SAFETY DATA SHEET

Seronorm™ CRP Liquid L-1, L-2 & L-3

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

1.1. Product identifier

Trade name:	Seronorm™ CRP Liquid L-1, L-2 & L-3
Product no.:	213005, 213105 & 213205

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. Restricted to professional users.
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:	05/04/2024
SDS Version:	3.0
Date of previous version:	25/09/2023 (2.0)

1.4. Emergency telephone number

In urgent situations: Call 113 and request the poison information centre. (24h service)
Poison Center at Tel.: + 47 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.
Precautionary statement(s):	
General:	-

Prevention:	Avoid release to the environment. (P273)
Response:	-
Storage:	-
Disposal:	-
Hazardous substances:	Sodium azide
▼Additional labelling:	Not applicable.

2.3. Other hazards

▼Additional warnings: This mixture/product does not contain any substances known to fulfil the criteria for PBT and vPvB classification.
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
Sodium azide	CAS No.: 26628-22-8 EC No.: 247-852-1 REACH: 01-2119457019-37-XXXX Index No.: 011-004-00-7	<0,1%		[1]

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 serum 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: If in eyes: Flush eyes with plenty of water or salt water (20-30 °C) and continue until irritation stops. Remove contact lenses.

Ingestion: Rinse and flush mouth thoroughly and consume large quantities of water. In case of continued discomfort: seek medical assistance and bring this safety data sheet.

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
Treat symptomatically.

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.
Keep unauthorized persons away from the spill

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

Sodium azide
Long term exposure limit (8 hours) (mg/m^3): 0,1
Short term exposure limit (15 minutes) (mg/m^3): 0,3
Annotations:
E = The EU has set an indicative limit value and/or remark for the substance.
S = Short term value is a value for the average concentration of a chemical in the breathing zone of an employee not to be exceeded for a specified reference period. The reference period is 15 minutes unless otherwise stated.

Regulations concerning action and limit values for physical and chemical agents in the working environment and classified biological agents (Regulations concerning Action and Limit values) FOR-2011-12-06-1358. Last update: FOR-2023-03-24-412.

DNEL

No data available.

PNEC

No data available.

8.2. Exposure controls

Compliance with the given occupational exposure limits values should be controlled on a regular basis.

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:	Professional users are subjected to the legally set maximum concentrations for occupational exposure. See occupational hygiene limit values above.
Appropriate technical measures:	The formation of vapours must be kept at a minimum and below current limit values (see

above). Installation of a local exhaust system if normal air flow in the work room is not sufficient is recommended. Ensure eyewash and emergency showers are clearly marked. 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

Respiratory Equipment:
No specific requirements

Skin protection:
No specific requirements.

Hand protection:
No specific requirements.

Eye protection:
No specific requirements.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state:	Liquid
Colour:	Pale yellow
Odour / Odour threshold:	Mild
pH:	6-10
Density (g/cm^3):	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 (LogKow):	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.
Oxidizing properties:	Testing not relevant or not possible due to the nature of the product.

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
This mixture/product does not contain any substances known to have hormone-disrupting properties in relation to health.

Other information
None known.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity
No data available.

12.2. ▼Persistence and degradability

Product/substance	Sodium azide
Result:	Water soluble
Conclusion:	-

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 known to fulfil the criteria for PBT and vPvB classification.

12.6. ▼Endocrine disrupting properties
This mixture/product does not contain any substances considered to have endocrine-disrupting properties in relation to the environment.

12.7. Other adverse effects
None known.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. ▼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	-	-	-	-	-	-

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: Commission Regulation (EU) No 1357/2014 of 18 December 2014 on waste.
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

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 (European conformity)
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
EuPCS = European Product Categorisation System
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 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