Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.1 Application

Application Number: 2021-5563
Application: New End-use Product (Product Chemistry)-Guarantee
Product: Lumination LBU22 Series
Registration Number: 34964
Active ingredient (a.i.): Ultraviolet A (wavelength 315 - 400 nm)
PMRA Document Number: 3443979

Purpose of Application

The purpose of this application was to register a device, Lumination LBU22 Series, which produces ultraviolet A light (UVA, wavelength 315 - 400 nm) for use as a commercial hard surface sanitizer in occupied indoor spaces such as bathrooms, food processing facilities, gym locker rooms, hospitals, restaurants, commercial offices, retail, entrances and lobbies.

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 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.

The Lumination LBU22 Series device produces visible light (405 nm), and there is also the expectation that UVA radiation (365 nm) will be generated by the LEDs.

Occupational exposure is expected, since continuous operation of the device is recommended in commercial and industrial settings. The risk due to exposure to individuals is acceptable when the device is used according to label directions.

Because of the use pattern and the design of the device, bystander exposure to violet light and UVA radiation is expected. However, the risk due to exposure to bystanders is considered acceptable for the device.

The device is not intended for residential use. Consequently, the risk due to residential exposure is not a concern.

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

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Value Assessment

Lumination LBU22 Series device provides UVA light for the continuous sanitization of surfaces in a variety of occupied indoor spaces. The laboratory studies provided demonstrated that the device is capable of killing 99.9% of bacteria on hard non-porous surfaces following a 36-h exposure time with an irradiance of 1 W/cm^2.

Chemistry and Environmental Assessments

Chemistry and environmental assessments were not required for this application.

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 Lumination LBU22 Series.

References

PMRA Document Number	Reference
3389122	2019, 2021-5563 - Photobiological Safety Test Report, DACO: 5.2
3389123	2020, 2021-5563 - Photobiological_Test_Report_PTLED20E39752, DACO: 5.2
3389124	2020, 2021-5563 - Photobiological_Test_Report_PTLED20E39753, DACO: 5.2
3300574	2020, E516898-20200903-Certificate of Compliance, DACO: 0.8.9,10.6,5.2
3300562	2021, DACO 10.2.1 - Mode of Action - LBU, DACO: 10.2.1
3389118	2022, DACO 10.2.3.2. Efficacy Laboratory Trials Summary - Addendum - 13Sept22, DACO: 10.2.3.2
3389119	2022, 2021-5563 - Microchem Custom Device Study Report NG19838-A1 22JUL2022, DACO: 10.2.3.2
3389120	2022, 2021-5563 - Microchem Custom Device Study Report NG20063 25AUG2022, DACO: 10.2.3.2
3389121	2022, DACO 5.2. Use Description Scenario - Addendum - 13Sep22, DACO: 5.2
3300573	2020, A-1024654_Notice of Authorization-20200903-4789533999, DACO: 0.8.9,10.6,5.2
3300575	2021, DACO 5.2. Use Description Scenario - LBU, DACO: 5.2
3483130	2022. Current response to PMRA 09-27-22 email, DACO: 10.2.3.2