

Material Safety Data Sheet (MSDS)

Summary Material Safety Data Sheet (MSDS)

Product: MASTAZYME AI ELISA

Art.-No.: various

Basic UDI-DI: various

UDI-DI: various

Hersteller

Mast Diagnostica GmbH
Feldstraße 20
23858 Reinfeld
Deutschland
Tel. +49 (0) 4533 2007 0
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mast@mast-diagnostics.de

Product components

The following components are part of the kit:

Component	Description	Page
MASTAZYME AI ELISA controls	1.5 mL stabilized human plasma	3-18
MASTAZYME Cardiolipin controls	1.5 mL stabilized human plasma	19-34
MASTAZYME dsDNA controls	1.5 mL stabilized human plasma	35-49
MASTAZYME AI diluent	60 mL sample diluent	50-65
MASTAZYME Cardiolipin diluent	60 mL sample diluent	66-81
MASTAZYME AI ELISA conjugate	12 mL HRP-labelled goat anti-human-IgG	82-95
MASTAZYME Cardiolipin conjugate	12 mL HRP-labelled goat anti-human-IgG	96-109
MASTAYME TMB-substrate autoimmune	12 mL 3,3', 5,5' Tetramethylbenzidin	110-125
MASTAZYME stop solution 0.25 M	12 mL 0.25 M H ₂ SO ₄ (sulfuric acid)	126-139
MASTAZYME wash buffer	50 mL washing buffer	140-153

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

1.1 Product identifier

Trade name/designation MASTAZYME AI-ELISA 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

The mixture is not classified as hazardous according to Regulation (EC) No 1272/2008 [CLP].

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

sodium azide	0 - <=0,09 %
CAS 26628-22-8	
EC 247-852-1	
INDEX 011-004-00-7	
Acute Tox. 2, H300 / Aquatic Acute 1, H400 / Aquatic Chronic 1, H410	
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	>=0,03 - <=0,05 %
CAS 55965-84-9	
INDEX 613-167-00-5	
Acute Tox. 2, H330 / Acute Tox. 2, H310 / Acute Tox. 3, H301 / Skin Corr. 1C, H314 / Eye Dam. 1, H318 / Skin Sens. 1A, H317 / Aquatic Acute 1, H400 / Aquatic Chronic 1, H410	

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.

Self-protection of the first aider

none

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
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 ≥ 2 - ≤ 8 °C

7.3 Specific end use(s)

Recommendation

Observe instructions for use.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limit values

CAS No.	Substance name	LTV	STV	remark
26628-22-8	Sodium azide	0,1 mg/m ³	0,3 (1) mg/m ³	(1) 15 minutes average value Bold-type: Indicative Occupational Exposure Limit Value (IOELV) ~

European Union

LTV = long-term occupational exposure limit value

STV = short-term occupational exposure limit value

source: GESTIS International Limit Values (<http://limitvalue.ifa.dguv.de/>)

Monitoring and observation processes: GESTIS Analytical Methods (<http://amcaw.ifa.dguv.de/>)

Exposure limits at intended use

biological limit values

remark

No data available

DNEL-/PNEC-values

DNEL Consumer

Substance name sodium azide

type

systemic

source

TRGS900

Value 0,493 mg/m³

Substance name reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

type

local

source

Deutschland. MAK- und BAT Anhang IIa

Value 0,02 mg/m³

PNEC

Value 0,35 µg/L

PNEC type

aquatic, freshwater

Value 0,015 µg/L

PNEC type

aquatic, marine water

Value 0,0167 mg/kg

PNEC type

sediment, freshwater

Value 30 µg/L

PNEC type

sewage treatment plant

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

liquid

Colour

yellow

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

Testing can be waived because substance is a liquid.

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

Testing can be waived because substance is a liquid.

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 dermal toxicity

ingredient sodium azide

Acute dermal toxicity 18 mg/kg

Effective dose

LD50:

Species:

Rabbit

ingredient reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

Acute dermal toxicity 2,8 mg/kg

Effective dose

LD50:

Species:

Rabbit

Acute inhalation toxicity (dust/mist)

ingredient sodium azide

Acute inhalation toxicity (dust/mist) 5,4 mg/kg

Effective dose

LC50:

Exposure time 4

Species:

Rat

Acute inhalation toxicity (vapour)

ingredient reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

Acute inhalation toxicity (vapour) 16,67 mg/L

Exposure time 4 d

Acute oral toxicity

ingredient sodium azide

Acute oral toxicity 27 mg/kg

Effective dose

LD50:

Species:

Rat

ingredient reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

Acute oral toxicity 862 mg/kg

Effective dose

LD50:

Species:

Rat

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

Genetic endpoint

not relevant

In vivo mutagenicity/genotoxicity

Result / evaluation

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

remark

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) 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

ingredient sodium azide

Acute (short-term) toxicity to algae and cyanobacteria 0,348 mg/L

Effective dose

EC50

Test duration 4 d

species

Alge/Wasserpflanze

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

evaluation parameter:

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

The substance meets the criteria of ready degradability as defined in Regulation (EC) No 1272/2008.

12.3 Bioaccumulative potential

Assessment/classification

not applicable

12.4 Mobility in soil

Assessment/classification

No data available

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

remark

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

All transport carriers

No dangerous good in sense of these transport regulations.

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



restrictions on use

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 MASTAZYME Cardioliipin 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

The mixture is not classified as hazardous according to Regulation (EC) No 1272/2008 [CLP].

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

sodium azide	0 - <=0,09 %
CAS 26628-22-8	
EC 247-852-1	
INDEX 011-004-00-7	
Acute Tox. 2, H300 / Aquatic Acute 1, H400 / Aquatic Chronic 1, H410	
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	>=0,03 - <=0,05 %
CAS 55965-84-9	
INDEX 613-167-00-5	
Acute Tox. 2, H330 / Acute Tox. 2, H310 / Acute Tox. 3, H301 / Skin Corr. 1C, H314 / Eye Dam. 1, H318 / Skin Sens. 1A, H317 / Aquatic Acute 1, H400 / Aquatic Chronic 1, H410	

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.

Self-protection of the first aider

none

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

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 ≥ 2 - ≤ 8 °C

7.3 Specific end use(s)

Recommendation

Observe instructions for use.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limit values

CAS No.	Substance name	LTV	STV	remark
26628-22-8	Sodium azide	0,1 mg/m ³	0,3 (1) mg/m ³	(1) 15 minutes average value Bold-type: Indicative Occupational Exposure Limit Value (IOELV) ~

European Union

LTV = long-term occupational exposure limit value

STV = short-term occupational exposure limit value

source: GESTIS International Limit Values (<http://limitvalue.ifa.dguv.de/>)

Monitoring and observation processes: GESTIS Analytical Methods (<http://amcaw.ifa.dguv.de/>)

Exposure limits at intended use

biological limit values

remark

No data available

DNEL-/PNEC-values

DNEL Consumer

Substance name sodium azide

type

systemic

source

TRGS900

Value 0,493 mg/m³

Substance name reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

type

local

source

Deutschland. MAK- und BAT Anhang IIa

Value 0,02 mg/m³

PNEC

Value 0,35 µg/L

PNEC type

aquatic, freshwater

Value 0,015 µg/L

PNEC type

aquatic, marine water

Value 0,0167 mg/kg

PNEC type

sediment, freshwater

Value 30 µg/L

PNEC type

sewage treatment plant

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

liquid

Colour

yellow

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

Testing can be waived because substance is a liquid.

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

Testing can be waived because substance is a liquid.

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 dermal toxicity

ingredient sodium azide

Acute dermal toxicity 18 mg/kg

Effective dose

LD50:

Species:

Rabbit

ingredient reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

Acute dermal toxicity 2,8 mg/kg

Effective dose

LD50:

Species:

Rabbit

Acute inhalation toxicity (dust/mist)

ingredient sodium azide

Acute inhalation toxicity (dust/mist) 5,4 mg/kg

Effective dose

LC50:

Exposure time 4

Species:

Rat

Acute inhalation toxicity (vapour)

ingredient reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

Acute inhalation toxicity (vapour) 16,67 mg/L

Exposure time 4 d

Acute oral toxicity

ingredient sodium azide

Acute oral toxicity 27 mg/kg

Effective dose

LD50:

Species:

Rat

ingredient reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

Acute oral toxicity 862 mg/kg

Effective dose

LD50:

Species:

Rat

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

Genetic endpoint

not relevant

In vivo mutagenicity/genotoxicity

Result / evaluation

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

remark

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) 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

ingredient sodium azide

Acute (short-term) toxicity to algae and cyanobacteria 0,348 mg/L

Effective dose

EC50

Test duration 4 d

species

Alge/Wasserpflanze

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

evaluation parameter:

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

The substance meets the criteria of ready degradability as defined in Regulation (EC) No 1272/2008.

12.3 Bioaccumulative potential

Assessment/classification

not applicable

12.4 Mobility in soil

Assessment/classification

No data available

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

remark

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

All transport carriers

No dangerous good in sense of these transport regulations.

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

restrictions on use

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 MASTAZYME dsDNA 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

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

health hazards

Skin Sens. 1

hazard statements for health hazards

H317 May cause an allergic skin reaction.

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]

Hazard pictograms



GHS07

Signal word

Warning

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

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.

P332 + P313 If skin irritation occurs: Get medical advice/attention.

P363 Wash contaminated clothing before reuse.

Storage:

none

Disposal:

P501 Dispose of contents/container to an appropriate recycling or disposal facility.

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

2-methylisothiazol-3(2H)-one

<0,1 %

CAS 2682-20-4

EC 220-239-6

INDEX 613-326-00-9

Acute Tox. 2, H330 / Acute Tox. 3, H311 / Acute Tox. 3, H301 / Skin

Corr. 1B, H314 / Eye Dam. 1, H318 / Skin Sens. 1A, H317 / Aquatic

Acute 1, H400 / Aquatic Chronic 1, H410

SECTION 4: First aid measures

4.1 Description of first aid measures

General information

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

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. In case of skin irritation, consult a physician.

After eye contact

In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist.

Following ingestion

Rinse mouth thoroughly with water.

Self-protection of the first aider

none

4.2 Most important symptoms and effects, both acute and delayed

Effects

none

Symptoms

Allergic reactions

4.3 Indication of any immediate medical attention and special treatment needed

Notes for the doctor

Treat symptomatically. Kann bei empfindlichen Personen eine Sensibilisierung hervorrufen.

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

Sand

Carbon dioxide (CO₂)

Extinguishing powder

Unsuitable extinguishing media

Full water jet

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

Use personal protection equipment.

Protective equipment

none

For emergency responders

Personal protection equipment

Wear breathing apparatus if exposed to vapours/dusts/aerosols.

6.2 Environmental precautions

see chapter 12 for additional information

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

Exposure limits at intended use

biological limit values

remark

No data available

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

liquid

Colour

yellow

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



parameter	Method - source - remark
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
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

Testing can be waived because substance is a liquid.

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

Testing can be waived because substance is a liquid.

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 dermal toxicity

ingredient 2-methylisothiazol-3(2H)-one

Acute dermal toxicity 200 mg/kg

Effective dose

LD50:

Species:

Rabbit

Acute inhalation toxicity (vapour)

ingredient 2-methylisothiazol-3(2H)-one

Acute inhalation toxicity (vapour) 0,11 mg/L

Effective dose

LC50:

Exposure time 4 h

Acute oral toxicity

ingredient 2-methylisothiazol-3(2H)-one

Acute oral toxicity 120 mg/kg

Effective dose

LD50:

Species:

Rat

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

Genetic endpoint

not relevant

In vivo mutagenicity/genotoxicity

Result / evaluation

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

remark

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

Result / evaluation

keine/keiner

Chronic (long-term) fish toxicity

Result / evaluation

none

Acute (short-term) toxicity to algae and cyanobacteria

Result / evaluation

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

The substance meets the criteria of ready degradability as defined in Regulation (EC) No 1272/2008.

12.3 Bioaccumulative potential

Assessment/classification

not applicable

12.4 Mobility in soil

Assessment/classification

No data available

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

remark

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

All transport carriers

No dangerous good in sense of these transport regulations.

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

restrictions on use

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 MASTAZYME AI Diluent

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

The mixture is not classified as hazardous according to Regulation (EC) No 1272/2008 [CLP].

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

sodium azide	0 - <=0,09 %
CAS 26628-22-8	
EC 247-852-1	
INDEX 011-004-00-7	
Acute Tox. 2, H300 / Aquatic Acute 1, H400 / Aquatic Chronic 1, H410	
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	>=0,03 - <=0,05 %
CAS 55965-84-9	
INDEX 613-167-00-5	
Acute Tox. 2, H330 / Acute Tox. 2, H310 / Acute Tox. 3, H301 / Skin Corr. 1C, H314 / Eye Dam. 1, H318 / Skin Sens. 1A, H317 / Aquatic Acute 1, H400 / Aquatic Chronic 1, H410	

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.

Self-protection of the first aider

none

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
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 ≥ 2 - ≤ 8 °C

7.3 Specific end use(s)

Recommendation

Observe instructions for use.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limit values

CAS No.	Substance name	LTV	STV	remark
26628-22-8	Sodium azide	0,1 mg/m ³	0,3 (1) mg/m ³	(1) 15 minutes average value Bold-type: Indicative Occupational Exposure Limit Value (IOELV) ~

European Union

LTV = long-term occupational exposure limit value

STV = short-term occupational exposure limit value

source: GESTIS International Limit Values (<http://limitvalue.ifa.dguv.de/>)

Monitoring and observation processes: GESTIS Analytical Methods (<http://amcaw.ifa.dguv.de/>)

Exposure limits at intended use

biological limit values

remark

No data available

DNEL-/PNEC-values

DNEL Consumer

Substance name sodium azide

type

systemic

source

TRGS900

Value 0,493 mg/m³

Substance name reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

type

local

source

Deutschland. MAK- und BAT Anhang IIa

Value 0,02 mg/m³

PNEC

Value 0,35 µg/L

PNEC type

aquatic, freshwater

Value 0,015 µg/L

PNEC type

aquatic, marine water

Value 0,0167 mg/kg

PNEC type

sediment, freshwater

Value 30 µg/L

PNEC type

sewage treatment plant

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

liquid

Colour

green

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

Testing can be waived because substance is a liquid.

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

Testing can be waived because substance is a liquid.

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 dermal toxicity

ingredient sodium azide

Acute dermal toxicity 18 mg/kg

Effective dose

LD50:

Species:

Rabbit

ingredient reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

Acute dermal toxicity 2,8 mg/kg

Effective dose

LD50:

Species:

Rabbit

Acute inhalation toxicity (dust/mist)

ingredient sodium azide

Acute inhalation toxicity (dust/mist) 5,4 mg/kg

Effective dose

LC50:

Exposure time 4

Species:

Rat

Acute inhalation toxicity (vapour)

ingredient reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

Acute inhalation toxicity (vapour) 16,67 mg/L

Exposure time 4 d

Acute oral toxicity

ingredient sodium azide

Acute oral toxicity 27 mg/kg

Effective dose

LD50:

Species:

Rat

ingredient reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

Acute oral toxicity 862 mg/kg

Effective dose

LD50:

Species:

Rat

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

Genetic endpoint

not relevant

In vivo mutagenicity/genotoxicity

Result / evaluation

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

remark

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) 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

ingredient sodium azide

Acute (short-term) toxicity to algae and cyanobacteria 0,348 mg/L

Effective dose

EC50

Test duration 4 d

species

Alge/Wasserpflanze

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

evaluation parameter:

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

The substance meets the criteria of ready degradability as defined in Regulation (EC) No 1272/2008.

12.3 Bioaccumulative potential

Assessment/classification

not applicable

12.4 Mobility in soil

Assessment/classification

No data available

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

remark

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

All transport carriers

No dangerous good in sense of these transport regulations.

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



restrictions on use

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 MASTAZYME Cardioliipin Diluent

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

The mixture is not classified as hazardous according to Regulation (EC) No 1272/2008 [CLP].

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

sodium azide	0 - <=0,09 %
CAS 26628-22-8	
EC 247-852-1	
INDEX 011-004-00-7	
Acute Tox. 2, H300 / Aquatic Acute 1, H400 / Aquatic Chronic 1, H410	
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	>=0,03 - <=0,05 %
CAS 55965-84-9	
INDEX 613-167-00-5	
Acute Tox. 2, H330 / Acute Tox. 2, H310 / Acute Tox. 3, H301 / Skin Corr. 1C, H314 / Eye Dam. 1, H318 / Skin Sens. 1A, H317 / Aquatic Acute 1, H400 / Aquatic Chronic 1, H410	

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.

Self-protection of the first aider

none

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

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 ≥ 2 - ≤ 8 °C

7.3 Specific end use(s)

Recommendation

Observe instructions for use.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limit values

CAS No.	Substance name	LTV	STV	remark
26628-22-8	Sodium azide	0,1 mg/m ³	0,3 (1) mg/m ³	(1) 15 minutes average value Bold-type: Indicative Occupational Exposure Limit Value (IOELV) ~

European Union

LTV = long-term occupational exposure limit value

STV = short-term occupational exposure limit value

source: GESTIS International Limit Values (<http://limitvalue.ifa.dguv.de/>)

Monitoring and observation processes: GESTIS Analytical Methods (<http://amcaw.ifa.dguv.de/>)

Exposure limits at intended use

biological limit values

remark

No data available

DNEL-/PNEC-values

DNEL Consumer

Substance name sodium azide

type

systemic

source

TRGS900

Value 0,493 mg/m³

Substance name reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

type

local

source

Deutschland. MAK- und BAT Anhang IIa

Value 0,02 mg/m³

PNEC

Value 0,35 µg/L

PNEC type

aquatic, freshwater

Value 0,015 µg/L

PNEC type

aquatic, marine water

Value 0,0167 mg/kg

PNEC type

sediment, freshwater

Value 30 µg/L

PNEC type

sewage treatment plant

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

liquid

Colour

green

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

Testing can be waived because substance is a liquid.

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

Testing can be waived because substance is a liquid.

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 dermal toxicity

ingredient sodium azide

Acute dermal toxicity 18 mg/kg

Effective dose

LD50:

Species:

Rabbit

ingredient reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

Acute dermal toxicity 2,8 mg/kg

Effective dose

LD50:

Species:

Rabbit

Acute inhalation toxicity (dust/mist)

ingredient sodium azide

Acute inhalation toxicity (dust/mist) 5,4 mg/kg

Effective dose

LC50:

Exposure time 4

Species:

Rat

Acute inhalation toxicity (vapour)

ingredient reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

Acute inhalation toxicity (vapour) 16,67 mg/L

Exposure time 4 d

Acute oral toxicity

ingredient sodium azide

Acute oral toxicity 27 mg/kg

Effective dose

LD50:

Species:

Rat

ingredient reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

Acute oral toxicity 862 mg/kg

Effective dose

LD50:

Species:

Rat

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

Genetic endpoint

not relevant

In vivo mutagenicity/genotoxicity

Result / evaluation

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

remark

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) 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

ingredient sodium azide

Acute (short-term) toxicity to algae and cyanobacteria 0,348 mg/L

Effective dose

EC50

Test duration 4 d

species

Alge/Wasserpflanze

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

evaluation parameter:

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

The substance meets the criteria of ready degradability as defined in Regulation (EC) No 1272/2008.

12.3 Bioaccumulative potential

Assessment/classification

not applicable

12.4 Mobility in soil

Assessment/classification

No data available

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

remark

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

All transport carriers

No dangerous good in sense of these transport regulations.

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



restrictions on use

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 MASTAZYME AI-ELISA conjugate

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

The mixture is not classified as hazardous according to Regulation (EC) No 1272/2008 [CLP].

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

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) $\geq 0,05 - \leq 0,08 \%$

CAS 55965-84-9

INDEX 613-167-00-5

Acute Tox. 2, H330 / Acute Tox. 2, H310 / Acute Tox. 3, H301 / Skin

Corr. 1C, H314 / Eye Dam. 1, H318 / Skin Sens. 1A, H317 / Aquatic

Acute 1, H400 / Aquatic Chronic 1, H410

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.

Self-protection of the first aider

none

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

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 ≥ 2 - ≤ 8 °C

7.3 Specific end use(s)

Recommendation

Observe instructions for use.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Exposure limits at intended use

biological limit values

remark

No data available

DNEL-/PNEC-values

DNEL Consumer

Substance name reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

type

local

source

Deutschland. MAK- und BAT Anhang IIa

Value 0,02 mg/m³

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

liquid

Colour

red

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

parameter	Method - source - remark
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
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

Testing can be waived because substance is a liquid.

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

Testing can be waived because substance is a liquid.

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 dermal toxicity

ingredient reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

Acute dermal toxicity 2,8 mg/kg

Effective dose

LD50:

Species:

Rabbit

Acute inhalation toxicity (vapour)

ingredient reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

Acute inhalation toxicity (vapour) 16,67 mg/L

Exposure time 4 d

Acute oral toxicity

ingredient reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

Acute oral toxicity 862 mg/kg

Effective dose

LD50:

Species:

Rat

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

Genetic endpoint

not relevant

In vivo mutagenicity/genotoxicity

Result / evaluation

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

remark

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) toxicity to crustacea

Result / evaluation

none

Chronic (long-term) toxicity to aquatic invertebrate

remark

none

Chronic (long-term) fish toxicity

Result / evaluation

none

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

evaluation parameter:

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

The substance meets the criteria of ready degradability as defined in Regulation (EC) No 1272/2008.

12.3 Bioaccumulative potential

Assessment/classification

not applicable

12.4 Mobility in soil

Assessment/classification

No data available

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

remark

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

All transport carriers

No dangerous good in sense of these transport regulations.

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

restrictions on use

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 MASTAZYME Cardioliipin conjugate

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

The mixture is not classified as hazardous according to Regulation (EC) No 1272/2008 [CLP].

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

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) $\geq 0,05 - \leq 0,08 \%$

CAS 55965-84-9

INDEX 613-167-00-5

Acute Tox. 2, H330 / Acute Tox. 2, H310 / Acute Tox. 3, H301 / Skin

Corr. 1C, H314 / Eye Dam. 1, H318 / Skin Sens. 1A, H317 / Aquatic

Acute 1, H400 / Aquatic Chronic 1, H410

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.

Self-protection of the first aider

none

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

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

Exposure limits at intended use

biological limit values

remark

No data available

DNEL-/PNEC-values

DNEL Consumer

Substance name reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

type

local

source

Deutschland. MAK- und BAT Anhang IIa

Value 0,02 mg/m³

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

liquid

Colour

red

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

parameter	Method - source - remark
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
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

Testing can be waived because substance is a liquid.

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

Testing can be waived because substance is a liquid.

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 dermal toxicity

ingredient reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

Acute dermal toxicity 2,8 mg/kg

Effective dose

LD50:

Species:

Rabbit

Acute inhalation toxicity (vapour)

ingredient reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

Acute inhalation toxicity (vapour) 16,67 mg/L

Exposure time 4 d

Acute oral toxicity

ingredient reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

Acute oral toxicity 862 mg/kg

Effective dose

LD50:

Species:

Rat

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

Genetic endpoint

not relevant

In vivo mutagenicity/genotoxicity

Result / evaluation

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

remark

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) toxicity to crustacea

Result / evaluation

none

Chronic (long-term) toxicity to aquatic invertebrate

remark

none

Chronic (long-term) fish toxicity

Result / evaluation

none

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

evaluation parameter:

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

The substance meets the criteria of ready degradability as defined in Regulation (EC) No 1272/2008.

12.3 Bioaccumulative potential

Assessment/classification

not applicable

12.4 Mobility in soil

Assessment/classification

No data available

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

remark

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

All transport carriers

No dangerous good in sense of these transport regulations.

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

restrictions on use

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 MASTAZYME autoimmune substrate TMB

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-diagnostics.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

The mixture is not classified as hazardous according to Regulation (EC) No 1272/2008 [CLP].

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

Description

Das Gemisch enthält keine gefährlichen Inhaltsstoffe (gemäß Verordnung (EG) Nr. 1907/2006 (REACH)).

Hazardous ingredients

2-Pyrrolidon

1 - <3 %

CAS 210-483-1

REACHNo 01-2119475471-37

Repr. 1B, H360 / Eye Irrit. 2, H319

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.

Self-protection of the first aider

none

4.2 Most important symptoms and effects, both acute and delayed

Effects

No data available

Symptoms

No data available

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

Carbon dioxide (CO₂)

Foam

Dry extinguishing powder

Unsuitable extinguishing media

Full water jet

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products

Carbon monoxide

Carbon dioxide (CO₂)

5.3 Advice for firefighters

No data available

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

Persönliche Schutzausrüstung verwenden.

For emergency responders

Personal protection equipment

Vorgeschriebene persönliche Schutzausrüstung verwenden.

6.2 Environmental precautions

Dilute with water.

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

Storage class according to TRGS 510: 10 (Flammable liquids that cannot be assigned to any of the aforementioned LGK)

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

Exposure limits at intended use

biological limit values

remark

No data available

Occupational exposure limit values

Substance name Butan-1,4-diol

CAS No. 110-63-4

long-term occupational exposure limit value 50 ppm

source

TRGS 900

Substance name Dimethylsulfoxid (DMSO)

CAS No. 67-68-5

long-term occupational exposure limit value 50 ppm

source

TRGS 900

Substance name Zitronensäure

CAS No. 77-92-9

long-term occupational exposure limit value 2 mg/m³

source

TRGS 900

DNEL-/PNEC-values

DMEL worker

Substance name 2-Pyrrolidon

type

Long-term – inhalation, systemic effects

remark

29,62 mg/m³

Substance name 2-Pyrrolidon

type

Long-term - dermal, systemic effects

remark

4,2 mg/kg KG/d

PNEC

Value 0,5 mg/L

PNEC type

aquatic, freshwater

Value 0,05 mg/L

PNEC type

aquatic, marine water

Value 0,4205 mg/kg

PNEC type

sediment, freshwater

Value 10 mg/L

PNEC type

sewage treatment plant

Value 0,0612 mg/kg

PNEC type

soil

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)

Required properties:

Dicke des Handschuhmaterials ≥ 0.1 mm

Durchbruchzeit > 480 min

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

liquid

Colour

colourless

light yellow

Odour

charakteristisch

Odour threshold

not relevant

		parameter	Method - source - remark
Melting point/freezing point			No data available
Boiling point or initial boiling point and boiling range	100 °C		Berechnungsmethode
flammability			not relevant
Upper explosion limit			not relevant
lower explosion limit			not relevant
Flash point (°C)	120 °C		Berechneter Flammpunkt
Auto-ignition temperature			not relevant
Decomposition temperature			not relevant
pH	3,5 - 4	Temperature 20 °C	Experimentelle Daten
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	-0,71		2-Pyrrolidon
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

Testing can be waived because substance is a liquid.

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

Testing can be waived because substance is a liquid.

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

Avoid high temperatures or direct sunlight.

10.5 Incompatible materials

Metalle

Oxidationsmittel

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 dermal toxicity

ingredient 2-Pyrrolidon

Acute dermal toxicity >2000 mg/kg

Effective dose

LD50:

Species:

Rabbit

source

Europäische Chemikalienagentur

Acute oral toxicity

ingredient 2-Pyrrolidon

Acute oral toxicity >2000 mg/kg

Effective dose

LD50:

Species:

Rat

Method

OECD 401

source

Europäische Chemikalienagentur

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

Genetic endpoint

not relevant

In vivo mutagenicity/genotoxicity

Result / evaluation

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

remark

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

ingredient 2-Pyrrolidon

Acute (short-term) fish toxicity 10000 mg/L

Effective dose

LC50:

Test duration 96 h

species

Danio rerio (zebrafish)

remark

Quelle: Europäische Chemikalienagentur

Acute (short-term) toxicity to crustacea

ingredient 2-Pyrrolidon

Acute (short-term) toxicity to crustacea >500 mg/L

Effective dose

EC50

Test duration 48 h

species

Daphnia magna (Big water flea)

remark

Quelle: Europäische Chemikalienagentur

Chronic (long-term) toxicity to aquatic invertebrate

remark

none

Chronic (long-term) fish toxicity

Result / evaluation

none

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

ingredient 2-Pyrrolidon

Chronic (long-term) toxicity to aquatic algae and cyanobacteria >500 mg/L

Effective dose

ErC50

Test duration 72 h

species

Desmodesmus subspicatus

source

Europäische Chemikalienagentur

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

The substance meets the criteria of ready degradability as defined in Regulation (EC) No 1272/2008.

12.3 Bioaccumulative potential

Assessment/classification

not applicable

12.4 Mobility in soil

Assessment/classification

No data available

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

remark

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

All transport carriers

No dangerous good in sense of these transport regulations.

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



restrictions on use

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 MASTAZYME stopping solution 0.25 M

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

The mixture is not classified as hazardous according to Regulation (EC) No 1272/2008 [CLP].

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

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

sulphuric acid ... %	<=1,4 %
CAS 7664-93-9	
EC 231-639-5	
INDEX 016-020-00-8	
Skin Corr. 1A, H314	

SECTION 4: First aid measures

4.1 Description of first aid measures

General information

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible). Change contaminated, saturated clothing.

Following skin contact

After contact with skin, wash immediately with plenty of water and soap. In case of skin irritation, consult a physician.

After eye contact

Rinse immediately carefully and thoroughly with eye-bath or water. In case of eye irritation consult an ophthalmologist.

Following ingestion

Rinse mouth thoroughly with water. Let 1 glass of water be drunken in little sips (dilution effect). Do not induce vomiting.

Self-protection of the first aider

First aider: Pay attention to self-protection!

4.2 Most important symptoms and effects, both acute and delayed

If decomposition products are inhaled the following symptoms can occur

Vomiting
Headache
Gastrointestinal complaints
Sweating
Nausea

Effects

Nausea
Gastrointestinal complaints

Symptoms

Headache
Gastrointestinal complaints
Nausea

4.3 Indication of any immediate medical attention and special treatment needed

Notes for the doctor

Recovery usually happens spontaneously. Treat symptomatically.

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

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

Rubber boots

rubber gloves. protective clothing.

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

Emergency procedures

Provide adequate ventilation. Remove persons to safety.

Personal precautions

Use personal protection equipment.

Protective equipment

Wear breathing apparatus if exposed to vapours/dusts/aerosols.

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

Exposure limits at intended use

biological limit values

remark

No data available

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

Unsuitable protective clothing

No data available

Required properties

No data available

Recommended material

Natural fibres (e.g. cotton)

heat-resistant synthetic fibres

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

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

parameter	Method - source - remark
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
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

parameter	Method - source - remark
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

Testing can be waived because substance is a liquid.

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

Testing can be waived because substance is a liquid.

Organic peroxides

Justification for data waiving

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

Corrosive to metals

Justification for data waiving

not relevant

Desensitised explosives

Justification for data waiving

No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

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

10.2 Chemical stability

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

10.3 Possibility of hazardous reactions

No hazardous reaction when handled and stored according to provisions.

10.4 Conditions to avoid

Further information on storage conditions: see subsection 7.2.

10.5 Incompatible materials

No further relevant information available.

10.6 Hazardous decomposition products

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

SECTION 11: Toxicological information

Additional information

Toxicological data are not available.

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

Toxicokinetics, metabolism and distribution

Human toxicological data

No data available

Non-human toxicological data

remark

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

skin corrosion/irritation

Assessment/classification

No data available

Respiratory or skin sensitisation

Sensitisation to the respiratory tract

Assessment/classification

No data available

Skin sensitisation

Assessment/classification

No data available

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

Germ cell mutagenicity

Human toxicological data

Result

not relevant

In vitro mutagenicity/genotoxicity

Genetic endpoint

not relevant

In vivo mutagenicity/genotoxicity

Result / evaluation

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

remark

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

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

remark

No data available

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

No information available.

12.3 Bioaccumulative potential

Assessment/classification

not applicable

12.4 Mobility in soil

Assessment/classification

No data available

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

remark

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

All transport carriers

No dangerous good in sense of these transport regulations.

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

restrictions on use

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

H317 May cause an allergic skin reaction.

H290 May be corrosive to metals.

Training advice

none

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

1.1 Product identifier

Trade name/designation MASTAZYME AI-ELISA washing 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

The mixture is not classified as hazardous according to Regulation (EC) No 1272/2008 [CLP].

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

Description

none

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. Let 1 glass of water be drunken in little sips (dilution effect).

Self-protection of the first aider

none

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

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

Exposure limits at intended use

biological limit values

remark

No data available

DNEL-/PNEC-values

DNEL Consumer

type

local

source

Deutschland. MAK- und BAT Anhang IIa

Value 0,02 mg/m³

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

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

parameter	Method - source - remark
particle characteristics	not relevant
Dynamic viscosity	No data available
flow time	No data available
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

Testing can be waived because substance is a liquid.

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

Testing can be waived because substance is a liquid.

Organic peroxides

Justification for data waiving

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

Corrosive to metals

Justification for data waiving

not relevant

Desensitised explosives

Justification for data waiving

No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

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

10.2 Chemical stability

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

10.3 Possibility of hazardous reactions

No hazardous reaction when handled and stored according to provisions.

10.4 Conditions to avoid

Further information on storage conditions: see subsection 7.2.

10.5 Incompatible materials

No further relevant information available.

10.6 Hazardous decomposition products

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

SECTION 11: Toxicological information

Additional information

Toxicological data are not available.

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

Toxicokinetics, metabolism and distribution

Human toxicological data

No data available

Non-human toxicological data

remark

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

Acute toxicity

Acute dermal toxicity

remark

none

Acute inhalation toxicity (vapour)

remark

none

Acute oral toxicity

remark

none

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

Genetic endpoint

not relevant

In vivo mutagenicity/genotoxicity

Result / evaluation

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

remark

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

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

remark

No data available

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

The substance meets the criteria of ready degradability as defined in Regulation (EC) No 1272/2008.

12.3 Bioaccumulative potential

Assessment/classification

not applicable

12.4 Mobility in soil

Assessment/classification

No data available

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

remark

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

All transport carriers

No dangerous good in sense of these transport regulations.

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

restrictions on use

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