



SAFETY DATA SHEET

DRAFT VERSION

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

1.1. Product identifier

Name of the substance	Heparin, sodium salt
Trade name of the substance	BD Vacutainer® Sodium Heparin Tubes
Identification number	618-546-9 (EC number)
Registration number	-
Synonyms	None.
Product code	367869, 367876, 368480, 369622, 369623
Issue date	None.
Version number	00
Revision date	Draft version.
Supersedes date	-

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

Identified uses	Blood collection (In-Vitro Diagnostic) device.
Uses advised against	None known.

1.3. Details of the supplier of the safety data sheet

Supplier

Company name	Becton, Dickinson and Company
Address	Belliver Industrial Estate Belliver Way, Roborough, Plymouth , PL6 7BP, United Kingdom
Telephone	+44 (0) 1752 701281
Contact person	Not available.
e-mail	pas_tech_services@bd.com

1.4. Emergency telephone number	Chemtrec EU 703-527-3887 US 1-800-424-9300
---------------------------------	--

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

The substance has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Classification according to Regulation (EC) No 1272/2008 as amended

This substance does not meet the criteria for classification according to Regulation (EC) 1272/2008 as amended.

Hazard summary	Low hazard for recommended handling by trained personnel. Product dust may be irritating to eyes, skin and respiratory system. Dust may form explosive mixture in air.
----------------	---

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

Hazard pictograms	None.
Signal word	None.
Hazard statements	The substance does not meet the criteria for classification.

Precautionary statements

Prevention	Observe good industrial hygiene practices.
Response	Wash skin with soap and water.
Storage	Store away from incompatible materials.
Disposal	Dispose of waste and residues in accordance with local authority requirements.

Supplemental label information	None.
--------------------------------	-------

2.3. Other hazards	May form combustible dust concentrations in air.
--------------------	--

SECTION 3: Composition/information on ingredients

3.1. Substances

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
Heparin, sodium salt	100	9041-08-1 618-546-9	-	-	
Classification:	-				

Composition comments All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

SECTION 4: First aid measures

General information Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

4.1. Description of first aid measures

Inhalation	No specific precautions due to the small quantities handled. However: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTRE or doctor/physician if you feel unwell.
Skin contact	No specific precautions due to the small quantities handled. However: Wash skin thoroughly with soap and water. Get medical attention if irritation develops and persists.
Eye contact	No specific precautions due to the small quantities handled. However, rinse with water. Do not rub eye. Make sure to remove any contact lenses from the eyes before rinsing. Get medical attention if irritation develops and persists.
Ingestion	No specific precautions due to the small quantities handled. However: Rinse mouth thoroughly if dust is ingested. Get medical attention if any discomfort occurs.

4.2. Most important symptoms and effects, both acute and delayed Under normal conditions of intended use, this material does not pose a risk to health.

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

SECTION 5: Firefighting measures

General fire hazards May form combustible dust concentrations in air.

5.1. Extinguishing media

Suitable extinguishing media	In case of fire: Use Water fog, alcohol resistant foam, dry chemical powder for extinction.
Unsuitable extinguishing media	None.

5.2. Special hazards arising from the substance or mixture Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard. During fire, gases hazardous to health may be formed.

5.3. Advice for firefighters

Special protective equipment for firefighters	Selection of respiratory protection for firefighting: follow the general fire precautions indicated in the workplace. Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Special fire fighting procedures	Use standard firefighting procedures and consider the hazards of other involved materials. Containers close to fire should be removed or cooled with water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Provide adequate ventilation. Avoid dust formation. Avoid inhalation of dust and contact with skin and eyes. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. See Section 8 for personal protective equipment. As supplied, the product is expected to pose no immediate health.
For emergency responders	Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.

6.2. Environmental precautions Avoid discharge into drains, water courses or onto the ground unless authorised by permit.

6.3. Methods and material for containment and cleaning up Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Minimise dust generation and accumulation. Collect dust using a vacuum cleaner equipped with HEPA filter.

6.4. Reference to other sections For personal protection, see section 8. For waste disposal, see section 13 of the SDS.

SECTION 7: Handling and storage

7.1. Precautions for safe handling	Explosion-proof general and local exhaust ventilation. Minimise dust generation and accumulation. Dry powders can build static electricity charges when subjected to the friction of transfer and mixing operations. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. Do not breathe dust. When using, do not eat, drink or smoke. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Keep the workplace clean. Observe good industrial hygiene practices. As supplied, the product is expected to pose no immediate health.
7.2. Conditions for safe storage, including any incompatibilities	Keep away from heat, sparks and open flame. Store in original tightly closed container. Store in a cool, dry place. Store away from incompatible materials.
7.3. Specific end use(s)	Blood collection (In-Vitro Diagnostic) device.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters	
Occupational exposure limits	No exposure limits noted for ingredient(s).
Biological limit values	No biological exposure limits noted for the ingredient(s).
Recommended monitoring procedures	Follow standard monitoring procedures.
Derived no-effect level (DNEL)	Not available.
Predicted no effect concentrations (PNECs)	Not available.
8.2. Exposure controls	
Appropriate engineering controls	Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.
Individual protection measures, such as personal protective equipment	
General information	Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.
Eye/face protection	Wear dust goggles.
Skin protection	
- Hand protection	Wear appropriate chemical resistant gloves. Suitable gloves can be recommended by the glove supplier.
- Other	No skin protection is ordinarily required under normal conditions of use. In accordance with good industrial hygiene practices, precautions should be taken to avoid skin contact.
Respiratory protection	In case of inadequate ventilation or risk of inhalation of dust, use suitable respiratory equipment with particle filter (type P2).
Thermal hazards	None.
Hygiene measures	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. When using, do not eat, drink or smoke.
Environmental exposure controls	Environmental manager must be informed of all major spillages.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	
Physical state	Solid.
Form	Powder.
Colour	Clear, colourless.
Odour	Odourless.
Odour threshold	Not applicable.
pH	Not applicable.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.

Flammability (solid, gas)	Fine particles may form explosive mixtures with air.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Vapour pressure	Not applicable.
Vapour density	Not applicable.
Relative density	Not available.
Solubility(ies)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not applicable.
Decomposition temperature	Not available.
Viscosity	Not available.
Explosive properties	Not explosive.
Oxidizing properties	Not oxidising.
9.2. Other information	No relevant additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
10.4. Conditions to avoid	Keep away from heat, sparks and open flame. Minimise dust generation and accumulation. Contact with incompatible materials.
10.5. Incompatible materials	Strong oxidising agents.
10.6. Hazardous decomposition products	None under normal temperatures and pressures.

SECTION 11: Toxicological information

General information	Occupational exposure to the substance or mixture may cause adverse effects.
Information on likely routes of exposure	
Inhalation	Dust may irritate respiratory system.
Skin contact	Dust may irritate skin.
Eye contact	Dust may irritate the eyes.
Ingestion	May cause discomfort if swallowed.
Symptoms	Under normal conditions of intended use, this material does not pose a risk to health.
11.1. Information on toxicological effects	
Acute toxicity	Not expected to be acutely toxic.
Skin corrosion/irritation	Due to lack of data the classification is not possible.
Serious eye damage/eye irritation	Due to lack of data the classification is not possible.
Respiratory sensitisation	Due to lack of data the classification is not possible.
Skin sensitisation	Due to lack of data the classification is not possible.
Germ cell mutagenicity	Due to lack of data the classification is not possible.
Carcinogenicity	Due to lack of data the classification is not possible.
Reproductive toxicity	Due to lack of data the classification is not possible.
Specific target organ toxicity - single exposure	Due to lack of data the classification is not possible.
Specific target organ toxicity - repeated exposure	Due to lack of data the classification is not possible.
Aspiration hazard	Due to the physical form of the product it is not an aspiration hazard.
Mixture versus substance information	No information available.
Other information	As supplied, the product is expected to pose no immediate health.

SECTION 12: Ecological information

12.1. Toxicity	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
12.2. Persistence and degradability	No data available.
12.3. Bioaccumulative potential	No data available.
Partition coefficient n-octanol/water (log K_{ow})	Not available.
Bioconcentration factor (BCF)	Not available.
12.4. Mobility in soil	No data available.
Mobility in general	No data available.
12.5. Results of PBT and vPvB assessment	Not a PBT or vPvB substance or mixture.
12.6. Other adverse effects	The product is not volatile but may be spread by dust-raising handling.

SECTION 13: Disposal considerations

13.1. Waste treatment methods	
Residual waste	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.
EU waste code	16 03 04 The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Disposal methods/information	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Dispose of contents/container in accordance with local/regional/national/international regulations.

SECTION 14: Transport information

ADR	Not regulated as dangerous goods.
RID	Not regulated as dangerous goods.
ADN	Not regulated as dangerous goods.
IATA	Not regulated as dangerous goods.
IMDG	Not regulated as dangerous goods.
14.7. Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture	
EU regulations	
Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I and II, as amended	Not listed.
Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended	Not listed.
Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended	Not listed.
Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended	Not listed.
Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended	Not listed.
Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended	Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry, as amended

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(10) Candidate List as currently published by ECHA

Not listed.

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended

Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

Not listed.

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work, as amended

Not listed.

Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding, as amended

Not listed.

Other EU regulations

Directive 2012/18/EU on major accident hazards involving dangerous substances

Not listed.

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Not listed.

Directive 94/33/EC on the protection of young people at work

Not listed.

Other regulations

The product is classified and labelled in accordance with EC directives or respective national laws. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006, as amended.

National regulations

Follow national regulation for work with chemical agents.

15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations

DNEL: Derived No-Effect Level.
PNEC: Predicted No-Effect Concentration.

References

HSDB® - Hazardous Substances Data Bank
ACGIH: American Conference of Governmental and Industrial Hygienists.
US. IARC Monographs on Occupational Exposures to Chemical Agents
National Toxicology Program (NTP) Report on Carcinogens
ACGIH Documentation of the Threshold Limit Values and Biological Exposure Indices
IARC Monographs. Overall Evaluation of Carcinogenicity

Information on evaluation method leading to the classification of mixture

The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available. For details, refer to Sections 9, 11 and 12.

Full text of any H-statements not written out in full under Sections 2 to 15

None.

Training information

Follow training instructions when handling this material.

Disclaimer

BD Diagnostics Preanalytical Systems cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.