

RESPILON Group s.r.o.
Cejl 12
602 00 Brno
Czech Republic

YOUR REFERENCE:

DATE: December 07, 2020

OUR REFERENCE: 14067/2020

CTZB 187-14067/20-261-262, EX 201730

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Date: March 12, 2021

Subject: EXPERT OPINION on the assessment of in vitro cytotoxicity, human skin irritation and skin sensitization.

SUBJECT OF APPLICATION:

Regarding your application of December 07, 2020 for evaluation of in vitro cytotoxicity, human skin irritation and skin sensitization, we hereby report:

SUBMITTED SAMPLES:

TM 3/20/261: RespiPro VK – RPVK-M/L/S-000

TM 3/20/262: RespiPro White – RPW-M/L/S-000

Manufacturer:

RESPILON Group s.r.o., Cejl 12, 602 00 Brno – Czech Republic

SUBMITTED DOCUMENTATION:

Not submitted.

PERFORMED TESTS:

SOP 1/3 – Tests for in vitro cytotoxicity (EN ISO 10993-5: 2009 Biological evaluation of medical devices – Part 5, Articles 1, 2, 3, 4, 5, 6, 7, 8.1, 8.2, 8.3, 8.5, 9, 10, Annex A).

SOP 2/3 – Tests for irritation and delayed-type hypersensitivity (EN ISO 10993-10: 2014 Biological evaluation of medical devices – Part 10, Articles 1, 2, 3, 4, 5, 6.2, 6.3, 6.4, 6.5, 7.5, Annex A, B.1, B.2, C, E, F) – skin irritation in a group of human volunteers.

SOP 8/3 – Skin Sensitization – Local Lymph Node Assay: DA (OECD Test Guideline 442A, 2010; EN ISO 10993-10: 2010 Biological evaluation of medical devices – Part 10, Articles 1, 2, 3, 4, 5, 7, 7.1, 7.2, 7.3, 7.4, 8, Annex A; Council Regulation (EC) No. 440/2008, Method B.50, 2017).

EXPERT OPINION:

Tests were performed by the Centre for Laboratory Testing, accredited by the Czech Accreditation Institute (Accredited Laboratory No.1206), Centre of Toxicology and Health Safety.

CONCLUSION:

Under the test conditions (test of extracts), the test materials TM 3/20/261 and TM 3/20/262 did not exert any cytotoxic effects.

The test material TM 3/20/262 is not regarded as a significant skin irritant.

Under the test conditions, the test material TM 3/20/261 and TM 3/20/262 have no skin sensitization potential.



Dagmar Jírová, M.D., Ph.D.

Director

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ANNEXES:

Test Report No. 3/20/261-262 – Test Report Cytotoxicity in Vitro

Test Report No. 3/20/262 – Test Report Evaluation of Human Skin Irritation

Test Report No. 3/20/261-262 – Test Report Assessment of Skin Sensitization