

SAFETY DATA SHEET

Seronorm™ HbA1c Liquid L-1 & L-2

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Trade name: Seronorm™ HbA1c Liquid L-1 & L-2
Product no.: 209005 & 209105

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

Relevant identified uses of the substance or mixture: Quality control material for in-vitro diagnostics.
Uses advised against : Not applicable.

1.3. Details of the supplier of the safety data sheet

Company and address: **SERO AS**
Stasjonsveien 44
NO-1396 Billingstad
Norge
Telephone: +47 66 85 89 00

Contact person: Scientific manager
E-mail: seronorm@sero.no
Revision: 3/3/2023
SDS Version: 1.0

1.4. Emergency telephone number

In urgent situations: Call 113 and request the poison information centre. (24h service)
Poison Center at Tel.: 22 59 13 00
See section 4 on 'First Aid Measures'

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Not classified according to 21 CFR Sec. 1910.1200.

Not classified according to Regulation (EC) No. 1272/2008 (CLP).

2.2. Label elements

Hazard pictogram(s): Not applicable.
Signal word: Not applicable.
Hazard statement(s): Not applicable.
Safety statement(s):

General: -
Prevention: -
Response: -

Storage: -
Disposal: -
Hazardous substances: Gentamicin Sulfate
Additional labelling: Not applicable.

2.3. Other hazards

Additional warnings: This mixture/product does not contain any substances considered to meet the criteria classifying them as PBT and/or vPvB. This product does not contain any substances considered to be endocrine disruptors in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Not applicable. This product is a mixture.

3.2. Mixtures

Product/substance	Identifiers	% w/w	Classification	Note
Gentamicin Sulfate	CAS No.: 1405-41-0 EC No.: 215-778-9 REACH: Index No.:	<0.0017%	Skin Sens. 1, H317 Resp. Sens. 1, H334	

See full text of H-phrases in section 16. Occupational exposure limits are listed in section 8, if these are available.

Other information

The material is a human- based control produced from blood collected from voluntary blood donors. The material has been tested by CE- marked or FDA- approved methods to be negative for HBs antigen, HIV p24- antigen and HIV I, II and HCV antibodies. However, since no method can completely exclude the presence of infectious agents, this material should be handled as an ordinary patient sample.

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

General information:

In the case of accident: Contact a doctor or casualty department – take the label or this safety data sheet.
 Contact a doctor if in doubt about the injured person’s condition or if the symptoms persist. Never give an unconscious person water or other drink.

Inhalation:

Not applicable.

Skin contact:	Upon irritation: rinse with water. In the event of continued irritation, seek medical assistance.
Eye contact:	Upon irritation of the eye: Remove contact lenses. Flush eyes with plenty of water or salt water (20-30 °C) and continue until irritation stops.
Ingestion:	If the person is conscious, rinse the mouth with water and stay with the person. Never give the person anything to drink. In case of malaise, seek medical advice immediately and bring the safety data sheet or label from the product. Do not induce vomiting, unless recommended by the doctor. Have the person lean forward with head down to avoid inhalation of or choking on vomited material.
Burns:	Not applicable.
4.2. Most important symptoms and effects, both acute and delayed	None known.
4.3. Indication of any immediate medical attention and special treatment needed	None known.
Information to medics:	Bring this safety data sheet or the label from this product.

SECTION 5: FIREFIGHTING MEASURES

- 5.1. Extinguishing media**
Use extinguishing media appropriate for the surrounding fire.
- 5.2. Special hazards arising from the substance or mixture**
Not flammable.
- 5.3. Advice for firefighters**
Fire fighters should wear appropriate personal protective equipment.

SECTION 6: ACCIDENTAL RELEASE MEASURES

- 6.1. Personal precautions, protective equipment and emergency procedures**
Handle as potentially infectious.
Gloves recommended.
- 6.2. Environmental precautions**
Avoid discharge to lakes, streams, sewers, etc.
- 6.3. Methods and material for containment and cleaning up**
Absorb with liquid-binding material. Pick up mechanically. Clean with soap and water. Use disinfectant.
- 6.4. Reference to other sections**
See section 13 "Disposal considerations" on handling of waste.
See section 8 "Exposure controls/personal protection" for protective measures.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Handle as potentially infectious.
No special precautions are necessary if used correctly.

7.2. Conditions for safe storage, including any incompatibilities

Recommended storage material:	Store according to documentation provided.
Storage temperature:	Store according to documentation provided.
Incompatible materials:	Strong acids, strong bases, strong oxidizing agents, and strong reducing agents.

7.3. Specific end use(s)

This product should only be used for applications quoted in section 1.2.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

No substances are listed in the national list of substances with an occupational exposure limit.

DNEL

No data available.

PNEC

No data available.

8.2. Exposure controls

Control is unnecessary if the product is used as intended.

General recommendations:	Smoking, drinking and consumption of food is not allowed in the work area.
Exposure scenarios:	There are no exposure scenarios implemented for this product.
Exposure limits:	Occupational exposure limits have not been defined for the substances in this product.
Appropriate technical measures:	Apply standard precautions during use of the product. Avoid inhalation of vapours.
Hygiene measures:	Wash hands after use.
Measures to avoid environmental exposure:	No specific requirements.

Individual protection measures, such as personal protective equipment

Generally:	No specific requirements
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Respiratory Equipment:	No specific requirements
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Skin protection:	No specific requirements.
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Hand protection:	No specific requirements.
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Eye protection:	No specific requirements.
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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state:	Liquid
Colour:	Blood red
Odour / Odour threshold:	Mild
pH:	6-10
Density (g/cm³):	Testing not relevant or not possible due to the nature of the product.
Kinematic viscosity:	Testing not relevant or not possible due to the nature of the product.
Particle characteristics:	Does not apply to liquids.

Phase changes

Melting point/Freezing point (°C):	Not applicable
Softening point/range (waxes and pastes) (°C):	Does not apply to liquids.
Boiling point (°C):	Not applicable
Vapour pressure:	Not applicable
Relative vapour density:	Testing not relevant or not possible due to the nature of the product.
Decomposition temperature (°C):	Testing not relevant or not possible due to the nature of the product.

Data on fire and explosion hazards

Flash point (°C):	Not applicable
Flammability (°C):	Testing not relevant or not possible due to the nature of the product.
Auto-ignition temperature (°C):	Testing not relevant or not possible due to the nature of the product.
Lower and upper explosion limit (% v/v):	Testing not relevant or not possible due to the nature of the product.

Solubility

Solubility in water:	Soluble
n-octanol/water coefficient:	Testing not relevant or not possible due to the nature of the product.
Solubility in fat (g/L):	Testing not relevant or not possible due to the nature of the product.

9.2. Other information

Other physical and chemical parameters:	No data available.
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SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

No data available.

10.2. Chemical stability

The product is stable under the conditions, noted in section 7 "Handling and storage".

10.3. Possibility of hazardous reactions

None known.

10.4. Conditions to avoid

None known.

10.5. Incompatible materials

Strong acids, strong bases, strong oxidizing agents, and strong reducing agents.

10.6. Hazardous decomposition products

The product is not degraded when used as specified in section 1.

SECTION 11: TOXICOLOGICAL INFORMATION

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

Acute toxicity

Based on available data, the classification criteria are not met.

Skin corrosion/irritation

Based on available data, the classification criteria are not met.

Serious eye damage/irritation

Based on available data, the classification criteria are not met.

Respiratory sensitisation

Based on available data, the classification criteria are not met.

Skin sensitisation

Based on available data, the classification criteria are not met.

Germ cell mutagenicity

Based on available data, the classification criteria are not met.

Carcinogenicity

Based on available data, the classification criteria are not met.

Reproductive toxicity

Based on available data, the classification criteria are not met.

STOT-single exposure

Based on available data, the classification criteria are not met.

STOT-repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

11.2. Information on other hazards

Long term effects

None known.

Endocrine disrupting properties

Not applicable.

Other information

None known.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

No data available.

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No potential of bioaccumulation.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

This mixture/product does not contain any substances considered to meet the criteria classifying them as PBT and/or vPvB.

12.6. Endocrine disrupting properties

Not applicable.

12.7. Other adverse effects

None known.

SECTION 13: DISPOSAL CONSIDERATIONS

Waste treatment methods

Product is not covered by regulations on dangerous waste.
Disposal to the sewer is discouraged.
Commission Regulation (EU) No 1357/2014 of 18 December 2014 on waste.

EWC code

Not applicable.

Specific labelling

Dispose of waste in accordance to applicable national, regional or local regulations. Waste should be handled with the same care as potentially infected biological waste.

Contaminated packing

Packaging containing residues of the product must be disposed of similarly to the product.

SECTION 14: TRANSPORT INFORMATION

	14.1 UN / ID	14.2 UN proper shipping name	14.3 Hazard class(es)	14.4 PG*	14.5 Env**	Other information:
ADR	-	-	-	-	-	-
IMDG	-	-	-	-	-	-
IATA	-	-	-	-	-	-

* Packing group

** Environmental hazards

Additional information

Not dangerous goods according to ADR, IATA and IMDG.

14.6. Special precautions for user

Not applicable.

14.7. Maritime transport in bulk according to IMO instruments

No data available.

SECTION 15: REGULATORY INFORMATION**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****Restrictions for application:**

Restricted to professional users.

Demands for specific education:

No specific requirements.

SEVESO - Categories / dangerous substances:

Not applicable.

Additional information:

Not applicable.

Sources:

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 (CLP).

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).

15.2. Chemical safety assessment

No

SECTION 16: OTHER INFORMATION**Full text of H-phrases as mentioned in section 3**

H317, May cause an allergic skin reaction.

H334, May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Abbreviations and acronyms

ADN = European Provisions concerning the International Carriage of Dangerous Goods by Inland Waterway

ADR = The European Agreement concerning the International Carriage of Dangerous Goods by Road

ATE = Acute Toxicity Estimate

BCF = Bioconcentration Factor

CAS = Chemical Abstracts Service

CE = Conformité Européenne

CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]

CSA = Chemical Safety Assessment

CSR = Chemical Safety Report

DMEL = Derived Minimal Effect Level

DNEL = Derived No Effect Level

EINECS = European Inventory of Existing Commercial chemical Substances

ES = Exposure Scenario

EUH statement = CLP-specific Hazard statement

EWC = European Waste Catalogue

GHS = Globally Harmonized System of Classification and Labelling of Chemicals
IARC = International Agency for Research on Cancer (IARC)
IATA = International Air Transport Association
IBC = Intermediate Bulk Container
IMDG = International Maritime Dangerous Goods
LogPow = logarithm of the octanol/water partition coefficient
MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
OECD = Organisation for Economic Co-operation and Development
PBT = Persistent, Bioaccumulative and Toxic
PNEC = Predicted No Effect Concentration
RID = The Regulations concerning the International Carriage of Dangerous Goods by Rail
RRN = REACH Registration Number
SCL = A specific concentration limit
SVHC = Substances of Very High Concern
STOT-RE = Specific Target Organ Toxicity - Repeated Exposure
STOT-SE = Specific Target Organ Toxicity - Single Exposure
TWA = Time weighted average
UN = United Nations
UVBC = Unknown or variable composition, complex reaction products or of biological materials
VOC = Volatile Organic Compound
vPvB = Very Persistent and Very Bioaccumulative

Additional information

This safety data sheet has been created as required by Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and to distribute relevant information as required under Article 32 of REACH. This safety data sheet also complies with 21 CFR Sec. 1910.1200 and GHS.

The safety data sheet is validated by

Scientific Manager

Other

A change (in proportion to the last essential change (first cipher in SDS version, see section 1)) is marked with a blue triangle.

The information in this safety data sheet applies only to this specific product (mentioned in section 1) and is not necessarily correct for use with other chemicals/products.

It is recommended to hand over this safety data sheet to the actual user of the product.

Information in this safety data sheet cannot be used as a product specification.

Country-language: NO-en