

1. Identification of the substance/mixture and of the company/undertaking

Product identifier

Lyostypt

Art. No.

1069020, 1069039, 1069128, 1069152, 1069209, 1069306

Relevant identified uses of the substances or mixture and uses advised against

Use of the substance/mixture

For local haemostasis of bleeding and haemorrhages

Details of the supplier of the safety data sheet

B. Braun Surgical, S.A

Carretera de Terrassa, 121
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2. Hazards identification

Classification of the substance or mixture

This mixture is not classified as hazardous according to directive 1999/45/EC

Label elements

Additional advice on labeling

The product does not require a hazard warning label in accordance with EC directives/the relevant national laws.

Others hazards

Not known.

3. Composition/information on ingredients

Mixtures

Chemical characterization

Collagen of bovine origin (Bovine hide splits)

4. First aid measures

Description of first aid measures

General information

No specific precautions required

After inhalation

Move to fresh air in case of accidental inhalation of fumes from overheating or combustion.
In the event of symptoms refer for medical treatment.

After contact with skin

Wash with water and soap as a precaution

After contact with eyes

Rinse thoroughly with plenty of water, also under the eyelids.

If eye irritation persists, consult a specialist.

After ingestion

Do not induce vomiting.

Rise mouth.

Summon a doctor immediately.

Induce vomiting only upon the advice of a physician.

Most important symptoms and effects, both acute and delayed.

Ingestion causes irritation of upper respiratory system and gastrointestinal disturbance.

Attention, Beware, danger of aspiration!

Indication of any immediate medical attention and special treatment needed.

Treat symptoms.

5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media

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

Extinguishing media which must not be used for safety reasons

Full water jet

Special hazards arising from the substance or mixture

Fire may produce:

Carbon monoxide, carbon dioxide, sulphur oxides and nitrogen oxides (NO_x).

Advice for firefighters

Use breathing apparatus with independent air supply.

Protective suit.

Additional information

Cool containers at risk with water spray jet.

Fire residues and contaminated firefighting water must be disposed of in accordance with the local regulations.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation.

Avoid contact with skin, eyes and clothing.

Remove all sources of ignition.

Environmental precautions

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

Methods and material for containment and cleaning up.

Take up mechanically and collect in suitable container for disposal.

Reference to others sections.

Observe protective instructions (see point No. 7 and 8). Information for disposal see point No13.

7. Handling and storage

Precautions for safe handling

Advice on safe handling.

Ensure adequate ventilation.

Avoid contact with skin, eyes and clothing.

Advice on protection against fire and explosion.

No special protective measures against fire required.

Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep containers tightly closed in a cool, well-ventilated place.

Avoid temperatures above 30°C.

Advice on storage compatibility

Incompatible with strong acids and oxidizing agents.

Further information on storage conditions

Keep away from food, drink and animal feeding stuffs.

Specific end use(s).

For mechanical control of hemorrhages in bone injuries.

8. Exposure controls/personal protection

Control parameters

Exposure controls

Occupational exposure controls

Ensure adequate ventilation, especially in confined areas.

Protective and hygiene measures

Wash hands before breaks and at the end of workday.

Avoid contact with eyes and skin.

When using, do not eat, drink or smoke.

Take off immediately all contaminated clothing.

Respiration protection

No personal respiratory protective equipment normally required.

Hand protection

Glove made of nitrile.

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.

Safety goggles with side protection (EN 166).

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state:	Solid
Colour:	White
Odour:	Characteristic

Changes in the physical state

Flash point:

Lower explosion limits:

Ignition temperature:

Water solubility:

(at 20°C)

Water content

Test method

>175°C

n.d.

n.d.

Immiscible

10% – 16%

10. Stability and reactivity

Reactivity

No decomposition if stored and applied as directed.

Chemical stability

Stable under normal conditions

Possibility of hazardous reactions

Reactions with acids and strong oxidizing agents.

Conditions to avoid

To avoid thermal decompositions, do not overheat.

Incompatible materials

Strong acids and oxidizing agents.

Hazardous decomposition products

Carbon monoxide, carbon dioxide, sulphur oxides, and nitrogen oxides (NO_x).

11. Toxicological information

Information on toxicological effects

Acute toxicity

No toxicological data available.

Irritation and corrosivity

Skin irritation: Not classified.

Eye irritation: Not classified.

Sensitive effects

Not classified

Severe effects after repeated or prolonged exposure

STOT - Single exposure: Not classified

STOT - Repeated exposure: Not classified.

Aspiration hazard: Not classified.

Carcinogenic/mutagenic/toxic effects for reproduction

Carcinogenicity: Not classified

Mutagenicity: Not classified.

Teratogenicity: Not classified

Additional information on tests.

Classification in compliance with the assessment procedure specified in the EC guidelines 1999/45/EC.

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.

Attention. Beware, danger of aspiration!

12 Ecological information

Toxicity.

Ecological data are not available.

Persistence and degradability

Not readily biodegradable.

Bioaccumulative potential

No data available

Mobility in soil

No data available.

Results of PBT and vPvB assessment

According to Regulation (EC) No 1907/2006 (REACH) none of the substances, contained in this product are a PBT/vPvB substance.

Other adverse effects.

No data available

Further information

Do not flush into surface water or sanitary sewer system.

The product is slightly soluble in water. It can be largely eliminated from the water by abiotic processes, e.g. mechanical separation.

13. Disposal considerations

Waste treatment methods

Advice on disposal

Can be incinerated, when in compliance with local regulations.

Waste disposal number or waste residues/unused products

180107

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; chemicals consisting of or containing dangerous substances Classified as hazardous waste.

Contaminated packaging

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

Contaminated packaging should be emptied as far as possible and after appropriate cleansing may be taken for reuse.

Packaging that cannot be cleaned should be disposed of like the product.

14. Transport information

Other applicable information

No hazardous material as defined by the transport regulations.

15. Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulatory information

1999/13/EC (VOC): 0%

National regulatory information

Water contaminating class (D): --not water contaminating

Chemical safety assessment

For this substance a chemical safety assessment has not been carried out.

16. Other information

Abbreviations and acronyms

ADR: Accord européen relatif au transport international des marchandises Dangereuses par Route

RID: Règlement concernant le transport international ferroviaire des marchandises dangereuses.

AND: Accord européen relatif au transport international des marchandises dangereuses par coie de navigation intérieure.

IMDG: International Maritime Code for Dangerous Goods.

IATA/ICAO: International Air Transport Association/ International Civil Aviation Organization.

MARPOL: International Convention for the Prevention of Pollution from Ships.

IBC: Code International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk.

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

REACH: Registration, Evaluation, Authorization and Restriction of Chemicals

CAS: Chemical Abstract Service

EN: European norm

ISO: International Organization for Standardization

VOC: Volatile organic compound

STOT SE: Specific target organ toxicity single exposure

STOT RE: Specific target organ toxicity repeated exposure

PBT: Persistent Bioaccumulative and Toxic

vPvB: Very Persistent and very Bio-accumulative

bw: body weight

LD: Lethal dose

EC: Effect concentration

IC: Median immobilization concentration or median inhibitory concentration

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; = not determined).

Safety Data Sheet according Regulation (EC) No 1907/2006



Revision date: 02.04.2014 No.: 1

Bone Wax / Bone Wax Stick