



Safety Data Sheet

According to the regulatory (CE) n° 1907/2006 [REACH] and (CE) n° 1272/2008 [CLP]

Revision date: 25/08/2021 Version: 2.6

SECTION 1: Identification of the substance/mixture and the supplier/manufacturer

1.1. Product identifier

Trade name/designation: TOXOPLASMA ICT IgG IgM
 Product No.: TOXO Ab ICT20
 TOXO Ab ICT100

1.2. Composition/information on components

The product is a multi-component IVD kit (see Instructions for Use of the kit) which does not contain any toxic component except the eluent.

Reagent R2-ELUTANT, is a mixture of hazardous components whose classification according to Regulation (EC) No. 1272/2008 can be obtained in section 3. Section 2 "Labelling Elements" contains the resulting labelling for the eluent vial and the kit.

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

Recommended Use: In Vitro Diagnostic – for professional users only

1.4. Details of the supplier of the safety data sheet

Supplier

LDBIO DIAGNOSTICS
 19 A rue Louis Loucheur
 69009 Lyon, France
 Phone number: +33 4 78 83 34 87
 Fax number: +33 4 78 83 34 30
 Email: contact@ldbiodiag.com
 Web site: www.ldbiodiagnostics.com

Manufacturer

LDBIO DIAGNOSTICS
 19 A rue Louis Loucheur
 69009 Lyon, France
 Phone number: +33 4 78 83 34 87
 Fax number: +33 4 78 83 34 30
 Email: contact@ldbiodiag.com
 Web site: www.ldbiodiagnostics.com

Emergency telephone

Telephone: 112 (emergency service) - 999 or Call a POISON CENTRE or doctor/physician

SECTION 2: Hazards identification

2.1 substance or mixture identifier

Trade name/designation:	R2-ELUENT from the Toxoplasma ICT IgG IgM kit
Product No.:	not applicable
EC identification No:	not applicable
REACH identification No:	not applicable
CAS No:	not applicable
Other means of identification:	no data available

2.2 Classification of the substance or mixture

2.2.1 GHS Classification in accordance with (CE) N° 1272/2008 [CLP]

Hazard classes and hazard categories	Code
Skin sensitization (Category 1)	H317

2.3 Label elements

2.3.1 Labelling in accordance with (CE) N° 1272/2008 [CLP]

- Hazard pictograms



- Signal word:
Warning

- Hazard statements

Code	Hazard statements
H317	May cause an allergic skin reaction

- **Precautionary statements**

Code	Prevention
P261	Avoid breathing spray
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves and protective clothing
	Intervention
P302+P352 P333+P313 P363	IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention Wash contaminated clothing before reuse
	Disposal
P501	Dispose of contents and container in accordance with relevant regulations

- **Hazards not otherwise classified (HNOC)**
none
- **Annotation on the IFU:**
EUH 210 Material Safety Data Sheet available on request

Note: Because of the small size of the vial, ≤125ml, and in accordance with EC Regulation N° 1272/2008 [CLP], statements only appear on the IFU.

SECTION 3: Composition / information on ingredients

3.1 Substances

Nanoforms: no data available

3.2 Mixtures

Hazardous ingredients Classification according to (CE) N° 1272/2008 [CLP]

Substance name	Substance identifier	Hazard classes and hazard categories of the substance		Hazard classes and hazard categories of the mixture (eluent)
Maleic acid	n°CAS: 110-16-7 N°CE: 204-709-8 N° REACH: not available	Acute Tox. Oral 4 H302 Eye Irrit. 2 H319 STOT SE 3 H335 Skin Irrit. 2 H315	<1%	H317

SECTION 4: First aid measures

4.1 General information

IF exposed or if you feel unwell: Call a POISON CENTER or doctor/physician. If unconscious place in recovery position and seek medical advice. Never give anything by mouth to an unconscious person or a person with cramps. Change contaminated, saturated clothing. Do not leave affected person unattended.

After inhalation

Call a POISON CENTER/doctor. Remove casualty to fresh air and keep warm and at rest. If breathing is irregular or stopped, administer artificial respiration.

In case of skin contact

After contact with skin, wash immediately with plenty of water and soap. Remove contaminated, saturated clothing immediately. In case of skin reactions, consult a physician.

After eye contact

In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist. Protect uninjured eye. Remove contact lenses, if present and easy to do. Continue rinsing.

In case of ingestion

If accidentally swallowed rinse the mouth with plenty of water (only if the person is conscious) and obtain immediate medical attention. Do NOT induce vomiting. Give nothing to eat or drink.

4.2 Most important symptoms/effects, acute and delayed

no data available

4.3 Indication of any immediate medical attention and special treatment needed

No data available

4.4 Self-protection of the first aider

First aider: Pay attention to self-protection!

4.5 Information to physician

No data available

SECTION 5: Firefighting measures**5.1 Extinguishing media****Suitable extinguishing media**

The product itself is not flammable.

Co-ordinate fire-fighting measures to the fire surroundings.

Extinguishing media which must not be used for safety reasons

no restriction

5.2 Specific hazards arising from the chemical

In case of fire may be liberated:

Pyrolysis products, toxic

5.3 Advice for firefighters

Protective equipment and precautions for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing if necessary.

Additional information

Standard procedure for chemical fires: Use extinguishing media appropriate to local conditions and the surrounding environment.

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

In case of major fire and large quantities: Remove persons to safety.

6.2 Environmental precautions

Discharge into the environment must be avoided.

6.3 Methods and material for containment and cleaning up

Spilled product must never be returned to the original container for recycling. Collect in closed and suitable containers for disposal.

6.4 Additional information

Clear spills immediately.

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

All work processes must always be designed so that the following is as low as possible: Inhalation, ingestion, skin contact, eye contact. Do not eat, drink or smoke in the work area. Handle in accordance with good laboratory practice.

7.2 Conditions for safe storage, including any incompatibilities

Recommended storage temperature: see operating instructions and labels.

Storage class: no data available.

7.3 Specific end use(s)

In vitro diagnostics. For professional users only

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Does not contain substances with professional exposure limit values

8.2 Engineering controls

Appropriate engineering controls

Technical measures and the application of suitable work processes have priority over personal protection equipment. If handled uncovered, arrangements with local exhaust ventilation have to be used.

Personal protection equipment (PPE)

Wear suitable protective clothing. When handling with chemical substances, CE approved protective clothing must be worn.

Eye/face protection

Eye glasses with side protection (norms DIN/EN: DIN EN 166)

Skin protection

Wear suitable gloves. When handling with chemical substances, CE approved protective gloves must be worn (norms DIN/EN: EN ISO 374). In the case of wanting to use the gloves again, clean them before taking off and air them well. Check leak tightness/impermeability prior to use.

Respiratory protection

Respiratory protection necessary at: aerosol or mist formation If exposure limits are exceeded or irritation is experienced, CE approved respiratory protection should be worn (norms NF EN 136/140).

Additional information

Wash hands before breaks and after work. Avoid contact with skin and eyes. When using do not eat, drink or smoke. Provide eye shower and label its location conspicuously.

Environmental exposure controls

No data available

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- | | |
|----------------------|-------------------|
| (a) Appearance | |
| Physical state: | liquid |
| Color: | colourless |
| (b) Odour: | no data available |
| (c) Odour threshold: | no data available |

Safety relevant basic data

- | | |
|--|-------------------|
| (d) pH: | no data available |
| (e) Melting point/freezing point: | no data available |
| (f) Initial boiling point and boiling range: | no data available |
| (g) Flash point: | no data available |
| (h) Evaporation rate: | no data available |
| (i) Flammability (solid, gas): | not applicable |
| (j) Flammability or explosive limits | |
| Lower explosion limit: | no data available |
| Upper explosion limit: | no data available |
| (k) Vapour pressure: | no data available |
| (l) Vapour density: | no data available |
| (m) Relative density: | no data available |
| (n) Solubility(ies) | |
| Water solubility (g/L): | no data available |

Soluble (g/L) in Ethanol:	no data available
(o) Partition coefficient: n-octanol/water:	no data available
(p) Auto-ignition temperature:	no data available
(q) Decomposition temperature:	no data available
(r) Viscosity	
Kinematic viscosity:	no data available
Dynamic viscosity:	no data available
(s) Explosive properties:	not applicable
(t) Oxidising properties:	not applicable

9.2 Other information

Bulk density:	not applicable
Refraction index:	no data available
Dissociation constant:	no data available
Surface tension:	no data available
Henry constant:	no data available
Explosive substances and mixtures:	no data available
Flammable gases:	no data available
Minimum flammable gas content:	no data available
Basic Burning Rate:	no data available
Aerosols:	no data available
Oxidizing gases:	no data available
Gases under pressure:	no data available
Flammable liquids:	no data available
Flammable solids:	no data available
Self-reactive substances and mixtures:	no data available
Pyrophoric liquids:	no data available
Pyrophoric solids:	no data available
Self-heating substances and mixtures:	no data available
Substances and mixtures which evolve flammable gases in contact with water:	no data available
Oxidizing liquids:	no data available
Oxidizing solids:	no data available
Organic peroxides:	no data available
Substances or mixtures corrosive to metals:	no data available
Desensitized explosives:	no data available
Mechanical sensitivity:	no data available
Accelerated polymerization temperature:	no data available
Formation of explosive dust/air mixtures:	no data available
Acid/alkali reserve:	no data available
Evaporation rate:	no data available
Miscibility:	no data available
Conductivity:	no data available
Corrosivity:	no data available
Gas group:	no data available
Redox potential:	no data available
Free radical potential:	no data available
Photocatalytic properties:	no data available

SECTION 10: Stability and reactivity

10.1 Reactivity

no data available

10.2 Chemical stability

The product is chemically stable under standard ambient conditions (room temperature).

Identified desensitized explosives: not applicable

10.3 Possibility of hazardous reactions

no data available

10.4 Conditions to avoid

no data available

10.5 Incompatible materials

no data available

10.6 Hazardous decomposition products

In case of fire, risk of release of toxic pyrolysis products

10.7 Additional information

no data available

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute effects

Acute oral toxicity:

Not classified on the basis of available information

Acute dermal toxicity:

Not classified on the basis of available information

Acute inhalation toxicity:

Not classified on the basis of available information

Irritant and corrosive effects

irritation to the skin:

Not classified on the basis of available information

Irritation to eyes:

Not classified on the basis of available information

Irritation to respiratory tract:

Not classified on the basis of available information

Respiratory or skin sensitization

The eluent contains Maleic acid (<1%). May produce an allergic reaction.

STOT-single exposure

Not classified on the basis of available information

STOT-repeated exposure

Not classified on the basis of available information

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

Carcinogenicity

Not classified on the basis of available information

Germ cell mutagenicity

Not classified on the basis of available information

Reproductive toxicity

Not classified on the basis of available information

Aspiration hazard

Not classified on the basis of available information

Properties that disrupt endocrine system

No data available

Other adverse effects

No data available

Additional information

No data available

SECTION 12: Ecological information

12.1 Ecotoxicity

Fish toxicity:

Not classified on the basis of available information

Daphnia toxicity:

Not classified on the basis of available information

Algae toxicity:

Not classified on the basis of available information

Bacteria toxicity:

Not classified on the basis of available information

12.2 Persistence and degradability

Not classified on the basis of available information

12.3 Bioaccumulative potential

Not classified on the basis of available information

12.4 Mobility in soil:

Not classified on the basis of available information

12.5 Results of PBT/vPvB assessment

Not classified on the basis of available information

12.6 Properties that disrupt endocrine system

No data available

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Appropriate disposal / Product

Dispose according to legislation. Consult the appropriate local waste disposal expert about waste disposal.

Waste code product:

No data available

Appropriate disposal / Package

Dispose according to legislation. Handle contaminated packages in the same way as the substance itself.

Additional information

No data available

SECTION 14: Transport information

Land transport (ADR/RID)

No dangerous good in sense of this transport regulation.

Sea transport (IMDG)

No dangerous good in sense of this transport regulation.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not relevant

Air transport (ICAO-TI / IATA-DGR)

No dangerous good in sense of this transport regulation.

SECTION 15: Regulatory information

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

- Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC
- 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
- Commission Regulation (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
- Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

National Regulations

No data available

Information on national legislations :

Social Security Code Art. L 461-6, Art. D.461-1, Annex A, No. 601

Professional diseases Applicable table(s)

Not applicable

Water hazard class (WGK) :

No data available

SECTION 16: Other information

Abbreviations and acronyms

IVD – In Vitro Diagnostic

INRS - The National Research and Safety Institute for the Prevention of Occupational Accidents and Diseases

VLE - Exposure limit value

VME - Average exposure value

ACGIH - American Conference of Governmental Industrial Hygienists

ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road AGS - Committee on Hazardous Substances (Ausschuss für Gefahrstoffe)

CLP - Regulation on Classification, Labelling and Packaging of Substances and Mixtures DFG - German Research Foundation (Deutsche Forschungsgemeinschaft)

Gestis - Information system on hazardous substances of the German Social Accident Insurance (Gefahrstoffinformationssystem der Deutschen Gesetzlichen Unfallversicherung)

IATA-DGR - International Air Transport Association-Dangerous Goods Regulations ICAO-TI - International Civil Aviation Organization-Technical Instructions

IMDG - International Maritime Code for Dangerous Goods LTV - Long Term Value

NIOSH - National Institute for Occupational Safety and Health OSHA - Occupational Safety & Health Administration

PBT - Persistent, Bioaccumulative and Toxic

RID - Regulation concerning the International Carriage of Dangerous Goods by Rail STV - Short Term Value

SVHC - Substances of Very High Concern vPvB - very Persistent, very Bioaccumulative

Additional information

Indication of changes: 25/08/2021 sections 2, 3, 9, 11, 12

General update: 01/10/2020

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guidance. The information in this document is based on the present state knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the

properties of the product. LDBIO DIAGNOSTICS shall not be held liable for any damage resulting from handling.