

# Safety Data Sheet

According to Regulation (EU) No. 1907/2006 (REACH)

Product Name: ISOFLUX

Version: 03

Date: March 20, 2024



## Section 1. Identification of the substance/mixture and of the company/undertaking

### 1.1. Product Identifier

Product Name: ISOFLUX

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

#### Relevant identified use

Isoflux is a laboratory reagent for in-vitro diagnostics for human and veterinary use as well

#### Uses advised against

No further relevant information available.

### 1.3. Details of the supplier of the safety data sheet

Dialab Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H  
Hondastrasse, Objekt M55, IZ-NOE Sued, 2351 Wr. Neudorf, Austria

Phone / e-mail: +43 2236 660 910 0 / [office@dialab.at](mailto:office@dialab.at)

#### **Responsible person:**

[safety@dialab.at](mailto:safety@dialab.at)

### 1.4. Emergency telephone number

+43 1 406 43 43 (Gesundheit Österreich GmbH, 24 h)

## Section 2. Hazards identification

### 2.1. Classification of the substance or mixture

#### **Regulation (EC) 1272/2008 (CLP):**

The product is not classified, according to the C.L.P. regulation.

### 2.2. Label elements

#### **Regulation (EC) 1272/2008 (CLP):**

#### **Pictogram(s) and signal words:**

Not classified as hazardous

#### **Hazard-determining components of labelling:**

Not classified as hazardous

#### **Hazard statements:**

Not classified as hazardous

### 2.3. Other hazards

The mixture shall not contain substances listed in accordance with Article 59(1) R.E.A.C.H as having endocrine disrupting properties, or be recognised 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 in a concentration equal to or greater than 0.1%.

#### **· Results of PBT and vPvB assessment**

· PBT: Not applicable.

· vPvB: Not applicable.

· **Determination of endocrine-disrupting properties** No further information available

## Section 3. Composition / information on ingredients

### 3.1. Substances

This product is a mixture.

### 3.2. Mixtures

# Safety Data Sheet

According to Regulation (EU) No. 1907/2006 (REACH)

Product Name: ISOFLUX

Version: 03

Date: March 20, 2024

## Composition/information on ingredients:

**Description:** Preparation: composed of the substances listed below.

**Dangerous components:** Not classified as hazardous

**SVHC** Not applicable

**Additional information:** For the wording of the listed risk phrases, refer to section 16.

## Section 4. First aid measures

### 4.1. Description of first aid measures

**General notes:**

No special measures required.

**Following inhalation:**

Provide fresh air; consult a doctor in case of medical complaints.

**Following skin contact:**

Generally, the product does not irritate the skin.

**Following eye contact:**

Rinse opened eye for several minutes under running water.

**Following ingestion:**

Do not induce vomiting; call for medical help immediately.

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

No further relevant information is available.

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

No further relevant information is available.

## Section 5. Firefighting measures

### 5.1. Extinguishing media

**Suitable extinguishing media:**

Use fire extinguishing methods suitable to surrounding conditions.

**Unsuitable extinguishing media:**

No further relevant information available.

### 5.2. Special hazards arising from the substance or mixture

No further relevant information available.

### 5.3. Advice for firefighters

Protective equipment: No special measures required.

## Section 6. Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

**For non-emergency personnel:**

No other relevant information available.

**For emergency responders:**

No other relevant information available.

### 6.2. Environmental precautions

Do not allow product to reach sewage system or any water course.

# Safety Data Sheet

According to Regulation (EU) No. 1907/2006 (REACH)

Product Name: ISOFLUX

Version: 03

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Inform respective authorities in case of seepage into water course or sewage system. Dilute with plenty of water. Do not allow the product to enter sewers/ surface water or ground water.

## 6.3. Methods and material for containment and cleaning up

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

## 6.4. Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protective equipment.

See Section 13 for disposal information.

## Section 7. Handling and storage

### 7.1. Precautions for safe handling

No special measures required.

**Information about fire - and explosion protection:** No special measures required.

### 7.2. Conditions for safe storage, including any incompatibilities

**Storage:**

**Requirements to be met by storerooms and receptacles:** No special requirements.

**Information about storage in one common storage facility:** Not required.

**Further information about storage conditions:** Protect from frost.

### 7.3. Specific end use(s):

No further relevant information available.

## Section 8. Exposure controls/personal protection

### 8.1. Control parameters

Ingredients with limit values that require monitoring at the workplace:

The product does not contain any significant quantities of materials with critical values that have to be monitored at the workplace.

Additional information:

The most current valid lists have been used as a basis for the production of this document.

### 8.2. Exposure controls

#### **Appropriate engineering controls**

No further data; see section 7.

#### **Individual protection measures, such as personal protective equipment**

##### **General protective and hygienic measures:**

Wash hands before breaks and at the end of work.

The usual precautionary measures are to be adhered to when handling chemicals.

**Respiratory protection:** No special measures required.

**Hand protection:** No special measures required.

**Gloves material:** Not applicable

**Eye/face protection:** Goggles recommended during refilling

#### **Environmental exposure controls**

Not applicable.

## Section 9. Physical and chemical properties

### 9.1. Information on basic physical and chemical properties:

Parameter	Value / test method / remarks
Physical State	Liquid
Colour	Colourless
Odour	Odourless
Odour threshold	Not determined.

# Safety Data Sheet

According to Regulation (EU) No. 1907/2006 (REACH)

Product Name: ISOFLUX

Version: 03

Date: March 20, 2024

Melting point / freezing point	0 °C
Boiling point or initial boiling point and boiling range	100 °C (CAS: 7732-18-5 water, distilled, conductivity or of similar purity)
Flammability	Not applicable.
Lower and upper explosion limit	Not applicable.
Flash point	Not applicable.
Auto-ignition temperature	Not applicable.
Decomposition temperature	Not applicable.
pH at 20 °C	6.9+/-10%
Kinematic viscosity	Not determined.
Dynamic at 20 °C	0.952 mPas
Solubility in water / in other solvents	Fully miscible.
Partition coefficient n-octanol/water (log value)	Not determined.
Vapour pressure at 20 °C	23 hPa (CAS: 7732-18-5 water, distilled, conductivity or of similar purity)
Density and/or relative density	Not determined.
Relative vapour density	Not determined.
Particle characteristics	Not determined.

## 9.2. Other information

Osmolarity : 350 +/-10%

**Important information on protection of health and environment, and on safety.**

**Ignition temperature:** Product is not self igniting.

**Explosive properties:** Product does not present an explosion hazard.

**Solvent content:**

**COV (USA) :** 0.00 %

**COV (CH) :** 0.00 %

**Change in condition**

**Evaporation rate:** Not determined.

**Information with regard to physical hazard classes:**

**Explosives:** Not classified as hazardous

**Flammable gases:** Not classified as hazardous

**Aerosols:** Not classified as hazardous

**Oxidising gases:** Not classified as hazardous

**Gases under pressure:** Not classified as hazardous

**Flammable liquids:** Not classified as hazardous

**Flammable solids:** Not classified as hazardous

**Self-reactive substances and mixtures:** Not classified as hazardous

**Pyrophoric liquids:** Not classified as hazardous

**Pyrophoric solids:** Not classified as hazardous

**Self-heating substances and mixtures:** Not classified as hazardous

**Substances and mixtures, which emit flammable gases in contact with water:** Not classified as hazardous

**Oxidising liquids:** Not classified as hazardous

**Oxidising solids:** Not classified as hazardous

**Organic peroxides:** Not classified as hazardous

**Corrosive to metals:** Not classified as hazardous

**Desensitised explosives:** Not classified as hazardous

**Other safety characteristics:**

Not determined.

## Section 10. Stability and reactivity

### 10.1. Reactivity

No further relevant information available.

### 10.2. Chemical stability

# Safety Data Sheet

According to Regulation (EU) No. 1907/2006 (REACH)

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**Thermal decomposition / conditions to be avoided:**

No decomposition if used according to specifications.

## 10.3. Possibility of hazardous reactions

No dangerous reactions known.

## 10.4. Conditions to avoid

No further relevant information available.

## 10.5. Incompatible materials

No further relevant information available.

## 10.6. Hazardous decomposition products

No dangerous decomposition products known.

## Section 11. Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

**Acute toxicity:** Based on available data, the classification criteria are not met.

**On the skin:** Based on available data, the classification criteria are not met.

**On the eyes:** Based on available data, the classification criteria are not met.

**Respiratory or skin sensitization:** Based on available data, the classification criteria are not met.

**Germ cell mutagenicity:** Based on available data, the classification criteria are not met.

**Carcinogenicity:** Based on available data, the classification criteria are not met.

**Reproductive toxicity:** Based on available data, the classification criteria are not met.

**STOT-single exposure:** Based on available data, the classification criteria are not met.

**STOT-repeated exposure:** Based on available data, the classification criteria are not met.

**Aspiration hazard:** Based on available data, the classification criteria are not met.

### 11.2. Information on other hazards

**Endocrine disrupting properties**

None of the ingredients is listed.

## Section 12. Ecological information

### 12.1. Toxicity

**Aquatic toxicity:** No further relevant information available.

### 12.2. Persistence and degradability

No further relevant information available.

### 12.3. Bioaccumulative potential

No further relevant information available.

### 12.4. Mobility in soil

No further relevant information available.

### 12.5. Results of PBT and vPvB assessment

**PBT:** Not applicable.

**vPvB:** Not applicable.

### 12.6. Endocrine disrupting properties

For information on endocrine disrupting properties see section 11.

### 12.7. Other adverse effects

No further relevant information available.

# Safety Data Sheet

According to Regulation (EU) No. 1907/2006 (REACH)

Product Name: ISOFLUX

Version: 03

Date: March 20, 2024



## Additional ecological information:

### General notes:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

## Section 13. Disposal considerations

### 13.1. Waste treatment methods

**Recommendation** : Smaller quantities can be disposed of with household waste.

#### Information regarding the disposal of the product:

No further relevant information available.

#### Information regarding the disposal of the packaging:

No further relevant information available.

#### Physical/chemical properties that may affect waste treatment options shall be specified:

Water, if necessary together with cleansing agents.

#### Sewage disposal:

No further relevant information available.

#### Special precautions for any recommended waste treatment:

Disposal must be made according to official regulations.

## Section 14. Transport information

### 14.1. UN number or ID number

DOT, ADR, IMDG, IATA none

### 14.2. UN proper shipping name

ADR, IMDG, IATA none

### 14.3. Transport hazard class(es)

ADR, ADN, IMDG, IATA

Class none

### 14.4. Packing group

ADR, IMDG, IATA none

### 14.5. Environmental hazards

Not applicable.

### 14.6. Special precautions for user

Not applicable.

### 14.7. Maritime transport in bulk according to IMO instruments

Not applicable.

UN "Model Regulation": none

## Section 15. Regulatory information

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

Poisons Act

Regulated explosives precursors

# Safety Data Sheet

According to Regulation (EU) No. 1907/2006 (REACH)

Product Name: ISOFLUX

Version: 03

Date: March 20, 2024

None of the ingredients is listed.

## Regulated poisons

None of the ingredients is listed.

## Reportable explosives\_precursors

None of the ingredients is listed.

## Reportable poisons

CAS: 7681-49-4 sodium fluoride: Listed

## Directive 2012/18/EU

**Named dangerous substances - ANNEX I** None of the ingredients is listed.

**DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**

None of the ingredients is listed.

## REGULATION (EU) 2019/1148

**Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**

None of the ingredients is listed.

## Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

## Regulation (EC) No 273/2004 on drug precursors

None of the ingredients is listed.

**Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**

None of the ingredients is listed.

## 15.2. Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

## Section 16. Other information

### Reason of Change:

Classification in accordance with Delegated Regulation (EU) 2022/692 of 16 February 2022 adapting to technical and scientific progress GB CLP for the 18th time and amending table 3 of Annex VI part 3 of Regulation (EC) 1272/2008.

Classification in accordance with Delegated Regulation (EU) 2023/1434 of 25 April 2023 adapting to technical and scientific progress for the 19th time GB CLP and amending Annex VI part 1, section 1.1.3 of Regulation (EC) 1272/2008.

Classification in accordance with Delegated Regulation (EU) 2023/1435 of 2 May 2023 adapting to technical and scientific progress for the 20th time GB CLP and amending Annex VI part 3 of Regulation (EC) 1272/2008.

This Safety Data Sheet is in compliance with Regulation (EC) No 1907/2006, Article 31 as amended by Regulation (EU) 2020/878.

### Hazard statements mentioned in Sections 2 and 3:

#### Directive (EC) 127/2008:

Not applicable.

Dialab GmbH provides the information in this data sheet in good faith, declaring it is up to date at time of revision. However, this document is intended only as a guide for professional use, according to the intended purposes of the product. It does not represent a guarantee for the properties of the product described in terms of the legal warranty regulations.

### Version number of previous version: 2

#### Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods DOT:

US Department of Transportation

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances ELINCS:

European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

# Safety Data Sheet

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VOCV: Lenkungsabgabe auf flüchtigen organischen Verbindungen, Schweiz (Swiss Ordinance on volatile organic compounds) VOC:

Volatile Organic Compounds (USA, EU)

PBT: Persistent, Bioaccumulative and Toxic