



NATIONAL INSTITUTE OF PUBLIC HEALTH

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Czech Republic

NYKLÍČEK a spol. s r.o.
Rašínova 278
549 01 Nové Město nad Metují
Czech Republic

YOUR REFERENCE
DATE
OUR REFERENCE
PHONE/FAX
E-MAIL
Date:

16.9.2016
SZÚ 3020/2016
CTZB 187-3020/16-306
EX 161242
RNDr. M. Rucki, PhD.
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14.11.2016

Subject: EXPERT OPINION on health safety of Emergency evacuation suit.

SUBJECT OF APPLICATION:

Regarding your application from 16.9.2016 for evaluation of health safety of Emergency evacuation suit according to the requirements of Act No.102/2001 Coll., on general safety of products, in current wording, we hereby notify:

SUBMITTED SAMPLE: Emergency evacuation suit

**Manufacturer: NYKLÍČEK a spol. s r.o., Rašínova 278, 549 01 Nové Město nad Metují
Czech Republic**

SUBMITTED DOCUMENTATION:

Specification of the products was described in the application from 16. 9.2016.

PERFORMED TESTS:

Chemical analyses ((Determination of pH of aqueous extracts according to ČSN EN ISO 3071, Determination of free and hydrolyzed formaldehyde ČSN EN ISO 14184-1) and test Evaluation of human skin compatibility (EN ISO 10993-10, Part 10) were performed by the Accredited Laboratory No. 1206, accredited by ČIA, Centre of Toxicology and Health Safety. The analyses were performed in the scope of the Method Guideline SZÚ No. 1/200 for the evaluation of products coming into direct contact with human skin and/or mucous membranes (AHM No. 3/2000).

The submitted sample was used up for the purpose of testing.

EXPERT OPINION:

The subject of evaluation was the determination of possible adverse biological effects of the material when coming into contact with human skin.

The value of pH is in the range safe for direct contact with human skin.

The amount of free and hydrolyzed formaldehyde is under the detection limit of used method.

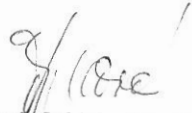
Values of determined metals are under the detection limit of used method or in the range for safe product.

Evaluation of the human skin compatibility showed no evidence of primary skin irritation.

CONCLUSION:

Based on the analysis of submitted documentation, on the results of chemical analyses and human skin compatibility, we come to the conclusion that the Emergency evacuation suit are safe for human health when coming into prolonged contact with skin. The products comply with the safety requirements of Act No. 102/2001 Coll., on general safety of products, in current wording. This opinion refers solely to the submitted samples and the conclusions from its evaluation may be applied only to other products of the same type, which have identical composition and parameters as the samples tested in our laboratories.

National Institute of Public Health
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Dagmar Jírová, M.D., Ph.D.
Head of the Centre of Toxicology and Health Safety

ANNEXES:

Test Report on cl
Test Report on el
Test Report on ex



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