

Hollande



In-vitro diagnostic medical device

EMDN : W01030705

BASIC UDI: 080341202W01030705AJ

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

| Catalog number | Unit size | UDI-DI |
|----------------|-----------|----------------|
| 05-01030E | 2,5 l | 08034120277204 |

Packaging

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.

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 : 3,78

Density : 1,036 (25°C)

Application

Histological and cytological fixative. Excellent for trichrome staining.

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 2 hours, for greater thickness 1-3 days

Components

| Components | CAS | CE | Index |
|---------------------|----------|---------|--------------|
| Picric acid | 88-89-1 | 2018659 | 609-009-00-X |
| Copper acetate | 142-71-2 | 2055533 | - |
| Acetic acid | 64-19-7 | 2005807 | 607-002-00-6 |
| Formaldehyde 4% w/v | 50-00-0 | 2000018 | 605-001-00-5 |
| Deionized water | | | |

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|-------------------------------|---|
| 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. 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 |