

**Protega d.o.o.**

**22.lipnja 3, 51 000 Rijeka, Republic of Croatia**

## **Safety Assessment of Cosmetic Products for Human Health**

### List of products :

- **SILVEREX soap**
- **SILVEREX spray**

### Manufacturer:

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

### **Expert Opinion.**

This expert opinion is elaborated in compliance with generally binding valid regulations on cosmetic products and is used solely as an assessment of their safety for human health. It has been made out in accordance with current legislative, scientific and technical knowledge.

On the basis of documents provided with the products, reports on laboratory examinations and other accessible information the chemical composition of the products, the toxicological profile of the ingredients and the level of exposure according to the purpose of use and the way of application were assessed. The compliance of the products with contemporary requirements of the Act No. 258/2000 Coll. and the Decree of the Ministry of Health No. 448/2009 Coll. (harmonized with the Cosmetics Directive 76/768/EEC) was evaluated.

The cosmetic products contain ingredients whose general toxicological profile does not endanger the users' health when used in given concentration and for the purpose specified. The use of the products by healthy people under normal or reasonably foreseeable conditions does not represent any risk of irritation, sensitisation or other local or system undesirable effects. The composition of the products is in compliance with requirements of the contemporary valid regulations for cosmetic products.

*J. Mirošević* 1

The laboratory reports available include chemical analysis and microbiological tests performed by Nastavni ZAVOD ZA JAVNO ZDRAVSTVO PRIMORSKO-GORANSKE ŽUPANIJE RJEKA and skin compatibility clinical test, performed by accredited laboratories of the National Institute of Public Health No.1206.3 ( test report CTZB 187-2649/12-411). The test results are stored at the seat of the responsible person. The laboratory and clinical reports confirm the health safety and good local tolerance of the cosmetic product listed above.

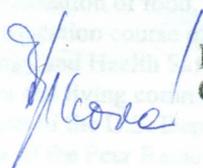
The basic declared cleaning function of the products is justified by the composition of the products and qualities of the used ingredients.

**On the basis of all accessible information and with the use of generally recognised toxicological criteria it is possible to designate the product as safe for human health when used in the declared way and when following compulsory instructions on the product packaging according to requirements of the valid regulations for cosmetic products.**

This conclusion can be applied only to those products whose composition and qualities conform to the presented documents and results of the laboratory tests.

Before the marketing of any cosmetic product in the EU, if marketed for the first time in the Czech Republic, the manufacturer is obliged to notify the authority for human health protection (Ministry of Health of the Czech Republic, register of chemical agents) of the data under section 27, subsection 1 of the Act No. 258/2000 Coll. The manufacturer is also obliged to provide on request of a supervising authority the documents of the products under section 27, subsection 2 of the Act No. 258/2000 Coll., in the extent provided for by the Decree of the Ministry of Health No. 448/2009 Coll., section 4, letter a) to h). Before the marketing of a cosmetic product it is necessary to ensure the compulsory information on the product packaging in the extent under section 3, subsection 1, letter a) to g) and subsections 2 and 3 of the Decree No. 448/2001 Coll. including warnings and precautions provided for especially in the Annexes No. 3, 4, 6, and 7 Coll.

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## Dagmar Jírová, M.D., Ph.D.

### CV / Qualification

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### Curriculum Vitae

Born	December 18, 1952, Prague.
1971 – 1977	Study at the Medical Faculty of Hygiene, Charles University, Prague.
1977 – 1980	Post-graduate study, Ph.D. in hygiene.
Since 1980	Scientist in the Institute of Hygiene and Epidemiology (later the National Institute of Public Health - NIPH).
Since 1988	Head of the Research Group for Dermatotoxicology and Immunotoxicology, Head of the National Reference Centre for Cosmetics and the National Reference Laboratory for Experimental Immunotoxicology.
1994	Risk Assessment, Course of U.S.EPA and the NIPH.
1992-1996	Affiliations in R&D laboratories of world manufacturers of cosmetics.
1992-1996	Teacher at the 3 <sup>rd</sup> Medical Faculty in Prague, and the Pharmaceutical Faculty of the Charles University in Hradec Králové.
1998	Post-graduate study of ethics in medicine at the 1 <sup>st</sup> Medical Faculty Prague.
Since 1998	Expert of the Ministry of Health of the Czech Republic on cosmetics legislation and its harmonisation with the EU legislative measures.
1999	Awarded a Certificate on qualification according to the §17 of the Animal protection Act No.246/1992 Coll.
Since 2000	Chairman of the Ethical Review Committee of the NIPH. Member of the Working Group and the Standing Committee on Cosmetics of the European Commission on behalf of the Czech Republic. Member of the Scientific Committee ESAC of the ECVAM-JRC of the European Commission. Head of the CZECOPA (Consensus Platform of the CR on Alternatives to Animal Experimentations).
2000	Awarded a diploma of the NIPH Scientific Board for significant participation in the scientific progress in preventive medicine and improving public health.
2001	Holder of a certificate on the "Safety Assessment of Cosmetics in the EU" on Vrije University, Brussels, Belgium.
2006	Awarded a Certificate for sensoric evaluation of food, cosmetics and food contact materials, Accredited postgraduate education course of the MŠ SR.
Since 2008	Head of the Department of Toxicology and Health Safety
2008	Holder of Certificates on negotiation and living communication techniques Awarded a Certificate of Appreciation of the U.S. Dep. of Health and Human Services and ICCVAM as a member of the Peer Review Panel for LLNA.

She is the author of more than 200 publications in scientific journals, proceedings and monographs, posters or articles and publications for the public. She was a principal investigator in research projects of the Ministry of Health of the CR and co-investigator in research projects under the 6FP of the EC in the field of the alternative toxicological methods for evaluation of health risks in chemicals and consumer products.

She is a member of the Czech Society of Cosmetology, Czech Medical Society JEP, Society of Corrective Dermatology and Cosmetology, European Society of Toxicology In Vitro, Association PROKOS, CZECOPA and ECOPA.

Her professional specialisation is dermatotoxicology and immunotoxicology in the field of products of everyday use including cosmetics and their ingredients. She is focused on safety assessment of cosmetics and other consumer products, introduction of alternative in vitro methods for the assessment of local skin tolerance, identification of immunotoxic, dermatotoxic and phototoxic effects, evaluation and proof of specific effects of active substances and identification of protective effects using instrumental and clinical methods.