

**MSDS/02/QA/SUT_es.2 SUTURE MATERIAL IN DIFFERENT PACKAGINGS
MATERIAL SAFETY DATA SHEET****1. Identification of the substance/preparation and of the company/undertaking****Identification of the substance or preparation**

SUTURE MATERIAL IN DIFFERENT PACKAGINGS

Use of the substance/preparation

Medical suture material

Company/undertaking identification**B. Braun Surgical, S.A.U.**Carretera de Terrassa, 121
08191 Rubí (Barcelona) Spain
Telephone +(34) 93 586 62 00
Telefax + (34) 93 563 60 40**2. Composition/information on ingredients**

<u>Chemical Characterization</u>	<u>Applies to trade name:</u>
Polyamide 6/6.6	Dafilon,
Polypropylene	Securex,
Polyamide 6 & polyamide 6.6	Supramid
Cotton	Surgical loop Cotton
Polyester. Polyethylene terephthalate	Dagrofil,
Silicone Elastomer	Surgical loop Silicona
Stainless Steel	Steelex, Steelex Sternum set,
Silk	Silkam
Poly(4-hidroxibutyrate)	MonoMax
Glycolide + E-caprolactone + trimethylenecarbonate	Monosyn Quick, Monosyn
Polytetrafluoroethylene	Premipatch PTFE Pledgets

<u>Chemical Characterization</u>	<u>Applies to trade name:</u>
Polydioxanone	Monoplus
Polyglycolic acid	Safil,
Stainless Steel + polyethylene	Steelex Electrode Set
Polypropylene + Polyethylene	Optilene
Poly(glycolide-co-L-lactide) acid	Novosyn, Novosyn Quick
Polyester. Polyethylene terephthalate	PremiCron
Stainless steel	Surgical needles attached to sutures

3.Hazards identification

Classification of the substance or mixture.

Certain stainless steel needles contain > 0.1% w/w of cobalt and are classified as CMR substance according to Regulation (EC) No 1272/2008 (CLP).

Explication of special hazards for human health and environment.

Highly flammable. Irritating to eyes.
Vapours may cause drowsiness and dizziness.

4.First aid measures

General information

No hazards which require special first aid measures.

After inhalation

No hazards which require special first aid measures.

After contact with skin

No hazards which require special first aid measures.

After contact with eyes

No hazards which require special first aid measures.

After ingestion

Ingestion is not considered a potential route of exposure.

5.Fire-fighting measures

Suitable extinguishing media

Foam, carbon dioxide (CO₂), dry chemical, water-spray.

Extinguishing media which must not be used for safety reasons

Full water jet.

Special protective equipment for fire-fighters

No special protective equipment required.

Additional information

Cool containers at risk with water spray jet.

6.Accidental release measures

Personal precautions

No special precautions required.

Environmental precautions

Do not discharge into the drains/surface waters/groundwater.

Methods for cleaning up/taking up

Take up mechanically and collect in suitable container for disposal. [Dispose surgical needles in containers intended for disposal of "sharps" in order to avoid needle stick injuries.](#) Where possible recycling is preferred to disposal.

7.Handling and storage

Handling

Advice on safe handling

[When working with suture materials, great care should be taken to ensure that the use of surgical instruments, such as forceps and needle holders, does not cause any crushing or crimping damage to the suture material.](#)

[Adequate knot security requires the standard surgical technique of flat, square ties, with additional throws as indicated by surgical circumstances and the experience of the surgeon.](#)

[Care should be taken to avoid damage when handling surgical needles. Grasp the needle in an area one-third \(1/3\) to one-half \(1/2\) of the distance from the attachment end to the point. Grasping in the point area could impair the penetration performance and cause fracture of the needle. Grasping at the butt or attachment end could cause bending or breakage. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking. Users should exercise caution when handling surgical needles to avoid inadvertent needle stick injury. Discard used needles in "Sharps" containers.](#)

Advice on protection against fire and explosion

No special protective measures against fire required.

Storage**Requirements for storage rooms and vessels**

Keep in a dry, cool place.

Further information on storage conditions

Keep away from food, drink and animal feeding stuffs.

Storageclass (VCI): 11

8.Exposure controls/personal protection**Exposure limit values**

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

Exposure controls

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

Protective and hygiene measures

No specific precautions necessary.

Respiratory protection

No personal respiratory protective equipment normally required.

Hand protection

Rubber globes.

Requirements can vary as a function of the use. Therefore it is necessary to adhere additionally to the recommendations given by the manufacturer of protective gloves.

Eye protection

No personal eye protective equipment normally required.

Skin protection

No personal skin protective equipment normally required.

9. Physical and chemical properties

General information: appearance

Physical state	Solid
Colour	Various
Odour	Odourless

Important health, safety and environmental information

Results:

pH Value	n.d
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Changes in the physical state

Boiling point	n.d
Flash point	n.d
Ignition temperature	n.d
Lower Explosion limit	n.d
Density (at 20°C)	n.d
Water solubility (at 20°C)	Insoluble
Viscosity dynamic (at 20°C)	n.d

10.Stability and reactivity

Conditions to avoid

No special precautions required.

Materials to avoid

No materials to be especially mentioned.

Additional information

No decomposition if stored and applied as directed.

11.Toxicological information

Empirical data on effects on humans

If appropriately handled and if in accordance with the general hygienic rules, no damages to health have become known.

Certain surgical needles attached to the surgical sutures can contain up to 1% w/w of cobalt in their stainless steel alloy. Cobalt is classified as a CMR substance according to Carcinogen Category 1B, Mutagenic Category 2, Skin Sensitizer 1, Respiratory Sensitizer 1, Reprotoxic 1B and Aquatic Chronic 4 (Regulation EU 2020/217 amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, Labeling and Packaging of Substances and Mixtures (CLP)). However, the behavior of stainless

steel is different from cobalt metal, because due to the alloying effect and the self-repairing layer of chromium oxide and therefore the release of these elements is extremely low in any fluids. On the other hand the contact time of the surgical suture with the patient is of transitory nature and are not implanted in the patient. Surgical needles are discarded after implantation of the suture.

The biocompatibility of the surgical needles attached to the sutures was evaluated regarding the fulfilment of the ISO 10993-1:2018 standard in and it was concluded that the needles are biologically safe for their intended use.

12.Ecological information

Additional information

Ecological injuries are not known or expected under normal use.

13.Advice on disposal

Dispose

Dispose surgical needles in containers intended for disposal of "sharps" in order to avoid needle stick injuries.

Can be landfilled or incinerated, when in compliance with local regulations.

Where possible recycling is preferred to disposal.

Waste disposal number of waste from residues/unused products: 180104

WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (except kitchen and restaurant wastes not arising from immediate health care); wastes from natal care, diagnosis, treatment or prevention of disease in humans; wastes whose collection and disposal is not subject to special requirements in order to prevent infection (for example dressings, plaster casts, linen, disposable clothing, diapers).

Contaminated Packaging

Empty containers should be taken for local recycling, recovery or waste disposal.

14.Transport information

Land transport (ADR/RID)

Inland waterways transport

Marine transport

Air transport

Further Information

No hazardous material as defined by the transport regulations.

15.Regulatory information

Labelling

Additional advice on labelling

Some sutures are labeled to indicate that they do contain > 0.1% w/w of cobalt (in the stainless steel alloy of the surgical needles).

National regulatory information

Water contaminating class (D)
1999/13/EC (VOC)

Not water contaminating
0 %

16.Other information

Further Information

Data of items 4 to 8, as well as 10 to 12, do partly not refer to the use and the regular employing of the product (in this sense consult information on use and on product), but to liberation of major amounts in case of accidents and irregularities.

The information describes exclusively the safety requirements for the product (s) and is based on the present level of our knowledge.

The delivery specifications are contained in the corresponding product sheet.

This data does not constitute a guarantee for the characteristics of the product(s) as defined by the legal warranty regulations.

(n.a. = not applicable; n.d. = not determined)

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet).

CHANGE CONTROL				
REVISION	LAST ISSUE DATE	CHANGE(s) REASONS	REQUIRE TRAINING	
			Training and evaluation	Only difussion
01	18/01/18	New MSDS Training is not required. It's a document requested by the customer		X
02	16/05/22	<p>Table 2: updated</p> <p>Section 2: Include surgical needles (stainless steel) in the table of components.</p> <p>Section 3: Labeling cobalt (stainless steel needles) as CMR substance > 0.1 % w/w.</p> <p>Section 6 and 13: Add disposal advice for stainless steel needles</p> <p>Section 11: Information added regarding the CMR labeling concerning cobalt and the resulting impact on the biocompatibility of the stainlaess steel needles.</p> <p>Section 15: Updated information on labeling, cobalt in certain stainless steel needles.</p>		X

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