device is an ultraviolet light-emitting device intended to be used to kill bacteria and viruses on hard non-porous surfaces and soft surfaces. A laboratory study including antibacterial and antiviral testing demonstrated that the device is capable of killing 99.99% of bacteria and 99.99% of viruses, with the exposure time required varying with the distance from the device, and the height of the surface to be treated. The Aero HygenX SPARX UVC Device has acceptable value for the claims described above.

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 Aero HygenX SPARX UVC Device.

References

PMRA Document Number	Reference
3496350	2022, E-SAFE Certificate of Conformity, DACO: 0.8.9, 5.2
3346622	2022, User Manual - English, DACO: 10.6, 5.2
3346625	2021, EC Declaration of Conformity, DACO: 10.6
3346626	2021, Lamp Specifications-Physical Description of the device, DACO: 10.6
3346629	2022, SPARX - Spec Sheet, DACO: 10.6
3365459	2022. Use Scenario with suggested Precautions. 2022. DACO 5.2
3365463	2022, SPARX Irradiance Test, DACO: 10.2.3
3496351	2022, Response to Deficiency Letter dated August 9, 2022, DACO: 5.2
3403762	2022, Ozone Statement for Lamps, DACO: 10.6
3496352	2023 Response to Deficiency Letter dated 03MAR2023, DACO: 0.8.24, 5.2
3449310	2023, IUVA FAQs, DACO: 10.7.1
3399638	2022, SPARX Final Test Report (Western University), DACO: 10.2.3.2
3399636	2022, AeroHygenX SPARX - raw data from Western Experiments, DACO: 10.2.3.2
3365462	2022, Raw Data from SPARX Irradiance Tests, DACO: 10.2.3
3441207	2022, Evaluation of the degradation of materials by exposure to germicide UV-C light through colorimetry, tensile strength and surface microstructure analyses, DACO: 10.3.2

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