

Evaluation Report for Category B, Subcategory 2.1 Application

Application Number: 2021-0914
Application: New EP Product Chemistry-Guarantee
Product: AERO HYGENX RAY - AUTONOMOUS UVC ROBOT
Registration Number: 34541
Active ingredient (a.i.): Ultraviolet C (Wavelength 280 - 100 nm)
PMRA Document Number: 3358042

Purpose of Application

The purpose of this submission was to register a new commercial ultraviolet C (UVC) device, the AERO HYGENX RAY - AUTONOMOUS UVC ROBOT. This device uses UVC emitting bulbs mounted on a programmable, autonomous wheeled base to sanitize and disinfect high-touch, hard non-porous and soft surfaces within aircraft cabins.

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 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 are acceptable when AERO HYGENX RAY - AUTONOMOUS UVC ROBOT 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 risk assessment was not required for this application.

Value Assessment

The AERO HYGENX RAY - AUTONOMOUS UVC ROBOT would complement traditional sanitization practices within commercial aircraft to reduce microorganisms on surfaces. The laboratory studies demonstrated this device is capable of reducing the levels of representative bacteria by 99.9%, SARS-CoV-2 by 99.999%, and other viruses by 99.99% on both hard non-porous surfaces, and soft surfaces when used as directed on the 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 it sufficient to support the registration of AERO HYGENX RAY - AUTONOMOUS UVC ROBOT.

References

A. List of Studies/Information Submitted by Registrant

PMRA

Document

Number	Reference
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3207054	2021, CSA & UL Approval, DACO: 0.8.9
3207063	2021, USER MANUAL - English, DACO: 5.2
3306059	2021, Certificate of Electrical Safety, DACO: 5.2
3313709	2021, Irradiance Testing around RAY in X, Y and Z axis, DACO: 10.2.3.4
3313710	2021, UVC Irradiance Measurements in Aircraft Cabin Mockup, DACO: 10.6
3328438	2021, UVC Lamp Specs, DACO: 10.6
3302132	2021, UVC Lamp Specs, DACO: 10.6
3302133	2021, Dimensions of RAY - 1, DACO: 10.6
3302134	2021, Dimensions of RAY - 2, DACO: 10.6
3302135	2021, Dimensions of RAY - 3, DACO: 10.6
3310528	2021, CE Declaration of Conformity, DACO: 5.2
3304367	2021, IEC 62471 Photobiological Safety of Lamps and Lamps Systems, DACO: 10.6
3302131	2021, Calculation of UV Dosage from RAY, DACO: 10.2.3
3313706	2021, Final Report - Western University Virus and Bacteria Efficacy, DACO: 10.2.3.2
3313708	2022, Raw Data from Western University UVC Efficacy tests, DACO: 10.2.3.4
3313709	2021, Irradiance Testing around RAY in X, Y and Z axis, DACO: 10.2.3.4
3313710	2021, UVC Irradiance Measurements in Aircraft Cabin Mockup, DACO: 10.2.3.4
3316486	2020, Cabin Mockup Seat tests with Dosage, DACO: 10.2.3.2

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
3359026	Stephen F. Yates; Giorgio Isella; Emir Rahislic; Spencer Barbour; Lillian Tiznado, 2021, Effects of Ultraviolet-C Radiation Exposure on Aircraft Cabin Materials, , J Res Natl Inst Stan 126:126019, DACO 10.3.2
3359031	Michael D. West; Andrew J. Ruys; Stephen G. Bosi, 2005, The Effects of the Ultraviolet Radiation Environment of LEO upon Polycarbonate Materials, AIAA Aerospace Sciences Meeting and Exhibit - Meeting Papers. 10.2514/6.2005-662, DACO: 10.3.2

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