

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Reliant™ Gel System

Version 5.0

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SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name : Reliant™ Gel System

Material number : 54939

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

Use of the Substance/Mixture : For research use only.

Recommended restrictions on use : NOT FOR USE IN GMP MANUFACTURING, NOR HUMAN OR ANIMAL IN VIVO OR DIAGNOSTIC USE.

1.3 Details of the supplier of the safety data sheet

Company : **Lonza Ltd**
Muenchensteinerstrasse 38
CH-4002 Basel, Switzerland
Business Telephone: +41 61 316 81 11

Lonza Verviers Sprl
Parc Industriel de Petit-Rechain
BE-4800 Verviers, Belgium
Business Telephone: +32 8732 1611

Lonza Cologne GmbH
Nattermannallee 1
DE-50829 Köln, Germany
Business Telephone: + 49 221 99 1990

E-mail address / Responsible/issuing person : sds@lonza.com

1.4 Emergency telephone number

Emergency telephone number : Lonza Ltd, CH-4002 Basel, Switzerland
Telephone: +41 61 313 94 94 (24h)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Reproductive toxicity, Category 1B H360FD: May damage fertility. May damage the unborn child.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Danger

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Hazard statements	:	H360FD	May damage fertility. May damage the unborn child.
Precautionary statements	:	Prevention:	
		P201	Obtain special instructions before use.
		P202	Do not handle until all safety precautions have been read and understood.
		P280	Wear protective gloves/ eye protection/ face protection.
		Response:	
		P308 + P313	IF exposed or concerned: Get medical advice/ attention.
		Storage:	
		P405	Store locked up.
		Disposal:	
		P501	Dispose of contents/container in accordance with local regulation.

Hazardous components which must be listed on the label:

Boric acid

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. REACH Registration Number	Classification	Concentration (% w/w)
Boric acid	10043-35-3 233-139-2 005-007-00-2 01-2119486683-25-XX XX	Repr. 1B; H360FD	>= 0,3 - < 0,5

For explanation of abbreviations see section 16.

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SECTION 4: First aid measures**4.1 Description of first aid measures**

- If inhaled : Move to fresh air.
If unconscious, place in recovery position and seek medical advice.
Keep respiratory tract clear.
If breathing is irregular or stopped, administer artificial respiration.
- In case of skin contact : After contact with skin, wash immediately with plenty of soap and water.
If on clothes, remove clothes.
In the case of skin irritation or allergic reactions see a physician.
- In case of eye contact : Immediately flush eye(s) with plenty of water.
Remove contact lenses.
Keep eye wide open while rinsing.
Protect unharmed eye.
If eye irritation persists, consult a specialist.
- If swallowed : Clean mouth with water and drink afterwards plenty of water.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.

4.2 Most important symptoms and effects, both acute and delayed

- Symptoms : No information available.

4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : Treat symptomatically.
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SECTION 5: Firefighting measures**5.1 Extinguishing media**

- Suitable extinguishing media : Water spray
Alcohol-resistant foam
Dry chemical

5.2 Special hazards arising from the substance or mixture

- Specific hazards during firefighting : Heating or fire can release toxic gas.
- Hazardous combustion products : Carbon oxides (COx)

5.3 Advice for firefighters

- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.
- Further information : Use a water spray to cool fully closed containers.

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SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

Personal precautions : In the case of respirable dust and/or fumes, use self-contained breathing apparatus and dust impervious protective suit. Use personal protective equipment.

6.2 Environmental precautions

Environmental precautions : Prevent product from entering drains. Prevent further leakage or spillage if safe to do so.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Pick up and arrange disposal without creating dust. Shovel into suitable container for disposal.

6.4 Reference to other sections

For personal protection see section 8.

For disposal considerations see section 13.

SECTION 7: Handling and storage**7.1 Precautions for safe handling**

Advice on safe handling : Avoid formation of respirable particles. Do not breathe vapours/dust. Smoking, eating and drinking should be prohibited in the application area. For personal protection see section 8. Provide sufficient air exchange and/or exhaust in work rooms. Dispose of rinse water in accordance with local and national regulations.

Advice on protection against fire and explosion : Normal measures for preventive fire protection.

Hygiene measures : Wash hands before breaks and at the end of workday. Avoid contact with skin, eyes and clothing.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Observe label precautions. Keep container tightly closed. Keep in a well-ventilated place. To maintain product quality, do not store in heat or direct sunlight.

Further information on storage conditions : Avoid moisture.

Further information on storage stability : No decomposition if stored and applied as directed.

7.3 Specific end use(s)

Specific use(s) : No information available.

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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Countries not listed may have their own country specific values.

Occupational Exposure Limits

Switzerland

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Boric acid	10043-35-3	TWA (inhalable dust)	1,8 mg/m ³ (Boron)	CH SUVA
		STEL (inhalable dust)	1,8 mg/m ³ (Boron)	CH SUVA

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Substance name	End Use	Exposure routes	Potential health effects	Value
Boric acid	Workers	Inhalation	Long-term systemic effects	8,3 mg/m ³
	Workers	Dermal	Long-term systemic effects	392 mg/kg
	Consumers	Oral	Acute systemic effects	0,98 mg/kg
	Consumers	Oral	Long-term systemic effects	0,98 mg/kg
	Consumers	Dermal	Long-term systemic effects	196 mg/kg
	Consumers	Inhalation	Long-term systemic effects	4,15 mg/m ³

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

Substance name	Environmental Compartment	Value
Boric acid	Fresh water	2,02 mg/l
	Marine water	2,02 mg/l
	Soil	5,4 mg/kg
	Sewage treatment plant	10 mg/l
	Intermittent use/release	13,7 mg/l
	Fresh water	1,35 mg/l
	Marine water	1,35 mg/l
	Intermittent use/release	9,1 mg/l
	Fresh water sediment	1,8 mg/l
	Marine sediment	1,8 mg/l
	Soil	5,4 mg/l
	Sewage treatment plant	1,75 mg/l

8.2 Exposure controls

Engineering measures

Use only in area provided with appropriate exhaust ventilation.

Personal protective equipment

Eye protection : Safety glasses

Hand protection

Material : Nitrile rubber

Remarks : Take note of the information given by the producer concerning

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	permeability and break through times, and of special workplace conditions (mechanical strain, duration of contact). Impervious gloves Break through time : > 480 min The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it.
Skin and body protection	: Choose body protection according to the amount and concentration of the dangerous substance at the work place. Dust impervious protective suit
Respiratory protection	: Half mask with a particle filter P2 (EN 143)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	: solid
Appearance	: gel
Colour	: clear
Odour	: odourless
Melting point/freezing point	: No data available
Initial boiling point and boiling range	: No data available
Flammability	: No data available
Upper explosion limit / Upper flammability limit	: Not applicable
Lower explosion limit / Lower flammability limit	: Not applicable
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature Decomposition temperature	: No data available
pH	: No data available
Viscosity Viscosity, kinematic	: Not applicable
Solubility(ies) Water solubility	: soluble
Partition coefficient: n-octanol/water	: No data available
Vapour pressure	: No data available
Relative density	: No data available

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Density	:	No data available
Relative vapour density	:	Not applicable
Particle characteristics	:	
Particle size	:	No data available

9.2 Other information

No data available

SECTION 10: Stability and reactivity**10.1 Reactivity**

No decomposition if stored and applied as directed.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions	:	Stable under recommended storage conditions. No hazards to be specially mentioned.
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10.4 Conditions to avoid

Conditions to avoid	:	Heat
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10.5 Incompatible materials

Materials to avoid	:	Oxidizing agents Strong acids and strong bases
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10.6 Hazardous decomposition products

No decomposition if used as directed.

SECTION 11: Toxicological information**11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**

Information on likely routes of exposure	:	Eyes Skin
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Acute toxicity

Acute oral toxicity	:	Remarks: No data available
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Acute inhalation toxicity	:	Remarks: No data available
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Acute dermal toxicity	:	Remarks: No data available
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Skin corrosion/irritation

Remarks: No data available

Serious eye damage/eye irritation

Remarks: No data available

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Respiratory or skin sensitisation

Remarks: No data available

Germ cell mutagenicity

Genotoxicity in vitro : Remarks: No data available

Carcinogenicity

Remarks: No data available

Reproductive toxicity

Effects on fertility : Remarks: No data available

STOT - single exposure

Remarks: No data available

STOT - repeated exposure

Remarks: No data available

Aspiration toxicity

Remarks: No data available

No aspiration toxicity classification

11.2 Information on other hazards

Endocrine disrupting properties

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Further information

Remarks: No data available

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish : Remarks: No data available

12.2 Persistence and degradability

Biodegradability : Remarks: No data available

12.3 Bioaccumulative potential

Bioaccumulation : Remarks: No data available

12.4 Mobility in soil

Distribution among environmental : Remarks: No data available

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compartments

12.5 Results of PBT and vPvB assessment

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

Additional ecological information : No data available

SECTION 13: Disposal considerations**13.1 Waste treatment methods**

Product : Dispose of contents/container in accordance with local regulation.
Contact waste disposal services.
Do not dispose of waste into sewer.

Contaminated packaging : Dispose of as unused product.
Do not re-use empty containers.

SECTION 14: Transport information

IATA Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class(es) : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : no

IMDG Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class(es) : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : Marine pollutant: no

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ADR	:	Not dangerous goods
14.1 UN number	:	Not applicable
14.2 Proper shipping name	:	Not applicable
14.3 Transport hazard class(es)	:	Not applicable
14.4 Packing group	:	Not applicable
14.5 Environmental hazards	:	no
RID	:	Not dangerous goods
14.1 UN number	:	Not applicable
14.2 Proper shipping name	:	Not applicable
14.3 Transport hazard class(es)	:	Not applicable
14.4 Packing group	:	Not applicable
14.5 Environmental hazards	:	no
DOT	:	Not dangerous goods
14.1 UN number	:	Not applicable
14.2 Proper shipping name	:	Not applicable
14.3 Transport hazard class(es)	:	Not applicable
14.4 Packing group	:	Not applicable
TDG	:	Not dangerous goods
14.1 UN number	:	Not applicable
14.2 Proper shipping name	:	Not applicable
14.3 Transport hazard class(es)	:	Not applicable
14.4 Packing group	:	Not applicable
14.5 Environmental hazards	:	no

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Maritime transport in bulk according to IMO instruments

Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Boric acid

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

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REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Not applicable

Water hazard class (Germany) : WGK 1 slightly hazardous to water

15.2 Chemical safety assessment

No data available

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SECTION 16: Other information

Classification of the mixture:	Classification procedure:
Repr. 1B H360FD	Calculation method

Full text of H-Statements

H360FD : May damage fertility. May damage the unborn child.

Full text of other abbreviations

Repr. : Reproductive toxicity

ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; ATE - Acute Toxicity Estimate; AwSV - Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen / Ordinance on facilities for handling substances that are hazardous to water; BPR – Biocidal Product Regulation; bw - Body weight; CAS - Chemical Abstract Service; CLP - Classification Labelling Packaging Regulation, Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DNEL-Derived No Effect Level; DOT - Department of Transportation; EC – European Community; ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; EmS (Emergency Response Procedures for Ships Carrying Dangerous Goods); EN – European Standard; ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; EU OEL - European Occupational Exposure Limit; GHS -Globally Harmonized System of Classification and Labelling of Chemicals; GLP - Good Laboratory Practice; GV – Danish Exposure Limits for Substances and Materials; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; IMDG - International Maritime Dangerous Goods; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); LOFT - Danish Threshold Limit Value; MAK - German Threshold Limit Value; MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NIOSH/Guide – National Institute of Safety and Health Guidebook; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NTP - National Toxicology Program; OECD - Organization for Economic Co-operation and Development; PBT - Persistent, Bioaccumulative and Toxic substance; PEL - Permissible Exposure Limit; PNEC - Predicted no Effect Concentration; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; REL - Recommended Exposure Limit; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; STEL - Short-Term Exposure Limit; TDG - Transportation of Dangerous Goods; TGG – Dutch Threshold Limit Value; TGV – Swedish OEL; TLV Threshold Limit Value; TLV-C - Threshold Limit Value Ceiling; TWA -Time Weighted Average; UDS - Unscheduled DNA Synthesis; UN - United Nations; VLE - Valeurs limites d'exposition professionnelle aux agents chimiques en France; VME - Valeur (Limite) Moyenne d'Exposition; VOC - Volatile Organic Compound[s]; WEEL - Workplace Environmental Exposure Level; % w/w Percent weight by weight; %(V) Percent Volume

Further information

Other information : This Safety Data Sheet is a generic European Safety Data Sheet and therefore does not contain all specific information for each European country.

Date format : dd.mm.yyyy

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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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