

Material Safety Data Sheet (MSDS)

Summary Material Safety Data Sheet (MSDS)

Product: MAST ISOPLEX SARS-CoV-2

Art.-No.: 67COV2-2

Basic UDI-DI: 42507297IsoplexSARSCov29H

UDI-DI: 4250729702471

Hersteller

Mast Diagnostica GmbH
Feldstraße 20
23858 Reinfeld
Deutschland
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Product components

The following components are part of the kit:

Component	Description	Page
MAST ISOPLEX controls	200 / 1100 µL control, lyophilized, to be reconstituted before use	3-16
MAST ISOPLEX reaction mix	550 µL reaction mix	17-31
MAST ISOPLEX enzyme mix	270 µL enzyme mix	32-45
MAST ISOPLEX primer mix	550 µL primer mix	46-59
MAST ISOPLEX dye mix	55 µL dye mix	60-73
MAST ISOPLEX reconstitution buffer	1 mL reconstitution buffer	74-87

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 (CO₂)

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 toxikological 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 reaction mix

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

Trehalose

CAS 99-20-7

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 (CO₂)

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 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 toxikological data

remark

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

Acute toxicity

Acute oral toxicity

ingredient Trehalose

Acute oral toxicity >160000 mg/kg

Effective dose

LD50:

Species:

Rat

Method

OECD 401

skin corrosion/irritation

ingredient Trehalose

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

ingredient Trehalose

Chronic (long-term) toxicity to aquatic invertebrate >100 mg/L

Effective dose

EC50

Test duration 48 h

species

Daphnia magna (Big water flea)

Method

OECD 202

Chronic (long-term) fish toxicity

Result / evaluation

none

Acute (short-term) toxicity to algae and cyanobacteria

ingredient Trehalose

Acute (short-term) toxicity to algae and cyanobacteria 30,41 mg/L

Effective dose

ErC50:

Test duration 72 h

species

Desmodesmus subspicatus (Grünalge)

Method

OECD 201

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
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 enzyme mix

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 (CO₂)

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 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

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

1.1 Product identifier

Trade name/designation MAST ISOPLEX primer mix

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 (CO₂)

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

Lagerung ist unter der auf den Etikett aufgeführten Bedingungen zu erfolgen. Zusätzliche Informationen zur Lagerung sind in den Gebrauchsinformationen aufgeführt.

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 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 toxikological 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

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

1.1 Product identifier

Trade name/designation MAST ISOPLEX dye mix

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 (CO₂)

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 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 toxikological 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

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 (CO₂)

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