

# RS-BLUE

0.05% TRYPAN BLUE

0.05% TRYPAN BLUE IN PREFILLED SYRINGE, 0.7 ML

## TISSUE STAINING

	RS-BLUE
<b>Ingredients</b>	<ul style="list-style-type: none"> <li>▶ trypan blue</li> <li>▶ sodium chloride</li> <li>▶ sodium phosphate monobasic</li> <li>▶ sodium phosphate dibasic</li> <li>▶ water for injectables</li> </ul>
<b>Dye Concentration</b>	0.045 - 0.055 %w/V
<b>Hydrogenionic activity (pH)</b>	7.00 - 7.40 pH units
<b>Osmolality</b>	255 - 345 mOsm/kg
<b>Osmolarity</b>	254 - 344 mOsm/L
<b>Bacterial Endotoxins</b>	< 0.5 EU/ml
<b>Cytotoxicity Test</b>	Non-cytotoxic according to ISO 10993-5, direct contact test performed on two cell lines: - retinal pigment epithelial cells (ARPE-19) - mouse fibroblasts cells (BALB 3T3 clone A31)
<b>Form</b>	sterile liquid
<b>Volume</b>	0.7 ml
<b>Packaging</b>	syringe
<b>Sterilization</b>	moist heat according to EN 556-1 and EN ISO 17665-1
<b>Storage temperature</b>	+15°C / +32°C
<b>Expiry date</b>	36 months
<b>Intended use</b>	reversible tissue staining during ophthalmic surgery
<b>Class</b>	medical device
<b>GMDN code</b>	P 45180
<b>CND code</b>	Q 02030201
<b>MD registration number</b>	3610/R
<b>Medical device class</b>	Ila
<b>CE mark</b>	CE 0477

RS-BLUE is 0.05% trypan blue, 0.7 ml, packaged in syringe, for reversible staining of human tissues during surgery. Product warrants a prompt and effective staining of the capsule during cataract surgery, thus allowing a clear visualization of tissues without any risks for patients.

**Ref.:** RSB 002-00

**Contents:**

- ▶ 6 RS-Blue prefilled syringes, 0.7 ml
- ▶ 1 package insert
- ▶ 12 labels for product traceability

**GS1-128 barcode**

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