

IVD IN VITRO DIAGNOSTIC MEDICAL DEVICE **CE**

DESIGNATION **FORMALDEHYDE 4% W/V BUFF. RS**

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

Packaging available

524920	Formaldehyde 4% w/V buff.	Bottle 500mL
415694	Formaldehyde 4% w/V buff.	Bottle 1L
415691	Formaldehyde 4% w/V buff.	Can 5L
526912	Formaldehyde 10% V/V according to Lillie	Can 5L
526936	Formaldehyde 4% w/V buff.	Can 5L
415695	Formaldehyde 4% w/V buff.	Cubitainer 5L
526933	Formaldehyde 4% w/V buff.	Can 10L
415693	Formaldehyde 4% w/V buff.	Cubitainer 10L
415696	Formaldehyde 4% w/V buff.	Cubitainer 20L
526911	Formaldehyde 10% V/V according to Lillie	Can 25L
414692	Formaldehyde 4% w/V buff.	Can 30Kg
414697	Formaldehyde 4% w/V buff.	Drum 200L

Wide neck

508861 Formaldehyde 4% w/V buff.	Packaging of 500 x 30mL	bottle 60mL
508862 Formaldehyde 4% w/V buff.	Packaging of 100 x 120mL	bottle 180mL
508863 Formaldehyde 4% w/V buff.	Packaging of 32 x 300mL	bottle 500mL
526939 Formaldehyde 4% w/V buff.	Packaging of 24 x 400mL	bottle 1L
526938 Formaldehyde 4% w/V buff.	Packaging of 24 x 600mL	bottle 1L
526937 Formaldehyde 4% w/V buff.	Packaging of 24 x 800mL	bottle 1L
526931 Formaldehyde 4% w/V buff.	Bucket 2.5L	bucket 5L

Intended use

Fixation solution for the preparation of histological samples for examination in optical microscopy.

Principle of the method

Fixation means the neutralization of autolytic enzymes and bacteria that cause tissue putrefaction and confers structural stability to the chemical constituents of the protoplasm. Fixators are able to denature proteins and make other cellular constituents insoluble.

Formaldehyde 4% w/V buffered solution is one of the main non-coagulant fixators, hardens protein gels without separating water from proteins and fixes the protoplasm without causing the formation of a microscopic spongy mesh. It has a very low oxidation potential, penetrates tissues quite quickly and gradually hardens them. Does not alter proteins, creates bridges between amine groups and leaves hydrophilic groups intact. It can form a methylene bridge between two protein chains, binding to the thin groups of the side chains. It neutralizes the basic groups and increases the acidity of proteins. Formalin-attached fabrics therefore have a greater affinity with basic dyes than with acid dyes. It does not precipitate DNA, preserves most lipids and makes phospholipids insoluble in lipid solvents, does not fix soluble carbohydrates and dissolves glycogen and urea.

Main components

Formaldehyde at 40%, diluted to 1/10 in distilled water, with an addition in the solution of a buffer at pH 7 according to Lillie.

Warning and precautions

The product is intended for specialized technical staff.

The product is ready to use.

Carefully read the information on safety marks and precautionary statements on the label. Always **consult the safety data sheet** (accessible from the website at [Homepage | CARLO ERBA Reagents Export Site](#)) where information on the



risks posed by the product, precautionary measures to be taken during use, first aid measures and response measures in the event of accidental release are located.

Do not use in case of damaged primary container.

Reagents shall be produced with uniform methods in accordance with bibliographic references and verified in accordance with quality control specifications.

Procedure

The part to be kept must be immersed in about 20 times its volume in formic aldehyde solution (for reasons of transport or shipping convenience it is possible to use smaller quantities).

For body fluids add an equal volume of formaldehyde solution.

The duration of fixation depends on the size of the sample, as an indication, it is 2 to 4 hours for a puncture-biopsy, from 4 to 10 hours for a tissue fragment 0.5 cm wide, obtained surgically, 24 hours minimum for a large sample or an already open operating room. The theoretical penetration speed can be calculated with the equation: $d = 0,79 \sqrt{t}$ (d = penetrated depth in mm, t = time in hours)

For the rest of the protocol, the parts will have to be washed with running water for about 1 hour, then dehydrated, impregnated with paraffin, then cut with a microtome.

Remark

In order to avoid the risk of precipitation of the phosphates present, the fixed tissue must not, as a first step, be brought into contact with ethanol solutions in a concentration greater than 70%.

Stability

Over time, the product can give rise to the formation of polymers, including paraformaldehyde which is deposited at the bottom in the form of a white precipitate, while formaldehyde is oxidized to formic acid by oxygen from the air.

Shelf life of the product

The product has a shelf life of 2 years, in unopened packaging and properly stored.

Close the container 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

The products are packed in appropriate containers, with a sealed cap; they should be kept tightly closed, away from light, in a cool and dry place.

Recommended temperature range for storage: 5-30°C

Waste disposal

For more information on disposal, please refer to the safety data sheet. It is advisable to follow appropriate safety measures when handling, processing and disposal of all clinical samples, as pathogenic organisms may be present

References

Study Protocol in Anatomy and Pathological Cytology PHAT N. VUONG

GENERAL PATHOLOGICAL ANATOMY MANUAL

Revue Française d'Histo technologie (2004, vol 17, n°1)

English version

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