SAFETY DATA SHEET

# Autonorm™ Pharmaca Liq L-1 & L-2

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

### 1.1. Product identifier

**Trade name:** Autonorm™ Pharmaca Liq L-1 & L-2

**Product no.:** 211705 & 211805

### 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:** 3/7/2023

**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:** | None known. |
| **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

Does not contain any substances required to report

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

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|---|---|
| **General information:** | In the case of accident: Contact a doctor or casualty department – take the label or this safety data sheet.<br>Contact a doctor if in doubt about the injured person's condition or if the symptoms persist.<br>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.<br>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.

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| **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

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|---|---|
| **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 |

**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/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. |

## 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).<br>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
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