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EG Material Safety Data Sheet according to
Safety Data Sheet according to Regulation (EG) 2015/830 Regulation, (EU) No. 1272/2008 (+ Subsequent ATPs) and
REACH Regulation 1907/2006 EC (+ Subsequent Regulations)

Date: 28.05.2020

Rev. 1.0

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

1.1. 1.1. Product identifier: LD COVID-19 IgM Rapid Test (Art.-No. COV19_M_10_EN)

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

The LD COVID-19 IgM Rapid Test is a visual test for the qualitative detection of IgM antibodies to SARS-CoV-2 in human serum, plasma, or whole blood within 15 min (latest 20 min). The test is for professional in vitro diagnostic use only and intended to aid in the diagnosis of SARS-CoV-2 infection and to complement direct pathogen detection. Serology can also be used to collect epidemiological data. The product is intended for use as an IVD but can also be used for research purposes. Contains 2 components (test cassette and diluent buffer) as liquids or solid phase.

1.3. Details of the supplier of the safety data sheet

Lionex GmbH

Salzdahlumer Str. 196, Geb. 1A

D-38126 Braunschweig

Tel. +49(0)531 / 2601266

Contact person: Prof. Dr. Singh:

www.lionex.de

FAX +49(0)531 / 6180654

Tel. +49(0)175 / 594 2291

e-mail: info@lionex.de

1.4. Emergency telephone number

Germany:

Giftinformationszentrum-Nord der Länder Bremen,

Hamburg, Niedersachsen und Schleswig-Holstein

Robert-Koch-Straße 40

37075 Göttingen

Tel.: +49(0)0551 / 19240

International:

Belgien / Belgium:	+32(70) 245 245	Polen / Poland:	+48 (42) 657 99 00
Bulgarien / Bulgaria:	+359 (2) 515 32 34	Portugal / Portugal:	+351 (1) 795 01 43
Dänemark / Denmark:	+45 (35) 316 060	Russische – Föderation / Russia	+7 (95) 928 16 47
Finnland / Finland:	+358 (9) 471 977	Schweden / Sweden:	+46 (8) 736 03 84
Frankreich / France:	+33 (3) 883 737 37	Schweiz / Switzerland:	+41 (1) 251 51 51
Griechenland / Greece:	+30 (1) 799 37 77	Slowakei / Slovakia:	+00421 (17) 547 741 66
Großbritannien / GB:	+44 (171) 635 91 91	Slowenien / Slovenia:	+386 (61) 302 457
Holland / Dutch:	+31 (30) 274 88 88	Spanien / Spain:	+34 (91) 562 84 69
Israel / Israel:	+972 (4) 852 92 05	Tschechien / Czech Republik:	+42 (02) 249 192 93
Italien / Italia:	+39 (6) 490 663	Türkei / Turkey:	+90 (312) 433 70 01
Kroatien / Croatia:	+385 (1) 222 302	Ungarn / Hungary:	+36 (1) 215 215
Litauen / Lithuania:	+370 (2) 269 583	Österreich / Austria:	+43 (1) 406 43 43
Norwegen / Norway:	+47 (22) 591 300		

SECTION 2. Hazards identification

2.1. Classification of the substance or mixture

Classification of components of the whole preparation according to Regulation (EG) No. 1272/2008:


Not hazardous for human health or the environment in any way.

2.2. Label elements

Labelling and hazard notes according to Regulation (EG) No. 1272/2008:

Not hazardous. Labelling not required.

Signal word: none

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Hazard-determining component for labelling: none

Hazard statements: none

Precautionary statements: none

Additionally Statements: -

2.3. Other hazards

Use the product by following the standard safety precautions in a lab.



Use appropriate protective clothing (gloves, lab coat, work shoes, safety goggles).

Behavior in the lab: DO NOT SMOKE! DO NOT DRINK! DO NOT EAT!

PBT: not applicable. / **vPvB:** not applicable.

SECTION 3. Composition/information on ingredients

3.1. Substances

Not applicable. Mixtures from substances listed below contain non-hazardous components like water or proteins.

3.2. Mixtures

Composition of the substances in the mixtures:

Table of hazardous substances in the mixture:

Kit Component	Substance	CAS No.	EC No.	Concentration in the mixture	H rules	P rules
Test cassette	5-Bromo-5-Nitro-1,3-Dioxane C ₄ H ₅ BrNO ₄	30007-47-7	250-001-7	≤ 0.01 %	H302 H315	P280
	Nitrozellulose	9004-70-0	936-908-7	≤ 0.1 %	H201	P250-372
	Boric acid	10043-35-3	233-139-2	< 0.004 %	H360	P201 P202 P280 P308+P313 P405 P501
Diluent Buffer	5-Bromo-5-Nitro-1,3-Dioxane C ₄ H ₅ BrNO ₄	30007-47-7	250-001-7	0.05 %	H302 H315	P280

Substances with prescribed EC limit values:

Full description of H- and P-rules: refer to section 16.

Substances, which are listed in the "Candidate List of Substances of Very High Concern (SVHC) for authorisation" of European Chemicals Agency (ECHA) are not intended to be part of this product. Therefore it is not expected that the concentration of such substances is > 0.1 % in the product.

SECTION 4. First-aid measures




4.1. Description of first-aid measures

General advice: Remove contaminated clothing immediately. Consult a physician. Show this safety data sheet to the doctor in attendance. Move out the dangerous area. Hand out the medical doctor this MSDS.

If inhaled: Inhaling is not possible. If there should occur any troubles (e.g. shortness of breath): land the person on fresh air. In case of breathing difficulties transmit oxygen. Consult a doctor. Remove person to fresh air and keep comfortable for breathing.

Skin contact: Wash off with plenty of water and soap, rinse.

Eye contact: Rinse cautiously with water for minimum 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Seek medical advice.

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If swallowed: Immediately vigorous rinsing of the mouth. Drink plenty of water (200 - 300 mL) in small sips (dilution effect). Avoid vomiting. No neutralization experiments. Seek medical or contact emergency call.

Increased troubles because of excessive reaction: During recurring or continual reaction there is no expected aggravation of state of health.

4.2. Most important symptoms and effects, both acute and delayed

Skin contact: no symptoms expected.

Eye contact: no symptoms expected.

If swallowed: no symptoms expected.

If inhaled: it is not possible to inhale the test components under normal conditions of use. No symptoms expected.

4.3. Indication of any immediate medical attention and special treatment needed

Not available.

SECTION 5. Fire fighting measures

5.1. Extinguishing media

Every extinguishing agent, which is suitable for the controlling fire. Gear extinguishing agent to the surrounding.

For safety reasons unsuitable extinguishing agents: none

5.2. Special hazards arising from the substance or mixture

There are not known special risks, which can cause by the substance or the mixture. Generally: toxic vapours (Carbon monoxide, carbon dioxide) can be released in case of fire (see 10.1)

5.3. Advice for firefighters

Wear self-contained breathing apparatus and suitable protective clothing for fighting against a fire, whereby chemicals are involved.

Move container from fire area if it can be done without risk. Use water spray to keep fire exposed containers cool.

Evacuate area. Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire.

Prevent runoff from fire control or dilution from entering streams, sewers, or drinking water supply.

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

SECTION 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Note for non-emergency personnel: Use suitable personal protective equipment (safty glasses, white coat, gloves).

Information for emergency responders: Use protective equipment according to section 8.

6.2. Environmental precautions

Avoid entering major volumes of buffer solution in sewerage. Cover drains to prevent the product from entering the sewer system. Wipe up the liquid with an absorbent material (paper).


6.3. Methods and material for containment and cleaning up

For larger quantities: not relevant. The volume of all liquid components is ≤ 100 mL.

If left over: Collect spillage with absorbent material (paper towel) and collect in appropriate containers for disposal in accordance with local regulations

6.4. Reference to other sections

Applicable limits for occupational exposition are listed in section 7, 8. For disposal refer to section 13.

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SECTION 7. Handling and storage

7.1. Precautions for safe handling

Advice for safe handling:

Close containers immediately after use to avoid spillage. Wear protective clothing (gloves / safety clothes / goggles).
Hygiene measures: Do not smoke, drink or eat in the laboratory. Wash hands after use, put off contaminated clothes and protective equipment before entering a break room. Clean hands after use.

Information about fire and explosion protection:

Specific fire and explosion protection measures are not required.

No risk of corrosion known.

All solutions are not flammable

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storerooms and containers:

Specific devices for fire explosion protection or to prevent corrosion are not required

The solutions are not flammable.

Interactions of the ingredients with incompatible substances: none known

Conditions for evaporation: no dangerous effects known

Potential sources of ignition: not present in the product

Effects of weather conditions: none known

Effects of ambient conditions: none known

Effects of the temperature: store at 2-30 °C, can be stored up to the expiration date

Effects of sunlight: non known

Effects of moisture: protect the enclosed test cassette from moisture

Effects of vibrations: non known

7.3. Specific end use(s)

none

SECTION 8. Limitation and monitoring of the exposition/ personal protective equipments

8.1. Control parameters according to German TRGS 903: none.

Substance	CAS-No.	EC-No.	MAK (by TRGS 900)	content (%)
5-Bromo-5-Nitro-1,3-Dioxan	30007-47-7	250-001-7	not listed	≤ 0.05%

For National exposition limits in other Countries than Germany refer to the corresponding rules!

Current recommended monitoring procedures:

In case of proper use of the product no air pollution load will be expected. Therefore no current monitoring procedures are necessary.

8.2. Exposure controls




Personal protective equipment: select personal protective equipment according to the concentration of hazardous substances on the specific work station.

Eye and face protection: wear safety goggles according to EN 166 (EU), NIOSH (US)



Skin protection: protective gloves according to EN 374 (nitrile rubber > 0,11 mm or natural latex ≥ 0,22 mm and AQL 1,5). Respect allergies!

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Further protective measures: wear a lab coat, closed footwear, follow the hygiene instructions in the laboratory.

Breathing protection: respirator mask is not necessary.

Limitation and monitoring of environmental exposure

See sections 6 and 7.

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Test cassette


Appearance:	solid phase, test cassette (PE), contains one test strip, sealed in aluminum foil in combination with desiccant bag.
Odor:	no typical odor
pH-value:	not specified, solid
melting point/freezing point:	not specified, unknown
boiling point and boiling range:	not specified, solid
flashpoint:	not specified, solid
rate of vaporization:	not specified, solid
inflammability (solid, gaseous):	flammable in open fire
upper/ lower inflammability or explosion limit:	not specified
Vapor pressure:	not specified, solid
Vapor density:	not specified, solid
specific gravity:	not specified, solid
solubility:	not specified, solid
distribution coefficient:	not specified, solid
self-ignition point:	no self-ignition possible
decomposition temperature:	not specified, solid
viscosity:	not specified, solid
explosive properties:	none, no explosive substances are used for production.
oxidizing properties:	none, no oxidizing substances are used for production.

Sample diluent, aqueous solution

Appearance:	liquid, 3.5 – 4.0 mL in a PE-dropper vial, transparent white
Odor:	no typical odor
Odor threshold:	not specified
pH-value:	5.7 – 5.9
melting point/freezing point:	0°C
boiling point and boiling range:	100°C
flashpoint:	not specified, aqueous solution without flammable ingredients
rate of vaporization:	not specified, like water
inflammability (solid, gaseous):	not flammable
upper/ lower inflammability or explosion limit:	not explosive
vapor pressure:	not specified, aqueous solution
vapor density:	not specified, aqueous solution
specific gravity:	not specified, like water
solubility:	not specified, aqueous solution
distribution coefficient:	not specified
self-ignition point:	no self-ignition possible
decomposition temperature:	not specified
viscosity:	not specified, aqueous solution
explosive properties:	none, contains no explosive substances
oxidizing properties:	none, contains no oxidizing substances

9.2. Further information

All liquid components of the preparation are infinite water-soluble. No potential for the formation of radicals. No photocatalytic properties.

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SECTION 10. Stability and reactivity

10.1. Reactivity

The application of all these components during preparation is not attendant on especial hazards. The mixture is stable under current lab conditions. Down below data of the mixture are denoted.

Ingredients	Incompatible material	Hazardous decomposition product
Nitrocellulose	strong oxidants, strong acids and bases	in case of thermic decomposition: nitroses gas, carbon oxides
5-Bromo-5-Nitro-1,3-Dioxane	strong oxidant	In case of thermic decomposition carbon oxides, nitrogen oxides and bromide can occur.
Boric acid	strong oxidants and bases	unknown

10.2. Chemical stability

Under normal conditions of the environment, temperature and pressure all products are stable while they are stored or in use. The storage conditions of the whole preparation are remarked on the label. The preparation is stable within the expiration date which is denoted at the label.

10.3. Potential hazardous reactions

All the components of the preparation do not cause hazardous reactions at all, such as polymerisation.

10.4. Conditions to avoid

There is no dangerous reaction, but the product becomes unusable due to inappropriate conditions. Avoid heating over a temperature of 30 °C. Accordingly it does not provoke a hazardous reaction, however the product becomes defective.

Under normal conditions of the environment, temperature and pressure all components are stable till the expiration date has passed.

10.5. Incompatible materials

None of the components of the preparation reacts with other materials in that way, that a hazardous situation could arise.

10.6. Hazardous decomposition products

Under normal temperature and storage conditions the components of preparation do not form hazardous decomposition products.


SECTION 11. Toxicologic information

11.1. Information about toxicologic effects

The information about the toxicological effects applies to the ingredients of the preparation. The components of the preparation as a whole is categorised as non-hazardous, because the concentration of the ingredients are very low. The whole preparation, unless otherwise specified, is classified as non-toxic, non-corrosive, non-irritant, non-sensitizing, not carcinogen and not mutagenic.

Acute toxicity

Substance	Acute toxicity / species	concentration
5-Bromo-5-Nitro-1,3-Dioxane	LD ₅₀ oral (rat):	455 mg/kg
	LD ₅₀ oral (mouse):	590 mg/mg
Skin corrosion/irritation:	not expected.	

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Eye irritation:	not expected.
Respiratory or skin sensitization:	not expected.
Toxicity at repeated exposition:	not expected.
Genetic toxicity:	not expected.
Toxicity to reproduction:	not expected.
Teratogenicity:	not expected.
Carcinogenicity:	not expected.

Substance	Acute toxicity / species	concentration
Boric acid	LD ₅₀ oral (Rat): LD ₅₀ dermal (rabbit):	2660 mg/kg 2000 mg/kg
Skin corrosion/irritation:	Slightly irritating to the skin.	
Eye irritation:	Slightly irritating to the eye.	
Respiratory or skin sensitization:	not expected.	
Toxicity at repeated exposition:	not expected.	
Genetic toxicity:	not expected.	
Toxicity to reproduction:	Can affect fertility. May damage the unborn child.	
Teratogenicity:	Can affect fertility. May damage the unborn child.	
Carcinogenicity:	not expected.	

Carcinogenicity (relevant component: 5-Bromo-5-Nitro-1,3-Dioxane):

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.2

Danger of aspiration: No information available.

If swallowed, contact to skin or eye: No information available.

SECTION 12. Ecological information

12.1. Toxicity

Because of the low concentration an **aquatic toxicity is not to be expected**. Hazardous effects for long term are not to be expected. The mixture contains only substances in very low concentrations and is also available in small volumes (\leq 100 mL). Environmental toxicity is therefore not expected.

Acute toxicity of the row substances to aquatic organisms: no data available except of boric acid

Working substance	Endpoint	Value	Species	Source	Exposure time
Boric acid	EC50	133 mg/l	<i>Daphnia magna</i>	SDS Roth	48 h
Boric acid	LC50	50 mg/l	Rainbow trout (<i>Oncorhynchus mykiss</i>)	SDS Roth	96 h


Chronic toxicity of the row substances to aquatic organisms: no data available

Terrestrial environment: It is expected that the preparation is non-toxic to plants, animals and earth organisms. No long-term environmental effects known.

12.2. Persistence and degradability

Available information about persistence and degradability of the mixture.

Substance	Ecological details:
5-Bromo-5-Nitro-1,3-Dioxan	Not available. Concentration very low (\leq 0.05 %).
Sodium Chloride	Biological degradable.

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12.3. Potential of bioaccumulation

Agents that are hazardous to the environment occur just in a small concentration over the entire preparation. In case of a correct application and disposal there is no reason for potential bioaccumulation. For disposal remarks refer to section 13.

12.4. Mobility in the ground

There are no data available about the mobility in the ground.

12.5. Result of PBT- and vPvB-assessment

All substances used during the preparation are not listed in the PBT- data base. No data are available concerning the mobility in the ground.

12.6. Other adverse effects

Boric acid: slightly hazardous to water.

Potential of endocrine systems

Working substance	CAS-Nr.	Connected category	Category for human health	Category for the wildlife
Boric acid	10043-35-3	CAT1	CAT1	CAT2

Legend

CAT1 category 1 - Evidence of endocrine activity in at least one species with intact animals

CAT2 category 2 at least some in vitro evidence of biological activity related to endocrine effects

SECTION 13. Disposal considerations

13.1. Waste treatment methods

The disposal has to be done according to current regional, national and local laws and standards.

Relevant legal basic principles for disposal: see 16.2!

Waste production should be avoided or minimised as far as possible.

Excessive and not recyclable products are not allowed to be disposed by an accepted waste disposal company. The disposal of these products as well as solutions and coproducts has to be done at any time according to the environmental requirements, disposal laws and demand of the local administration.

The disposal must not take place in wastewater.

Especial measures of precaution related to the recommended solutions of waste management:

The disposal has to be done according to current regional, national and local laws and standards.

Disposal of the outer packaging: dispose according to current regional, national and local laws and standards.

SECTION 14. Transport remarks

14.1. UN-Number

ADR/RIS: - IMGD: - IATA: -

14.2. UN proper shipping name

ADR/RIS: no dangerous goods IMGD: no dangerous goods IATA: no dangerous goods

14.3. Transport hazard class

ADR/RIS: - IMGD: - IATA: -

14.4. Packing group


ADR/RIS: - IMGD: - IATA: -

14.5. Environmental hazards

ADR/RIS: no IMGD: Marine pollutant no IATA: no

14.6. Special precautions for user

See sections 6 – 8: none.

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14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

The delivery takes place exclusively in traffic law approved and suitable packaging.

Contamination category (X, Y or Z): not specified

Ship type (1, 2 or 3): not specified.

SECTION 15. Regulatory information

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

Safety, health and environmental regulations/legislation refer to national rules.

This material data sheet is prepared according to Regulation (EG) 2015/830, Regulation (EU) No. 1272/2008 (+ Subsequent ATPs) and REACH Regulation 1907/2006 EC (+ Subsequent Regulations).

Acute toxicity (ATE) of the mixtures are calculated according to Regulation (EG) 1272/2008, Annex I.

According to EG 1272/2008, Annex I the mixtures are not classified as water polluting substances.

15.2. Chemical safety assessment

For the product which was mentioned in chapter 1 no safety estimation was prepared.

SECTION 16. Other information

16.1 History of modifications

Volume 1: 1. Revision on 28.05.2020.

16.2 References and data source:

REACH-Regulation (EG) Nr. 1907/2006

CLP-Regulation (EG) Nr. 1272/2008

Internet:

<http://www.baua.de>

<http://publikationen.dguv.de>

<http://gestis.itrust.de>

<http://logkow.cisti.nrc.ca>

<http://www.gischem.de>

<http://echa.europa.eu/en/candidate-list-table>

<http://echa.europa.eu/de/information-on-chemicals/registered-substances>

<http://www.chemicalbook.com/>

<http://www.reach-clp-biozid-helpdesk.de/de/REACH/Zulassung-Beschaerung/Beschaerung/Anhang-XVII/Anhang17.html>

PBT- Database: <http://ecb.jrc.ec.europa.eu/esis/index.php?PGM=pbt>

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Ärztchammer Niedersachsen, authors: Dr. H.-Bernhard Behrends, H. Cremer, Dr. Claus Rink. Web page:

[http://www.aekn.de/web_aekn/home.nsf/ContentView/1E8914148D4E37BFC1256FB70036DAF7/\\$File/arbeitsmaterialien.pdf](http://www.aekn.de/web_aekn/home.nsf/ContentView/1E8914148D4E37BFC1256FB70036DAF7/$File/arbeitsmaterialien.pdf)

16.3 Hazard- and Precautionary rules

The list explains the meaning of the H rules that are given in chapter 2 and 3. The H rules are valid for the ingredients as a pure substance not for the preparation.

List H rules	Meaning
H201	Explosive, danger of mass explosion.
H302	Harmful if swallowed.
H315	Causes skin irritation.

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H360

May damage fertility or harm the unborn child.

The list explains the meaning of the P rules that are given in chapter 3.1. The P rules are valid for the ingredients as a pure substance not for the preparation.

List P rules	Meaning
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P280	Wear protective gloves / protective clothing / eye protection / face protection.
P250-372	Do not grind / bump / rub / risk of explosion.
P201	Obtain special instructions before use.
P202	Read and understand all safety instructions before use.
P308-313	If exposed or concerned: Get medical advice / attention.
P405	Keep locked up.
P501	Dispose of contents / container for disposal in accordance with local regulations.

16.4 Abbreviations

Abbreviations	Meaning
IARC	International Agency for Research on Cancer
ACGIH	American Conference of Governmental Industrial Hygienists
OSHA	Occupational Safety & Health Administration
PBT	persistent, bio accumulative and toxic substances
vPvB	very persistent and very bio accumulative substances
CAS	Chemical Abstracts Service registration number
EC/EG/EWG	Europäische Gemeinschaft
g	Gramm
h	Hour
kg	Kilogramm
LD ₅₀ , LC ₅₀	midl letale dosis of the agent for 50 % of the observed population
EC ₅₀	half maximal effective concentration (dosis/concentration which induces a response halfway between the baseline and maximum after a specified exposure time)
IC ₅₀	half maximal inhibitory concentration
NOEC	no observed effect level
m ³	Kubikmeter
MAK	Maximale Arbeitsplatzkonzentration
mg	Milligramm
mL	Milliliter
%	Percent (part of 100)

16.5 Method which was used to evaluate hazard information for the mixtures

Hazard information's are evaluated according to Regulation (EG) 2015/830 Regulation (EU) No. 1272/2008 (+ Subsequent ATPs) and REACH Regulation 1907/2006 EC (+ Subsequent Regulations).

Method used according to Article 9 of Regulation (EG) No. 1272/2008 for Assessment of Information for Classification of the mixtures: Calculation methods

16.6 Further information's

The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. The information does not constitute an assurance of product properties and does not establish any contractual legal relationship.