

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

1.1. Product identifier

Trade name or designation of the mixture ACTICHROME® Heparin LMWH Calibrator, ACTICHROME® Heparin UFH Calibrator, ACTICHROME® Heparin LMWH Control, ACTICHROME® Heparin LMWH Control

Registration number

Synonyms None.

Product code 832CALLMWH, 832CALUFH, 832CONLMWH, 832CONUFH

Issue date 07-July-2022

Version number 01

Revision date 07-July-2022

Supersedes date None

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

Identified uses Calibrators are for use to generate calibration curves for assays to measure heparin activity in human plasma; controls are for use to monitor the performance of assays that measure heparin activity.

Uses advised against Use in accordance with supplier's recommendations.

1.3. Details of the supplier of the safety data sheet

Corporate Headquarters BioMedica Diagnostics Inc.
94 Wentworth Road, PO Box 1030
Windsor, Nova Scotia CANADA B0N 2T0

Contact person Corporate Phone: 1-902-798-5105
Corporate Fax: 1-902-798-1025
Email: info@biomedicadiagnostics.com
Website: www.biomedicadiagnostics.com

1.4. Emergency telephone number US, Canada, Puerto Rico & Virgin Islands 1-800-255-3924
International +1-813-248-0585
Australia 1-300-954-583
Brazil 0-800-591-6042
China 400-120-0751
India 000-800-100-4086
Mexico 01-800-099-0731

Contract number MIS9591327

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Classification according to Directive 67/548/EEC or 1999/45/EC as amended

Classification Xn;R22, R32

The full text for all R-phrases is displayed in section 16.

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

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

Hazard summary

Physical hazards Not classified for physical hazards.
Health hazards Harmful if swallowed. Contact with acids liberates very toxic gas.
Environmental hazards Not classified for hazards to the environment.
Specific hazards Avoid contact with eyes and skin. Do not ingest or inhale.
Main symptoms Ingestion may cause irritation and malaise.

2.2. Label elements

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

Hazard pictograms None.

Signal word	None.
Hazard statements	None.
Precautionary statements	
Prevention	None.
Response	None.
Storage	None.
Disposal	None.
Supplemental label information	EUH032 - Contact with acids liberates very toxic gas.
2.3. Other hazards	Not a PBT or vPvB substance or mixture.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
Human Plasma	> 99.9	NA	NA	NA	
Sodium Azide	< 0.1	26628-22-8 247-852-1	-	11-004-00-7	#
Classification:	DSD: T+;R28, R32, N;R50/53				
	CLP: Acute Tox. 2;H300, Acute Tox. 1;H310, Aquatic Acute 1;H400, Aquatic Chronic 1;H410				

List of abbreviations and symbols that may be used above

#: This substance has been assigned Community workplace exposure limit(s).
DSD: Directive 67/548/EEC.
CLP: Regulation No. 1272/2008.

Composition comments All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume. The full text for all R- and H-phrases is displayed in section 16.

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	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	For skin contact flush with large amounts of water while removing contaminated clothing. Get medical attention if irritation develops and persists.
Eye contact	In case of contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.
Ingestion	If material is ingested, immediately contact a physician or poison control centre.

4.2. Most important symptoms and effects, both acute and delayed Ingestion may cause irritation and malaise.

4.3. Indication of any immediate medical attention and special treatment needed Provide general supportive measures and treat symptomatically.

SECTION 5: Firefighting measures

General fire hazards The product is not flammable.

5.1. Extinguishing media

Suitable extinguishing media	Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire.
Unsuitable extinguishing media	None known.

5.2. Special hazards arising from the substance or mixture Sodium azide may form explosive compounds in metal drain lines. When disposing of solutions through plumbing fixture, flush with copious amount of water.

5.3. Advice for firefighters

Special protective equipment for firefighters	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.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.
For emergency responders	Use personal protection as recommended in section 8 of the SDS.

6.2. Environmental precautions Do not allow to enter drains, sewers or watercourses. This mixture contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing systems and form potentially explosive metal azides. Follow proper disposal procedures.

6.3. Methods and material for containment and cleaning up Absorb spill with vermiculite or other inert material. Dispose of waste in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.

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

SECTION 7: Handling and storage

7.1. Precautions for safe handling Avoid contact with skin and eyes. Wash thoroughly after handling. In case of insufficient ventilation, wear suitable respiratory equipment. Handle and open container with care.

7.2. Conditions for safe storage, including any incompatibilities Store at 2-8°C (35-46°F). Store in a closed container away from incompatible materials.

7.3. Specific end use(s) Assorted.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value
Sodium azide (CAS 26628-22-8)	STEL	0.3 mg/m ³
	TWA	0.1 mg/m ³

EU. Indicative Exposure Limit Values in Directives 91/322/EEC, 2000/39/EC, 2006/15/EC, 2009/161/EU

Components	Type	Value
Sodium azide (CAS 26628-22-8)	STEL	0.3 mg/m ³
	TWA	0.1 mg/m ³

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.

Exposure guidelines

UK EH40 WEL: Skin designation

Sodium azide (CAS 26628-22-8)

Can be absorbed through the skin.

8.2. Exposure controls

Appropriate engineering controls Provide adequate ventilation. Observe Occupational Exposure Limits and minimise the risk of inhalation of vapours. Provide easy access to water supply and eye wash facilities.

Individual protection measures, such as personal protective equipment

General information Personal protective equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.

Eye/face protection Wear approved safety glasses or goggles.

Skin protection

- Hand protection Wear appropriate chemical resistant gloves.

- Other Wear lab coat or other protective garments. Remove contaminated clothing promptly.

Respiratory protection Under normal conditions, respirator is not normally required.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

Hygiene measures Handle in accordance with good industrial hygiene and safety practices.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Clear pale yellow liquid.
Physical state	Liquid.
Form	Liquid.
Colour	Yellow.
Odour	Odourless.

Odour threshold	Not available.
pH	Not Available
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)	Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.

Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.
Solubility(ies)	Soluble in water.
Partition coefficient (n-octanol/water)	Not available.

Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Explosive properties	Not available.
Oxidizing properties	Not available.
9.2. Other information	No relevant additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity	This mixture contains a small amount of sodium azide, which can react with copper, lead, brass or solder in plumbing systems and form potentially explosive metal azides.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	Hazardous polymerisation does not occur.
10.4. Conditions to avoid	Keep away from heat.
10.5. Incompatible materials	Strong acids. Strong oxidising agents. Strong reducing agents.
10.6. Hazardous decomposition products	Carbon oxides.

SECTION 11: Toxicological information

General information	Occupational exposure to the substance or mixture may cause adverse effects.
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Information on likely routes of exposure

Inhalation	Vapours may irritate throat and respiratory system and cause coughing.
Skin contact	May cause skin irritation.
Eye contact	May cause eye irritation.
Ingestion	May cause discomfort if swallowed.
Symptoms	Ingestion may cause irritation and malaise.

11.1. Information on toxicological effects

Acute toxicity	May cause discomfort if swallowed.		
Components	Species	Test results	
Sodium azide (CAS 26628-22-8)			
Acute			
Dermal, LD50	Rabbit	20 mg/kg	
Oral,LD50	Rat	27 mg/kg	
Skin corrosion/irritation	May cause skin irritation.		
Serious eye damage/eye irritation	May cause eye irritation.		
Respiratory sensitisation	Not classified.		
Skin sensitisation	Not classified.		
Germ cell mutagenicity	Not classified.		
Carcinogenicity	Not classifiable as to carcinogenicity to humans.		
Reproductive toxicity	Not classified.		
Specific target organ toxicity - single exposure	Not classified.		
Specific target organ toxicity - repeated exposure	Not classified.		
Aspiration hazard	Not classified.		
Mixture versus substance information	Not available.		
Other information	No other specific acute or chronic health impact noted.		

SECTION 12: Ecological information

12.1. Toxicity

Components		Species	Test results
Sodium azide (CAS 26628-22-8)			
Aquatic			
Algae	EC50	Pseudokirchnerella subcapitata	0.35 mg/l, 96 hours
Fish	LC50	Fish	5.7 mg/l, 96 hours

12.2. Persistence and degradability No data is available on the degradability of this product.

12.3. Bioaccumulative potential

Partition coefficient n-octanol/water (log Kow) Not available.

Bioconcentration factor (BCF) Not available.

12.4. Mobility in soil Not available.

Mobility in general The product is soluble in water.

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 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.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Residual waste	Dispose in accordance with all applicable regulations.
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal.
EU waste code	The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Disposal methods/information	This preparation contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing systems and form potentially explosive metal azides. If preparation enters drain, flush with a large volume of water to prevent azide build-up.

SECTION 14: Transport information

ADR	Not regulated as dangerous goods.
RID	Not regulated as dangerous goods.
AND	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 73/78 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

Sodium azide (CAS 26628-22-8)

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

Sodium azide (CAS 26628-22-8)

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

Sodium azide (CAS 26628-22-8)

Other regulations

The product is classified and labelled in accordance with Regulation (EC) 1272/2008 (CLP Regulation) as amended and respective national laws implementing EC directives. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006. In the European Union this product is regulated under Regulation (EU) 2017/746 on In vitro Diagnostic Medical Devices.

National regulations

The product has not been classified as dangerous according to the legislation in force.

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.
LD50: Lethal Dose, 50%.

References

IARC Monographs. Overall Evaluation of Carcinogenicity
HSDB® - Hazardous Substances Data Bank

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.

Full text of any statements or R-phrases and H-statements under Sections 2 to 15

R22 Harmful if swallowed.
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
H300 Fatal if swallowed.
H310 Fatal in contact with skin.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.

Training information

Follow training instructions when handling this material.

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