

4. Part B – Cosmetic product safety assessment

4.1. Assessment conclusion

The cosmetic product Neurogan CBD Mouthwash 4000, 60 ml is assessed as safe for use as a mouthwash with a daily usage of six drops in accordance with the European Cosmetics Regulation (EC) No 1223/2009 if the instructions of use on the label clearly states that the product is a mouthwash with a daily dosage of 6 drops. It is recommended making sure that the label complies with Article 19 of the European Cosmetics Regulation (EC) No 1223/2009, that a storage stability test is conducted and to ensure compatibility between the product and the packaging.

4.2. Labelled warnings and instructions of use

The following warnings and instructions of use are mentioned on the packaging material/label of the product:

A label has not been provided. Warnings and/or instructions of use according to the product summary file: Designated to promote healthy mouth. To moisturize, calm and balance your mouth. Use the dropper to take the right amount into your mouth or mix it with water. Recommended daily dosage, no more than 6 drops per day.

Ingredients (INCI): Caprylic/Capric Triglyceride, Cannabis Sativa Stem Extract.

The product name includes the wording “Mouthwash”, but the instructions of use do not mention that the product should be spit out again. This makes it unclear to the consumer, how the product should be used. Therefore, further instructions of use are needed to define the use of the product as a mouthwash.

There are no ingredients incorporated in the finished product, which require additional directions, specific indications or warnings in accordance to the relevant Annexes of the European Cosmetics Regulation (EC) No 1223/2009 (as amended) or due to their toxicological and/or physical-chemical properties or because of their concentrations in the finished product.

Mediator A/S recommends making sure that the label complies with Article 19 of the European Cosmetics Regulation (EC) No 1223/2009.

4.3. Reasoning

The safety assessment of Neurogan CBD Mouthwash 4000, 60 ml is based on the toxicological profile of each ingredient and evaluation of the data collected on the product. The product is manufactured in accordance with Good Manufacturing Practice (GMP) for cosmetics.

4.3.1. Physical/chemical characteristics, stability and microbiological quality of the cosmetic product

Neurogan CBD Mouthwash 4000, 60 ml is an oil-based formulation. No preservatives have been added. Microbial stability testing is not necessary for this kind of product.