PART B

Cosmetic product safety assessment

1. Conclusions of the assessment

On the basis of all available information and using generally accepted toxicological criteria, a cosmetic product may be labeled as safe for human health when used in the declared manner and with mandatory labeling on the product packaging in accordance with current cosmetic regulations. The product complies with the safety requirements specified in Regulation (EC) No. 1223/2009 of the European Parliament and of the Council on cosmetic products.

This conclusion can only be applied to those products whose composition and properties correspond to the submitted documentation and the results of laboratory or clinical tests.

2. Warnings and instructions for use on the label

No specific warnings required by Regulation (EC) No. 1223/2009 of the European Parliament and of the Council on cosmetic products are obligatory for the labeling of the product. The purpose of use follows from the product name "Tea Tree Desinfectant - Liquid Hand Disinfectant". Instructions for the correct application of the product are included in the printed text of the consumer packaging, which is part of this report.

The concentration of certain allergenic components of the essential oil in the product exceeds 0.001% and should therefore be labeled in the composition as separate ingredients..

INCI Labeling of ingredients on the product packaging:

Ingredients:
Aqua, Glycerin, Phenoxyethanol, Ethyl Lauroyl Arginate HCI, Melaleuca Alternifolia Leaf Oil, Geraniol, Linalool, Limonene.

3. Justification

Based on the documentation provided by the manufacturing plant for the product and its raw materials , laboratory examination protocols and other available information , the chemical composition of the product , the toxicological profile of the ingredients and the level of exposure according to the purpose and method of application of the product were assessed. The composition of a cosmetic product includes ingredients whose general toxicological profile, when used at a given concentration and for a given purpose, does not pose a health risk to the user. Use of the product in healthy persons under normal or normally foreseeable conditions and in accordance with the instructions for use does not present a risk of irritation , sensitization or other local or systemic , toxicological adverse effects. The composition of the product corresponds to the requirements of current regulations that are valid for cosmetic products. Ingredients that are classified as skin or eye irritant or sensitizing are incorporated into the formulation in a concentration that does not pose any risk to human health. The safety margins for the individual ingredients far exceed 100, see Section 7 of Part A of this report.

The material of the used product packaging is inert , there is no release of substances or interaction of the packaging material with the product mass.

Available test protocols include a microbiological quality test, a stress microbiological test, a skin tolerance test and an evaluation of antibacterial properties (see section 3 and section 10 of this report). 12

The results of the microbiological quality test, the effectiveness of the preservation system and the skin compatibility test confirm the health safety and good local tolerance of the cosmetic product.

The basic function of the product declared in the text for consumers results from the composition of the product, the properties of the ingredients used and the evaluation of antibacterial properties confirm the declared function of the product. The text of the label is part of this report. This opinion is issued in accordance with the requirements of current, generally binding valid regulations for cosmetic products and serves exclusively as an assessment of their safety for human health. It is prepared according to the current state of legislative, scientific and technical knowledge.

Any changes in the product formulation or in the requirements of binding regulations require a reassessment of the product safety and the preparation of a new safety report. The report may not be reproduced other than in its entirety without the written consent of the person responsible for the safety assessment.

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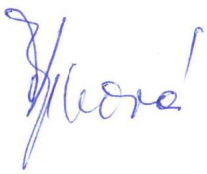
4. Assessment and approval details of Part B:



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