	DiaSorin S.p.A. Via Crescentino snc - 13040 Saluggia (VC) - Italy www.diasorin.com	SAFETY DATA SHEET IMSDS40
	Language: en Revision No.: 06 Date: 2022-01-05	

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

1.1 Product identifier

1.1.1 Trade name/designation	1.1.2 Code						
<table border="0"> <tr> <td>CAL A</td> <td>Calibrator A</td> </tr> <tr> <td>CAL B</td> <td>Calibrator B</td> </tr> </table>	CAL A	Calibrator A	CAL B	Calibrator B	Kit components: LIAISON® Direct Renin REF 310350		
CAL A	Calibrator A						
CAL B	Calibrator B						
<table border="0"> <tr> <td>CONTROL 1</td> <td>Control 1</td> </tr> <tr> <td>CONTROL 2</td> <td>Control 2</td> </tr> </table>	CONTROL 1	Control 1	CONTROL 2	Control 2	Kit components: LIAISON® Control Direct Renin REF 310351		
CONTROL 1	Control 1						
CONTROL 2	Control 2						
<table border="0"> <tr> <td>CAL A</td> <td>Calibrator A</td> </tr> <tr> <td>CAL B</td> <td>Calibrator B</td> </tr> </table>	CAL A	Calibrator A	CAL B	Calibrator B	Kit components: LIAISON® Direct Renin REF 310470		
CAL A	Calibrator A						
CAL B	Calibrator B						
<table border="0"> <tr> <td>CONTROL 1</td> <td>Control 1</td> </tr> <tr> <td>CONTROL 2</td> <td>Control 2</td> </tr> </table>	CONTROL 1	Control 1	CONTROL 2	Control 2	Kit components: LIAISON® Control Direct Renin REF 310471		
CONTROL 1	Control 1						
CONTROL 2	Control 2						
<table border="0"> <tr> <td>CAL A</td> <td>Calibrator A</td> </tr> <tr> <td>CAL B</td> <td>Calibrator B</td> </tr> <tr> <td>CONJ</td> <td>Conjugate</td> </tr> </table>	CAL A	Calibrator A	CAL B	Calibrator B	CONJ	Conjugate	Kit components: LIAISON® QuantiFERON®-TB Gold Plus REF 311010
CAL A	Calibrator A						
CAL B	Calibrator B						
CONJ	Conjugate						
<table border="0"> <tr> <td>CAL A</td> <td>Calibrator A</td> </tr> <tr> <td>CAL B</td> <td>Calibrator B</td> </tr> <tr> <td>CONJ</td> <td>Conjugate</td> </tr> </table>	CAL A	Calibrator A	CAL B	Calibrator B	CONJ	Conjugate	Kit components: LIAISON® QuantiFERON®-TB Gold Plus REF 311020
CAL A	Calibrator A						
CAL B	Calibrator B						
CONJ	Conjugate						
<table border="0"> <tr> <td>CONTROL 1</td> <td>Control 1</td> </tr> <tr> <td>CONTROL 2</td> <td>Control 2</td> </tr> </table>	CONTROL 1	Control 1	CONTROL 2	Control 2	Kit components: LIAISON® Control QuantiFERON®-TB Gold Plus REF 311011		
CONTROL 1	Control 1						
CONTROL 2	Control 2						
<table border="0"> <tr> <td>CONTROL 1</td> <td>Control 1</td> </tr> <tr> <td>CONTROL 2</td> <td>Control 2</td> </tr> </table>	CONTROL 1	Control 1	CONTROL 2	Control 2	Kit components: LIAISON® Control QuantiFERON®-TB Gold Plus REF 311021		
CONTROL 1	Control 1						
CONTROL 2	Control 2						

The information included in this safety data sheet exclusively refers to the components mentioned in point 1.1.1.

Chemical denomination

Mixture containing:

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one

[EC no. 220-239-6] (3:1)

Gentamycin sulfate salt

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

Laboratory reagents for in vitro diagnostics.

1.3 Details of the supplier of the safety data sheet

DiaSorin S.p.A.

Via Crescentino s.n.c

13040 SALUGGIA (VC) - ITALY

Tel.+39.0161.4871

www.diasorin.it

e-mail: msds@Diasorin.it

USA Distributor:


DiaSorin Inc.

1951 Northwestern Avenue

Stillwater, MN 55082 USA

Tel: 651-439-9710

1.4 Emergency telephone number

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European emergency number: 112

United Kingdom of Great Britain and Northern Ireland

National Poisons Information Service (Birmingham Unit)
 City Hospital
 Dudley Rd
 Birmingham

Telephone number: +44 121 507 4123
Emergency telephone number: 844 892 0111
Fax: +44 121 507 55 88
E-mail: mail@npis.org

National Poisons Information Service Edinburgh
 Scottish Poisons Information Bureau
 Royal Infirmary
 51 Little France Crescent
 Edinburgh

Telephone number: +44 131 242 1383
Emergency telephone number: 844 892 0111
Fax: +44 131 242 13 87
E-mail: spib@luht.scot.nhs.uk

Emergency number: 999

Ireland

Poisons Information Centre of Ireland
 Beaumont Hospital
 PO Box 1297
 Dublin

Telephone number: +353 1 809 25 66
Emergency telephone number:
 +353 1 837 9964 (medical professionals)
 +353 1 809 2166 (public)
Fax: +353 1 836 84 76
E-mail: npicdublin@beaumont.ie

Emergency number: 999

The Netherlands

National Poisons Information Centre, The Netherlands
 University Medical Centre Utrecht
 Postbus 85500
 Utrecht

Telephone number: +31 88 755 85 61
Emergency telephone number: +31 30 274 88 88
Fax: +31 30 254 15 11
E-mail: nvic@umcutrecht.nl

Malta

Mater Dei Hospital
 Msida MSD 2090
 MALTA

Telephone number: 2545-0000
Fax: 2545 4154
E-mail: mdh@gov.mt

Australia

NSW Poisons Information Centre
 Childrens Hospital Westmead
 Hawkesbury Road
 Westmead

Telephone number: +61 2 9845 3969
Emergency telephone number: 131126 (national calls)
Fax: +61 2 9845 3597
E-mail: www.poisonsinfo.nsw.gov.au

South Africa


Tygerberg Poison Information Centre
 Division of Pharmacology, Department of Medicine
 Faculty of Health Sciences
 Tygerberg Campus
 Stellenbosch University
 Tygerberg

Telephone number: +27 21 938 6084
Emergency telephone number: +27 (0)861 555 777
Fax: +27 21 938 91 22
E-mail: toxicology@sun.ac.za

Canada

IWK Regional Poison Center
 5850/5980 University Avenue
 Halifax

Telephone number: +1 902 470 81320
Emergency telephone number: +1 902 470 8161 / 1 800 565 8161
Fax: +1 902 470 7213
E-mail: poison.center@iwk.nshelath.ca

	DiaSorin S.p.A. Via Crescentino snc - 13040 Saluggia (VC) - Italy www.diasorin.com	SAFETY DATA SHEET IMSDS40
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Ontario Poison Centre
 Hospital for Sick Children
 555 University Avenue
 Toronto

Telephone number: +1 416 813 6437
Emergency telephone number: +1 416 813 5900 or 1 800 268 9017
Fax: +1 416 813 7489
E-mail: poison.information@sickkids.ca

USA

DiaSorin Inc.

Telephone number: 651-439-9710 (8:00a.m. – 4:30p.m. CST)

National Poison Control Centers:


Emergency telephone number: +1 800 222 1222

SECTION 2 HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

REGULATION (EC) No 1272/2008	
Eye Irrit. 2.	H319
Skin Irrit. 2	H315
Skin Sens. 1	H317
Aquatic Chronic 3	H412

2.2 Label elements


	REGULATION (EC) No 1272/2008
SIGNAL WORD:	Warning
SYMBOLS / PICTOGRAMS:	 GHS07 Exclamation mark
HAZARD STATEMENTS:	H315 Causes skin irritation. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. H412 Harmful to aquatic life with long lasting effects.
PRECAUTIONARY STATEMENTS:	P261 Avoid breathing dust/fume/gas/mist/vapours/spray. P280 Wear protective gloves/protective clothing/eye protection/face protection. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minute. Remove contact lenses, if present, and easy to do. Continue rinsing. P273 Avoid release to the environment

Contains:

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1);
 Gentamycin sulfate salt.

2.3 Other hazards

Potential biological hazard: contains biological materials of human/animal origin.

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SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

N.A.

3.2 Mixtures

Contains:

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1)

CAS No.	CE No.	Index No.	Concentration	Classification Reg. 1272/2008 (pure substance)
55965-84-9	--	613-167-00-5	0.06% ≤ C ≤ 0.6%	Acute Tox. 3 H331 Acute Tox. 3 H311 Acute Tox. 3 H301 Skin Corr. 1B H314 Skin Sens. 1 H317 Aquatic Acute 1 H400 Aquatic Chronic 1 H410

Gentamycin sulfate

CAS No.	CE No.	Index No.	Concentration	Classification Reg. 1272/2008 (pure substance)
1405-41-0	215-778-9	--	0,1% ≤ C < 1%	Skin Sens. 1 H317 Resp. Sens. 1 H334

Refer to §16 for complete text of hazard statements and class.

SECTION 4 FIRST AID MEASURES

4.1 Description of first aid measures

Seek medical advice for first aid; protect first aid providers; wear suitable hand and eye protection and, if necessary, breathing protection.

Inhalation: Take the person outdoors to fresh air and seek medical advice. If not breathing give artificial respiration. If breathing is difficult, give oxygen.

Skin contact: if on skin: disinfect and wash with plenty of soap and water. Remove contaminated clothing. Seek medical advice.

Eye contact: Rinse thoroughly with water or suitable eyewash. Seek medical advice.


Ingestion: Rinse mouth. Do not induce vomiting. Seek medical advice.

4.2 Most important symptoms and effects, both acute and delayed

No information available

4.3 Indication of any immediate medical attention and special treatment needed

Seek medical advice as soon as possible.

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SECTION 5 FIREFIGHTING MEASURES

5.1 Extinguishing media

Use suitable extinguishing media, such as: carbon dioxide, foams, sprayed water, sand or aggregates.

5.2 Special hazards arising from the substance or mixture

Non-combustible preparation. Ambient fire may liberate hazardous vapours.

5.3 Advice for firefighters

Wear suitable protective clothing, including helmet and mask with self-contained breathing apparatus, CE certified according with Directive 89/686/EEC or NIOSH approved (USA).

Remove containers from the area of the fire if it is possible to do so without incurring risks.

Prevent fire-fighting water from entering surface water or groundwater. Collect in containers suitable for disposal.

SECTION 6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Free the contaminated area of non-emergency personnel.

Let fresh air enter contaminated area.

Avoid coming into contact with the substance and handling damaged containers without wearing suitable protective clothing and personal protection equipment for the face, hands and air-ways, CE certified according with Directive 89/686/EEC or NIOSH approved (USA).

6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. Should not be released into the environment.

6.3 Methods and material for containment and cleaning up

Cover spillage with inert absorbent material.

Recover spilled material by mechanical means and collect in clean and suitably labelled containers.

Thoroughly wash and disinfect contaminated surfaces

6.4 Reference to other sections

Dispose of recovered material as waste (see section 13); use personal protection equipment as indicated in section 8.

SECTION 7 HANDLING AND STORAGE

7.1 Precautions for safe handling


Avoid contact with eyes, skin or clothing. Use in a suitably ventilated room. Do not eat, drink or smoke during use. Do not pipette by mouth. Wear lab coats, safety goggles and disposable gloves. Avoid splashing or forming an aerosol. Wash hands carefully on completion of operations.

7.2 Conditions for safe storage, including any incompatibilities

Store the preparation at 2-8°C hermetically sealed and away from the light. Keep away from foodstuffs, drinks and animal feed. Protect containers against damage.

7.3 Specific end uses

The mixtures are intended specifically for in vitro use, for the examination of samples of human origin. Handle in accordance with good laboratory practice (GLP), while also considering the risks deriving from the materials under analysis.

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SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Not available

8.2 Exposure controls

Eye/face protection: wear safety goggles or visor CE-certified in accordance with Directive 89/686/EEC or (for USA) meeting at a minimum ANSI standard Z87.1; do not use contact lenses.

Hand protection: wear CE-certified protective gloves in accordance with Directive 89/686/EEC suitable for handling chemical and biological agents.

Body protection: select any protection equipment according to the quantities of hazardous materials in the work place.

Breathing protection: avoid inhaling aerosol. If necessary use suitable fume hoods and/or full face-masks with type ABEKP combined filters (EN 14387), CE certified.


SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

- (a) Appearance: solid
- (b) Odour: N.A.
- (c) Odour threshold: N.A.
- (d) pH: N.A.
- (e) Melting point/freezing point: no information available
- (f) Initial boiling point and boiling range: no information available
- (g) Flash point: no information available
- (h) Evaporation rate: no information available
- (i) Flammability (solid, gas): N.A.
- (j) Upper/lower flammability or explosive limits: N.A.
- (k) Vapour pressure: no information available
- (l) Vapour density: no information available
- (m) Relative density: no information available
- (n) Solubility(ies): no information available
- (o) Partition coefficient: n-octanol/water: no information available
- (p) Auto-ignition temperature: no information available
- (q) Decomposition temperature: no information available
- (r) Viscosity: no information available
- (s) Explosive properties: N.A.
- (t) Oxidising properties: no information available

9.2 Other information

Not available

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SECTION 10 STABILITY AND REACTIVITY

10.1 Reactivity

No information available

10.2 Chemical stability

Stable in recommended storage conditions

10.3 Possibility of hazardous reactions

No information available

10.4 Conditions to avoid

No information available

10.5 Incompatible materials

No information available

10.6 Hazardous decomposition products

No information available

SECTION 11 TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Mixture: no information available.

available information on hazardous components:

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1)

LD-50 (oral), rat: 60 mg/kg (active isothiazol)


LD-50 (dermal), rabbit: 80 mg/kg (active isothiazols)

LC-50 4-hour (inhalation), rat: 330 mg/m³ (active isothiazols)

In humans, solutions containing more than 0.5% (5000 ppm) active isothiazols cause severe skin irritation and may be corrosive to the mucous membranes and cornea.

gentamycin sulfate salt

LD50 (oral), rat: 5.000 mg/kg

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SECTION 12 ECOLOGICAL INFORMATION

12.1 Toxicity

Mixture: no information available.
 available information on hazardous components:

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1); short-term effects:

Parameter	Animal species	Time of exposure	Data
LC50	Fish	96 hours	0.19 mg/l
EC50	Crustaceans	48 hours	0.16 mg/l

12.2 Persistence and degradability

No information available.

12.3 Bioaccumulative potential

No information available.

12.4 Mobility in soil

If spilled, may enter ground

12.5 Results of PBT and vPvB assessment

No information available.

12.6 Other adverse effects

No information available.

SECTION 13 DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Dispose of contents/container in accordance with local/regional/national/international regulation in force. Use a dedicated company for dangerous waste disposal. Send for disposal as dangerous waste. Recommended disposal method: incineration. Normative references: Directives 94/62/EC, 2008/98/EC, Commission Decision 2000/532/EC.

SECTION 14 TRANSPORT INFORMATION

The mixture is not to be considered hazardous within the meaning of the provisions in force governing the transport of hazardous materials by road (ADR), rail (RID), sea (IMDG code) and air (ICAO, IATA); transport at 2-8°C.

14.1 **UN number:** N.A.

14.2 **UN proper shipping name:** N.A.


14.3 **Transport hazard class(es):** N.A.

14.4 **Packing group:** N.A.

14.5 **Environmental hazards:** N.A.

14.6 **Special precautions for user:** N.A.

14.7 **Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:** N.A.

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SECTION 15 REGULATORY INFORMATION

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

EU	Restriction pursuant to Annex XVII to EC Regulation 1907/2006	Point 3		
	Seveso category	none		
	Candidate List (art. 59 Regulation 1907/2006)	NA		
	authorization (Annex XIV REACH)	NA		
	Water Hazard Class (Germany):	WGK 2		
UNITED STATES	Product components listed in Section 1.1 are classified in accordance with OSHA Hazard Communication Standard, 29 CFR 1910.1200, and individual US state Right-to-Know laws.			
	CAA:	N – Does not contain any hazardous air pollutants (HAPs) or Class 1 Ozone depletors.		
	CWA:	N		
	CERCLA:	N		
	SARA 302:	N		
	SARA 311/312:	Acute: Y Chronic: Y Fire: N Pressure: N Reactivity: N		
	SARA 313:	N		
	TSCA:	Y		
	CA Prop 65:	N		
Canada	DSL:	CAS 55965-84-9		
	NDSL:	N		
Rotterdam Convention - annex III		NA		
Stockholm Convention		NA		
NFPA	Health: 1	Flammability: 0	Reactivity: 0	

15.2 Chemical safety assessment

No chemical safety assessment has been produced for the mixture and the substances contained therein

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SECTION 16 OTHER INFORMATION

Hazard statements and class

Acute Tox.: Acute toxicity

Skin Corr.: Skin corrosion

Skin Sens.: Skin sensitization

Aquatic Acute: Hazardous to the aquatic environment, acute toxicity

Aquatic Chronic: Hazardous to the aquatic environment, chronic toxicity

H331 Toxic if inhaled

H311 Toxic in contact with skin

H301 Toxic if swallowed

H314 Causes severe skin burns and eye damage

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.

H400 Very toxic to aquatic life

H410 Very toxic to aquatic life with long-lasting effects

H412 Harmful to aquatic with long lasting effects

Note: after reconstitution according to instruction for use, the product is classified:

REGULATION (EC) No 1272/2008
Skin sens. 1 H317

GENERAL BIBLIOGRAPHY

1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. The Merck Index. - 10th Edition
4. Handling Chemical Safety
5. CDC - NIOSH website – Guide to Chemical Hazards
6. INRS - Fiche Toxicologique (toxicological sheet)
7. Patty - Industrial Hygiene and Toxicology
8. N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
9. ECHA website
10. US OSHA 29 CFR 1910.1200
11. eChemPortal website
12. IARC website – Evaluation of carcinogenic risks to humans
13. Health Canada website
14. Canada Labour Health and Safety website
15. CCOHS website
16. World Health Organization - Laboratory biosafety manual, 3rd ed.
17. OECD – Principles of good laboratory practice

Further information

All information is correct, to the best of our knowledge, on the date of issue of the data sheet. It is provided for information purposes only, however, and does not constitute a guarantee.

Procedures for use: see instructions in the package. Do not use the product for any purpose other than that for which it is intended.

Judgments as to the suitability of information herein for the purchaser's purposes are necessarily the purchaser's responsibility.

Although reasonable care has been taken in the preparation of such information, the company extends no warranties, makes no representations and assumes no responsibility as to accuracy or suitability of such information for application to purchaser's intended purposes and accepts no responsibility for any injury, loss or damage deriving from improper use of the product.

The product is employed under its users' control and it is their responsibility to comply with the correct operating procedures indicated, as well as to observe proper laboratory hygiene.

Nature of changes with respect to previous edition:

Product codes added in § 1.1	-
Product codes deleted from § 1.1	310340, 310341
Other changes	-