

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



MagNA Pure 96 External Lysis Buffer

Version
4.1

Revision Date:
28.09.2023

Date of last issue: 17.02.2022
Date of first issue: 07.11.2011

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

1.1 Product identifier

Trade name : MagNA Pure 96 External Lysis Buffer
Product code : 06374913001

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

Recommended restrictions : For use in research only
on use

1.3 Details of the supplier of the safety data sheet

Company : Roche Diagnostics Deutschland GmbH
Sandhoferstrasse 116
68305 Mannheim
Deutschland

Telephone : +496217590
Telefax : +496217592890
Responsible Department : +49(0)621-759-4223
E-mail address : info.dia-sds@roche.com

1.4 Emergency telephone number

In case of emergencies: : Central Works Security +49(0)621-759-2203
Roche Diagnostics GmbH

Centre for detoxification: : Mainz +49(0)6131-19240

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Acute toxicity, Category 4	H302: Harmful if swallowed.
Skin corrosion, Sub-category 1C	H314: Causes severe skin burns and eye damage.
Serious eye damage, Category 1	H318: Causes serious eye damage.
Long-term (chronic) aquatic hazard, Category 3	H412: Harmful to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

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Hazard pictograms

:



Signal word

:

Danger

Hazard statements

:

H302 Harmful if swallowed.
H314 Causes severe skin burns and eye damage.
H412 Harmful to aquatic life with long lasting effects.

Supplemental Hazard
Statements

:

EUH032 Contact with acids liberates very toxic gas.
EUH071 Corrosive to the respiratory tract.

Precautionary statements

:

Prevention:

P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection.

Response:

P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/ doctor.
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.

Hazardous components which must be listed on the label:

593-84-0

guanidinium thiocyanate

9002-93-1

4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: This substance/mixture contains components considered to have endocrine disrupting properties for environment, according to REACH Article 57(f), Commission Regulation (EU) 2018/605 or Commission Delegated Regulation (EU) 2017/2100.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
guanidinium thiocyanate	593-84-0 209-812-1 615-004-00-3 01-2120735072-65	Acute Tox. 4; H302 Acute Tox. 4; H332 Acute Tox. 4; H312 Skin Corr. 1C; H314 Eye Dam. 1; H318 Aquatic Chronic 3; H412 EUH032, EUH071 Acute toxicity estimate Acute oral toxicity: 593 mg/kg	>= 30,0 - < 50,0
4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated	9002-93-1	Acute Tox. 4; H302 Eye Dam. 1; H318 Aquatic Chronic 2; H411 Acute toxicity estimate Acute oral toxicity: 500 mg/kg	>= 20,0 - < 25,0

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

- General advice : Move out of dangerous area.
Consult a physician.
Show this safety data sheet to the doctor in attendance.
Do not leave the victim unattended.
- If inhaled : Move to fresh air.
If unconscious, place in recovery position and seek medical advice.
If symptoms persist, call a physician.
- In case of skin contact : Immediate medical treatment is necessary as untreated wounds from corrosion of the skin heal slowly and with difficulty.
If on skin, rinse well with water.

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If on clothes, remove clothes.

In case of eye contact : Small amounts splashed into eyes can cause irreversible tissue damage and blindness.
In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
Continue rinsing eyes during transport to hospital.
Remove contact lenses.
Protect unharmed eye.
Keep eye wide open while rinsing.
If eye irritation persists, consult a specialist.

If swallowed : Clean mouth with water and drink afterwards plenty of water.
Keep respiratory tract clear.
Do NOT induce vomiting.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.
Take victim immediately to hospital.

4.2 Most important symptoms and effects, both acute and delayed

Risks : Harmful if swallowed.
Causes serious eye damage.
Corrosive to the respiratory tract.
Causes severe burns.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media : High volume water jet

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Do not allow run-off from fire fighting to enter drains or water courses.

Hazardous combustion products : Ammonia
Carbon oxides
Hydrogen cyanide (hydrocyanic acid)

5.3 Advice for firefighters

Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary.

Further information : Collect contaminated fire extinguishing water separately. This

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must not be discharged into drains.
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.
Refer to protective measures listed in sections 7 and 8.

6.2 Environmental precautions

Environmental precautions : Prevent product from entering drains.
Prevent further leakage or spillage if safe to do so.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).
Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

Treat recovered material as described in the section "Disposal considerations".

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : Do not breathe vapours/dust.
Avoid contact with skin and eyes.
For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.
Dispose of rinse water in accordance with local and national regulations.
To prevent leaks or spillages from spreading, provide a suitable liquid retention system.

Advice on protection against fire and explosion : Normal measures for preventive fire protection.

Hygiene measures : When using do not eat or drink. When using do not smoke.
Wash hands before breaks and at the end of workday.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully re-sealed and kept upright to prevent leakage. Electrical installations / working materials must comply with the technological safety standards.

Further information on storage conditions : See label, package insert or internal guidelines

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Storage class (TRGS 510) : 8B

Further information on storage stability : No decomposition if stored and applied as directed.

7.3 Specific end use(s)

Specific use(s) : This product contains a substance on REACH Annex XIV (substance of very high concern due to endocrine disrupting properties for the environment) at or above 0.1% w/w and may only be used under the exemption from authorisation for scientific research and development (including analytical activities, quality control and In-Vitro Diagnostics) under controlled conditions. Only trained and authorised personnel is allowed to handle the substance.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
guanidinium thiocyanate	593-84-0	IOEL	100 microgram per cubic meter	Category 1 (Roche Group Directive K1, Annex 3): OEL = 100 µg/m ³

8.2 Exposure controls

Engineering measures

No data available

Personal protective equipment

Eye/face protection : Eye wash bottle with pure water
Tightly fitting safety goggles
Wear face-shield and protective suit for abnormal processing problems.

Use eye protection according to EN 166.

Hand protection

In case of contact through splashing:
Material : Nitrile rubber
Break through time : > 30 min
Glove thickness : > 0,11 mm

In case of full contact:
Material : butyl-rubber
Break through time : > 480 min
Glove thickness : > 0,4 mm

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Remarks	: The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it. This recommendation is only valid for the product mentioned in the safety data sheet and provided by us and for the application specified by us. Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. The suitability for a specific workplace should be discussed with the producers of the protective gloves.
Skin and body protection	: Impervious clothing Choose body protection according to the amount and concentration of the dangerous substance at the work place.
Respiratory protection	: In the case of vapour formation use a respirator with an approved filter.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	: liquid
Colour	: colourless
Odour	: odourless
Odour Threshold	: No data available
Melting point/range	: No data available
Boiling point/boiling range	: No data available
Flammability	: The product is not flammable., Does not sustain combustion.
Upper explosion limit / Upper flammability limit	: No data available
Lower explosion limit / Lower flammability limit	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: Hazardous decomposition products formed under fire conditions.
pH	: 6,0 - 7,0
Viscosity	

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Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Solubility(ies)		
Water solubility	:	completely miscible
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Vapour pressure	:	No data available
Relative density	:	No data available
Relative vapour density	:	No data available
Particle characteristics		
Particle Size Distribution	:	Not applicable

9.2 Other information

Explosives	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Flammability (liquids)	:	Does not sustain combustion.
Self-ignition	:	No data available
Evaporation rate	:	No data available
Miscibility with water	:	completely miscible

SECTION 10: Stability and reactivity

10.1 Reactivity

No dangerous reaction known under conditions of normal use.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions	:	Contact with acids liberates very toxic gas. Toxic gases may be released if in contact with the following: sodium hypochlorite Acids Strong oxidizing agents No decomposition if stored and applied as directed.
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10.4 Conditions to avoid

Conditions to avoid	:	Exposure to light.
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Exposure to moisture
Heat

10.5 Incompatible materials

Materials to avoid : Strong acids
Strong oxidizing agents
Cyanides
sodium hypochlorite

10.6 Hazardous decomposition products

Thermal decomposition can lead to release of irritating gases and vapours.
In case of fire hazardous decomposition products may be produced such as:
Carbon oxides
Nitrogen oxides (NO_x)
Sulphur oxides
Hydrogen cyanide (hydrocyanic acid)

SECTION 11: Toxicological information

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

Acute toxicity

Harmful if swallowed.

Product:

Acute oral toxicity : Acute toxicity estimate: 834,98 mg/kg
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 20 mg/l
Exposure time: 4 h
Test atmosphere: vapour
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 2.000 mg/kg
Method: Calculation method

Components:

guanidinium thiocyanate:

Acute oral toxicity : LD50 Oral (Rat, female): 593 mg/kg
Method: OECD Test Guideline 401
Symptoms: Vomiting
GLP: yes

Acute toxicity estimate: 593 mg/kg
Method: ATE value derived from LD50/LC50 value

Acute inhalation toxicity : Assessment: Corrosive to the respiratory tract., The component/mixture is moderately toxic after short term inhalation.

Acute dermal toxicity : Assessment: The component/mixture is moderately toxic after single contact with skin.

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4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated:

Acute oral toxicity : LD50 Oral (Rat): 1.900 - 5.000 mg/kg

Acute toxicity estimate: 500 mg/kg
Method: Expert judgement

Acute dermal toxicity : LD50 Dermal (Rabbit): > 3.000 mg/kg

Skin corrosion/irritation

Causes severe burns.

Product:

Remarks : Extremely corrosive and destructive to tissue.

Components:

guanidinium thiocyanate:

Species : Rabbit
Exposure time : 4 h
Method : OECD Test Guideline 404
Result : Corrosive after 1 to 4 hours of exposure
GLP : yes

Serious eye damage/eye irritation

Causes serious eye damage.

Product:

Remarks : May cause irreversible eye damage.

Components:

4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated:

Result : Risk of serious damage to eyes.
Remarks : May cause irreversible eye damage.

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Components:

guanidinium thiocyanate:

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative

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GLP: yes

Test Type: Chromosome aberration test in vitro
Test system: Human lymphocytes
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 473
Result: negative
GLP: no

Test Type: gene mutation test
Test system: mouse lymphoma cells
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 476
Result: negative
GLP: yes

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

Components:

guanidinium thiocyanate:

Effects on fertility : Species: Rat, female
Application Route: Oral
Dose: 25
GLP: no
Remarks: No significant adverse effects were reported
Based on data from similar materials

Effects on foetal development : Species: Rat, female
Application Route: Oral
Dose: 50, 150, 350 mg/kg bw/day
General Toxicity Maternal: NOAEL: 150 mg/kg bw/day
Embryo-foetal toxicity: NOAEL: 350 mg/kg body weight
Method: OECD Test Guideline 414
GLP: yes

STOT - single exposure

Corrosive to the respiratory tract.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

guanidinium thiocyanate:

Species : Rat, male and female
NOAEL : 100 mg/kg
Application Route : Oral
Exposure time : 90 d
Number of exposures : daily

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Dose : 25, 100, 300 mg/kg bw/day
Method : OECD Test Guideline 408
GLP : yes

Aspiration toxicity

Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 12: Ecological information

12.1 Toxicity

Product:

Ecotoxicology Assessment

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

Components:

guanidinium thiocyanate:

Toxicity to fish : LC50 (Poecilia reticulata (guppy)): 89,1 mg/l
End point: mortality
Exposure time: 96 h
Test Type: static test
Analytical monitoring: no
Method: OECD Test Guideline 203
GLP: no

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia (water flea)): 42,4 mg/l
End point: Immobilization
Exposure time: 48 h
Test Type: static test
Analytical monitoring: no
Method: OECD Test Guideline 202
GLP: no

Toxicity to algae/aquatic plants : EC50 (Desmodesmus subspicatus (green algae)): 130 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: static test
GLP: No information available.

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Toxicity to microorganisms : EC50 (activated sludge): > 185 mg/l
Exposure time: 28 d
Test Type: static test
Method: OECD Test Guideline 302B
GLP: yes

Ecotoxicology Assessment

Chronic aquatic toxicity : Harmful to aquatic life with long lasting effects.

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 4 - 8,9 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 18 - 26 mg/l
Exposure time: 48 h

Ecotoxicology Assessment

Chronic aquatic toxicity : Toxic to aquatic life with long lasting effects.

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

12.2 Persistence and degradability

Components:

guanidinium thiocyanate:

Biodegradability : Test Type: aerobic
Inoculum: activated sludge, non-adapted
Concentration: 343 mg/l
Result: Inherently biodegradable.
Biodegradation: 46 %
Exposure time: 28 d
Method: OECD Test Guideline 302B
GLP: no

4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated:

Biodegradability : Biodegradation: > 60 %
Exposure time: 28 d
Method: OECD Test Guideline 301B
Remarks: According to the results of tests of biodegradability this product is not readily biodegradable.

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12.3 Bioaccumulative potential

Components:

guanidinium thiocyanate:

Partition coefficient: n-octanol/water : log Pow: -1,11 (25 °C)
pH: > 5,1
Method: Regulation (EC) No. 440/2008, Annex, A.8
GLP: no

4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated:

Bioaccumulation : Remarks: No bioaccumulation is to be expected (log Pow <= 4).

Partition coefficient: n-octanol/water : Remarks: No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment : This substance/mixture contains components considered to have endocrine disrupting properties for environment, according to REACH Article 57(f), Commission Regulation (EU) 2018/605 or Commission Delegated Regulation (EU) 2017/2100.

Components:

4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated:

Assessment : The substance is considered to have endocrine disrupting properties according to REACH Article 57(f) for the environment.

12.7 Other adverse effects

Product:

Additional ecological information : An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.
Harmful to aquatic life with long lasting effects.

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SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : The product contains a substance on REACH Annex XIV at or above 0.1% w/w. Cartridges / rests of product to be disposed of as if it was hazardous waste.

The product should not be allowed to enter drains, water courses or the soil.
Do not contaminate ponds, waterways or ditches with chemical or used container.
Send to a licensed waste management company.

Contaminated packaging : Empty remaining contents.
Dispose of as unused product.
Empty containers should be taken to an approved waste handling site for recycling or disposal.
Do not re-use empty containers.

SECTION 14: Transport information

14.1 UN number or ID number

ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.2 UN proper shipping name

ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.3 Transport hazard class(es)

ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.4 Packing group

ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA (Cargo) : Not regulated as a dangerous good
IATA (Passenger) : Not regulated as a dangerous good

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14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADN, IMDG-Code, ICAO/IATA-DGR

14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered: Number on list 3

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated
For customers in the European Economic Area:, Contains SVHC:, octyl/nonylphenol ethoxylates., For use in research and under controlled conditions only, – acc. to Art. 56.3 and 3.23 REACH Regulation.

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances. : Not applicable

Water hazard class (Germany) : WGK 2 obviously hazardous to water
Classification according to AwSV, Annex 1 (5.2)

TA Luft List (Germany) : 5.2.1 Total dust:
others: 0,1 %

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Tetrabromophenol blue

5.2.2 Inorganic substances in powdered form:

Not applicable

5.2.4 Inorganic substances in gaseous form:

Not applicable

5.2.5 Organic Substances:

Not applicable

5.2.7.1.1 Carcinogenic substance:

Not applicable

5.2.7.1.1 Quartz fine dust PM4:

Not applicable

5.2.7.1.1 Formaldehyde:

Not applicable

5.2.7.1.2 Germ cell mutagens:

Not applicable

5.2.7.1.3 Substances toxic to reproduction:

Not applicable

5.2.7.2 Poorly degradable, easily enrichable and highly toxic organic substances:

Not applicable

Volatile organic compounds : Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control)
Not applicable

Other regulations:

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

The components of this product are reported in the following inventories:

AIIC : On the inventory, or in compliance with the inventory

DSL : All components of this product are on the Canadian DSL

NZIoC : Not in compliance with the inventory

ENCS : On the inventory, or in compliance with the inventory

ISHL : On the inventory, or in compliance with the inventory

KECI : Not in compliance with the inventory

PICCS : On the inventory, or in compliance with the inventory

IECSC : On the inventory, or in compliance with the inventory

TCSI : On the inventory, or in compliance with the inventory

TSCA : All substances listed as active on the TSCA inventory

TECI : Not in compliance with the inventory

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



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15.2 Chemical safety assessment

Chemical Safety Assessments for all substances in this product are either Complete or Not applicable.

SECTION 16: Other information

Full text of H-Statements

H302	: Harmful if swallowed.
H312	: Harmful in contact with skin.
H314	: Causes severe skin burns and eye damage.
H318	: Causes serious eye damage.
H332	: Harmful if inhaled.
H411	: Toxic to aquatic life with long lasting effects.
H412	: Harmful to aquatic life with long lasting effects.
EUH032	: Contact with acids liberates very toxic gas.
EUH071	: Corrosive to the respiratory tract.

Full text of other abbreviations

Acute Tox.	: Acute toxicity
Aquatic Chronic	: Long-term (chronic) aquatic hazard
Eye Dam.	: Serious eye damage
Skin Corr.	: Skin corrosion

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA

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The Roche logo, consisting of the word "Roche" in a bold, sans-serif font, enclosed within a hexagonal border.

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- Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

Classification of the mixture:

Acute Tox. 4	H302
Skin Corr. 1C	H314
Eye Dam. 1	H318
Aquatic Chronic 3	H412

Classification procedure:

Calculation method
Calculation method
Calculation method
Calculation method

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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