

Safety Data Sheet

according to Regulations REACH 1907/2006/EC

REF: 743220	NucleoType DirectLyse Reagent	Page: 1/11
Printing date: 30.11.2023	Date of issue: 21.11.2023	Version: 2.3.1.1

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

1.1 Product identifier

REF 743220
 Product name NucleoType DirectLyse Reagent

REACH Registration number(s): see SECTION 3.1/3.2 or
 A registration number for the substance(s) does not exist because the annual tonnage does not require registration or the substance or its use is excluded from registration.

1 x 250 µL Liquid Proteinase K UFI: TTWV-43C9-R202-NTGN
 1 x 60 mL Lysis Buffer M

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

Relevant identified uses
 Product for analytical use.
 Exposure Scenario Classification according REACH, RIP 3.2 Codes: SU 0-2, PC 21, PROC 15, AC 0
 The exposure scenario is integrated into sections 1-16.

Uses advised against
 not described

1.3 Details of the supplier of the safety data sheet

Manufactured by:
 MACHEREY-NAGEL GmbH & Co. KG
 Valencienner Str. 11, 52355 Düren, Germany
 Phone: +49 2421 969 0 E-mail: sds@mn-net.com (msds@mn-net.com)

1.4 Emergency telephone number

Outside Germany (DE): Call your regional Poisons Information Service or call local Life Saving Service.
 DE: Gemeinsames Giftinformationszentrum (GGIZ)
 99089 Erfurt tel. +49 361 730 730, <<https://www.ggiz-erfurt.de>>

You find our current versions of SDS in Internet: <<http://www.mn-net.com/SDS>>

SECTION 2: Hazard identification

2.0 Classification of the complete product according to Regulation (EC) 1272/2008



GHS08

Signal word DANGER

Hazard identification	Hazard classes/categories
H334	Resp. Sens. 1

2.1 Classification of the substance or mixture according to Regulation (EC) 1272/2008

250 µL Liquid Proteinase K



GHS08

Signal word DANGER

Hazard identification	Hazard classes/categories
H334	Resp. Sens. 1



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 52355 Düren · Germany
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60 mL Lysis Buffer M

Signal word

Do not need labelling as hazardous

-

No hazard class

List of H phrases: see section 16.2

2.2 Label elements according regulation (EC) 1272/2008

According **CLP directive** inner packages must be only labelled with GHS symbol(s) and product identifier(s) (EU 1272/2008 Annex I - 1.5.1.2). This labelling exemption is NOT valid for sensibilizing substances.

250 µL Liquid Proteinase K



GHS08

Signal word: DANGER

H334

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

P261sh, P284, P342+311, P501

Avoid breathing dust/vapours.[In case of inadequate ventilation] wear respiratory protection.If experiencing respiratory symptoms: Call a POISON CENTER/doctor.Dispose of contents/container to regulated waste treatment.

60 mL Lysis Buffer M

Do not need labelling as hazardous

Signal word: -

Label elements of the complete product



GHS08

Signal word: DANGER

H334

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

P261sh, P284, P342+311, P501

Avoid breathing dust/vapours.[In case of inadequate ventilation] wear respiratory protection.If experiencing respiratory symptoms: Call a POISON CENTER/doctor.Dispose of contents/container to regulated waste treatment.

2.3 Other hazards

Possible hazards from physicochemical properties

no data available

Information pertaining to particular risks to human and possible symptoms

Cause after impairments of health when ingested in small quantities.

Kit contains small amounts of enzymes: May cause allergy or asthma symptoms or breathing difficulties if inhaled. In liquid form no hazard H334.

Information pertaining to particular risks to the environment

PBT: not applicable

vPvB: not applicable

Possible endocrine disrupting effects

no data available

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SECTION 3: Composition / information on ingredients

3.1 Substances or 3.2 Mixtures

250 µL Liquid Proteinase K

Substance name: *proteinase K, liquid*
 CAS No.: 39450-01-6

Substance rating: H315, Skin Irrit. 2, H319, Eye Irrit. 2, H334, Resp. Sens. 1
 Formula: Enzyme Comm. No. 3.4.21.64, origin: tritirachium album
 Pseudonym (de): Endopeptidase K
 EC No.: 254-457-8 Index No.: 647-014-00-9
 Concentration: 1 - <3 %
 acc. CLP (GHS): H334, Resp. Sens. 1

Substance name: *glycerole*
 CAS No.: 56-81-5

Substance rating: No criteria for classification or naming of chemical not required.
 Formula: C₃H₈O₃
 Pseudonym (de): 1,2,3-Propantriol
 REACH Reg. No.: 01-2119471987-18-xxxx
 EC No.: 200-289-5 Index No.: n/a
 Concentration: 10 - <50 %
 acc. CLP (GHS): The criteria for classification are not fulfilled.

60 mL Lysis Buffer M

Substance name: *water*
 CAS No.: 7732-18-5

Substance rating: No criteria for classification or naming of chemical not required.
 Formula: H₂O
 REACH Reg. No.: exempt, Annex IV
 EC No.: 231-791-2
 Concentration: 90 - <100 %
 acc. CLP (GHS): The criteria for classification are not fulfilled.

Substance name: *chemicals/mixture until 1%*
 CAS No.: -

Substance rating: No criteria for classification or naming of chemical not required.
 Concentration: 0,1 - <1 %
 acc. CLP (GHS): The criteria for classification are not fulfilled.

3.3 Remarks

When not listed, mixtures are added with water [CAS No. 7732-18-5] to 100%.List of H and P phrases: see section 16.2.

SECTION 4: First aid measures

4.1 Description of first aid measures

Place insured person out of danger zone to fresh air immediately. Ensure quiet, warmth, and provide resuscitation if necessary. If necessary contact medical advice. Take to a doctor, in a raised position if there are breathing difficulties.

- 4.1.1 **After SKIN Contact**
Remove contaminated clothing. Rinse the affected skin or mucous membrane thoroughly under running water. (If possible) use soap.
- 4.1.2 **After EYE Contact**
After contact with the eyes rinse thoroughly under running water with the eyelid wide open with eye washing bottle, eye douche or running water (protect intact eye).
- 4.1.3 **After INHALATION of vapours**



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After inhalation of foam or vapour fresh air should be inhaled. Keep airways free. Administer a Dexamethasone spray as soon as possible. Ensure quiet, warmth, and provide resuscitation if necessary. In the event of respiratory distress ensure that the patient inhales oxygen. Secure the breathing, heart and circulatory function. ---

4.1.4 After ORAL Intake

After oral intake lots of water should be drunk after it has been ingested.

4.2 Most important symptoms and effects, both acute and delayed

May cause allergy or asthma symptoms or breathing difficulties if inhaled. Chronic effects: Repeated contact, even in small amounts, can lead to sensitization.

4.3 Indication of any immediate medical attention and special treatment needed

Inform patient respectively further measures and the possibility of long-term damages. ---

SECTION 5: Firefighting measures

5.1 Extinguishing media

5.1.1 Suitable extinguishing media

Fire extinguishers appropriate to the fire classification, and, if applicable, a fire blanket must be available in a prominent location in the work area. All extinguishers like FOAM, WATER SPRAY, DRY POWDER, CARBON DIOXIDE can be used.

5.1.2 Unsuitable extinguishing media

no data available

5.2 Special hazards arising from the substance or mixture

Formation of hazardous and caustic vapour-air mixtures possible.

5.3 Advice for firefighters

Product package burns like paper or plastic.

5.4 Additional information

no data available

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Do not breathe vapours. Regular staff training is necessary, indicating hazards and precautions on the basis of operating instructions. Restrictions on activity must be observed.

6.2 Environmental precautions

PBT: not applicable

vPvB: not applicable

6.3 Methods and material for containment and cleaning up

Bind any escaping liquid with inert absorbent. And dispose in accordance to local regulations for the disposal of hazardous chemicals. Clean any contaminated equipment and floors with plenty of water. Collect small amounts of leaked liquid and flush with water into drains.

6.4 Reference to other sections

no data available

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Handling in accordance with the test instruction, that comes with the product. Use only in well-ventilated working areas.

7.2 Conditions for safe storage, including any incompatibilities

Safe storage is guaranteed in the original packaging from MACHEREY-NAGEL. Storage class (German chemical industry): see chapter 12.1

Storage class (VCI): 10

Water hazard class (DE): 1

7.2.1 Requirements for stock rooms and containers

Keep original product packages tightly closed during handling and storage.



MACHEREY-NAGEL GmbH & Co. KG
Valencienner Str. 11
52355 Düren · Germany
www.mn-net.com

DE Tel.: +49 24 21 969-0 info@mn-net.com
CH Tel.: +41 62 388 55 00 sales-ch@mn-net.com
FR Tel.: +33 388 68 22 68 sales-fr@mn-net.com
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7.3 Specific end use(s)

Product for analytical use.

SECTION 8: Exposure controls /personal protection

8.1 Control parameters

60 mL Lysis Buffer M

Chemical: *water*

CAS No.: 7732-18-5

Chemical: *chemicals/mixture until 1%*

CAS No.: -

250 µL Liquid Proteinase K

Chemical: *glycerole*

CAS No.: 56-81-5

DNEL: [inh] 56 mg/m³

DNEL = Derived No-Effect Level (for workers)

PNEC (fresh water): 0.885 mg/L

PNEC = Predicted No Effect Concentration

TRGS 900 (DE): 200 E mg/m³
E/e respirable

Short-term exposure factor: 2 (I), Y
skin resorptive (H), respiratory sensitizable (Sa), skin sensitizable (Sh), teratogenic (Z) not securely excluded / (Y) certainly excluded

SUVA(CH) MAK value: 50 e* mg/m³

Chemical: *proteinase K, liquid*

CAS No.: 39450-01-6

SUVA(CH) MAK value: 0,00006 15min mg/m³

8.2 Exposure controls

Good ventilation and extraction system in the room, floor resistant to chemicals with floor drainage and washing facilities. The highest level of cleanliness must be maintained at the workplace.

8.2.1 Respiratory protection

Use for open access of these substances for example a protection filter, class A/AX. No additional recommendations.

8.2.2 Skin protection / Hand protection

Yes, gloves according EN 374 (permeation time >30 min - level 2), consist of PVC, natural latex, Neopren, or Nitril (f.ex. from Ansell or KCL). Use for short times chemical resistant latex gloves with code EN 374-3 level 1.

8.2.3 Eye / Face Protection

Yes, safety glasses according EN 166 with integrated side shields or wrap-around protection.

8.2.4 Skin protection

Recommended to avoid contamination with these hazards.

8.2.5 Personal hygiene

Eating, drinking, smoking, taking snuff and storage of food in work areas and at outdoor workplaces is prohibited. Avoid contact with the skin, eyes and clothing. Rinse any clothing on which the substance has been spilled, and soak it in water. Wash hands thoroughly with soap and water when stopping work and before eating, and then apply protective skin cream.

8.2.6 Thermal hazards

no data available

8.3 Limitation and monitoring of environmental exposure

Do not release product into environment.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

60 mL Lysis Buffer M

a) State of aggregation:

liquid

b) Colour:

colourless

c) Odor:

odorless

d) Melting point:

no data available

e) Boiling point:

no data available

f) Flammability:

no data available

g) Explosive limits (lower / upper):

no data available

h) Flash point:

no data available

i) Flashing temperature:

no data available

j) Decomposition temperature:

no data available



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k) pH value:	no data available
l) Kinematic viscosity:	no data available
m) Solubility in water:	no data available
n) Dispersion coefficient ($K_{o/w}$):	no data available
o) Vapour pressure (20°C):	no data available
p) Specific gravity:	no data available
q) Relative vapour density ($air=1$):	no data available
r) Particle size:	no data available

250 µL Liquid Proteinase K

a) State of aggregation:	liquid
b) Colour:	colourless
c) Odor:	odorless
d) Melting point:	no data available
e) Boiling point:	no data available
f) Flammability:	no data available
g) Explosive limits (lower / upper):	no data available
h) Flash point:	no data available
i) Flashing temperature:	no data available
j) Decomposition temperature:	no data available
k) pH value:	7-8
l) Kinematic viscosity:	no data available
m) Solubility in water:	0-100 %
n) Dispersion coefficient ($K_{o/w}$):	no data available
o) Vapour pressure (20°C):	no data available
p) Specific gravity:	1.1 g/cm ³
q) Relative vapour density ($air=1$):	no data available
r) Particle size:	no data available

9.2 Other information

9.2.1 Information on physical hazard classes

no data available

9.2.2 Other safety-related parameters

No data is available for the other parameters for the mixtures, since no registration and no chemical safety report is required.

□ □

SECTION 10: Stability and reactivity

10.1 Reactivity

no further data available.

10.2 Chemical stability

no known instability.

10.3 Possibility of hazardous reactions

No further data available.

10.4 Conditions to avoid

No more required.

10.5 Incompatible materials

no additional data available

10.6 Hazardous decomposition products

In the original package all parts/all reagents are safety and separated stored. Decompositions are not observed during the expiration period under recommended conditions.



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SECTION 11: Toxicological information

11.1 Information on the hazard classes according regulation (EC) 1272/2008

Following information is valid for pure substances. Quantitative data on the toxicity of this product are not available.

60 mL Lysis Buffer M

Chemical: *water* CAS No.: 7732-18-5
 TSCA Inventory: listed
 Korea Exist.Chem.Inventory: KE-35400
 LD50 orl rat : > 90000 mg/kg

Chemical: *chemicals/mixture until 1%* CAS No.: -
 TSCA Inventory: all listed, <1%
 Korea Exist.Chem.Inventory: listed

250 µL Liquid Proteinase K

Chemical: *glycerole* CAS No.: 56-81-5
 TSCA Inventory: listed (1,2,3-Propanetriol)
 Exposure Routes: inhalation, skin and/or eye contact
 Target Organs: Eyes, skin, respiratory system, kidneys
 Symptoms: irritation eyes, skin, respiratory system; headache, nausea, vomiting; kidney injury
 Japan CSCL/PRTR: not listed, Japan PDSCL: not listed
 Japan ISHL: not listed
 Korea Exist.Chem.Inventory: KE-29297
 LD50 orl rat : 12600 mg/kg

TRGS 905 (DE): R F C

Chemical: *proteinase K, liquid* CAS No.: 39450-01-6
 TSCA Inventory: listed (CAS 102925-54-2)
 Japan CSCL/PRTR: not listed
 Japan ISHL: not listed
 Korea Exist.Chem.Inventory: not listed

Acute Effects: Cause after impairments of health when ingested in small quantities.

Chronic Effects: May cause sensitization by skin contact, also in repeated contact of small amounts. May cause allergy or asthma symptoms or breathing difficulties if inhaled.

11.2 Other hazards

Possible endocrine disrupting effects

no data available

Other information

no additional data available

SECTION 12: Ecological information

12.1 Toxicity

Following information is valid for pure substances.

60 mL Lysis Buffer M

Substance name: *water* CAS-Nr.: 7732-18-5

Substance name: *chemicals/mixture until 1%* CAS-Nr.: -
 Water hazard class (DE): 1
 Storage class (VCI): 12-13

250 µL Liquid Proteinase K

Substance name: *glycerole* CAS-Nr.: 56-81-5

PNEC (fresh water) : 0.885 mg/L
 PNEC = Predicted No Effect Concentration = concentration at which no effect on the environment is expected

LC50 fish/96h : >5000 24h mg/L

EC50 daphnia/48h : >10 24h g/L

IC50 scenedesmus quadricauda/72h : IC5 7d >10 g/L

EC10 pseudomonas putida/16h : EC5: >10 g/L

Water hazard class (DE): 0



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Storage class (VCI): 10

Substance name: *proteinase K, liquid*

CAS-Nr.: 39450-01-6

Water hazard class (DE): 1

Storage class (VCI): 13

12.2 Persistence and degradability

12.3 Bioaccumulative potential

250 µL Liquid Proteinase K

Substance name:

glycerole

CAS-Nr.: 56-81-5

Dispersion coefficient (K_{o/w}):

-1,76

12.4 Mobility in soil

12.5 Results of PBT and vPvB 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

no data available

12.7 Other adverse effects

no additional data available

SECTION 13: Disposal considerations

Please observe local regulations for collection and disposal of hazardous waste and contact waste disposal company, where you will obtain information on laboratory waste disposal (waste code number 16 05 06).

13.1 Waste treatment methods

Normally it is possible to empty small amounts (diluted!) into drains.

SECTION 14: Transport information

14.1 - 14.4 Not necessary

14.5 Environmental hazards

none, contains only small quantities of hazardous substances

14.6 Special precautions for user

not necessary

14.7 Carriage in bulk by sea in accordance with IMO instruments

Not applicable.

SECTION 15: Regulatory information

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

Dangerous Substances Protection Act (DE: Chemikaliengesetz - ChemG), Aug 2013, Stand: Okt 2020

Ordinance on protection against dangerous substances (E: Gefahrstoffverordnung - GefStoffV), Nov 2010, Stand: Mrz 2017

TRGS 201, Classification and labeling of activities involving hazardous substances, Feb 2017

TRGS 220, National aspects when preparing safety data sheets, Jan 2017

TRGS 400, Risk assessment for activities involving hazardous substances, Jul 2017

BekGS 408, Application of the GefStoffV and the TRGS with the entry into force of the CLP regulation, December 2009, status: Jan 2012

Wasserhaushaltsgesetz - WHG, Section 3 Handling substances hazardous to water, Jul 2009, status: Aug 2016

MN leaflet/instructions for use, also at www.mn-net.com

If necessary, observe other country-specific regulations.



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52355 Düren · Germany
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15.2 Chemical safety assessment
not necessary for these small amounts

SECTION 16: Other information

16.1 Changes compared to the last version

Between versions 2.3.1.1 and 2.2.2.2 following changes were applied: - 1 product component data corrected

16.2 List of H and P phrases

16.2.1 List of relevant H phrases

H Between versions 2.3.1.1 and 2.2.2.2 following changes were applied: - 1 product component data corrected
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

16.2.2 List of relevant P phrases

P261sh Avoid breathing dust/vapours.
P284 [In case of inadequate ventilation] wear respiratory protection.
P342+311 If experiencing respiratory symptoms: Call a POISON CENTER/doctor.
P501 Dispose of contents/container to regulated waste treatment.

16.3 Recommended restriction on use

Only for professional user.
Look about employee restrictions for young people (f. ex. 94/33/EC or DE § 22 JArbSchG)!
Look about employee restrictions for pregnant women and nursing women (f.ex. 92/85/EEC or for DE §§ 11-13 MuSchG 2017)!
An individual package of this product or test kit has a moderate hazardous potential.

16.4 Sources of key data

KÜHN, BIRETT, Leaflets on hazardous materials, 2021
Directive 1999/92/EG Minimum requirements to improve the safety and health protection of workers at risk from potentially explosive atmospheres
SUVA .CH, limit values in the air at work 2009, revised on 01/2009
Regulation 790/2009/EU, adaptation of Regulation 1272/2008/EU to technical and scientific progress (1st ATP)
Regulation 453/2010/EU, adaptation of the REACH regulation 1907/2006/EG
TRGS 907, German technical rules for listing substances and causes of sensitization, updated November 2011
Regulation 487/2013/EU, adaptation of regulation 1272/2008/EG to technical and scientific progress (4th ATP)
Regulation 1221/2015/EU, adaptation of regulation 1272/2008/EG to technical and scientific progress (7th ATP)
Regulation 776/2017/EU, adaptation of regulation 1272/2008/EG to technical and scientific progress (10th ATP)

Regulation 669/2018/EU, adaptation of Regulation 1272/2008/EC to technical and scientific progressText (11th ATP)
Regulation 1480/2018/EU, adaptation of regulation 1272/2008/EG to technical and scientific progress (13th ATP)
Regulation 521/2019/EU, adaptation of regulation 1272/2008/EG to technical and scientific progress (12th ATP)
TRGS 900, German rules of technology on limit values in the air at work, as of 03/2019
Regulation 217/2020/EU, adaptation of Annex VI, Part 3, of Regulation 1272/2008/EC to technical and scientific progress (14th ATP)
Regulation 878/2020/EU, adaptation of Annex II of the REACH regulation 1907/2006/EG
Regulation 1182/2020/EU, adaptation of Annex VI, Part 3, of Regulation 1272/2008/EC to technical and scientific progress (15th ATP)
Regulation 643/2021/EU, adaptation of Annex VI, Part 1, of Regulation 1272/2008/EC to technical and scientific progress (16th ATP)
Regulation 849/2021/EU, adaptation of Annex VI, Part 3, of Regulation 1272/2008/EC to technical and scientific progress (17th ATP)
Regulation 692/2022/EU, adaptation of Annex VI, Part 1, of Regulation 1272/2008/EC to technical and scientific progress (18th ATP)

revisions/updates

Reason for revision: 2014-02 Corrected structure of the sections according to Regulation 453/2010/EU, if necessary
2014-04 adjustment according Regulation 487/2013/EU
2016-03 adjustment according Regulation 1221/2015/EU

2017-11 adjustment according the ECHA registration dossier
2022-11 adjustment according Regulation 878/2020/EU

16.5 Further information

MACHEREY-NAGEL GmbH & Co. KG provides the information contained herein in good faith being up-to-date of own realizations at revision time. This document is intended only as a guide to the appropriate precautionary handling of the material by a properly trained person using this product. Individuals receiving the information must exercise their independent judgement in determining its appropriateness for a particular purpose.
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MACHEREY-NAGEL GmbH & Co. KG
Valencienner Str. 11
52355 Düren · Germany
www.mn-net.com

DE Tel.: +49 24 21 969-0 info@mn-net.com
CH Tel.: +41 62 388 55 00 sales-ch@mn-net.com
FR Tel.: +33 388 68 22 68 sales-fr@mn-net.com
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16.6 Legend / Abbreviations

acc:	according
ADR:	Convention concerning the International Carriage of Dangerous Goods by Road
Act:	acute
BAT:	biological workplace tolerance value
CAO:	Cargo Aircraft Only
Carc:	carcinogen
CAS:	Chemical Abstracts Service
CLP:	Classification, Labelling and Packaging regulation
CMR:	carcinogen, mutagen, reproduction toxic
Corr:	corrosive
COD:	chemical oxygen demand
CSCL:	Chemical Substance Control Law (Jp)
Dam:	damage
DNEL:	Derived No-Effect Level (for workers)
derm:	dermal
dog:	dog
EC10:	Concentration causing a toxic effect in 10% of the test organisms
EC:	European Community
EC-Nr:	Substance number of the EC substance inventory
EmS:	Guide to accident management measures on ships
EU:	European Union
fish:	fish (not specified)
GHS:	Global Harmonized System of Classification and Labeling of Chemicals
gpg:	guinea pig
ICAO:	International Civil Aviation Organization
ihl:	inhaled
IMDG:	International Maritime Dangerous Goods Code
intrav:	intravenous
ipt:	intraperitoneal
ISHL:	Industrial Safety and Health Law (Jp)
LC50:	lethal concentration 50%
LD50:	lethal dose 50%
leuciscus idus:	fisch, ide, orfe
MAK:	maximum workplace concentration
Met:	Metall
mus:	mouse
Muta:	mutagen
NIOSH:	National Institute for Occupational Safety and Health (US)
NRD:	Non-rapidly degradable
onchorhynchus mykiss:	fisch, rainbow trout
orl:	oral
OSHA:	Occupational Safety and Health Administration
PAX:	transport on passenger planes allowed
PBT:	persistent, bioaccumulating, toxic substance
pH:	pH value
pimephales promelas:	fisch, fathead minnow
PNEC:	Predicted No Effect Concentration
PROC 15:	Process category 'for laboratory use'
PRTR:	Law for PRTR and Promotion of Chemical Management (Jp)
PVC:	polyvinyl chloride
quail:	bird, quail
rat:	rat
rbt:	rabbit
RD:	rapidly degradable
RE:	repeated
REACH:	Registration, Evaluation, Authorisation and Restriction of Chemicals
REF:	item number, reference number
Reg.No.:	rRegistration number
Repr:	harmful to reproduction
Resp:	respiratory
RIP:	REACH Implementations Projects
scu:	sub cutan
SDS:	safety data sheet
Sens:	sensitisation
STEL:	short term exposure limit
STOT:	Specific Target Organ Toxicity
SVHC:	Substance of Very High Concern
t/a:	tons per year



Safety Data Sheet

according to Regulations REACH 1907/2006/EC

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- TCCA: Toxic Chemicals Control Act (S. Korea)
- Tox: toxic
- TSCA: The Toxic Substances Control Act (US)
- TWA: time weighted average
- TRGS: technical regulations (DE)
- vPvB: very persistent, very bioaccumulating substance

16.7 Training advice

Regular safety training. Multiple safety training of staffs about danger and protection by using hazards in working area. Additionally training and introduction of staffs for using these products.



MACHEREY-NAGEL GmbH & Co. KG
 Valencienner Str. 11
 52355 Düren · Germany
www.mn-net.com

DE Tel.: +49 24 21 969-0 info@mn-net.com
 CH Tel.: +41 62 388 55 00 sales-ch@mn-net.com
 FR Tel.: +33 388 68 22 68 sales-fr@mn-net.com
 US Tel.: +1 888 321 62 24 sales-us@mn-net.com