

To whom it may concern

Safety declaration Cederroth Eye Wash/Emergency Eye Wash

The Cederroth Eye Wash is to be regarded as a safe product when used as intended for external ophthalmic rinsing

Background:

Boric acid and sodium borate has been added to the REACH Candidate list of substances of very high concern (SVHC) in June 2010. This document is issued according to REACH 1907/2006 Article 33 since the Cederroth Eye Wash contains > 0.1 % (w/w) of boric acid/sodium borate.

Product description:

The Cederroth Eye Wash products (variants REF 7251,7251A, 7255,7255A, 7221, 722110,725200,725200A) contain a sterile, isotonic sodium chloride solution, buffered with a low concentration of sodium 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 boric acid/ sodium borate:

	<u>% (by weight)</u>	<u>CAS-no</u>
Boric acid	0.28%	10043-35-3
Sodium borate	0.03%	1303-96-4

The total concentration of boron ions, the active metabolites formed in the system, thus adds up to 0.3%. This is 18 times below the decided warning text limit of 5.5% for chemical products, based on oral consumption¹.

The Cederroth Eye Wash is intended only for external rinsing of the eye globe, which is stated on the product itself.

REACH: The background to the decision to include boric acid and sodium borate on the candidate list can be found in a corresponding support document¹. The reason for the inclusion is that there exist at present insufficient epidemiological studies in humans to demonstrate the absence of an adverse effect on reproduction.

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.

In animal studies repeated exposure (by feeding once a day for between 9 weeks and 2 years) of boric acid was done with various concentrations. It was concluded that at high concentrations an effect on reproduction can be seen, documented as impaired fertility and impaired fetus development.

It is not known whether there are significant differences in the toxicodynamics between humans and laboratory animal models and in the absence of such knowledge it must be assumed that the effects seen in animals could possibly also occur in humans.

Investigations of potentially reproductive effects in humans have been done among worker populations or among a highly exposed population and no significant adverse effects on reproduction or reproductive outcome have been reported. However, all epidemiological studies performed exhibited methodological deficiencies. It was concluded, that there was no clear evidence of reproductive toxicity in highly boron-exposed workers. Thus, epidemiological studies in humans are insufficient to demonstrate the absence of an adverse effect of inorganic borate on fertility.

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

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¹Member 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.