

SAFETY ASSESSMENT according to EU-Directive 1223/2009

The product Ohrloch Hygiene Gel

With the formula-No. EX500648

is assessed by me **as safe for use**

considering the general toxicological profile of the ingredients, their chemical structure and the level of exposure, in accordance with the principle of good laboratory practice, when applied as intended and reasonably foreseeable, taking the cautionary notice and instructions for use into account.

This assessment is based on the safety report, which contains the following information:

1. The quantitative and qualitative composition of the cosmetic product
2. The physical/chemical characteristics and stability of the cosmetic product
3. The microbiological quality
4. The impurities, the traces and information about the packaging material
5. The normal and reasonably foreseeable use
6. The exposure to the cosmetic product
7. The exposure to the substances
8. The toxicological profile of the substances

Reasoning: I could not find banned or overdosed regulated substances in the formula. With the ingredients of the product I could neither find evidence of dangerous effects by the ingredients itself in the determined doses nor by interactions to each other, provided that the product is used as intended or reasonably foreseeable.

Restriction: The intended composition and specification of the product must be assured in the manufacturing process by observing the Good Manufacturing Practice (GMP) and a suitable quality management (QM) system.

Attachment: assessed formula, calculation of exposure, labelling data

Assessor: Wolfgang J. Beckermann, Diplom-Biologe, Dr.rer.nat.

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