

Bio Plast waxes

IVD In vitro diagnostic – medical device

CND code: W01030799

General features

Mixture of pure paraffins (aliphatic hydrocarbons) and additive polymers (concentration: 0.3%) for histological samples embeddings.



The product validity, correctly stored, is 5 years.

Code	Description	Size	Packaging
08-7910	Bio Plast	2 kg	6 bags of 2 kg each in cardboard box
08-7920	Bio Plast Plus	2 kg	6 bags of 2 kg each in cardboard box
08-7920K	Bio Plast Plus	1 kg	12 bags of 1 kg each in cardboard box
08-7910/20	Bio Plast	20 kg	1 bag of 20 kg



Manufacturer: **Bio-Optica Milano S.p.A.**

Technical data

Bio Plast

Melting point

Oil percentage (ASTM D721)

Shape

Colour

Needle penetration (25°C) (ASTM D1321)

Use

Bio plast

56–58°C

0,5% c.a.

Drops

White

21±3 dmm

Routine, high quality

Bio plast plus

56 - 58°C

0,5% c.a.

Drops

White

21±3 dmm

Extra pure mixture for high performances

All mixtures are purified with a triple filtration, before solidification in drops.

Plasticizer additive

	Features	Method
Physical state	Solid	
Colour	Transparent	
Smell	Typical	
Viscosità (200°C)	3000 ± 500 Cps	ASTM D3236
Fluidity index	6 ± 1	ASTM D1238

Warnings and use's method

- At a temperature higher than 63°C paraffins lose their plastic properties. This fact may produce a black precipitate on the bottom of processor container and embedding station and induce cracks in the blocks and problems during the cutting.
Always check the temperatures of the paraffins baths in the processing system and in the inclusion station.
- During the embedding passage, set the cold plate temperature up about - 5°C.
Too low temperatures (- 15 / - 20°C) cause thermal shock and produce cracks in the blocks, making difficult cutting.
- The products do not contain DMSO.

Storage

Store the paraffin at maximum temperature 38°C. At temperature higher than 38°C paraffin drops begin to aggregate. Keep the bags closed.

Stability

After the first opening, the paraffin is valid until the expiry date, if correctly stored.

Disposal

After use with tissue processor/embedding station, dispose as special waste and keep it to specialized and authorized company, in conformity with local legislation.

If not used, dispose as written in safety datasheet.

Productive process and quality control

The manufacturing process concerning the Bio Plast waxes is managed and controlled by a company managerial system which is completely computerized. This system provides for the allotment of the production formula by the staff of the Laboratory, as a result of the introduction of the sale order and of the opening of the production block in the informatics system.

This formula has been filed away and is available in the managerial informatics system of the company and it includes the list of the raw materials, essential for the production of the final product and the required amount.

The assignment of the production formula by the Laboratory enables the authorized staff of the production to start the output: the exact amount of product is automatically taken from the tank, in order to follow the typology and the right amount marked by the pre-assigned formula.

The course parameters (stated in the production note which concerns the formula that has to be produced) are constantly controlled by the computerized system, which warns in event of irregularity.

Operation	Operation's description	Responsibility	Process parameters –Productive line	Registration
1	Assignment of the production formula, concerning the item to produce, with the list of the components and related percentages: • Paraffin (in precise %) • Paraffin (in precise %) • Plasticizer additive (in precise %).	Laboratory	Informatics' Company System.	/
2	Melting and blending of the raw materials: production starting following the assigned formula. The installation automatically draws out the constituent stated in the production formula given by the laboratory, in the exact amount and by the storage tank, in which you find the components to use (always automatically).	Production operators	Melter line production and company informatics' system. Parameters reported in the notes of the production in the company automated system.	/
3	Quality check on taken sample.	Laboratory/ Quality check	Check specifics reported in the informatics' system.	Test bill
4	Solidification of the paraffins: the manufacturing is automatically run by the production installation.	Automatic	Pad line installation and managing company system, following the parameters reported in the notes of the production, concerning the assigned production formula.	/
5	Packing.	Production staff	Packing specifics.	/
6	Flying check on the packing.	Production staff- Laboratory	/	/

Note

For any information concerning the risks of the preparation, precautionary measures that have to be taken during use and first aid measures, can be found in the concerning security record.