

Instructions for Use

Boule Hypochlorite (4%) Cleaner



Intended use

The Boule Hypochlorite (4%) Cleaner 100 mL is intended for use with the Quintus instrument system, as given below, for corrective and preventive cleaning of inlets and tubing in contact with blood (protein).



Summary and principles

The Boule Hypochlorite (4%) Cleaner is a cleaner containing hypochlorite in a stabilized solution with added surfactants. The hypochlorite and surfactants will dissolve protein and clots including those attached to surfaces facilitating the removal during rinsing. The cleaner has the ability to act as a disinfectant, significantly reducing the number of viable microorganisms. Using this cleaning solution at the stated regular intervals will ensure low background counts (PLT) and longer time between failures.

Storage and stability

The Boule Hypochlorite (4%) Cleaner can be transported at ambient temperature (avoid freezing and allow adaption to room temperature before use). Prolonged storage above 30°C may result in lessened cleaning and disinfecting activity of the product due to degradation of the hypochlorite. Always store the bottles in an upright position to avoid any leakage from the cap. The cleaner is stable at least up to the expiration date as shown on the label when stored at a temperature between 15°C and 30°C.

Instructions for Use

A detailed description of use of the Boule Hypochlorite (4%) Cleaner can be found in the Quintus instrument User's Manual under 9.1 Daily Cleaning



Note! At least 3 mL of cleaner should be filled into a vial which fits into the sample rotor.

Precautions

- For In Vitro diagnostic use only on instruments as stated above.
- Please read the relevant Safety Data Sheet (SDS) before use. SDSs are available at www.boule.com.
- The Hypochlorite (4%) Cleaner is classified as hazardous to health and the environment according to CLP [Regulation (EC) no 1272/2008]. The required labeling is given below, detailed information is given in the SDS.

Hazard pictogram	
Signal word	Danger
Hazard statements	H314 Causes severe skin burns and eye damage. H410 Very toxic to aquatic life with long lasting effects.
Precautionary statements	P260 Do not breathe gas, mist, vapors, or spray. P273 Avoid release to the environment. P280 Wear protective gloves, protective clothing and eye or face protection. P303 + P361 + P353 IF ON SKIN (or hair): Remove immediately all contaminated clothing. Rinse skin with water. P305+P351+P338 IF IN EYES Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 Immediately call a POISON CENTER or doctor/physician.
Contains	Contains: SODIUM HYPOCHLORITE, SOLUTION ≥1 - <5 % CL ACTIVE, SODIUM HYDROXIDE

- The cleaner should be disposed of according to local regulations. When draining remaining solution through the sewage system, always use plenty of water. The plastic bottle can be recycled after rinsing.
- Solution passing through the instrument during cleaning will be collected and disposed of as a part of the general waste from the instrument.
- This product is intended for use as supplied. Adulteration by dilution or addition of any materials to the product invalidates any IVD use of the product.

Serious Incident

If a serious incident occurs in relation with Boule Medical's product, a notice shall be reported to the distributor, the manufacturer Boule and the competent authority of the Member State in which the user and /or the patient is established.

Ordering information and service

Contact your local Boule representative for orders and support. Please have the catalogue number ready for orders. For other assistance contact Boule Medical AB at phone +46 8 7447700, fax +46 8 7447720 or info@boule.com.

REF	Description	Packaging
1504385	Boule Hypochlorite (4%) Cleaner	100 mL