

## To whom it may concern

### Safety declaration Cederroth Eye Wash/Emergency Eye Wash

**The Cederroth Eye Wash is a safe product when used as intended for external ophthalmic rinsing.**

#### **Background:**

Boric acid and sodium borate have been classified as toxic to reproduction (CMR 1B) and have therefore been included in the REACH Candidate list of substances of very high concern (SVHC). This document has been issued according to REACH 1907/2006 Article 33 since the Cederroth Eye Wash contains > 0.1 % (w/w) of boric acid/borate.

#### **Product description:**

The Cederroth Eye Wash products (variants REF 725200, 725201, 51011042, 7221, 722110) contain a sterile, isotonic sodium chloride solution, buffered with a low concentration of boric acid/borate to neutral pH.

The Eye Wash is intended for washing away foreign particles and dangerous liquids from an eye in an emergency First Aid situation. The Eye Wash is to be used for transient use (typically a few seconds to 30 minutes) for mechanical rinsing of the eye surface. The Eye Wash has no pharmacological action and is intended for external use only. It should not be used for children under 3 years of age.

#### Content of borates in the Eye Wash liquid:

Boric acid	CAS 10043-35-3
Sodium borate (Disodium tetraborate decahydrate)	CAS 1303-96-4

The total concentration of boron ions, the active metabolites formed in the system, adds up to 0.29%.

#### **REACH (EC No 1907/2006) and CLP (EC No 1272/2008):**

The background to the decision to include boric acid and sodium borate on the SVHC list is provided in a corresponding support document<sup>1</sup>.

In the support document it is stated that:

- Absorption of boric acid via the oral route is nearly 100%.
- Dermal absorption through the skin is very low.
- Boric acid is not further metabolized.
- Boron is excreted rapidly, with mean elimination half-lives of 13.4 hours in humans and has low potential for accumulation.
- Boric acid is mainly excreted in the urine.

The available animal studies are based on repeated oral exposure to boric acid with various concentrations. At high concentrations an effect on reproduction could be seen, documented as impaired fertility and impaired fetus development.

The available (recent) human data collectively show no effects on fertility and sexual function. However, there is no evidence that the effects observed in animals are not relevant to humans, so the borates have been classified as toxic to reproduction, Class 1B.

Mixtures containing boron in concentrations  $\geq 0,3\%$  shall be classified as hazardous according to CLP.

#### **Conclusion:**

The Cederroth Eye Wash

- is intended only for **external** rinsing of the eye globe, not for oral intake,
- is intended for transient use, up to 30 minutes, probably not repeated many times during a lifetime,
- has a concentration of borates below 0.3%, so the mixture is not classified as hazardous according to CLP.

The conclusion is that the Cederroth Eye Wash is a safe product when used as intended for external ophthalmic rinsing.

**Issued by:** Regulatory department, Orkla Wound Care AB

<sup>1</sup>Member state committee draft support document for identification of boric acid as a substance of very high concern because of its CMR properties, adopted June 9 2010.