

Trade name: Delta-Cast® Elite

Current version : 4.0.1, issued: 13.01.2022

Replaced version: 4.0.0, issued: 12.04.2021

Region: GB

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Trade name

Delta-Cast® Elite**1.2 Relevant identified uses of the substance or mixture and uses advised against****Relevant identified uses of the substance or mixture**

Support bandage for immobilisation for the treatment of fractures and injuries; for circular cast bandages

Uses advised against

No data available.

1.3 Details of the supplier of the safety data sheet**Address**

Essity

BSN medical GmbH

Schützenstraße 1-3

D-22761 Hamburg

Telephone no. +49 40 593612-100

Fax no. +49 40 82210592

e-mail BSN-Vigilance@essity.com

Advice on Safety Data Sheet

sdb_info@umco.de

1.4 Emergency telephone number

For medical advice (in German and English):

+49 (0)551 192 40 (Giftinformationszentrum Nord)

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture****Classification information**

This product is an article in the sense of Article 3 of Regulation (EC) 1907/2006 (REACH) and is not subject to labelling according to Article 1, Regulation (EC) 1272/2008 (CLP).

Provision of a safety data sheet is not mandatory for articles according to Article 31 of Regulation (EC) 1907/2006 (REACH) and is done on a voluntary basis.

2.2 Label elements**Supplemental label elements**

'As from 24 August 2023 adequate training is required before industrial or professional use'

Labelling information

The product is a medical device according to the Medical Device Regulation 2017/745 and European Medical Device Directive 93/42/EEC and is therefore not subject to Regulation (EC) No 1272/2008.

2.3 Other hazards

For the resin component:

Material is irritating to eyes, respiratory system and skin.

Excessive exposure may cause irritation of the respiratory tract and lungs and pulmonary oedema.

May cause sensitisation by inhalation. Very low concentrations may cause asthmatic signs and symptoms in hypersensitive people.

SECTION 3: Composition/information on ingredients**3.1 Substances**

Not applicable. The product is not a substance.

3.2 Mixtures**Chemical characterization**

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Polyester knitted fabric which is impregnated with a water activated polyurethane resin

Hazardous ingredients

This product does not contain substances to be mentioned according to EU Regulation No 1907/2006 (REACH), annex II.

3.3 Other information

The data given in this material safety data sheet mostly refer to the resin component. The product contains free isocyanate (< 8 wt.%).

SECTION 4: First aid measures**4.1 Description of first aid measures****General information**

If the patient is likely to become unconscious, place and transport in stable sideways position. Never give anything by mouth to an unconscious person.

After inhalation

Ensure supply of fresh air. In case of breathing difficulties give oxygen. In the event of symptoms take medical treatment.

After skin contact

When in contact with the skin, clean with soap and water. Get medical attention if pain still persists.

After eye contact

Separate eyelids, wash the eyes thoroughly with water (15 min.). Get medical attention if pain still persists.

After ingestion

Do not induce vomiting. Seek medical advice immediately.

4.2 Most important symptoms and effects, both acute and delayed

No data available.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures**5.1 Extinguishing media****Suitable extinguishing media**

Water mist; Carbon dioxide; Dry chemical extinguisher; Alcohol-resistant foam; Extinguishing measures to suit surroundings.

Unsuitable extinguishing media

No data available.

5.2 Special hazards arising from the substance or mixture

Fire will produce dense black smoke. Exposure to decomposition products may cause a health hazard.

5.3 Advice for firefighters

When extinguishing fires, use breathing apparatus with an independent source of air.

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures****For non-emergency personnel**

Take the precautions customary when handling chemicals. Ensure adequate ventilation.

For emergency responders

No data available. Personal protective equipment (PPE) - see Section 8.

6.2 Environmental precautions

Avoid release in the environment.

6.3 Methods and material for containment and cleaning up

Take up with absorbent material (e.g., sand, kieselguhr, universal binder). When collected, handle material as

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described under the section heading "Disposal considerations". Absorbed material should be treated with following substances:

| | |
|---|----------|
| Water | 45 Vol.% |
| Ethanol or Isopropyl Alcohol | 50 Vol.% |
| Ammonia solution (density=0.88) | 5 Vol.% |
| Alternative applicable to that (not flammable): | |
| Sodium Carbonate | 5 Vol.% |
| Water | 95 Vol.% |

6.4 Reference to other sections

No data available.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling

Refer to protective measures listed in section 8.

General protective and hygiene measures

Avoid product contact with skin, eyes and clothing

Advice on protection against fire and explosion

No special measures necessary.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Store in original packing at room temperature.

Incompatible products

None known

7.3 Specific end use(s)

No data available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

No parameters available for monitoring.

8.2 Exposure controls

Appropriate engineering controls

No data available.

Personal protective equipment

Respiratory protection

None, but avoid breathing vapours if possible.

Eye / face protection

Safety glasses recommended

Hand protection

Protective gloves (EN 374)

Other

No special measures required.

Environmental exposure controls

No data available.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

| |
|-----------------------------|
| State of aggregation |
| solid |
| Form/Colour |

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| |
|----------------------------------|
| Polyester knitted fabric |
| Various, depending on coloration |

| |
|-------------------|
| Odour |
| No data available |

| |
|-------------------|
| pH value |
| No data available |

| | |
|--------------------------------------|--------|
| Boiling point / boiling range | |
| Value | 200 °C |
| Reference substance | Resin |

| |
|-------------------------------------|
| Melting point/freezing point |
| No data available |

| |
|----------------------------------|
| Decomposition temperature |
| No data available |

| | |
|---------------------|----------|
| Flash point | |
| Value | > 177 °C |
| Reference substance | Resin |

| |
|-----------------------------|
| Ignition temperature |
| No data available |

| |
|---------------------|
| Flammability |
| No data available |

| |
|------------------------------|
| Lower explosion limit |
| No data available |

| |
|------------------------------|
| Upper explosion limit |
| No data available |

| |
|------------------------|
| Vapour pressure |
| No data available |

| |
|--------------------------------|
| Relative vapour density |
| No data available |

| |
|-------------------------|
| Relative density |
| No data available |

| | |
|-----------------------|------------------------|
| Density | |
| Value | 1.23 g/cm ³ |
| Reference temperature | 43 °C |
| Reference substance | Resin |

| |
|-------------------|
| Solubility |
| No data available |

| |
|--|
| Partition coefficient n-octanol/water (log value) |
| No data available |

| |
|-------------------|
| Viscosity |
| No data available |

| |
|---------------------------------|
| Particle characteristics |
| No data available |

9.2 Other information

| |
|--------------------------|
| Other information |
| No data available. |

SECTION 10: Stability and reactivity

10.1 Reactivity

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No data available.

10.2 Chemical stability

Stable under recommended storage and handling conditions (See section 7).

10.3 Possibility of hazardous reactions

Dangerous reactions are not to be expected when handling product according to its intended use.

10.4 Conditions to avoid

Heat

10.5 Incompatible materials

Water; Alcohols; strong bases; Metals

10.6 Hazardous decomposition products

May form carbon dioxide gas on exposure to water or moist air.

SECTION 11: Toxicological information**11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008****Acute oral toxicity**

No data available

Acute dermal toxicity

No data available

Acute inhalational toxicity

No data available

Skin corrosion/irritation

No data available

Serious eye damage/irritation

No data available

Respiratory or skin sensitisation

No data available

Germ cell mutagenicity

No data available

Reproduction toxicity

No data available

Carcinogenicity

No data available

STOT - single exposure

No data available

STOT - repeated exposure

No data available

Aspiration hazard

No data available

11.2 Information on other hazards**Endocrine disrupting properties**

No data available.

Other information

Based on the properties of the isocyanate components and considering toxicological data on similar preparations: This preparation may cause acute irritation and/or sensitisation of the respiratory system leading to an asthmatic condition, wheeziness and a tightness of the chest. Sensitized persons may subsequently show asthmatic symptoms when exposed to atmospheric concentrations well below the OEL. Repeated exposure may lead to permanent respiratory disability.

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SECTION 12: Ecological information

12.1 Toxicity

| |
|---------------------------------|
| Toxicity to fish (acute) |
| No data available |

| |
|-----------------------------------|
| Toxicity to fish (chronic) |
| No data available |

| |
|------------------------------------|
| Toxicity to Daphnia (acute) |
| No data available |

| |
|--------------------------------------|
| Toxicity to Daphnia (chronic) |
| No data available |

| |
|----------------------------------|
| Toxicity to algae (acute) |
| No data available |

| |
|------------------------------------|
| Toxicity to algae (chronic) |
| No data available |

| |
|--------------------------|
| Bacteria toxicity |
| No data available |

12.2 Persistence and degradability

No data available.

12.3 Bioaccumulative potential

No data available.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

No data available.

12.6 Endocrine disrupting properties

No data available.

12.7 Other adverse effects

No data available.

12.8 Other information

| |
|--|
| Other information |
| Do not discharge product unmonitored into the environment. |

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Allocation of a waste code number, according to the European Waste Catalogue, should be carried out in agreement with the regional waste disposal company.

Dispose of in accordance with official local regulation, e.g. suitable incineration plant.

Packaging

Dispose of in accordance with federal, state and local regulations.

SECTION 14: Transport information

14.1 Transport ADR/RID/ADN

The product is not subject to ADR/RID/ADN regulations.

14.2 Transport IMDG

The product is not subject to IMDG regulations.

14.3 Transport ICAO-TI / IATA

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The product is not subject to ICAO-TI / IATA regulations.

14.4 Other information

No data available.

14.5 Environmental hazards

Information on environmental hazards, if relevant, please see 14.1 - 14.3.

14.6 Special precautions for user

No data available.

14.7 Maritime transport in bulk according to IMO instruments

Not relevant

SECTION 15: Regulatory information**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture****EU regulations****Regulation (EC) No 1907/2006 (REACH) Annex XIV (List of substances subject to authorisation)**

According to the data available and/or specifications supplied by upstream suppliers, this product does not contain any substances considered as substances requiring authorisation as listed on Annex XIV of the REACH regulation (EC) 1907/2006.

REACH candidate list of substances of very high concern (SVHC) for authorisation

According to available data and the information provided by preliminary suppliers, the article does not contain substances that are considered substances meeting the criteria for inclusion in annex XIV (List of Substances Subject to Authorisation) as laid down in Article 57 and article 59 of REACH (EC) 1907/2006.

Regulation (EC) No 1907/2006 (REACH) Annex XVII: RESTRICTIONS ON THE MANUFACTURE, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES, MIXTURES AND ARTICLES

The product contains following substance(s) that are considered being subject to REACH regulation (EC) 1907/2006 annex XVII.

| No | Substance name | CAS no. | EC no. | No |
|----|--------------------------------|------------|-----------|--------|
| 1 | methylenediphenyl diisocyanate | 26447-40-5 | 247-714-0 | 56, 74 |

Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances

This product is not subject to Part 1 or 2 of Annex I.

15.2 Chemical safety assessment

No data available.

SECTION 16: Other information**Sources of key data used to compile the data sheet:**

Regulation (EC) No 1907/2006 (REACH), 1272/2008 (CLP) as amended in each case.

Directives 2000/39/EC, 2006/15/EC, 2009/161/EU, (EU) 2017/164.

National Threshold Limit Values of the corresponding countries as amended in each case.

Transport regulations according to ADR, RID, IMDG, IATA as amended in each case.

The data sources used to determine physical, toxic and ecotoxic data, are indicated directly in the corresponding section.

Creation of the safety data sheet

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This information is based on our present knowledge and experience.

The safety data sheet describes products with a view to safety requirements.

It does not however, constitute a guarantee for any specific product properties and shall not establish a legally valid contractual relationship.

Alterations/supplements:

Alterations to the previous edition are marked in the left-hand margin.

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