IVD IN VITRO DIAGNOSTIC MEDICAL DEVICE CE

NAME **FIXALL-HIS FIXATIVE LIQUID**

European Medical Device Nomenclature (EMDN) **W01030705** **FIXING REAGENTS (HISTOLOGY/CYTOLOGY)**

Packaging available

526274	**FIXALL-HIS Fixative Liquid**	Packaging 5 l

Intended use Fabric Fixation.

Principle of the method
Fixation is intended to immobilize cellular and tissue structures, in a state as close as possible to their living state. It should be done as early as possible, by immersing the material in a large volume of fixative fluid. The duration of fixation varies depending on the size of the samples.
FIXALL-HIS is a formaldehyde-free alternative to AFA liquid, which offers an equivalent quality of fixation in microscopy, for an orange-red color (characteristic of the presence of ethanol) with good differentiation and slight nuclear retraction.

Main Components
- ETHANOL ABSOLUTE
- PROPYLENE GLYCOL

Warnings and Precautions
The product is intended for specialized technical personnel.
The product is ready to use.
Carefully read the safety and precautionary statements on the label. Always refer to the **Safety Data Sheet** (available from the website at https://www.carloerbareagents.com/fr/) which contains information on the risks posed by the product, the precautionary measures to be taken during use, first aid measures and response measures in the event of an accidental release.
Do not use if primary container is damaged.

Reagents are produced with uniform methods and verified in accordance with quality control specifications.

Procedure
Less than 15 minutes after extraction, immerse the sample in at least 10 times its volume. The average fixing time depends on the size of the parts.
For information purposes only:
- For small parts of 1 to 2 cm (digestive polyps, lymph nodes,...): The fixation time is about 24 h. Extending the contact time is not helpful, the broadcast is over. The nuclei appear smaller when the nucleolus, chromatin and connective tissue are well differentiated.
- For parts > 2cm (e.g. prostate,...): FIXALL-HIS does not penetrate deep into the tissues. Attachment is only done on the surface. The tissue will appear soft and therefore more difficult to remove. After 24 hours, it is therefore necessary to make a new fixation in the form of a slice in a new FIXALL-HIS bath.

For PLC processing, the method should be adapted, e.g. with the following adjustments:
- Work at room temperature.
- Perform two successive baths of FIXALL-HIS of 5 minutes each.
- Perform two ethanol baths at 70° for 20 minutes for the first and 30 minutes for the second.
- Perform two 95° ethanol baths of 20 minutes for the first and 30 minutes for the second.
- Perform two baths of absolute ethanol of 60 minutes for the first and 90 minutes for the second
- Following the xylene baths, the paraffining process lasts until the end of the 12-hour program.

Stability
The product is stable under normal storage conditions.
There is no particular risk of reaction with other substances under normal conditions of use.

Shelf life of the product
The product has a shelf life of 2 years, in unopened packaging and properly stored.
Close the bottle after use.
After the first opening, the product can be used for 6 months or within the limit of the total shelf life.

Storage conditions
Products are packaged in appropriate containers, with a sealed cap; They should be kept tightly closed, away from light, in a cool, dry place.
Recommended temperature range for storage: 5-30°C

Waste Disposal
For more information regarding disposal, please refer to the Safety Data Sheet. It is advisable to follow proper safety measures when handling, processing, and disposing of all clinical specimens, as pathogenic organisms may be present

References
Study Protocol in Anatomy and Pathological Cytology PHAT N. VUONG
TEXTBOOK OF GENERAL PATHOLOGICAL ANATOMY

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