

# SAFETY DATA SHEET

In accordance with 1907/2006 annex II and 1272/2008

(All references to EU regulations and directives are abbreviated into only the numeric term)

Revision date 2024-10-01

Replaces SDS issued 2022-06-29

Version number 3.0

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1. Product identifier

Trade name	Boule Con-5Diff A1, L / N / H
Article number	1504518, 1504519, 1504520, 1504521, 1504522

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses	Instrument Calibration
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### 1.3. Details of the supplier of the safety data sheet

Company	BOULE MEDICAL AB Domnarvsgatan 4 163 53 Spånga Sweden
Telephone	+46(0)8 - 7447700
E-mail	info@boule.com

### 1.4. Emergency telephone number

Phone number for emergencies: 999 or 112. The numbers are available 24/7.

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

Upon assessment, this mixture is not classified as hazardous according to 1272/2008

### 2.2. Label elements

Hazard pictogram	Not applicable
Signal word	Not applicable
Hazard statement	Not applicable

### Supplemental hazard information

EUH210 Safety data sheet available on request.

### 2.3. Other hazards

This product does not contain any substances that are assessed to be a PBT or a vPvB

The product contains substance(s) of biological origin which may contain pathogens.

The product does not contain any substances identified as having endocrine disruptive properties in accordance with the criteria set out in (EU) 2017/2100 or (EU) 2018/605.

## SECTION 3: Composition/information on ingredients

### 3.2. Mixtures

Note that the table shows known hazards of the ingredients in pure form. These hazards are reduced or eliminated when mixed or diluted, see Section 16d.

Constituent	Classification	Concentration
<b>ALBUMINS, BLOOD SERUM</b>		
CAS No: 9048-46-8 EC No: 232-936-2	Acute Tox. 4; H302	≤6 %

Explanations to the classification and labelling of the ingredients are given in Section 16e. Official abbreviations are printed in normal font. Text in italics are specifications and/or complements used in the calculation of the classification of this mixture, see Section 16b.

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

#### Generally

In case of concern, or if symptoms occur, call a doctor/physician.

#### Upon breathing in

Fresh air and rest. If symptoms persist seek medical advice.

#### Upon eye contact

Rinse the eye for several minutes with lukewarm water. If irritation persists call a doctor/ophthalmologist.

#### Upon skin contact

Normal washing of the skin is considered sufficient; If nevertheless symptoms do occur, contact a physician.

#### Upon ingestion

Rinse nose, mouth and throat with water.

Get medical attention if you feel unwell.

### 4.2. Most important symptoms and effects, both acute and delayed

#### Upon eye contact

Transient eye irritation.

#### Upon ingestion

May cause irritation of mucous membranes, nausea and vomiting.

### 4.3. Indication of any immediate medical attention and special treatment needed

Symptomatic treatment.

Upon contact with a doctor, make sure to have this safety data sheet with you.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Extinguish with water mist, powder, carbon dioxide or alcoholresistant foam.

### 5.2. Special hazards arising from the substance or mixture

In case of fire, substances hazardous to health, or substances harmful in other respects, may be dispersed.

### 5.3. Advice for firefighters

Protective measures to be taken with regard to other materials at the scene of the fire.

In case of fire use proper breathing apparatus.

Wear full protective clothing.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

Keep unauthorized and unprotected people at a safe distance.  
Avoid inhalation and exposure to skin and eyes.  
Ensure good ventilation.  
Use recommended safety equipment, see section 8.

### 6.2. Environmental precautions

Avoid release to drains, soil or watercourses.

### 6.3. Methods and material for containment and cleaning up

Absorb the liquid with an inert absorbent, vermiculite, for example. Collect the material for disposal at a waste disposal facility.

### 6.4. Reference to other sections

See section 8 and 13 for personal protection equipment and disposal considerations.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Take the necessary preventive and protective measures for safe handling.  
Avoid inhalation and contact with skin and eyes.  
Work in order to avoid spillage. If spillage does occur, address it immediately in accordance with the directions specified in Section 6 of this safety data sheet.  
Store this product separately from food items and keep it out of the reach of children and pets.  
Do not eat, drink or smoke in premises where this product is handled.  
Wash your hands after using the product.  
Remove contaminated clothing.  
Wash contaminated clothing before reuse.  
Keep away from incompatible products.  
Use recommended safety equipment, see section 8.  
Implement appropriate engineering controls if necessary, see Section 8.

### 7.2. Conditions for safe storage, including any incompatibilities

The product should be stored in a manner which prevents hazards to health and the environment. Avoid exposure to humans and animals and do not discharge the product in a sensitive environment.  
Take the necessary preventive and protective measures for safe storage.  
Keep out of reach for children.  
To be stored away from food and animal fodder and away from devices or surfaces that are in contact with those items.  
Store tightly, in original packaging.  
Always use sealed and visibly labeled packages.  
Store in dry and cool area.  
Store in a well-ventilated space.  
Do not store close to incompatible materials (see section 10.5).

### 7.3. Specific end use(s)

See identified uses in Section 1.2.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### 8.1.1. National limit values

##### SODIUM HYDROXIDE

United Kingdom (EH40/2005)

Short term exposure limit (STEL) 2 mg/m<sup>3</sup>

##### SODIUM AZIDE

United Kingdom (EH40/2005)

Time-weighted-average exposure limit (TWA) 0.1 mg/m<sup>3</sup>

Short term exposure limit (STEL) 0.3 mg/m<sup>3</sup>

Note Sk

Explanations of abbreviations are given in Section 16b

**DNEL**

No data available.

**PNEC**

No data available.

**8.2. Exposure controls**

The risks posed by the product or its constituents must be considered in the task specific risk assessment, in accordance with current working environment legislation. The risk assessment should be reviewed regularly and updated if necessary.

**8.2.1. Appropriate engineering controls**

The ventilation in the workplace must ensure an air quality that meets the requirements of the current working environment legislation. Local exhaust ventilation should be used to remove airborne contaminants at the source.

**Eye/face protection**

Eye protection according to standard EN166 should be worn if there is any danger of direct exposure or splashing.

**Skin protection**

Use suitable protective clothing.

Use protective gloves fulfilling the standard EN374 if there is a risk of direct contact.

During continuous contact use gloves with a minimum breakthrough time of at least 240 minutes, preferably over 480 minutes.

The most suitable protective glove should be chosen in consultation with the glove supplier, taking into account the risk assessment for the specific task and the properties of the chemicals involved. Note that the breakthrough time of the material is affected by the duration of the exposure, temperature conditions, abrasion, etcetera.

Based on the chemical properties of the product, the following glove materials are recommended (EN 374):.

- Neoprene rubber.
- Nitrile rubber.

**Respiratory protection**

Use appropriate respiratory protective equipment in case of insufficient ventilation.

The most appropriate respiratory protective equipment should be decided in consultation with the appointed safety representative, taking into account the risk assessment for the specific task.

Based on the physical and chemical properties of the product, the following filter type(s) and/or filter combination(s) are recommended:.

- A/P2.

**8.2.3. Environmental exposure controls**

For limiting environmental exposure, see section 12.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

(a) Physical state	liquid Form: liquid
(b) Colour	red
(c) Odour	characteristic
(d) Melting point/freezing point	0 °C
(e) Boiling point or initial boiling point and boiling range	100 °C
(f) Flammability	Not indicated
(g) Lower and upper explosion limit	Not indicated
(h) Flash point	Not indicated
(i) Auto-ignition temperature	Not indicated
(j) Decomposition temperature	Not indicated
(k) pH	When supplied, pH is: 6 - 8
(l) Kinematic viscosity	Not indicated
(m) Solubility	Solubility in water: Soluble
(n) Partition coefficient n-octanol/water (log value)	Not indicated
(o) Vapour pressure	Not indicated
(p) Density and/or relative density	1 g/cm <sup>3</sup>
(q) Relative vapour density	Not indicated
(r) Particle characteristics	Not indicated

### 9.2. Other information

#### 9.2.1. Information with regard to physical hazard classes

Not indicated

#### 9.2.2. Other safety characteristics

Not indicated

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

The product contains no substances which can lead to hazardous reactions at normal use.

### 10.2. Chemical stability

The product is stable at normal storage and handling conditions.

### 10.3. Possibility of hazardous reactions

No hazardous reactions known during normal use.

### 10.4. Conditions to avoid

None in particular.

### 10.5. Incompatible materials

Avoid contact with strong acids and bases.

### 10.6. Hazardous decomposition products

None under normal conditions.

## SECTION 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on possible health hazards are based on experience and / or toxicological properties of several components in the product.

#### Acute toxicity

The product is not classified as acutely toxic.

#### Skin corrosion/irritation

The product is not classified for skin corrosion/irritation.

#### Serious eye damage/irritation

The product is not classified for serious eye damage/eye irritation.

### **Respiratory or skin sensitisation**

The product is not classified as sensitising.

### **Germ cell mutagenicity**

The product is not classified as mutagen.

### **Carcinogenicity**

The product is not classified as carcinogenic.

### **Reproductive toxicity**

The product is not classified as a reproductive toxicant.

### **STOT-single exposure**

The product is not classified for specific organ toxicity after single exposure.

### **STOT-repeated exposure**

The product is not classified for specific organ toxicity after repeated exposure.

### **Aspiration hazard**

The product is not classified as being toxic for aspiration.

## **11.2. Information on other hazards**

### **11.2.1. Endocrine disrupting properties**

The product does not contain any substances identified as having endocrine disruptive properties in accordance with the criteria set out in (EU) 2017/2100 or (EU) 2018/605.

### **11.2.2. Other information**

Not indicated.

## **SECTION 12: Ecological information**

### **12.1. Toxicity**

No ecological damage is known or expected in the event of normal use.

Prevent release on land, in water and drains.

### **12.2. Persistence and degradability**

No information is available.

### **12.3. Bioaccumulative potential**

Neither this product, nor its contents, accumulates in nature.

### **12.4. Mobility in soil**

No information is available.

### **12.5. Results of PBT and vPvB assessment**

This product does not contain any substances that are assessed to be a PBT or a vPvB.

### **12.6. Endocrine disrupting properties**

The product does not contain any substances identified as having endocrine disruptive properties in accordance with the criteria set out in (EU) 2017/2100 or (EU) 2018/605.

### **12.7. Other adverse effects**

No known effects or hazards.

## **SECTION 13: Disposal considerations**

### **13.1. Waste treatment methods**

#### **Waste handling of the product**

Avoid discharge into sewers.

The product is not classified as hazardous waste.

Empty, rinsed packaging is sent for recycling where practicable.

See directive 2008/98/EC on waste. Observe national or regional provisions on waste management.

## SECTION 14: Transport information

Where not otherwise stated the information applies to all of the UN Model Regulations, i.e. ADR (road), RID (railway), ADN (inland waterways), IMDG (sea), and ICAO (IATA) (air).

### 14.1. UN number or ID number

Not classified as dangerous goods

### 14.2. UN proper shipping name

Not applicable

### 14.3. Transport hazard class(es)

Not applicable

### 14.4. Packing group

Not applicable

### 14.5. Environmental hazards

Not applicable

### 14.6. Special precautions for user

Not applicable

### 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

### 14.8 Other transport information

Not applicable

## SECTION 15: Regulatory information

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

Not indicated.

### 15.2. Chemical safety assessment

Assessment and chemical safety report in accordance with 1907/2006 Annex I has not yet been performed.

## SECTION 16: Other information

### 16a. Indication of where changes have been made to the previous version of the safety data sheet Revisions of this document

Earlier versions

2022-06-29 Changes in section(s) 1, 2, 4, 6, 7, 8, 9, 11, 12.

### 16b. Legend to abbreviations and acronyms used in the safety data sheet

#### Full texts for Hazard Class and Category Code mentioned in section 3

Acute Tox. 4 Acute toxicity (oral), Hazard Category 4 - Acute Tox. 4, H302 - Harmful if swallowed

#### Explanations of the abbreviations in Section 8

##### United Kingdom

Sk Can be absorbed through the skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity

#### Explanations of the abbreviations in Section 14

ADR European Agreement concerning the International Transport of Dangerous Goods by Road

RID Regulations concerning the International Transport of Dangerous Goods by Rail

IMDG International Maritime Dangerous Goods Code

ICAO International Civil Aviation Organization (ICAO, 999 University Street, Montreal, Quebec H3C 5H7, Canada)

IATA The International Air Transport Association

## 16c. Key literature references and sources for data

### Sources for data

Primary data for the calculation of the hazards has preferentially been taken from the official European classification list, 1272/2008 Annex I, as updated to 2024-10-01.

Where such data was not available, alternative documentation used to establish the official classification was used, e.g. IUCLID (International Uniform Chemical Information Database). As a second alternative, information was used from reputable international chemical industries, and as a third alternative other available information was used, e.g. material safety data sheets from other suppliers or information from non-profit associations, where reliability of the source was assessed by expert opinion. If, in spite of this, reliable information could not be sourced, the hazards were assessed by expert opinions based on the known hazards of similar substances, and according to the principles in 1907/2006 and 1272/2008.

### Full texts for Regulations mentioned in this Safety Data Sheet

- 1907/2006 REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC
- 1272/2008 REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006
- 2008/98/EC DIRECTIVE 2008/98/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 19 November 2008 on waste and repealing certain Directives

## 16d. Methods of evaluating information referred to in 1272/2008 Article 9 which was used for the purpose of classification

Hazard calculation for this mixture has been performed as a cumulative assessment with the aid of expert assessments in accordance with 1272/2008 Annex I, where all available information which may be significant to establishing the hazards of the mixture was assessed together, and in accordance with 1907/2006 Annex XI.

## 16e. List of relevant hazard statements and/or precautionary statements

### Full texts for hazard statements mentioned in section 3

H302 Harmful if swallowed

## 16f. Advice on any training appropriate for workers to ensure protection of human health and the environment

### Warning for misuse

Not indicated.

### Other relevant information

Not indicated

### Editorial information



This material safety data sheet has been prepared and checked by KemRisk®, KemRisk Sweden AB, Platensgatan 8, SE-582 20 Linköping, Sweden, [www.kemrisk.se](http://www.kemrisk.se)