NATIONAL INSTITUTE OF PUBLIC HEALTH
Šrobárova 48
Praha 10
100 42
Czech Republic

YOUR REFERENCE: 10.10.2012
OUR REFERENCE: 2649/2012
CTZB 187-2649/12-411
EX 121487

Protega d.o.o.
22. lipnja 3
51000 Rijeka
Republic of Croatia

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Hana Bendová, M.Sc., Ph.D.

Date: 28.12.2012

Subject: EXPERT OPINION on the laboratory assessment of health safety of cosmetic products in the scope of performed testing.

SUBJECT OF APPLICATION:
Regarding your application of 10.10.2012 for evaluation of cosmetic products safety according to Act No. 258/2000 Coll., on public health protection, and Decree of the Ministry of Health No.448/2009 Coll., on hygienic requirements on cosmetic products, we hereby report:

SUBMITTED SAMPLES:
SILVEREX soap
SILVEREX spray

Producer:
Protega d.o.o.
22. lipnja 3
51000 Rijeka
Republic of Croatia

SUBMITTED DOCUMENTATION:
Qualitative and quantitative product composition.
Analitički izvještaj br. 10/1053b – 27.04.2010.

PERFORMED TESTS:
Test for human skin compatibility (Cosmetic Product Test Guidelines for Assessment of Human Skin Compatibility, Colipa, Bruxelles 1997, COLIPA = The European Cosmetic, Toiletry and Perfumery Association).
The test was performed by the Laboratories of Toxicology, Test Laboratory No. 1206, accredited by the Czech Accreditation Institute.

EXPERT OPINION:
The submitted documentation includes information on qualitative and quantitative composition of the cosmetic products. The ingredients in formulation are in compliance with requirements of the Decree of the Ministry of Health No.448/2009 Coll., on hygienic requirements on cosmetic products, which is harmonized with The Cosmetics Directive 76/768/EEC. The laboratory test performed according to the intended use of the product confirms health safety of the product regarding local tolerance.

CONCLUSION:
Based on the analysis of submitted documentation and on the result of the performed test, we come to the conclusion that in the scope of the performed test the above mentioned cosmetic products are in compliance with requirements of the Decree of the Ministry of Health No.448/2009 Coll., on hygienic requirements on cosmetic products, which is harmonized with The Cosmetics Directive 76/768/EEC.

This opinion refers solely to the submitted samples and the conclusions from their 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.

Dagmar Jírová, M.D., Ph.D.
Head
Centre of Toxicology and Health Safety

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ANNEX:
Test report evaluation of human skin compatibility, Reference Number CTZB 187-2649-12-411.

TEST REPORT
EVALUATION OF HUMAN SKIN COMPATIBILITY

Testing facility: National Reference Center for Cosmetics (National Institute of Public Health, Šrobárova 48, 100 42 Prague 10, Czech Republic).

Date of study: 31.10. - 2.11.2012

Study performance: Hana Bendová, M.Sc., Ph.D.

Reference Number: CTZB 187-2649-12-411

The test was carried out in compliance with: Cosmetic Product Test Guidelines for Assessment of Human Skin Compatibility, Colipa, Bruxelles 1997, COLIPA = The European Cosmetic Toiletry and Perfumery Association

Aim of the study: Assessment of the potential of the test material to produce dermal irritation.

MATERIALS AND METHODS

TEST MATERIAL (TM):

1. **SILVEREX soap**
2. **SILVEREX spray**

Sponsor: **Protega d.o.o.**
22.lipnja 3
51000 Rijeka
Republic of Croatia

PREPARATION OF MATERIALS FOR TESTING

- **Test material**

TM 1: 5% aqueous solution - applied directly on skin (0.1 ml).
TM 1: applied directly on skin (0.1 ml).

CONTROLS

- **Reagent control (RC)**

Solvent – distilled water applied directly on skin (0.1 ml).

PARTICIPANTS IN THE STUDY

The selection of volunteers and the test methods were in accordance with the Declaration of Helsinki (1964) and subsequent revisions (CIOMS, 2002). The study was approved by the Ethical Review Committee of the National Institute of Public Health.

The volunteers were selected on the basis of inclusion and non-inclusion criteria and for this purpose had to fill in a special form. The volunteers were clearly informed regarding the nature of the study, timetable, constraints and possible risks. They gave their written informed consent before participation in the study was permitted. All the documentation is strictly confidential. 15 volunteers took part in the study.

Table 1 – Demographic data

Subject Number	Subject Initials	Age	Gender
1	JD	59	F
2	JD	59	M
3	PH	31	F
4	ŘM	38	F
5	CHD	22	M
6	BH	48	F
7	BI	50	F
8	BO	20	M
9	ŠJ	18	F
10	LM	32	F
11	SD	39	M
12	SM	38	M
13	OD	55	F
14	JM	38	M
15	JM	41	F

Test procedure

- single application closed patch epicutaneous test under semiocclusion

Single application closed patch epicutaneous test

The test materials were applied in semiocclusion on the upper back. The duration of treatment was 4 h. The test substances were removed by rinsing and gentle swabbing. The reactions were assessed 30 min. after patch removal, then after 24 h and 48 h.

Semiocclusive: Curatest (Lohmann / Rauscher)

Table 2 – Classification system for skin reactions

Reaction	Numerical grading
Erythema	
No evidence of erythema	0
Minimal or doubtful erythema	0,5
Slight redness, spotty and diffuse	1
Moderate, uniform redness	2
Strong uniform redness	3
Fiery redness	4
Dryness (Scaling)	
No evidence of scaling	0
Dry without scaling; appears smooth and taunt	0,5
Fine/mild scaling	1
Moderate scaling	2
Severe scaling with large flakes	3
Oedema	
absence of oedema	-
presence of oedema	+

RESULTS

The results are shown in the Annex I.

ASSESSMENT OF RESULTS

The products were dermatologically tested evaluating the human skin compatibility. It is our considered opinion that the results of the patch test study showed no evidence of primary skin irritation i case of all tested products.

Date of report: 2.11.2012

Study performance: Hana Bendová, M.Sc., Ph.D.

NATIONAL INSTITUTE OF PUBLIC HEALTH
National Reference Center for Cosmetics

Annex I

Table 3 – TM 1

Subject No.	Observation time/Skin reaction								
	30 min after patch removal			24 h after patch removal			48 h after patch removal		
	Erythema	Dryness	Oedema	Erythema	Dryness	Oedema	Erythema	Dryness	Oedema
1	0	0	-	0	0	-	0	0	-
2	0	0	-	0	0	-	0	0	-
3	0	0	-	0	0	-	0	0	-
4	0	0	-	0	0	-	0	0	-
5	0	0	-	0	0	-	0	0	-
6	0	0	-	0	0	-	0	0	-
7	0	0	-	0	0	-	0	0	-
8	0	0	-	0	0	-	0	0	-
9	0	0	-	0	0	-	0	0	-
10	0	0	-	0	0	-	0	0	-
11	0	0	-	0	0	-	0	0	-
12	0	0	-	0	0	-	0	0	-
13	0	0	-	0	0	-	0	0	-
14	0	0	-	0	0	-	0	0	-
15	0	0	-	0	0	-	0	0	-

Table 4 – TM 2

Subject No.	Observation time/Skin reaction								
	30 min after patch removal			24 h after patch removal			48 h after patch removal		
	Erythema	Dryness	Oedema	Erythema	Dryness	Oedema	Erythema	Dryness	Oedema
1	0	0	-	0	0	-	0	0	-
2	0	0	-	0	0	-	0	0	-
3	0	0	-	0	0	-	0	0	-
4	0	0	-	0	0	-	0	0	-
5	0	0	-	0	0	-	0	0	-
6	0	0	-	0	0	-	0	0	-
7	0	0	-	0	0	-	0	0	-
8	0	0	-	0	0	-	0	0	-
9	0	0	-	0	0	-	0	0	-
10	0	0	-	0	0	-	0	0	-
11	0	0	-	0	0	-	0	0	-
12	0	0	-	0	0	-	0	0	-
13	0	0	-	0	0	-	0	0	-
14	0	0	-	0	0	-	0	0	-
15	0	0	-	0	0	-	0	0	-

Table 5 – RC

Subject No.	Observation time/Skin reaction								
	30 min after patch removal			24 h after patch removal			48 h after patch removal		
	Erythema	Dryness	Oedema	Erythema	Dryness	Oedema	Erythema	Dryness	Oedema
1	0	0	-	0	0	-	0	0	-
2	0	0	-	0	0	-	0	0	-
3	0	0	-	0	0	-	0	0	-
4	0	0	-	0	0	-	0	0	-
5	0	0	-	0	0	-	0	0	-
6	0	0	-	0	0	-	0	0	-
7	0	0	-	0	0	-	0	0	-
8	0	0	-	0	0	-	0	0	-
9	0	0	-	0	0	-	0	0	-
10	0	0	-	0	0	-	0	0	-
11	0	0	-	0	0	-	0	0	-
12	0	0	-	0	0	-	0	0	-
13	0	0	-	0	0	-	0	0	-
14	0	0	-	0	0	-	0	0	-
15	0	0	-	0	0	-	0	0	-