Document reference number: SDS 980 IVD

Issue number: REV 4 / SEP 2025

# A CALIBRE SCIENTIFIC COMPANY

# ACCORDING TO EC-REGULATIONS 1907/2006 (REACH), 1272/2008 (CLP) & 2015/830

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

1.1 **Product identifier** 

> Product code(s) & Product Name 980500 Preservacell

Mixture EINECS No. Mixture

**Product Description** A solution of sodium chloride, calcium chloride, buffer salts, glucose,

adenine and inosine in water, containing 0.03% chloramphenicol, 0.001% gentamycin sulphate and 0.01% neomycin sulphate as

preservatives.

1.2 Relevant identified uses of the substance or mixture

and uses advised against

Identified Use(s) IVD. Preservation of human red blood cells Uses Advised Against Anything other than the above.

1.3 Details of the supplier of the safety data sheet

> Company Identification Lorne Laboratories Ltd

> > Unit 1 Cutbush Park Industrial Estate

Danehill Lower Earley Berkshire RG6 4UT United Kingdom +44(0) 0118 921 2264

Telephone Fax +44(0) 0118 986 4518 E-Mail (competent person) Info@lornelabs.com

1.4 **Emergency telephone number** +44(0) 0118 921 2264

Available 0900 - 1700 (GMT)

Languages spoken English

#### 2. SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

2.1.1 Regulation (EC) No. 1272/2008 (CLP) Not classified as hazardous for supply/use

2.2 According to Regulation (EC) No. 1272/2008 (CLP) Label elements

Hazard Pictogram(s) None assigned

Signal Word(s) None assigned

Hazard Statement(s) None assigned

Precautionary Statement(s) None assigned

2.3 Other hazards

> The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %.

#### 3. **SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

3.1 Substances -Not applicable

3.2 Mixtures -EC Classification Regulation (EC) No. 1272/2008 (CLP)

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Chemical identity of the substance	%W/W	CAS No.	EC No.	REACH Registration No.	Hazard Statement(s)
Citric acid monohydrate	0.06	5949-29-1	201-069-1	Not yet assigned in the supply chain	Eye Irrit. 2; H319
Chloramphenicol	0.03	56-75-7	200-287-4	Not yet assigned in the supply chain	Carc. 1A; H350
Neomycin sulphate	0.01	1405-10-3	215-773-1	Not yet assigned in the supply chain	Skin Irrit. 2; H315 Skin Sens. 1; H317 Eye Irrit. 2; H319 Resp. Sens. 1; H334 Repr. 2; H361
Adenine	0.008	73-24-5	200-796-1	Not yet assigned in the supply chain	Acute Tox. 3; H301
Calcium chloride dihydrate	0.004	10035-04-8	233-140-8	Not yet assigned in the supply chain	Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Irrit. 2; H319
Gentamicin sulphate	0.001	1405-41-0	215-778-9	Not yet assigned in the supply chain	Skin Irrit. 2; H315 Skin Sens. 1; H317 Eye Irrit. 2; H319 Resp. Sens. 1; H334 Repr. 1B; H360

H301: Toxic if swallowed. H302: Harmful if swallowed. H315: Causes skin irritation. H317: May cause an allergic skin reaction. H319: Causes serious eye irritation. H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled. H335: May cause respiratory irritation. H350: May cause cancer. H360: May damage fertility or the unborn child. H361: Suspected of damaging fertility or the unborn child.

## 4. SECTION 4: FIRST AID MEASURES



4.1 Description of first aid measures

Inhalation Remove from exposure. Remove victim to fresh air and keep at rest in a position

comfortable for breathing. Keep warm and at rest. Get medical advice/attention if

you feel unwell.

Skin Contact Wash affected skin with soap and water. Remove contaminated clothing and

wash clothing before reuse. If irritation (redness, rash, blistering) develops, get

medical attention.

Eye Contact Flush eyes with water for at least 15 minutes while holding eyelids open.

None known.

Remove contact lenses, if present and easy to do. Continue rinsing. If eye

irritation persists, get medical advice/attention.

Ingestion Rinse mouth. Give plenty of water to drink. Do not give anything by mouth to an

unconscious person. Get medical advice/attention if you feel unwell.

4.2 Most important symptoms and effects, both acute

and delayed

4.3 Indication of any immediate medical attention and Treat symptomatically.

special treatment needed

## 5. SECTION 5: FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable Extinguishing Media

Unsuitable extinguishing Media

Special hazards arising from the substance or

mixture

5.2

5.3 Advice for fire-fighters

Non-flammable. As appropriate for surrounding fire. Water spray, foam, dry powder or CO<sub>2</sub>.

Do not use water jet. Direct water jet may spread the fire.

Combustion or thermal decomposition will evolve toxic vapours.

Fight fire with normal precautions from a reasonable distance. Fire fighters should wear complete protective clothing including self-contained breathing

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apparatus. Avoid all contact. Do not allow run-off from fire fighting to enter drains or water courses.

# 6. SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1	Personal precautions, protective equipment and	Ensure adequate ventilation. Avoid all contact. Ensure suitable personal
	emergency procedures	protection during removal of spillages. See Section: 8
6.2	Environmental precautions	Avoid release to the environment.
6.3	Methods and material for containment and cleaning	Absorb spillage in suitable inert material. Transfer to a lidded container for
	up	disposal or recovery. Ventilate the area and wash spill site after material pick-up

**6.4 Reference to other sections** See Section: 8, 13

# 7. SECTION 7: HANDLING AND STORAGE

**7.1 Precautions for safe handling** Avoid all contact. Use personal protective equipment as required. Ensure

adequate ventilation. Keep good industrial hygiene. Wash hands thoroughly

is complete. Avoid release to the environment.

after handling. Contaminated clothing should be thoroughly cleaned.

**Conditions for safe storage, including any**Keep only in the original container/package in a cool well-ventilated place. Keep away from food, drinks and animal food.

Storage temperature Storage temperature should be controlled to between 2 and 8°C.

Storage life Keep only in the original container/package in a cool well-ventilated place.

Incompatible materials

None known.

Specific end use(s)

See Section: 1.2

### 8. SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters
8.1.1 Occupational Exposure Limits None assigned.

8.1.2 Biological limit value Not established.

8.1.3 PNECs and DNELs Not established.

8.2 Exposure controls

7.2

7.3

**8.2.1 Appropriate engineering controls** Ensure adequate ventilation. Good hygiene practices and housekeeping measures.

IIIcast

**8.2.2** Individual protection measures, such as personal protective equipment as required. Avoid all contact. Keep good industrial hygiene. Wash hands before breaks and after work. Keep work clothes

separately. Wash contaminated clothing before reuse. Do not eat, drink or

smoke at the work place.

Eye/face protection Not normally required. Recommended: Wear eye protection with side protection



(EN166)

(EN166).

Skin protection

Prolonged, direct contact: Wear impervious gloves (EN374).



Respiratory protection



Not normally required. In case of insufficient ventilation, wear suitable respiratory equipment. Respiratory protective equipment should conform to the appropriate EN standard.

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Thermal hazards None anticipated.

**8.2.3** Environmental Exposure Controls Avoid release to the environment.

## 9. SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

#### 9.1 Information on basic physical and chemical properties

Appearance Liquid, Colourless
Odour Not established
Odour Threshold Not established

pH 7.1

Melting Point/Freezing Point Not established Initial boiling point and boiling range Not established Not established Flash Point **Evaporation Rate** Not established Flammability (solid, gas) Not established Upper/lower flammability or explosive limits Not applicable Not established Vapour pressure Vapour density Not established Relative density Not established Solubility(ies) Miscible with water Partition coefficient: n-octanol/water Not established Not established Auto-ignition temperature Not established **Decomposition Temperature** Viscosity Not established Explosive properties Not explosive Oxidising properties Not oxidising

9.2 Other information None known.

# 10. SECTION 10: STABILITY AND REACTIVITY

**10.1** Reactivity Stable under normal conditions.

10.2 Chemical stability Stable for 12 months after the date of production when stored at between 2 and

8°C.

10.3 Possibility of hazardous reactions
 10.4 Conditions to avoid
 None known. Hazardous polymerisation will not occur.
 Keep away from heat, sources of ignition and direct sunlight.

10.5 Incompatible materials Strong acids, strong oxidizing agents.

10.6 Hazardous decomposition product(s) Combustion or thermal decomposition will evolve toxic vapours.

### 11. SECTION 11: TOXICOLOGICAL INFORMATION

## 11.1 Information on toxicological effects (Substances in preparations / mixtures)

Acute toxicity

Inhalation

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

Acute Toxicity Estimate Mixture Calculation: LD50 >2000 mg/kg bw/day

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

Acute Toxicity Estimate Mixture Calculation: LD50 >20 mg/l.
Skin Contact Based on available data, the classification criteria are not met.

Acute Toxicity Estimate Mixture Calculation: LD50 >2000 mg/kg bw/day

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 or skin sensitization Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Germ cell mutagenicity 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** Other information None known.

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12.	<b>SECTION 12</b>	: ECOLOGICAL	. INFORMATION

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

Estimated LC50 (96 hour) Fish > 100 mg/l

12.2 Persistence and degradability Not established. Some of the ingredients are expected to be resistant to

biodegradation.

12.3 Bioaccumulative potential Not established. Predicted to be be unlikely.

12.4 Mobility in soil The product has high mobility in soil. Miscible with water.

Results of PBT and VPVB assessment Not classified as PBT or vPvB. None of the substances in this product fulfil the 12.5

criteria for being regarded as a PBT or vPvB substance.

12.6 Other adverse effects None known.

#### **SECTION 13: DISPOSAL CONSIDERATIONS** 13.

13.1 Waste treatment methods Disposal should be in accordance with local, state or national legislation. 13.2 **Additional Information** 

Empty containers may contain hazardous residues. Containers shall be

disposed of by incineration as soon as possible.

#### 14. **SECTION 14: TRANSPORT INFORMATION**

Not classified according to the United Nations 'Recommendations on the Transport of Dangerous Goods'.

		ADR/RID	IMDG	IATA/ICAO
14.1	UN number	None assigned.	None assigned.	None assigned.
14.2	UN proper shipping name	None assigned.	None assigned.	None assigned.
14.3	Transport hazard class(es)	None assigned.	None assigned.	None assigned.
14.4	Packing group	None assigned.	None assigned.	None assigned.
14.5	Environmental hazards	Not classified.	Not classified.	Not classified.
14.6	Special precautions for user	See Section: 2		
14.7	Transport in bulk according to Annex II of	Not applicable.	Not applicable.	Not applicable.
	MARPOL73/78 and the IBC Code			
14.8	Additional Information	None.		

#### **SECTION 15: REGULATORY INFORMATION** 15.

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

### 15.1.1 EU regulations

REACH Annex XVII (Restriction List): Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

REACH Annex XIV (Authorization List): Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC): Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent): Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

POP Regulation (Persistent Organic Pollutants): Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (1005/2009): Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

Explosives Precursors Regulation (2019/1148): Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004): Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances).

### 15.1.2 National regulations

Germany Water hazard class: 1

15.2 **Chemical Safety Assessment** None.

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## 16. SECTION 16: OTHER INFORMATION

The following sections contain revisions or new statements: 1-16.

**References:** Existing Safety Data Sheet (SDS). The classification and labelling inventory for; Citric acid monohydrate, Chloramphenicol, Neomycin sulphate, Adenine, Calcium chloride dihydrate, Gentamicin sulphate.

Literature References: Chloramphenicol (<a href="http://www.inchem.org/documents/iarc/vol50/08-chloramphenicol.html">http://www.inchem.org/documents/iarc/vol50/08-chloramphenicol.html</a>), Adenine (<a href="http://www.epa.govt.nz/search-databases/Pages/ccid-details.aspx?SubstanceID=14437">http://www.epa.govt.nz/search-databases/Pages/ccid-details.aspx?SubstanceID=3401</a>). Calcium chloride dihydrate (<a href="http://www.epa.govt.nz/search-databases/Pages/ccid-details.aspx?SubstanceID=3401">http://www.epa.govt.nz/search-databases/Pages/ccid-details.aspx?SubstanceID=3401</a>).

This Safety Data Sheet was prepared in accordance with EC Regulation (EC) 1907/2006 (REACH), 1272/2008 (CLP) & 2015/830.

### Legend to abbreviations and acronyms

LTEL Long Term Exposure Limit
STEL Short Term Exposure Limit
DNEL Derived No Effect Level

PNEC Predicted No Effect Concentration

OECD Organisation for Economic Cooperation and Development

Training advice: Consideration should be given to the work procedures involved and the potential extent of exposure as they may determine whether a higher level of protection is required.

#### **Disclaimers**

Customers are urged to ensure that the product is entirely suitable for their own purpose. It is the customers' responsibility to ensure that a suitable and sufficient assessment of the risks created by the use of the product is undertaken. The use of the reagent and the interpretation of results must be carried out by properly trained and qualified personnel in accordance with the requirements of the country where the reagent is in use.

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## Annex to the extended Safety Data Sheet (eSDS)

Not applicable

#### **Revision History**

Revision	Date	Description
3	AUG 2015	Issue 3
4	SEP 2025	Issue 4