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SAFETY DATA SHEET

SECTION 1: INDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/ $\,$

UNDERTAKING

1.1 Product identifier

Product name: Hb Hemoglobin Control Solution

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

Relevant identified uses:

For use in validating hemoglobin test using the Hb/Plus Hb Hemoglobin Testing System.

Uses advised against:

None.

1.3 Details of the supplier of the safety data sheet

Manufacturer:

Name: ACON Biotech (Hangzhou) Co., Ltd.

Address: No.210 Zhenzhong Road,

West Lake District, Hangzhou,

P.R. China, 310030

Phone: +86 571 87 96 35 69 E-mail: info@aconlabs.com

Authorized Representative in the EU:

Name: MedNet GmbH Address: Borkstrasse 10

48163 Muenster, Germany

Phone: +49 251 32266-0

1.4 Emergency telephone number: +49 030/19240

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of substance or mixture

This product does not classified as hazard according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

2.2 Label elements

The product does not need to be labelled according to Regulation (EC) No. 1272/2008.

2.3 Other Hazards

The product does not contain any substance that meet the criteria for PBT/vPvB according to Annex XIII of Regulation (EC) No. 1907/2006.

SECTION 3: COMPOSITION /INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable

3.2 Mixtures

3.2.1 Hazardous ingredients

The concentration of the hazardous ingredients in the control solution is shown in below table.

Components	CAS number	Concentration	Classification according to Regulation (EC) No. 1278/2008 (CLP)	Specific Concentration. Limits, M-factors
Sodium azide*	26628-22-8	0.06%	Acute Tox. 2 * (H300) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	N/A

^{*} Sodium azide with a Union workplace exposure limit

3.2.2 Additional information:

For full text of the Hazard Statements: see SECTION 16.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

GENERAL NOTES: When in doubt or if symptoms are observed, get medical advice. Show this safety

data sheet to the doctor in attendance.

If INHALATION: Move the person to fresh air

If SKIN Contact: Wash immediately with plenty of water. Immediately remove any contaminated

clothing, shoes or stockings In case of skin irritation, consult a physician.

If EYE Contact: Immediately flush eyes with plenty of water for at least 15 minutes. Assure adequate

flushing by separating the eyelids with fingers. Get medical attention immediately.

If INGESTION: Get medical attention immediately. Rinse mouth. Do NOT induce vomiting.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms/effects after skin contact: May cause skin irritation, corrosion and dermatitis. Drying-out effect

resulting in rough and chapped skin.

Symptoms/effects after eye contact: No data available.

Symptoms/effects after ingestion: No data available.

4.3 Indication of any immediate medical attention and special treatment needed

No data available.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Use water spray, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture

No data available.

5.3 Advice for firefighters

Ware self-Contained Breathing Apparatus (SCBA) with chemical resistant gloves..

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Avoid contact with skin, eyes and clothes. Wear personal protection equipment. Immediately remove any contaminated clothing, shoes or stockings. Wash contaminated clothing before reuse. Keep away from unprotected persons.

6.2 Environmental precautions

Do not allow to enter into surface water or drains. If necessary, inform the competent authorities.

6.3 Methods and material for containment and cleaning up

Wipe up with appropriate absorbent, placing in appropriate containers for disposal. Dispose of waste according to applicable legislation. Clean area thoroughly afterwards.

6.4 Reference to other sections

See protective measures under SECTION 7 and SECTION 8

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Provide good ventilation in storage and work areas. Avoid contact with skin, eyes and clothes. Wear personal protection equipment. Immediately remove any contaminated clothing, shoes or stockings. Wash contaminated clothing before reuse. Keep away from unprotected persons. When using do not eat, drink or smoke.

7.2 Conditions for safe storage, including any incompatibilities

Do not store this material near food, feed or drinking water. Store only in original container. Keep container tightly closed at refrigerated $(2-8^{\circ}\text{C})$.

7.3 Specific end use(s)

No specific uses.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

8.1.1 Occupational Exposure Limit Values:

Substance:	Sodium azide					
CAS No.	26628-22-8					
Country	Limit Value-Eight hours		Limit Value-Short term		Legal basis	
	ppm	mg/m ³	ppm	mg/m ³		
Belgium		0.1		0.3	Data from GESTIS	
Denmark		0.1		0.2	Database	
European Union		0.1		0.3 (1)		
Finland		0.1		0.3 (1)		
France		0.1		0.3		
Germany (AGS)		0.2		0.4 (1)		
Germany (DFG)		0.2 inhalable aerosol		0.4 inhalable aerosol		

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Hungary	0.1	0.3			
Ireland	0.1	0.3 (1)			
Italy	0.1	0.3			
Latvia	0.1	0.3 (1)			
Poland	0.1	0.3			
Spain	0.1	0.3			
Sweden		0.29 (1)			
Switzerland	0.2 inhalable aerosol	0.4 inhalable aerosol			
The Netherlands	0.1	0.3			
Turkey	0.1	0.3 (1)			
United Kingdom	0.1	0.3			
	Remarks	•			
European Union	Bold-type: Indicative Occupational Exposure Limit Values and Limit Values for Occupational Exposure Binding Occupational Exposure Limit Value - BOELV ~ (1) 15 minutes average value				
Finland	(1) 15 minutes average value				
France	Bold type: Restrictive statutory limit values				
Germany (AGS)	(1) 15 minutes average value				
Germany (DFG)	STV 15 minutes average value				
Ireland	(1) 15 minutes reference period				
Italy	skin				
Latvia	(1) 15 minutes average value				
Spain	Skin				
Sweden	(1) Ceiling Limit value				
Turkey	(1) 15 minutes average value				

8.1.2 Biological Limit Values:

No data available.

8.1.3 Monitoring Methods:

No data available.

8.2 Exposure controls

8.2.1 Appropriate engineering controls:

Provide adequate ventilation.

8.2.2 Personal protective equipment:

Eye/face protection: Safety glasses recommended.

Skin protection:

Hand protection: Wear suitable gloves. Replace when worn. The quality of the protective gloves

resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances.

Suitable material: Nitrile rubber

Body protection: Wear suitable protective clothing. Choose body protection according to the

amount and concentration of the dangerous substance at the work.

Respiratory protection: Not required under normal conditions of use. If occupational exposure limits

are exceeded, respiratory protection is necessary..

Thermal hazards: No data available. 8.2.3 Environmental exposure controls:

Do not allow to enter into surface water or drains.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance Dark brown Liquid
Odor No special odour

Odor threshold No data available

pH 6.5-7.5

Melting point/freezing pointNo data availableInitial boiling point and boiling rangeNo data availableFlash pointNo data availableEvaporation rateNo data availableFlammability (solid, gas)No data available

Upper/lower flammability or explosive limits No data available

Vapor pressure

No data available

Vapor density

No data available

No data available

Relative densityNo data availableSolubility (ies)Soluble in water

Partition coefficient: n-octanol/water No data available

Auto-ignition temperature No data available

Decomposition temperatureNo data available

Viscosity No data available

Explosive properties No data available

Oxidising properties No data available

9.2 Other information

No data available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No data available

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10.2 Chemical stability

The product is stabile under recommended conditions of use and storage.

10.3 Possibility of hazardous reactions

No data available.

10.4 Conditions to avoid

No data available

10.5 Incompatible material

Sodium azide is present in the Control(as a preservative). Contact with acidic solutions or metal compounds over time may form potentially explosive metal azides. Avoid disposal into a sanitary sewer system.

10.6 Hazardous decomposition products

No data available

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

The informations below are given in accordance of the ingredient Sodium azide [CAS no. 26628-22-8].

Acute toxicity

LD50 Oral (Mouse, rat): 27 mg/kg

LC50 Inhalation (Rats): Between 0.054 and 0.52 mg/L

LD50 Dermal (Rabbits): 18-60 mg/kg bw

Skin corrosion/irritationNo data available.Serious eye damage/irritationNo data available.Respiratory or skin sensitizationNo data available.Germ cell mutagenicityNo data available.

Carcinogenicity In a well-conducted 2-year rat study, no signs of carcinogenic effects

were found.

Reproductive toxicityNo data availableSTOT-single exposureNo data available.STOT-repeated exposureNo data available.Aspiration hazardNo data available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

The informations below are given in accordance of the ingredient Sodium azide [CAS no. 26628-22-8].

Acute toxicity

Fish: LC50(96h) = 0.7-5.5 mg/L

Aquatic invertebrates: LC50(48h) = 0.4-6.4 mg/L

Algae: EC50(96h) = 0.35 mg/L

12.2 Persistence and degradability

Soluble in water Persistence is unlikely based on information available.

12.3 Bioaccumulative potential

No data available.

12.4 Mobility in soil

Will likely be mobile in the environment due to its water solubility.

12.5 Results of PBT and vPvB assessment

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

12.6 Other adverse effects

No data available

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product

Do not allow to enter into surface water or drains. Dispose according to local, state or national legislation.

Contaminated packaging

Disposal should be in accordance with local, state or national legislation. Contaminated packaging must be disposed of in the same manner as the product.

SECTION 14: TRANSPORT INFORMATION

14.1 UN number

This product is not regulated for transport.

14.2 UN proper shipping name

This product is not regulated for transport.

14.3 Transport hazard class (es)

This product is not regulated for transport.

14.4 Packing group

This product is not regulated for transport.

14.5 Environmental hazards

No data available.

14.6 Special precautions for user

No data available.

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code

No data available.

SECTION 15: REGULATORY INFORMATION

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

No other regulatory information is available.

15.2 Chemical safety assessment

No data available.

SECTION 16: OTHER INFORMATION

16.1 Indication of Changes:

Version 1 Revision 0: First version

16.2 Abbreviations and acronyms:

Acute Tox. 2: Acute Toxicity, Category 2

Aquatic Acute 1: Hazard to the aquatic environment – Acute, category 1

Aquatic Chronic 1: Hazard to the aquatic environment – Chronic, category 1

PBT: Persistent, Bioaccumulative and Toxic;

vPvB: Very Persistent and Very Bioaccumulative

16.3 Classification and procedure used to derive the classification for mixtures according to

Regulation (EC) 1272/2008 (CLP):

The product is not classified as a hazard mixture as per Regulation (EC) 1272/2008 (CLP).

16.4 Relevant H-statements (number and full text):

H300 Fatal if swallowed.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

16.5 Further information

This information is based upon the present state of our knowledge.

This SDS has been compiled and is solely intended for this product.