

Bouin



In-vitro diagnostic medical device

EMDN : W01030705

BASIC UDI: 080341202W01030705AJ

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

Catalog number	Unit size	UDI-DI
05-M01008	500 ml	08033976234331
05-01008Q	4 x 2,5 l	08034120277129

Packaging

05-01008Q

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-M01008

Primary container: white bottle in High Density Polyethylene (HDPE). Useful capacity 500 ml. HDPE cap. Tamper evident cap.

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

pH : 1,75

Density : 1,028 (29°C)

Application

Histological and cytological fixative. It gives brilliant staining with cytoplasmic stains (recommended for trichrome staining). It leaves tissues soft and glycogen is well preserved. Not recommended for hemopoietic organs, hemorrhagic tissues and nervous system.

Fixation technique

1) Volume ratio specimen/ fixative 1 : 50

2) Specimen thickness 1 cm max

3) Fixation time at room temperature: for specimens up to 5 mm 5 hours, for greater

thickness 1-3 days

Note: do not wash in water after fixation, but pass directly in alcohol for dehydration.

Components

Components	CAS	CE	Index
Picric acid	88-89-1	2018659	609-009-00-X
Acetic acid	64-19-7	2005807	607-002-00-6
Formaldehyde 30% w/v	50-00-0	2000018	605-001-00-5
Deionized water			

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

Store the preparation at room temperature. Keep the containers tightly closed.

Stability

After the first opening, the product is reusable until the expiry date, if correctly stored. Product validity: 2 years.

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