Cosmetic Product Safety Report No. 020/2020 of 30/09/2020

as required by Regulation of the European Parliament and of the Council No. 1223/2009 on cosmetic products

Type of product/Trademark name/Labelling of product: MG TWINS GEL, RUVIREX GEL, LIQUICID GEL, MG TWINS SPRAY, RUVIREX SAFE, LIQUICID SPRAY

Manufacturer and domicile: MgCream s.r.o., Sarajevská 10, 120 00 Prague No. 2

Safety Assessor of Cosmetic product: PharmDr. Lucia Kalinovská, PhD.Košariská 161, 900 42 Dunajská Lužná

A safe component is considered to be a component with a calculated MoS value greater than 100.

9. Undesirable effects and serious undesirable effects

There is no evidence of any undesirable and adverse effects on the cosmetic product and no undesirable and adverse effects are expected with the normal or reasonably foreseeable conditions of use of a cosmetic product.

Dermatological test: protocol No. 720-2020-00170972, Dr. Med. Pawel Brzewski, Dr. Med. Marek Brzewski.

10. Information on the cosmetic product

The product is manufactured in the manufacturing company ensuring compliance with the principles of good manufacturing practice for cosmetic products including hygiene requirements.

The cosmetic product is packed in the packaging designed for this purpose and the correct labeling is ensured according to the valid legislation. The manufacturer is responsible for the labeling of consumer packaging and is not part of the safety assessment of the cosmetic product.

Information Resources:

- SCC´S Notes of Guidance for testing of cosmetic ingredients and their safety evaluation, 9th revision
- Commission implementing decision of Guidelines on Annex I regulation (EC) No. 1223/2009 of the European Parliament and of the Council on cosmetic products (2013/674/EU)
- https://www.specialchem4cosmetics.com
- https://en.wikipedia.org
- https://www.sigmaaldrich.com
- https://www.makingcosmetics.com
- ttps://www.cosmetics.specialchem.com

PART B- Cosmetic product safety assessment

Type of product/Trademark name/Labeling of product: MG TWINS GEL, RUVIREX GEL, LIQUICID GEL, MG TWINS SPRAY, RUVIREX SAFE, LIQUICID SPRAY
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1. Assessment conclusion

Based on all available data it can be assumed that there is no risk of irritation, sensibilisation, local or systemic reactions with human health.

Based on all available data and the above facts the assessed cosmetic product is safe for human health when used under normal or reasonably foreseeable conditions of use, consumer instructions of use and in compliance with all the requirements marked on the packaging of cosmetic products according to the legislation of the European Union valid on the date of this evaluation.

2. Labelled warnings and instructions of use

Statement on the need to label any particular warnings and instructions of use in accordance with Article 19(1) (d).

3. Reasoning

The assessment concludes the overall toxicological profile of the cosmetic product.
The basic monitored feature of the safety assessment was the identification of the risks of the individual components of the cosmetic product including their interaction. The risk and likelihood of the occurrence of an adverse effect under defined conditions such as the method of use, the amount applied and the frequency of application were assessed. The risk based on the synthesis of all available data according to current scientific knowledge used to determine the type and degree of risk posed by the cosmetic raw material or product. The following possible adverse reactions were assessed in relation to the individual components of the cosmetic product: irritant, allergenic, mutagenic, teratogenic, carcinogenic, systemic (neurotoxic, hepatotoxic, nephrotoxic, hepatotoxic, cardio toxic, toxic for gastrointestinal system and respiratory system). For all cosmetic products, the possibility of damage to health with long-term exposure to low concentrations of potentially toxic components was assessed.

4. Assessor´s credentials and approval

This assessment shall only cover the assessment of cosmetic products and the composition, qualities, consumer information and other materials relevant to the assessment shall be in accordance with the documentation submitted for this assessment and shall be the responsibility of the manufacturer.

Bratislava 30/09/2020

Name and address of the safety assessor: PharmDr. Lucia Kalinovská, PhD.
Košariská 161, 900 42 Dunajská Lužná, Slovak Republic