Electrolytic Decalcifying Solution

CE

IVD In-vitro diagnostic medical device
EMDN : W01030799
BASIC UDI: 080339762W01030799Y5
IVD in **Classe A**, Reg. UE 2017/746

Catalog number	Unit size	UDI-DI
05-M03004	500 ml	08033976234409
05-03004Q	2,5 l x 4	08033976232108

Packaging

05-M03004
Primary container: white bottle in High Density Polyethylene (HDPE). Useful capacity 500 ml. HDPE cap.
Tamper evident cap.

05-03004Q
Primary container: white bottle in polyethylene terephthalate (PET). Useful capacity 2.5 liters. HDPE cap. Tamper evident cap.
The polyethylenterephthalate 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.

Application

Rapid decalcifier, based on hydrochloric and formic acid. It acts on all mineralized tissues: compact bone, concretions or calcareous deposits in fleshy tissue. A saline corrector has been added to check tissue swelling caused by acid substances.

Principle

At the base of the demineralization process is the chemical reaction between the tissue calcium (mainly in the form of carbonate, phosphate, oxalate and urate) and hydrochloric acid and formic acid contained in the decalcifier solution

$$CaCO_3 \text{ (insoluble)} + 2\ HCl = CaCl_2 \text{ (soluble)} + H_2CO_3$$
$$CaCO_3 \text{ (insoluble)} + HCOOH = Ca(HCOO)_2 \text{ (soluble)} + H_2CO_3$$

Method

1) Volume ratio specimen/decalcifier 1 : 100
2) Procedure time 4 - 8 hours - < 5 mm thickness.
3) Post decalcifying procedure: reconditioning of the sample. Rinse with slowly running water for 1 hour or apply 3 changes of PBS pH 7.4, 20 minutes each.

Components

Components	CAS	CE	Index
Hydrochloric Acid	7647-01-0	2315957	017-002-00-2
Formic Acid	64-18-6	2005791	607-001-00-0
Saline Corrector			
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. 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