

SAFETY DATA SHEET

Document reference number: SDS156A RW Pos Ctrl

Issue number: REV 2 / 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 156050A Rose Waaler Positive Control
CAS No. Mixture
EINECS No. Mixture
Product Description Rheumatoid Factors positive human serum containing a buffer and Proclin 950, pH 8.1 – 8.3
- 1.2 Relevant identified uses of the substance or mixture and uses advised against**
Identified Use(s) Positive Control in Rose Waaler for detection of Rheumatoid Factors in human serum/plasma
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
Telephone +44(0) 0118 921 2264
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** **Classification according to Regulation (EC) No. 1272/2008 [CLP]**
Skin sensitization, Category 1 H317
Full text of H- and EUH-statements: see section 16
Adverse physicochemical, human health and environmental effects
No additional information available
- 2.2 Label elements** According to Regulation (EC) No. 1272/2008 (CLP)
Hazard pictograms (CLP)

GHS07
Signal word (CLP) Warning
Contains 2-Methyl-2H-isothiazol-3-one (Proclin 950)
Hazard Statements (CLP) H317 - May cause an allergic skin reaction
Precautionary Statements (CLP) P261 - Avoid breathing vapours
P272 - Contaminated work clothing should not be allowed out of the workplace
P501 - Dispose of contents/container to hazardous or special waste collection

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point, in accordance with local, regional, national and/or international regulation

2.3 Other hazards

Contains material from human origin. No known test method can guarantee that products derived from human or animal sources will not transmit infectious agents. It is recommended that this product and assay material are handled as a potential biohazard.

Contains no PBT/vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII

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

Name	Product identifier	Conc. (%)	Classification according to Regulation (EC) No. 1272/2008 [CLP]
2-methylisothiazol-3(2H)-one (PROCLIN 950)	CAS-No.: 2682-20-4 EC-No.: 220-239-6 EC Index-No.: 613-326-00-9	< 0.1	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Dermal), H311 Acute Tox. 2 (Inhalation), H330 Skin Corr. 1B, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Specific concentration limits:

Name	Product identifier	Specific concentration limits
2-methylisothiazol-3(2H)-one (PROCLIN 950)	CAS-No.: 2682-20-4 EC-No.: 220-239-6 EC Index-No.: 613-326-00-9	(0.0015 $\leq$ C $\leq$ 100) Skin Sens. 1A, H317

Full text of H- and EUH-statements: See section 16

4. SECTION 4: FIRST AID MEASURES



4.1 Description of first aid measures

First-aid measures general:

Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible)

Inhalation:

Allow affected person to breathe fresh air. Allow the victim to rest

Skin Contact:

Remove affected clothing and wash all exposed skin area with mild soap and

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Eye Contact:	water, followed by warm water rinse Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persists
Ingestion:	Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention
4.2 Most important symptoms and effects, both acute and delayed	Not expected to present a significant hazard under anticipated conditions of normal use
4.3 Indication of any immediate medical attention and special treatment needed	No additional information available

5. SECTION 5: FIRE-FIGHTING MEASURES

5.1 Extinguishing media Suitable Extinguishing Media	Foam. Dry powder. Carbon dioxide. Water spray. Sand
Unsuitable extinguishing Media	Do not use a heavy water stream
5.2 Special hazards arising from the substance or mixture	No additional information available
5.3 Advice for fire-fighters Firefighting instructions	Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent firefighting water from entering the environment
Protection during firefighting	Do not enter fire area without proper protective equipment, including respiratory protection

6. SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures	
For non-emergency personnel	Evacuate unnecessary personnel
For emergency responders Protective equipment Emergency procedures	Equip cleanup crew with proper protection Ventilate area
6.2 Environmental precautions	Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters
6.3 Methods and material for containment and cleaning up	Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials
6.4 Reference to other sections	See Section: 8, 13

7. SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling	Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour
7.2 Conditions for safe storage, including any incompatibilities Storage conditions Incompatible products Incompatible materials	Keep only in the original container in a cool, well-ventilated place away from : Heat sources. Keep container closed when not in use Strong bases. Strong acids Sources of ignition. Direct sunlight
7.3 Specific end use(s)	See Section: 1.2

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8. SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

National occupational exposure and biological limit values

Sodium azide (26628-22-8)	
EU - Indicative Occupational Exposure Limit (IOEL)	
Local name	Sodium azide
IOEL TWA	0.1 mg/m ³
IOEL STEL	0.3 mg/m ³
Remark	Skin

Recommended monitoring procedures

No additional information available

Air contaminants formed

No additional information available

DNEL and PNEC

No additional information available

Control banding

No additional information available

8.2 Exposure controls

Appropriate engineering controls:

No additional information available

Personal protective equipment:

Avoid all unnecessary exposure

Personal protective equipment symbol(s):

Eye/face protection

Chemical goggles or safety glasses



Skin protection

Wear protective gloves



Respiratory protection

Wear appropriate mask



Thermal hazards

No additional information available

Environmental Exposure Controls:

Do not eat, drink or smoke during use

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9. SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	Liquid, Colourless, Yellowish, Light Pink
Odour	Odourless
Odour threshold	Not available
Melting point	Not available
Freezing point	Not available
Boiling point	Not available
Flammability	Non flammable
Explosive limits	Not available
Lower explosion limit	Not available
Upper explosion limit	Not available
Flash point	Not available
Auto-ignition temperature	Not available
Decomposition temperature	Not available
pH	8.1 – 8.3
Viscosity, kinematic	Not available
Solubility	Not available
Partition coefficient n-octanol/water (Log Kow)	Not available
Vapour pressure	Not available
Vapour pressure at 50°C	Not available
Density	Not available
Relative density	Not available
Relative vapour density at 20°C	Not available
Particle characteristics	Not applicable

9.2 Other information

No additional information available

10. SECTION 10: STABILITY AND REACTIVITY

10.1	Reactivity	No additional information available
10.2	Chemical stability	Not established
10.3	Possibility of hazardous reactions	Not established
10.4	Conditions to avoid	Direct sunlight. Extremely high or low temperatures
10.5	Incompatible materials	Not known when used appropriately
10.6	Hazardous decomposition product(s)	No hazardous decomposition products known

11. SECTION 11: TOXICOLOGICAL INFORMATION

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

Acute toxicity

Acute toxicity (oral)	Not classified
Acute toxicity (dermal)	Not classified
Acute toxicity (inhalation)	Not classified
Skin corrosion/irritation	Not classified pH: 8.1 – 8.3
Additional information	Based on available data, the classification criteria are not met

Serious eye damage/irritation	Not classified pH: 8.1 – 8.3
Additional information	Based on available data, the classification criteria are not met

Respiratory or skin sensitization	May cause an allergic skin reaction. Based on available data, the classification criteria are not met
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Germ cell mutagenicity	Not classified. Based on available data, the classification criteria are not met
Carcinogenicity	Not classified. Based on available data, the classification criteria are not met
Reproductive toxicity	Not classified. Based on available data, the classification criteria are not met

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STOT - single exposure
STOT - repeated exposure
Aspiration hazard

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

11.2 Other information

Endocrine disrupting properties
Potential adverse human health effects and symptoms

No additional information available
Based on available data, the classification criteria are not met

12. SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Hazardous to the aquatic environment, short-term (acute)
Hazardous to the aquatic environment, long-term (chronic)

Not classified

Not classified

12.2 Persistence and degradability

Rose Waaler Positive Control

Not established

12.3 Bioaccumulative potential

Not established

12.4 Mobility in soil

No additional information available

12.5 Results of PBT and VPVB assessment

No additional information available

12.6 Endocrine disrupting properties

No additional information available

12.7 Other adverse effects

Avoid release to the environment

13. SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product/Packaging disposal recommendations
Ecological waste information

Dispose in a safe manner in accordance with local/national regulations
Avoid release to the environment

14. SECTION 14: TRANSPORT INFORMATION

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

In accordance with ADR / IMDG / IATA / ADN / RID

14.1 UN number

UN-No. (ADR)
UN-No. (IMDG)
UN-No. (IATA)
UN-No. (ADN)
UN-No. (RID)

Not applicable
Not applicable
Not applicable
Not applicable
Not applicable

14.2 UN proper shipping name

Proper Shipping Name (ADR)
Proper Shipping Name (IMDG)
Proper Shipping Name (IATA)
Proper Shipping Name (ADN)
Proper Shipping Name (RID)

Not applicable
Not applicable
Not applicable
Not applicable
Not applicable

14.3 Transport hazard class(es)

Transport hazard class(es) (ADR)
Transport hazard class(es) (IMDG)
Transport hazard class(es) (IATA)
Transport hazard class(es) (ADN)
Transport hazard class(es) (RID)

Not applicable
Not applicable
Not applicable
Not applicable
Not applicable

14.4 Packing group

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	Packing group (ADR)	Not applicable
	Packing group (IMDG)	Not applicable
	Packing group (IATA)	Not applicable
	Packing group (ADN)	Not applicable
	Packing group (RID)	Not applicable
14.5	Environmental hazards	
	Dangerous for the environment	No
	Marine pollutant	No
	Other information	No supplementary information available
14.6	Special precautions for user	
	Overland transport	Not applicable
	Transport by sea	Not applicable
	Air transport	Not applicable
	Inland waterway transport	Not applicable
	Rail transport	Not applicable
14.7	Maritime transport in bulk according to IMO instruments	Not applicable

15. SECTION 15: REGULATORY INFORMATION

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

EU-Regulations

REACH Annex XVII (Restriction List)

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

REACH Annex XIV (Authorisation 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)

National regulations

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No additional information available

15.2 Chemical Safety Assessment

No chemical safety assessment has been carried out

16. SECTION 16: OTHER INFORMATION

Indication of changes: Sections 1 - 16

Regulatory information

Data 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, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Full text of H- and EUH-statements:	
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H330	Fatal if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
Skin Corr. 1B	Skin corrosion/irritation, Category 1, Sub-Category 1B
Skin Sens. 1A	Skin sensitisation, category 1A

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:		
Skin Sens. 1	H317	Calculation method

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The classification complies with : ATP 12

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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Revision History

Revision	Date	Description
1	AUG 2020	Issue 1
2	SEP 2025	Issue 2