

Safety Data Sheet

1. PRODUCT IDENTIFICATION AND COMPANY

Trade name: Boule Con-Diff
Article no(s): 1504019, 1504020, 1504021, 1504022, 1504043, 1504176, 1504216, 1504040, 1504041, 1504042
Synonyms: --
Formula: --
CAS-no: Not applicable
EC-no: Not applicable
Manufacturer: Boule Medical AB, Västberga Allé 32, Hägersten
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2. HAZARD IDENTIFICATION

None, except that this preparation contains a component from human blood and should be labeled as potentially infectious for the safe handling in the laboratory, necessitating the use of an SDS. See sections 11 and 15.

3. COMPOSITION AND INFORMATION ON INGREDIENTS

Component/Substance	CAS-no	Concentration	Hazard information	R-phrases
Stabilized red blood cells	--	--	--	--
Buffered saline solution with preservatives	--	--	--	--

4. FIRST AID MEASURES

Ingestion If swallowed rinse mouth with water, in case of symptoms seek medical attention. . Contact poison information center or seek medical attention if swallowed.
Inhalation Not, probable, but if so move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately. Seek medical attention.
Contact with skin Wash affected area with soap and water for at least 15 minutes. Disinfect if possible.
Contact with eyes Rinse open eye with running water for several minutes. In case of symptoms seek medical attention.

5. FIRE-FIGHTING MEASURES

General information The preparation is not combustible, direct measure to general packaging material
Recommended fire extinguishing material Use fire fighting measures that suit the environment e.g. other material stocked together with these products

6. ACCIDENTAL RELEASE MEASURES

Personal protective measure Wear protective clothing including latex or equivalent gloves.
Environmental protective measure Contain spill to prevent contamination of surrounding areas. See also below
Spillage measures From single units, use absorbent material and dispose according to local regulations. Dispose of affected packing material in the same way. Disinfect surfaces with e.g. bleach diluted 1:10 (or other disinfectant), then use absorbent material and dispose as above. Dispose liquid material through a sanitary sewer. Disposal must comply with Federal, State and Local requirements.

7. HANDLING AND STORAGE

Handling Intact products may be handled as any laboratory material following universal laboratory precautions for blood-borne disease. Handle as if capable of transmitting infectious disease when using the product following local or federal regulations.
Storage Store according to instructions on label. Do not freeze.

8. EXPOSURE CONTROL/PERSONAL PROTECTION

Limitation of exposure Use only in designated laboratory areas following established methods for good laboratory practices. Close screw caps when not in use
Protective measures All chemical/biological preparations should be handled with appropriate care under good laboratory practices. Wear protective clothing including latex or equivalent gloves.

9. PHYSICAL AND CHEMICAL PROPERTIES

Boiling Point:	N/A	Vapor Pressure (mm Hg):	N/A
Melting Point:	N/A	Vapor Density (Air = 1):	N/A
Specific Gravity:	1.06 (Water = 1)	Evaporation Rate	
Solubility (water):	Miscible	(butyl acetate = 1):	N/A
Appearance and Color:	Red, opaque suspension	pH:	6.3 – 6.8

10. STABILITY AND REACTIVITY

Stability	Stable at normal temperatures and pressures. Avoid freezing.
Reactivity	None.
Hazardous products upon decomposition	No known hazardous decomposition products

11. TOXICOLOGICAL INFORMATION

Acute toxicity	None identified
Health effects	This product contains materials of human and non-human origin and may be capable of transmitting infectious diseases since it is not sterilized. All human source material used to manufacture this product was non-reactive for antigens to Hepatitis B and negative by tests for antibodies to HIV (HIV-1, HIV-2) and Hepatitis C. The manufacturing process also includes steps which further reduces the likelihood of presence of viable microorganisms.
Antidotes	None identified
Primary Routes of Exposure:	Contact with eyes, mucous membranes and skin (inhalation less likely)
Symptoms of Overexposure:	None identified.
Carcinogenicity:	Contains no ingredients listed as potential carcinogens by ACGIH, IARC, NTP or OSHA

12. ECOLOGICAL INFORMATION

No ecological effects expected from accidental release from single units.

Ecotoxicity:	No information available.
Biodegradability:	No information available.
Mobility:	No information available.

13. DISPOSAL CONSIDERATIONS

Water disposal:	Waste disposal after use must comply with Federal, State and Local requirements. Contact local authorities for information
Packaging material:	Contaminated packaging material including tubes should be handled as infectious material and disposed e.g. through incineration. Non-contaminated packaging material is recyclable (plastic clamshell).

14. TRANSPORT INFORMATION

<u>Transport</u>	<u>UN-no.</u>	<u>Class</u>
Road (ADR)	None identified	
Railway (RID)	None identified	
Sea (IMDG)	None identified	
Airway (DGR-IATA)	None identified	

15. REGULATORY INFORMATION

Classification/Labeling	None
Hazard classification:	The product is classified as potentially infectious for safe handling in the laboratory.
Risk phrases:	None
Safety phrases:	None



Europe: The safety data sheet has been designed according to the directions given by the EC directives 67/548/EEC, 1999/45/EC (classification, labelling) with amendments, and as given by the Swedish Chemicals Inspectorate in KIFS 2005:7 and applicable parts (safety data sheets) of REACH (regulation 1907/2007). Relevant EC directives regarding safe handling of blood components have also been reviewed.

US: These products are subject to regulation under the US Federal Food, and Cosmetic Act.

This information does not constitute an assessment of risk of use in the workplace, but may be used in such an assessment. Boule Medical believes that the information given in this document is reliable as of the date of release, but no representation guarantee or warranty, expressed or implied is made as to the accuracy, reliability or completeness of information. Any person receiving this document should make their own assessment as to the suitability and completeness of the information for their specific application.

16. OTHER INFORMATION

Further information can be supplied on request. The information given above relates only to the products specified. Upon any incident with suspected contact with hazardous substances or symptoms (malaise) following exposure to chemical substances it is recommended to take contact with a doctor.

It is recommended that each distributor of these products shall design country-specific material and safety data sheets.