

Formaldehyde solution 38-40%



Minimum titer: 37%



In-vitro diagnostic medical device

EMDN : W01030705

IVD in **Classe A**, Reg. UE 2017/746

Catalog number	Unit size	BASIC UDI	UDI-DI
05-01007Q	2.5 l x 4	080341202W01030705AJ	08034120277112
05-K01007	20 l	080339762W01030705X2	08033976234133

Packaging

05-01007Q

Primary container: white bottle in polyethylene terephthalate (PET). Useful capacity 2.5 liters. HDPE cap.

Tamper evident cap.

The polyethyleneterephthalate is a thermoplastic polymer of the polyester family. PET is an optimal oxygen, carbon dioxide and other gasses barrier. This material has an high resistance to ultraviolet radiation and an inertia toward the mainly chemical agents (solvents: xylene, limonene, liquid paraffines, alcohols, acids, bases etc.). It is biologically inert. It constitutes a good water and humidity barrier. It shows a great hardness and mechanical resistance.

The bottle has an optimal grip. The absence of the handles reduces space for storage. The anti-dropping cap permits a precise and clean use.

Secondary container: carton box.

05-K01007

Primary container: PE tank in neutral colour, capacity 20 liters, UN approved. Blue screwcap in PE with a seal. Watertight.

Secondary container: EUR pallet wood 80 x 120 cm. Protective coating: lateral film LLDPE, HDPE top. Wear, water, alcohol and solvents resistant PVC label. Scratchproof ink resistant to water and alcohol.

Expected aim

Product for the preparation of cyto-histological samples for optical microscopy.

Specifications

Assay	37-38%
Free acid (as formic acid)	0,03% max
Methanol	~10 %
Density	1,09 (20°C)
pH	3,0 - 4,0 (20°C)
Fe (iron)	< 0,0005%

Application

Universal fixative for histological specimens.

Principle The interaction between formaldehyde and functional groups present in tissue macromolecules (proteins and nucleic acids) occurs according to the following scheme:

- formation of methylene glycol: the molecule of formaldehyde in water gives rise to the following equilibrium

$$\text{CH}_2\text{O} + \text{H}_2\text{O} = \text{CH}_2(\text{OH})_2$$

- The methylene glycol is the chemical species that interacts primarily with the functional groups present in the side chains of the proteins and with acids stabilizing the nuclear structure.
- Secondly formaldehyde form crosslinks between the free amino groups present in the side chains of amino acids.

Fixation technique

- 1) Dilute 1:10 (1 part of product + 9 parts of deionized water)
- 2) Volume ratio specimen/fixative 1 : 50
- 3) Specimen thickness 1 cm max
- 4) Fixation time at room temperature: for specimens up to 5 mm 5 hours, for greater thickness 1-2 days

Components	Components	CAS	CE	Index
	Formaldehyde	50-00-0	200-001-8	605-001-00-5

Warning and precaution The product is intended for professional laboratory use for healthcare professionals. Carefully read the information on the label (danger symbols, risk and safety phrases) and always consult the safety data sheet. Do not use if the primary container is damaged. In the event of a serious accident, we recommended that you immediately inform Bio-Optica Milano S.p.A and the competent authorities.

Storage Storage temperature : > 15 °C. At temperatures below 15°C polymerization process with formation of insoluble precipitate occurs. Keep the containers tightly closed.

Stability After the first opening, the product is reusable until the expiry date, if correctly stored. Validity: 1 year.

Disposal Hazardous preparation: observe all state and local environmental regulations regarding waste disposal.

REVISION N°	REASON	REVISION DATE
001	Regulation adjustment UE 2017/746 - IVDR	16/05/2022