

# Material Safety Data Sheet (MSDS)

## Summary Material Safety Data Sheet (MSDS)

Product: MAST ISOPLEX *Malaria PfPv*

Art.-No.: 67MALA2

Basic UDI-DI: 42507297MalariaPfPvT7

UDI-DI: 4250729702501

**Hersteller**

Mast Diagnostica GmbH  
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# Product components

The following components are part of the kit:

<b>Component</b>	<b>Description</b>	<b>Page</b>
MAST ISOPLEX controls	50 / 250 µL control, lyophilized, to be reconstituted before use	3-16
MAST ISOPLEX Lyo Pellet	8 pellets for 10 reactions each, lyophilized, to be reconstituted before use	17-30
MAST ISOPLEX reconstitution buffer	1.1. mL reconstitution buffer	31-44

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

### 1.1 Product identifier

**Trade name/designation** MAST ISOPLEX controls

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

#### Relevant identified uses

##### remark

The product is intended for professional use.

##### Sector of uses [SU]

SU20 Health services

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

#### Manufacturer

Mast Diagnostica GmbH

Feldstraße 20

Deutschland-23858 Reinfeld

Telephone: +49 4533 20 07 00

Telefax: +49 4533 2007 68

E-mail: mast@mast-diagnostica.de

www.mast-group.com

### 1.4 Emergency telephone number

Only available during office hours.

## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture

#### Additional information

This mixture does not contain any substances presenting a health or environmental hazard within the means of Regulation (EC) No. 1272/2008, assigned a Community workplace exposure limit, classified as PBT/vPvB or included in the Candidate List.

#### Classification according to Regulation (EC) No 1272/2008 [CLP]

##### health hazards

###### hazard statements for health hazards

none

##### Physical hazards

###### hazard statements for physical hazards

none

##### Environmental hazards

none

##### Additional hazards

none

##### Specific concentration limit (SCL)

###### Hazard classes and hazard categories

none

### 2.2 Label elements

#### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

##### Signal word

none

##### Hazard statements

###### Hazard statements for physical hazards

none

## **hazard statements for health hazards**

none

## **Hazard statements for environmental hazards**

none

## **Hazard statements for additional hazards**

none

## **Precautionary statements**

### **General:**

none

### **Prevention**

none

### **Response:**

none

### **Storage:**

none

### **Disposal:**

none

## **Supplemental hazard information**

### **Physical properties**

none

### **health hazard properties**

none

### **Environmental properties**

none

## **Other labelling**

### **Standard phrases for special risks for humans or the environment**

none

### **Labelling for contents according to regulation (EC) No. 648/2004**

none

### **Standard phrases for safety precautions for the protection of humans or the environment**

#### **General provisions**

none

#### **Safety precautions for operators (SPo)**

none

#### **Safety precautions related to the environment (SPe)**

none

#### **Safety precautions related to good agricultural practice (SPa)**

none

#### **Specific safety precautions for rodenticides (SPr)**

none

### **Standard phrases for special risks for humans or the environment**

#### **Special risks related to humans (RSh):**

none

#### **Special risks related to the environment (RSe):**

none

## 2.3 Other hazards

### Adverse environmental effects

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

### Adverse human health effects and symptoms

This product does not contain a substance that has endocrine disrupting properties with respect to humans as no components meets the criteria.

### Adverse physicochemical effects

none

### Other adverse effects

none

### Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

## SECTION 3: Composition / information on ingredients

### 3.1/3.2 Substances/Mixtures

No data available

### Hazardous ingredients

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

#### General information

No special First Aid measures are required.

#### Following skin contact

Remove mechanically (e.g. dab away using wadding or cellulose material) then thoroughly wash the affected skin with a mild cleansing agent and water.

#### After eye contact

Rinse immediately carefully and thoroughly with eye-bath or water.

#### Following ingestion

Rinse mouth thoroughly with water.

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

#### Effects

none

#### Symptoms

none

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

#### Notes for the doctor

none

#### Special treatment

none

## SECTION 5: Firefighting measures

### Additional information

The product itself does not burn. Co-ordinate fire-fighting measures to the fire surroundings.

### 5.1 Extinguishing media

#### Suitable extinguishing media

Water

Foam

Sand

Carbon dioxide (CO<sub>2</sub>)

Extinguishing powder

#### **Unsuitable extinguishing media**

none

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

##### **Hazardous combustion products**

none

#### **5.3 Advice for firefighters**

##### **Special protective equipment for firefighters**

No special equipment or techniques are required.

### **SECTION 6: Accidental release measures**

#### **Additional information**

Absorb and remove liquid with absorbent material. Clean the affected surface with standard cleaning agents.

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

##### **For non-emergency personnel**

###### **Personal precautions**

none

###### **Protective equipment**

none

##### **For emergency responders**

###### **Personal protection equipment**

none

#### **6.2 Environmental precautions**

none

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

##### **For containment**

###### **Suitable material for taking up**

Commercially available materials are sufficient.

##### **For cleaning up**

###### **Suitable material for diluting or neutralizing**

Water

#### **6.4 Reference to other sections**

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

### **SECTION 7: Handling and storage**

#### **7.1 Precautions for safe handling**

##### **Advices on general occupational hygiene**

Provide eye shower and label its location conspicuously

##### **Protective measures**

##### **Advices on safe handling**

No special technical protective measures are necessary.

##### **Measures to prevent fire**

No special fire protection measures are necessary.

##### **Environmental precautions**

No special technical protective measures are necessary.



## 7.2 Conditions for safe storage, including any incompatibilities

### Technical measures and storage conditions

Storage conditions are listed on the labels. Additional information concerning the storage are given in the instructions for use.

### Hints on joint storage

### Materials to avoid

none

### Further information on storage conditions

Protect against:

UV-radiation/sunlight

Temperatures outside the listed range.

### storage temperature

Value  $\geq 2 - \leq 8$  °C

## 7.3 Specific end use(s)

### Recommendation

Observe instructions for use.

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### remark

To date, no national critical limit values exist.

### 8.2 Exposure controls

#### Appropriate engineering controls

#### remark

See section 7. No additional measures necessary.

#### Personal protection equipment

##### Eye/face protection

##### Suitable eye protection

Eye glasses

Eye glasses with side protection

##### Skin protection

##### Suitable gloves type

Disposable gloves

##### Suitable material

NBR (Nitrile rubber)

##### Body protection

##### Suitable protective clothing

lab coat

##### Respiratory protection

none

#### Environmental exposure controls

#### remark

See section 7. No additional measures necessary.

#### Consumer exposure controls

#### Measures related to consumer uses of the substance (as such or in preparations).

not relevant

#### Measures related to the service life of the substance in articles

not relevant

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

#### Appearance

#### Physical state

solid

#### Colour

colourless

#### Odour

odourless

#### Odour threshold

not relevant

parameter	Method - source - remark
Melting point/freezing point	No data available
Boiling point or initial boiling point and boiling range	No data available
flammability	not relevant
Upper explosion limit	not relevant
lower explosion limit	not relevant
Flash point (°C)	not relevant
Auto-ignition temperature	not relevant
Decomposition temperature	not relevant
pH	No data available
Kinematic viscosity	No data available
Water solubility	No data available
Soluble (g/L) in	not relevant
Fat solubility	No data available
Partition coefficient: n-octanol/water	No data available
Vapour pressure	No data available
Density and/or relative density	No data available
Relative vapour density	No data available
particle characteristics	not relevant
Dynamic viscosity	No data available
flow time	No data available



parameter	Method - source - remark
Thermal sensitivity	A.14: The tests need not be performed when available thermodynamic information (e.g. heat of formation, heat of decomposition) and/ or absence of certain reactive groups in the structural formula establishes beyond reasonable doubt that the substance is incapable of rapid decomposition with evolution of gases or release of heat (i.e. the material does not present any risk of explosion).
Sensitiveness to impact (J)	A.14: The tests need not be performed when available thermodynamic information (e.g. heat of formation, heat of decomposition) and/ or absence of certain reactive groups in the structural formula establishes beyond reasonable doubt that the substance is incapable of rapid decomposition with evolution of gases or release of heat (i.e. the material does not present any risk of explosion).
Sensitivity to friction (N)	A.14: The tests need not be performed when available thermodynamic information (e.g. heat of formation, heat of decomposition) and/ or absence of certain reactive groups in the structural formula establishes beyond reasonable doubt that the substance is incapable of rapid decomposition with evolution of gases or release of heat (i.e. the material does not present any risk of explosion).
Oxidising liquids	No data available
Oxidising solids	not relevant
Oxidising gas	not relevant

## 9.2 Other information

### Physical hazards

#### Explosives

##### Justification for data waiving

The study does not need to be conducted because there are no chemical groups associated with explosive properties present in the molecule.

#### Flammable gases

##### Justification for data waiving

not relevant

#### Aerosols

##### Justification for data waiving

Testing can be waived because substance is not an aerosol.

## **Oxidising gas**

### **Justification for data waiving**

Testing can be waived because substance is a solid.

## **Gases under pressure**

### **Justification for data waiving**

Testing can be waived because substance is a solid.

## **flammable liquids**

### **Justification for data waiving**

not relevant

## **Flammable solids**

### **Justification for data waiving**

No data available

## **Self-reactive substances and mixtures**

### **Justification for data waiving**

The classification procedures for self-reactive substances and mixtures need not be applied because there are no chemical groups present in the molecule associated with explosive or selfreactive properties.

## **Pyrophoric liquids**

### **Justification for data waiving**

The study does not need to be conducted because the substance is known to be stable at room temperature for prolonged periods of time (days).

## **Pyrophoric solids**

### **Justification for data waiving**

The study does not need to be conducted because the substance is known to be stable at room temperature for prolonged periods of time (days).

## **self-heating substances and mixtures**

### **Justification for data waiving**

not relevant

## **Substances or mixtures which, in contact with water, emit flammable gases**

### **Justification for data waiving**

not relevant

## **Oxidising liquids**

### **Justification for data waiving**

not relevant

## **Oxidising solids**

### **Justification for data waiving**

The study need not be conducted for organic compounds containing oxygen, fluorine or chlorine and these elements are chemically bonded only to carbon or hydrogen.

## **Organic peroxides**

### **Justification for data waiving**

Classification procedure not required, because the substance or the mixture is by definition not an organic peroxide.

## **Corrosive to metals**

### **Justification for data waiving**

not relevant

## **Desensitised explosives**

### **Justification for data waiving**

No data available

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

No specific test data related to reactivity available for this product or its ingredients.

### 10.2 Chemical stability

No hazardous reaction when handled and stored according to provisions. Further information on storage conditions: see subsection 7.2.

### 10.3 Possibility of hazardous reactions

No hazardous reaction when handled and stored according to provisions.

### 10.4 Conditions to avoid

Further information on storage conditions: see subsection 7.2.

### 10.5 Incompatible materials

No further relevant information available.

### 10.6 Hazardous decomposition products

Does not decompose when used for intended uses. No known hazardous decomposition products.

## SECTION 11: Toxicological information

### Additional information

Toxicological data are not available.

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

#### Toxicokinetics, metabolism and distribution

##### Human toxicological data

No data available

##### Non-human toxicological data

###### remark

There are no data available on the preparation/mixture itself.

##### skin corrosion/irritation

###### Assessment/classification

No data available

##### Respiratory or skin sensitisation

##### Sensitisation to the respiratory tract

###### Assessment/classification

No data available

##### Skin sensitisation

###### Assessment/classification

No data available

### CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

#### Germ cell mutagenicity

##### Human toxicological data

###### Result

not relevant

##### In vitro mutagenicity/genotoxicity

###### remark

not relevant

##### In vivo mutagenicity/genotoxicity

###### remark

not relevant

##### Carcinogenicity

---

**Result / evaluation**

No data available

**Reproductive toxicity****Assessment/classification**

No data available

**Adverse effects on sexual function and fertility****Result / evaluation**

No data available

**Adverse effects on developmental toxicity****Result / evaluation**

No data available

**Effects on or via lactation****Result**

No data available

**STOT-single exposure****STOT SE 1 and 2****Dermal specific target organ toxicity (single exposure)****remark**

No data available

**Inhalative specific target organ toxicity (single exposure)****remark**

No data available

**Oral specific target organ toxicity (single exposure)****remark**

No data available

**STOT SE 3****Irritation to respiratory tract****Assessment/classification**

No data available

**STOT-repeated exposure****STOT RE 1 and 2****Dermal specific target organ toxicity (repeated exposure)****Assessment/classification**

No data available

**Inhalative specific target organ toxicity (repeated exposure)****Assessment/classification**

No data available

**Oral specific target organ toxicity (repeated exposure)****Assessment/classification**

No data available

**Repeated dose toxicity (subacute, subchronic, chronic)****Subacute oral toxicity****Specific effects:**

No data available

**Subacute dermal toxicity**

#### Specific effects:

No data available

#### Subacute inhalation toxicity

##### Specific effects:

No data available

#### Subchronic dermal toxicity

##### Specific effects:

No data available

#### Subchronic inhalation toxicity

##### Specific effects:

No data available

#### Chronic oral toxicity

##### Specific effects:

No data available

#### Chronic dermal toxicity

##### Specific effects:

No data available

#### Chronic inhalation toxicity

##### Specific effects:

No data available

### 11.2 Information on other hazards

#### Endocrine disrupting properties

##### remark

This product does not contain a substance that has endocrine disrupting properties with respect to humans as no components meets the criteria.

#### Phototoxicity

##### In vitro phototoxicity

###### evaluation

No data available

##### In vivo phototoxicity

###### evaluation

No data available

## SECTION 12: Ecological information

### 12.1 Toxicity

#### Aquatic toxicity

##### Acute (short-term) fish toxicity

###### Result / evaluation

none

##### Acute (short-term) toxicity to crustacea

###### Result / evaluation

none

##### Chronic (long-term) toxicity to aquatic invertebrate

###### remark

none

##### Chronic (long-term) fish toxicity

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**Result / evaluation**

none

**Acute (short-term) toxicity to algae and cyanobacteria**

**Result / evaluation**

none

**Chronic (long-term) toxicity to aquatic algae and cyanobacteria**

**remark**

none

**Toxicity to other aquatic plants/organisms**

**Result / evaluation**

none

**Toxicity to microorganisms**

**Result / evaluation**

none

**Terrestrial toxicity**

**Effects on soil microorganisms**

**evaluation**

none

**Toxicity to soil macroorganisms except of arthropods**

**Acute earthworm toxicity**

**evaluation**

none

**Chronical earthworm toxicity (reproduction)**

**evaluation**

none

**Toxicity to terrestrial arthropods**

**Insect toxicity**

**evaluation**

none

**Toxicity to terrestrial plants**

**Acute plant toxicity**

**evaluation**

none

**Chronic plant toxicity**

**evaluation**

none

**Toxicity to birds**

**Acute and subchronic bird toxicity**

**evaluation**

none

**Bird reproduction toxicity**

**evaluation**

none

**Additional ecotoxicological information**

**General information**

none

## 12.2 Persistence and degradability

### Assessment/classification

No data available

## 12.3 Bioaccumulative potential

### Assessment/classification

not relevant

## 12.4 Mobility in soil

### Assessment/classification

Adsorption to solid soil phase is not expected.

## 12.5 Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

## 12.6 Endocrine disrupting properties

### Result / evaluation

No data available

## 12.7 Other adverse effects

No information available.

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

#### Directive 2008/98/EC (Waste Framework Directive)

##### Before intended use

**Waste code product** 180100

**hazardous waste** No

##### Waste name

wastes from natal care, diagnosis, treatment or prevention of disease in humans

**Waste code product** 180107

**hazardous waste** No

##### Waste name

chemicals other than those mentioned in 18 01 06

##### After intended use

**Waste code packaging** 180100

**hazardous waste** No

##### Waste name

wastes from natal care, diagnosis, treatment or prevention of disease in humans

**Waste code packaging** 180107

**hazardous waste** No

##### Waste name

chemicals other than those mentioned in 18 01 06

## SECTION 14: Transport information

	Land transport (ADR/RID)	Sea transport (IMDG)	Air transport (ICAO-TI / IATA-DGR)
14.1 UN number or ID number	not applicable	not applicable	not applicable
14.2 Proper Shipping Name	not applicable	not applicable	not applicable
14.3 Class(es)	not applicable	not applicable	not applicable
14.4 Packing group	not applicable	not applicable	not applicable
14.5 Environmental hazards	not applicable	not applicable	not applicable



	Land transport (ADR/RID)	Sea transport (IMDG)	Air transport (ICAO-TI / IATA-DGR)
14.6 Special precautions for user	not applicable	not applicable	not applicable
14.7 Maritime transport in bulk according to IMO instruments	not applicable	not applicable	not applicable

## Additional information - Land transport (ADR/RID)

### remark

not applicable

## Additional information - Sea transport (IMDG)

### remark

not applicable

## Additional information - Air transport (ICAO-TI / IATA-DGR)

### remark

not applicable

## SECTION 15: Regulatory information

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

#### EU legislation

#### Authorisations and/or restrictions on use

#### authorisations

none

### 15.2 Chemical Safety Assessment

Chemical safety assessments for substances in this mixture were not carried out.

## SECTION 16: Other information

### Classification for mixtures and used evaluation method according to regulation (EC) No 1272/2008 [CLP]

See SECTION 2.1 (classification).

#### Indication of changes

not relevant

#### Additional information

not relevant

#### Relevant R-, H- and EUH-phrases (Number and full text)

none

#### Training advice

none



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

### 1.1 Product identifier

**Trade name/designation** MAST ISOPLEX Lyo Pellet PfPv

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

#### Relevant identified uses

##### remark

The product is intended for professional use.

##### Sector of uses [SU]

SU20 Health services

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

#### Manufacturer

Mast Diagnostica GmbH

Feldstraße 20

Deutschland-23858 Reinfeld

Telephone: +49 4533 20 07 00

Telefax: +49 4533 2007 68

E-mail: mast@mast-diagnostica.de

www.mast-group.com

### 1.4 Emergency telephone number

Only available during office hours.

## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture

#### Additional information

This mixture does not contain any substances presenting a health or environmental hazard within the means of Regulation (EC) No. 1272/2008, assigned a Community workplace exposure limit, classified as PBT/vPvB or included in the Candidate List.

#### Classification according to Regulation (EC) No 1272/2008 [CLP]

##### health hazards

###### hazard statements for health hazards

none

##### Physical hazards

###### hazard statements for physical hazards

none

##### Environmental hazards

none

##### Additional hazards

none

##### Specific concentration limit (SCL)

###### Hazard classes and hazard categories

none

### 2.2 Label elements

#### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

##### Signal word

none

##### Hazard statements

###### Hazard statements for physical hazards

none

## **hazard statements for health hazards**

none

## **Hazard statements for environmental hazards**

none

## **Hazard statements for additional hazards**

none

## **Precautionary statements**

### **General:**

none

### **Prevention**

none

### **Response:**

none

### **Storage:**

none

### **Disposal:**

none

## **Supplemental hazard information**

### **Physical properties**

none

### **health hazard properties**

none

### **Environmental properties**

none

## **Other labelling**

### **Standard phrases for special risks for humans or the environment**

none

### **Labelling for contents according to regulation (EC) No. 648/2004**

none

### **Standard phrases for safety precautions for the protection of humans or the environment**

#### **General provisions**

none

#### **Safety precautions for operators (SPo)**

none

#### **Safety precautions related to the environment (SPe)**

none

#### **Safety precautions related to good agricultural practice (SPa)**

none

#### **Specific safety precautions for rodenticides (SPr)**

none

### **Standard phrases for special risks for humans or the environment**

#### **Special risks related to humans (RSh):**

none

#### **Special risks related to the environment (RSe):**

none

## 2.3 Other hazards

### Adverse environmental effects

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

### Adverse human health effects and symptoms

This product does not contain a substance that has endocrine disrupting properties with respect to humans as no components meets the criteria.

### Adverse physicochemical effects

none

### Other adverse effects

none

### Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

## SECTION 3: Composition / information on ingredients

### 3.1/3.2 Substances/Mixtures

No data available

### Hazardous ingredients

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

#### General information

No special First Aid measures are required.

#### Following skin contact

Remove mechanically (e.g. dab away using wadding or cellulose material) then thoroughly wash the affected skin with a mild cleansing agent and water.

#### After eye contact

Rinse immediately carefully and thoroughly with eye-bath or water.

#### Following ingestion

Rinse mouth thoroughly with water.

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

#### Effects

none

#### Symptoms

none

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

#### Notes for the doctor

none

#### Special treatment

none

## SECTION 5: Firefighting measures

### Additional information

The product itself does not burn. Co-ordinate fire-fighting measures to the fire surroundings.

### 5.1 Extinguishing media

#### Suitable extinguishing media

Water

Foam

Sand

Carbon dioxide (CO<sub>2</sub>)

Extinguishing powder

**Unsuitable extinguishing media**

none

**5.2 Special hazards arising from the substance or mixture**

**Hazardous combustion products**

none

**5.3 Advice for firefighters**

**Special protective equipment for firefighters**

No special equipment or techniques are required.

**SECTION 6: Accidental release measures**

**Additional information**

Absorb and remove liquid with absorbent material.

Clean the affected surface with standard cleaning agents

**6.1 Personal precautions, protective equipment and emergency procedures**

**For non-emergency personnel**

**Personal precautions**

none

**Protective equipment**

none

**For emergency responders**

**Personal protection equipment**

none

**6.2 Environmental precautions**

none

**6.3 Methods and material for containment and cleaning up**

**For containment**

**Suitable material for taking up**

Commercially available materials are sufficient.

**For cleaning up**

**Suitable material for diluting or neutralizing**

Water

**6.4 Reference to other sections**

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

**SECTION 7: Handling and storage**

**7.1 Precautions for safe handling**

**Advices on general occupational hygiene**

Provide eye shower and label its location conspicuously

**Protective measures**

**Advices on safe handling**

No special technical protective measures are necessary.

**Measures to prevent fire**

No special fire protection measures are necessary.

**Environmental precautions**

No special technical protective measures are necessary.

## 7.2 Conditions for safe storage, including any incompatibilities

### Technical measures and storage conditions

Storage conditions are listed on the labels. Additional information concerning the storage are given in the instructions for use.

### Hints on joint storage

#### Materials to avoid

none

### Further information on storage conditions

Protect against:

UV-radiation/sunlight

Temperatures outside the listed range.

#### storage temperature

Value  $\geq 2 - \leq 8$  °C

## 7.3 Specific end use(s)

### Recommendation

Observe instructions for use.

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### remark

To date, no national critical limit values exist.

### 8.2 Exposure controls

#### Appropriate engineering controls

#### remark

See section 7. No additional measures necessary.

#### Personal protection equipment

##### Eye/face protection

##### Suitable eye protection

Eye glasses

Eye glasses with side protection

##### Skin protection

##### Suitable gloves type

Disposable gloves

##### Suitable material

NBR (Nitrile rubber)

##### Body protection

##### Suitable protective clothing

lab coat

##### Respiratory protection

none

#### Environmental exposure controls

#### remark

See section 7. No additional measures necessary.

#### Consumer exposure controls

#### Measures related to consumer uses of the substance (as such or in preparations).

not relevant

#### Measures related to the service life of the substance in articles

not relevant

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

#### Appearance

#### Physical state

solid

#### Colour

colourless

#### Odour

odourless

#### Odour threshold

not relevant

parameter	Method - source - remark
Melting point/freezing point	No data available
Boiling point or initial boiling point and boiling range	No data available
flammability	not relevant
Upper explosion limit	not relevant
lower explosion limit	not relevant
Flash point (°C)	not relevant
Auto-ignition temperature	not relevant
Decomposition temperature	not relevant
pH	No data available
Kinematic viscosity	No data available
Water solubility	No data available
Soluble (g/L) in	not relevant
Fat solubility	No data available
Partition coefficient: n-octanol/water	No data available
Vapour pressure	No data available
Density and/or relative density	No data available
Relative vapour density	No data available
particle characteristics	not relevant
Dynamic viscosity	No data available
flow time	No data available

parameter	Method - source - remark
Thermal sensitivity	A.14: The tests need not be performed when available thermodynamic information (e.g. heat of formation, heat of decomposition) and/ or absence of certain reactive groups in the structural formula establishes beyond reasonable doubt that the substance is incapable of rapid decomposition with evolution of gases or release of heat (i.e. the material does not present any risk of explosion).
Sensitiveness to impact (J)	A.14: The tests need not be performed when available thermodynamic information (e.g. heat of formation, heat of decomposition) and/ or absence of certain reactive groups in the structural formula establishes beyond reasonable doubt that the substance is incapable of rapid decomposition with evolution of gases or release of heat (i.e. the material does not present any risk of explosion).
Sensitivity to friction (N)	A.14: The tests need not be performed when available thermodynamic information (e.g. heat of formation, heat of decomposition) and/ or absence of certain reactive groups in the structural formula establishes beyond reasonable doubt that the substance is incapable of rapid decomposition with evolution of gases or release of heat (i.e. the material does not present any risk of explosion).
Oxidising liquids	No data available
Oxidising solids	not relevant
Oxidising gas	not relevant

## 9.2 Other information

### Physical hazards

#### Explosives

##### Justification for data waiving

The study does not need to be conducted because there are no chemical groups associated with explosive properties present in the molecule.

#### Flammable gases

##### Justification for data waiving

not relevant

#### Aerosols

##### Justification for data waiving

Testing can be waived because substance is not an aerosol.

## Oxidising gas

### Justification for data waiving

Testing can be waived because substance is a solid.

## Gases under pressure

### Justification for data waiving

Testing can be waived because substance is a solid.

## flammable liquids

### Justification for data waiving

not relevant

## Flammable solids

### Justification for data waiving

No data available

## Self-reactive substances and mixtures

### Justification for data waiving

The classification procedures for self-reactive substances and mixtures need not be applied because there are no chemical groups present in the molecule associated with explosive or selfreactive properties.

## Pyrophoric liquids

### Justification for data waiving

The study does not need to be conducted because the substance is known to be stable at room temperature for prolonged periods of time (days).

## Pyrophoric solids

### Justification for data waiving

The study does not need to be conducted because the substance is known to be stable at room temperature for prolonged periods of time (days).

## self-heating substances and mixtures

### Justification for data waiving

not relevant

## Substances or mixtures which, in contact with water, emit flammable gases

### Justification for data waiving

not relevant

## Oxidising liquids

### Justification for data waiving

not relevant

## Oxidising solids

### Justification for data waiving

The study need not be conducted for organic compounds containing oxygen, fluorine or chlorine and these elements are chemically bonded only to carbon or hydrogen.

## Organic peroxides

### Justification for data waiving

Classification procedure not required, because the substance or the mixture is by definition not an organic peroxide.

## Corrosive to metals

### Justification for data waiving

not relevant

## Desensitised explosives

### Justification for data waiving

No data available



## SECTION 10: Stability and reactivity

### 10.1 Reactivity

No specific test data related to reactivity available for this product or its ingredients.

### 10.2 Chemical stability

No hazardous reaction when handled and stored according to provisions. Further information on storage conditions: see subsection 7.2.

### 10.3 Possibility of hazardous reactions

No hazardous reaction when handled and stored according to provisions.

### 10.4 Conditions to avoid

Further information on storage conditions: see subsection 7.2.

### 10.5 Incompatible materials

No further relevant information available.

### 10.6 Hazardous decomposition products

Does not decompose when used for intended uses. No known hazardous decomposition products.

## SECTION 11: Toxicological information

### Additional information

Toxicological data are not available.

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

#### Toxicokinetics, metabolism and distribution

##### Human toxicological data

No data available

##### Non-human toxicological data

###### remark

There are no data available on the preparation/mixture itself.

##### skin corrosion/irritation

###### Assessment/classification

No data available

##### Respiratory or skin sensitisation

##### Sensitisation to the respiratory tract

###### Assessment/classification

No data available

##### Skin sensitisation

###### Assessment/classification

No data available

### CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

#### Germ cell mutagenicity

##### Human toxicological data

###### Result

not relevant

##### In vitro mutagenicity/genotoxicity

###### remark

not relevant

##### In vivo mutagenicity/genotoxicity

###### remark

not relevant

##### Carcinogenicity

## Result / evaluation

No data available

## Reproductive toxicity

### Assessment/classification

No data available

## Adverse effects on sexual function and fertility

### Result / evaluation

No data available

## Adverse effects on developmental toxicity

### Result / evaluation

No data available

## Effects on or via lactation

### Result

No data available

## STOT-single exposure

### STOT SE 1 and 2

#### Dermal specific target organ toxicity (single exposure)

##### remark

No data available

#### Inhalative specific target organ toxicity (single exposure)

##### remark

No data available

#### Oral specific target organ toxicity (single exposure)

##### remark

No data available

### STOT SE 3

#### Irritation to respiratory tract

##### Assessment/classification

No data available

## STOT-repeated exposure

### STOT RE 1 and 2

#### Dermal specific target organ toxicity (repeated exposure)

##### Assessment/classification

No data available

#### Inhalative specific target organ toxicity (repeated exposure)

##### Assessment/classification

No data available

#### Oral specific target organ toxicity (repeated exposure)

##### Assessment/classification

No data available

## Repeated dose toxicity (subacute, subchronic, chronic)

### Subacute oral toxicity

#### Specific effects:

No data available

### Subacute dermal toxicity

**Specific effects:**

No data available

**Subacute inhalation toxicity**

**Specific effects:**

No data available

**Subchronic dermal toxicity**

**Specific effects:**

No data available

**Subchronic inhalation toxicity**

**Specific effects:**

No data available

**Chronic oral toxicity**

**Specific effects:**

No data available

**Chronic dermal toxicity**

**Specific effects:**

No data available

**Chronic inhalation toxicity**

**Specific effects:**

No data available

**11.2 Information on other hazards**

**Endocrine disrupting properties**

**remark**

This product does not contain a substance that has endocrine disrupting properties with respect to humans as no components meets the criteria.

**Phototoxicity**

**In vitro phototoxicity**

**evaluation**

No data available

**In vivo phototoxicity**

**evaluation**

No data available

**SECTION 12: Ecological information**

**12.1 Toxicity**

**Aquatic toxicity**

**Acute (short-term) fish toxicity**

**Result / evaluation**

none

**Acute (short-term) toxicity to crustacea**

**Result / evaluation**

none

**Chronic (long-term) toxicity to aquatic invertebrate**

**remark**

none

**Chronic (long-term) fish toxicity**

---

**Result / evaluation**

none

**Acute (short-term) toxicity to algae and cyanobacteria**

**Result / evaluation**

none

**Chronic (long-term) toxicity to aquatic algae and cyanobacteria**

**remark**

none

**Toxicity to other aquatic plants/organisms**

**Result / evaluation**

none

**Toxicity to microorganisms**

**Result / evaluation**

none

**Terrestrial toxicity**

**Effects on soil microorganisms**

**evaluation**

none

**Toxicity to soil macroorganisms except of arthropods**

**Acute earthworm toxicity**

**evaluation**

none

**Chronical earthworm toxicity (reproduction)**

**evaluation**

none

**Toxicity to terrestrial arthropods**

**Insect toxicity**

**evaluation**

none

**Toxicity to terrestrial plants**

**Acute plant toxicity**

**evaluation**

none

**Chronic plant toxicity**

**evaluation**

none

**Toxicity to birds**

**Acute and subchronic bird toxicity**

**evaluation**

none

**Bird reproduction toxicity**

**evaluation**

none

**Additional ecotoxicological information**

**General information**

none

## 12.2 Persistence and degradability

### Assessment/classification

No data available

## 12.3 Bioaccumulative potential

### Assessment/classification

not relevant

## 12.4 Mobility in soil

### Assessment/classification

Adsorption to solid soil phase is not expected.

## 12.5 Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

## 12.6 Endocrine disrupting properties

### Result / evaluation

No data available

## 12.7 Other adverse effects

No information available.

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

#### Directive 2008/98/EC (Waste Framework Directive)

##### Before intended use

**Waste code product** 180100

**hazardous waste** No

##### Waste name

wastes from natal care, diagnosis, treatment or prevention of disease in humans

**Waste code product** 180107

**hazardous waste** No

##### Waste name

chemicals other than those mentioned in 18 01 06

##### After intended use

**Waste code packaging** 180100

**hazardous waste** No

##### Waste name

wastes from natal care, diagnosis, treatment or prevention of disease in humans

**Waste code packaging** 180107

**hazardous waste** No

##### Waste name

chemicals other than those mentioned in 18 01 06

## SECTION 14: Transport information

	Land transport (ADR/RID)	Sea transport (IMDG)	Air transport (ICAO-TI / IATA-DGR)
14.1 UN number or ID number	not applicable	not applicable	not applicable
14.2 Proper Shipping Name	not applicable	not applicable	not applicable
14.3 Class(es)	not applicable	not applicable	not applicable
14.4 Packing group	not applicable	not applicable	not applicable
14.5 Environmental hazards	not applicable	not applicable	not applicable



	Land transport (ADR/RID)	Sea transport (IMDG)	Air transport (ICAO-TI / IATA-DGR)
14.6 Special precautions for user	not applicable	not applicable	not applicable
14.7 Maritime transport in bulk according to IMO instruments	not applicable	not applicable	not applicable

## Additional information - Land transport (ADR/RID)

### remark

not applicable

## Additional information - Sea transport (IMDG)

### remark

not applicable

## Additional information - Air transport (ICAO-TI / IATA-DGR)

### remark

not applicable

## SECTION 15: Regulatory information

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

#### EU legislation

#### Authorisations and/or restrictions on use

#### authorisations

none

### 15.2 Chemical Safety Assessment

Chemical safety assessments for substances in this mixture were not carried out.

## SECTION 16: Other information

### Classification for mixtures and used evaluation method according to regulation (EC) No 1272/2008 [CLP]

See SECTION 2.1 (classification).

#### Indication of changes

not relevant

#### Additional information

not relevant

#### Relevant R-, H- and EUH-phrases (Number and full text)

none

#### Training advice

none

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

### 1.1 Product identifier

**Trade name/designation** MAST ISOPLEX reconstitution buffer

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

#### Relevant identified uses

##### remark

The product is intended for professional use.

##### Sector of uses [SU]

SU20 Health services

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

#### Manufacturer

Mast Diagnostica GmbH

Feldstraße 20

Deutschland-23858 Reinfeld

Telephone: +49 4533 20 07 00

Telefax: +49 4533 2007 68

E-mail: mast@mast-diagnostica.de

www.mast-group.com

### 1.4 Emergency telephone number

Only available during office hours.

## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture

#### Additional information

This mixture does not contain any substances presenting a health or environmental hazard within the means of Regulation (EC) No. 1272/2008, assigned a Community workplace exposure limit, classified as PBT/vPvB or included in the Candidate List.

#### Classification according to Regulation (EC) No 1272/2008 [CLP]

##### health hazards

###### hazard statements for health hazards

none

##### Physical hazards

###### hazard statements for physical hazards

none

##### Environmental hazards

none

##### Additional hazards

none

##### Specific concentration limit (SCL)

###### Hazard classes and hazard categories

none

### 2.2 Label elements

#### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

##### Signal word

none

##### Hazard statements

###### Hazard statements for physical hazards

none

---

**hazard statements for health hazards**

none

**Hazard statements for environmental hazards**

none

**Hazard statements for additional hazards**

none

**Precautionary statements**

**General:**

none

**Prevention**

none

**Response:**

none

**Storage:**

none

**Disposal:**

none

**Supplemental hazard information**

**Physical properties**

none

**health hazard properties**

none

**Environmental properties**

none

**Other labelling**

**Standard phrases for special risks for humans or the environment**

none

**Labelling for contents according to regulation (EC) No. 648/2004**

none

**Standard phrases for safety precautions for the protection of humans or the environment**

**General provisions**

none

**Safety precautions for operators (SPo)**

none

**Safety precautions related to the environment (SPe)**

none

**Safety precautions related to good agricultural practice (SPa)**

none

**Specific safety precautions for rodenticides (SPr)**

none

**Standard phrases for special risks for humans or the environment**

**Special risks related to humans (RSh):**

none

**Special risks related to the environment (RSe):**

none



## 2.3 Other hazards

### Adverse environmental effects

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

### Adverse human health effects and symptoms

This product does not contain a substance that has endocrine disrupting properties with respect to humans as no components meets the criteria.

### Adverse physicochemical effects

none

### Other adverse effects

none

### Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

## SECTION 3: Composition / information on ingredients

### 3.1/3.2 Substances/Mixtures

#### Hazardous ingredients

Tris(hydroxymethyl)aminomethan  
CAS 77-86-1

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

#### General information

No special First Aid measures are required.

#### Following skin contact

Remove mechanically (e.g. dab away using wadding or cellulose material) then thoroughly wash the affected skin with a mild cleansing agent and water.

#### After eye contact

Rinse immediately carefully and thoroughly with eye-bath or water.

#### Following ingestion

Rinse mouth thoroughly with water.

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

#### Effects

none

#### Symptoms

none

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

#### Notes for the doctor

none

#### Special treatment

none

## SECTION 5: Firefighting measures

### Additional information

The product itself does not burn. Co-ordinate fire-fighting measures to the fire surroundings.

### 5.1 Extinguishing media

#### Suitable extinguishing media

Water

Foam

Sand

Carbon dioxide (CO<sub>2</sub>)

Extinguishing powder

### **Unsuitable extinguishing media**

none

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

### **Hazardous combustion products**

none

## **5.3 Advice for firefighters**

### **Special protective equipment for firefighters**

No special equipment or techniques are required.

## **SECTION 6: Accidental release measures**

### **Additional information**

Absorb and remove liquid with absorbent material. Clean the affected surface with standard cleaning agents.

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

### **For non-emergency personnel**

#### **Personal precautions**

none

#### **Protective equipment**

none

### **For emergency responders**

#### **Personal protection equipment**

none

## **6.2 Environmental precautions**

none

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

### **For containment**

#### **Suitable material for taking up**

Commercially available materials are sufficient.

### **For cleaning up**

#### **Suitable material for diluting or neutralizing**

Water

## **6.4 Reference to other sections**

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

## **SECTION 7: Handling and storage**

### **7.1 Precautions for safe handling**

#### **Advices on general occupational hygiene**

Provide eye shower and label its location conspicuously

#### **Protective measures**

#### **Advices on safe handling**

No special technical protective measures are necessary.

#### **Measures to prevent fire**

No special fire protection measures are necessary.

#### **Environmental precautions**

No special technical protective measures are necessary.

## 7.2 Conditions for safe storage, including any incompatibilities

### Technical measures and storage conditions

Storage conditions are listed on the labels. Additional information concerning the storage are given in the instructions for use.

### Hints on joint storage

### Materials to avoid

none

### Further information on storage conditions

Protect against:

UV-radiation/sunlight

Temperatures outside the listed range.

### storage temperature

Value  $\geq 2 - \leq 8$  °C

## 7.3 Specific end use(s)

### Recommendation

Observe instructions for use.

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### remark

To date, no national critical limit values exist.

### 8.2 Exposure controls

#### Appropriate engineering controls

#### remark

See section 7. No additional measures necessary.

#### Personal protection equipment

##### Eye/face protection

##### Suitable eye protection

Eye glasses

Eye glasses with side protection

##### Skin protection

##### Suitable gloves type

Disposable gloves

##### Suitable material

NBR (Nitrile rubber)

##### Body protection

##### Suitable protective clothing

lab coat

##### Respiratory protection

none

#### Environmental exposure controls

#### remark

See section 7. No additional measures necessary.

#### Consumer exposure controls

#### Measures related to consumer uses of the substance (as such or in preparations).

not relevant

#### Measures related to the service life of the substance in articles

not relevant

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

#### Appearance

#### Physical state

solid

liquid

#### Colour

colourless

#### Odour

odourless

#### Odour threshold

not relevant

parameter	Method - source - remark
Melting point/freezing point	No data available
Boiling point or initial boiling point and boiling range	No data available
flammability	not relevant
Upper explosion limit	not relevant
lower explosion limit	not relevant
Flash point (°C)	not relevant
Auto-ignition temperature	not relevant
Decomposition temperature	not relevant
pH	No data available
Kinematic viscosity	No data available
Water solubility	No data available
Soluble (g/L) in	not relevant
Fat solubility	No data available
Partition coefficient: n-octanol/water	No data available
Vapour pressure	No data available
Density and/or relative density	No data available
Relative vapour density	No data available
particle characteristics	not relevant
Dynamic viscosity	No data available
flow time	No data available

parameter	Method - source - remark
Thermal sensitivity	A.14: The tests need not be performed when available thermodynamic information (e.g. heat of formation, heat of decomposition) and/ or absence of certain reactive groups in the structural formula establishes beyond reasonable doubt that the substance is incapable of rapid decomposition with evolution of gases or release of heat (i.e. the material does not present any risk of explosion).
Sensitiveness to impact (J)	A.14: The tests need not be performed when available thermodynamic information (e.g. heat of formation, heat of decomposition) and/ or absence of certain reactive groups in the structural formula establishes beyond reasonable doubt that the substance is incapable of rapid decomposition with evolution of gases or release of heat (i.e. the material does not present any risk of explosion).
Sensitivity to friction (N)	A.14: The tests need not be performed when available thermodynamic information (e.g. heat of formation, heat of decomposition) and/ or absence of certain reactive groups in the structural formula establishes beyond reasonable doubt that the substance is incapable of rapid decomposition with evolution of gases or release of heat (i.e. the material does not present any risk of explosion).
Oxidising liquids	No data available
Oxidising solids	not relevant
Oxidising gas	not relevant

## 9.2 Other information

### Physical hazards

#### Explosives

##### Justification for data waiving

The study does not need to be conducted because there are no chemical groups associated with explosive properties present in the molecule.

#### Flammable gases

##### Justification for data waiving

not relevant

#### Aerosols

##### Justification for data waiving

Testing can be waived because substance is not an aerosol.

## **Oxidising gas**

### **Justification for data waiving**

Testing can be waived because substance is a liquid.

## **Gases under pressure**

### **Justification for data waiving**

Testing can be waived because substance is a liquid.

## **flammable liquids**

### **Justification for data waiving**

not relevant

## **Flammable solids**

### **Justification for data waiving**

Testing can be waived because substance is a liquid.

## **Self-reactive substances and mixtures**

### **Justification for data waiving**

The classification procedures for self-reactive substances and mixtures need not be applied because there are no chemical groups present in the molecule associated with explosive or selfreactive properties.

## **Pyrophoric liquids**

### **Justification for data waiving**

The study does not need to be conducted because the substance is known to be stable at room temperature for prolonged periods of time (days).

## **Pyrophoric solids**

### **Justification for data waiving**

Auf Tests kann verzichtet werden, da der Stoff eine Flüssigkeit ist.

## **self-heating substances and mixtures**

### **Justification for data waiving**

not relevant

## **Substances or mixtures which, in contact with water, emit flammable gases**

### **Justification for data waiving**

not relevant

## **Oxidising liquids**

### **Justification for data waiving**

not relevant

## **Oxidising solids**

### **Justification for data waiving**

Auf Tests kann verzichtet werden, da der Stoff eine Flüssigkeit ist.

## **Organic peroxides**

### **Justification for data waiving**

Classification procedure not required, because the substance or the mixture is by definition not an organic peroxide.

## **Corrosive to metals**

### **Justification for data waiving**

not relevant

## **Desensitised explosives**

### **Justification for data waiving**

No data available

## **SECTION 10: Stability and reactivity**

### **10.1 Reactivity**

No specific test data related to reactivity available for this product or its ingredients.

## 10.2 Chemical stability

No hazardous reaction when handled and stored according to provisions. Further information on storage conditions: see subsection 7.2.

## 10.3 Possibility of hazardous reactions

No hazardous reaction when handled and stored according to provisions.

## 10.4 Conditions to avoid

Further information on storage conditions: see subsection 7.2.

## 10.5 Incompatible materials

No further relevant information available.

## 10.6 Hazardous decomposition products

Does not decompose when used for intended uses. No known hazardous decomposition products.

## SECTION 11: Toxicological information

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

#### Toxicokinetics, metabolism and distribution

##### Human toxicological data

No data available

##### Non-human toxicological data

###### remark

There are no data available on the preparation/mixture itself.

#### Acute toxicity

**Acute oral toxicity** >160000 mg/kg

##### Effective dose

LD50:

##### Species:

Rat

##### Method

OECD 401

#### skin corrosion/irritation

##### Assessment/classification

none

##### Species:

Rabbit

#### Respiratory or skin sensitisation

##### Sensitisation to the respiratory tract

##### Assessment/classification

No data available

##### Skin sensitisation

##### Assessment/classification

No data available

#### CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

##### Germ cell mutagenicity

##### Human toxicological data

###### Result

not relevant

##### In vitro mutagenicity/genotoxicity

###### remark

not relevant

## In vivo mutagenicity/genotoxicity

### remark

not relevant

## Carcinogenicity

### Result / evaluation

No data available

## Reproductive toxicity

### Assessment/classification

No data available

## Adverse effects on sexual function and fertility

### Result / evaluation

No data available

## Adverse effects on developmental toxicity

### Result / evaluation

No data available

## Effects on or via lactation

### Result

No data available

## STOT-single exposure

### STOT SE 1 and 2

#### Dermal specific target organ toxicity (single exposure)

##### remark

No data available

#### Inhalative specific target organ toxicity (single exposure)

##### remark

No data available

#### Oral specific target organ toxicity (single exposure)

##### remark

No data available

### STOT SE 3

#### Irritation to respiratory tract

##### Assessment/classification

No data available

#### STOT-repeated exposure

### STOT RE 1 and 2

#### Dermal specific target organ toxicity (repeated exposure)

##### Assessment/classification

No data available

#### Inhalative specific target organ toxicity (repeated exposure)

##### Assessment/classification

No data available

#### Oral specific target organ toxicity (repeated exposure)

##### Assessment/classification

No data available

## Repeated dose toxicity (subacute, subchronic, chronic)

### Subacute oral toxicity



**Specific effects:**

No data available

**Subacute dermal toxicity**

**Specific effects:**

No data available

**Subacute inhalation toxicity**

**Specific effects:**

No data available

**Subchronic dermal toxicity**

**Specific effects:**

No data available

**Subchronic inhalation toxicity**

**Specific effects:**

No data available

**Chronic oral toxicity**

**Specific effects:**

No data available

**Chronic dermal toxicity**

**Specific effects:**

No data available

**Chronic inhalation toxicity**

**Specific effects:**

No data available

**11.2 Information on other hazards**

**Endocrine disrupting properties**

**remark**

This product does not contain a substance that has endocrine disrupting properties with respect to humans as no components meets the criteria.

**Phototoxicity**

**In vitro phototoxicity**

**evaluation**

No data available

**In vivo phototoxicity**

**evaluation**

No data available

**SECTION 12: Ecological information**

**12.1 Toxicity**

**Aquatic toxicity**

**Acute (short-term) fish toxicity**

**Result / evaluation**

none

**Acute (short-term) toxicity to crustacea**

**Result / evaluation**

none

**Chronic (long-term) toxicity to aquatic invertebrate**

**remark**

none

## **Chronic (long-term) fish toxicity**

**Result / evaluation**

none

## **Acute (short-term) toxicity to algae and cyanobacteria**

**remark**

none

## **Chronic (long-term) toxicity to aquatic algae and cyanobacteria**

**remark**

none

## **Toxicity to other aquatic plants/organisms**

**Result / evaluation**

none

## **Toxicity to microorganisms**

**Result / evaluation**

none

## **Terrestrial toxicity**

### **Effects on soil microorganisms**

**evaluation**

none

### **Toxicity to soil macroorganisms except of arthropods**

#### **Acute earthworm toxicity**

**evaluation**

none

#### **Chronical earthworm toxicity (reproduction)**

**evaluation**

none

### **Toxicity to terrestrial arthropods**

#### **Insect toxicity**

**evaluation**

none

### **Toxicity to terrestrial plants**

#### **Acute plant toxicity**

**evaluation**

none

#### **Chronic plant toxicity**

**evaluation**

none

### **Toxicity to birds**

#### **Acute and subchronic bird toxicity**

**evaluation**

none

#### **Bird reproduction toxicity**

**evaluation**

none

## Additional ecotoxicological information

### General information

none

### 12.2 Persistence and degradability

#### Assessment/classification

No data available

### 12.3 Bioaccumulative potential

#### Assessment/classification

not relevant

### 12.4 Mobility in soil

#### Assessment/classification

Adsorption to solid soil phase is not expected.

### 12.5 Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

### 12.6 Endocrine disrupting properties

#### Result / evaluation

No data available

### 12.7 Other adverse effects

No information available.

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

#### Directive 2008/98/EC (Waste Framework Directive)

##### Before intended use

**Waste code product** 180100

**hazardous waste** No

##### Waste name

wastes from natal care, diagnosis, treatment or prevention of disease in humans

**Waste code product** 180107

**hazardous waste** No

##### Waste name

chemicals other than those mentioned in 18 01 06

##### After intended use

**Waste code packaging** 180100

**hazardous waste** No

##### Waste name

wastes from natal care, diagnosis, treatment or prevention of disease in humans

**Waste code packaging** 180107

**hazardous waste** No

##### Waste name

chemicals other than those mentioned in 18 01 06

## SECTION 14: Transport information

	Land transport (ADR/RID)	Sea transport (IMDG)	Air transport (ICAO-TI / IATA-DGR)
14.1 UN number or ID number	not applicable	not applicable	not applicable
14.2 Proper Shipping Name	not applicable	not applicable	not applicable
14.3 Class(es)	not applicable	not applicable	not applicable



	Land transport (ADR/RID)	Sea transport (IMDG)	Air transport (ICAO-TI / IATA-DGR)
14.4 Packing group	not applicable	not applicable	not applicable
14.5 Environmental hazards	not applicable	not applicable	not applicable
14.6 Special precautions for user	not applicable	not applicable	not applicable
14.7 Maritime transport in bulk according to IMO instruments	not applicable	not applicable	not applicable

## Additional information - Land transport (ADR/RID)

### remark

not applicable

## Additional information - Sea transport (IMDG)

### remark

not applicable

## Additional information - Air transport (ICAO-TI / IATA-DGR)

### remark

not applicable

## SECTION 15: Regulatory information

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

#### EU legislation

#### Authorisations and/or restrictions on use

#### authorisations

none

### 15.2 Chemical Safety Assessment

Chemical safety assessments for substances in this mixture were not carried out.

## SECTION 16: Other information

### Classification for mixtures and used evaluation method according to regulation (EC) No 1272/2008 [CLP]

See SECTION 2.1 (classification).

### Indication of changes

not relevant

### Additional information

not relevant

### Relevant R-, H- and EUH-phrases (Number and full text)

none

### Training advice

none