

according to Regulation (EC) No. 1907/2006

Revision Date 24.04.2019

Version 13.16

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

1.1 Product identifier

Catalogue No. 7.4080

Product name Gram's crystal violet solution for the Gram staining method

REACH Registration

Number section 3.

This product is a mixture. REACH Registration Number see

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

Identified uses In vitro diagnostic reagent, Reagent for analysis

For additional information on uses please refer to the Merck

Chemicals portal (www.merckgroup.com).

1.3 Details of the supplier of the safety data sheet

Company NEUTRON PHARMACHEMICAL CO

98, 9th Floor, Borjsaz Building, Azadi Ave, Tehran, Iran.

T 021-66906732-3 - F 021-66581408 info@neutronco.com www.neutronco.com

1.4 Emergency telephone 125

number

SECTION 2. Hazards identification

2.1 Classification of the substance or mixture Classification (REGULATION (EC) No 1272/2008)

Flammable liquid, Category 3, H226

Long-term (chronic) aquatic hazard, Category 3, H412

For the full text of the H-Statements mentioned in this Section, see Section 16.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms



Signal word

according to Regulation (EC) No. 1907/2006

Catalogue No. 109218

Product name Gram's crystal violet solution for the Gram staining method

Warning

Hazard statements

H226 Flammable liquid and vapour.

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

Prevention

P210 Keep away from heat.

P273 Avoid release to the environment.

Reduced labelling (≤125 ml)

Hazard pictograms



Signal word Warning

Hazard statements H412 Harmful to aquatic life with long lasting effects.

2.3 Other hazards

None known.

SECTION 3. Composition/information on ingredients

Chemical nature A

Aqueous-ethanolic dye solution.

3.1 Substance

Not applicable

3.2 Mixture

Hazardous components (REGULATION (EC) No 1272/2008)

Chemical name (Concentration)

CAS-No. Registration Classification

number

ethanol (>= 3 % - < 10 %)

Substance does not meet the criteria for PBT or vPvB according to Regulation (EC) No 1907/2006, Annex XIII.

64-17-5 01-2119457610-

43-XXXX Flammable liquid, Category 2, H225

Eye irritation, Category 2, H319

Hexamethylpararosaniline chloride (crystal violet) (>= 0.25 % - < 1 %)

548-62-9 *)

Acute toxicity, Category 4, H302

Serious eye damage, Category 1, H318 Carcinogenicity, Category 2, H351

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Product name Gram's crystal violet solution for the Gram staining method

> Short-term (acute) aquatic hazard, Category 1, H400 Long-term (chronic) aguatic hazard, Category 1, H410

M-Factor: 1

Phenol (< 1 %)

Substance does not meet the criteria for PBT or vPvB according to Regulation (EC) No 1907/2006, Annex XIII.

108-95-2 01-2119471329-Germ cell mutagenicity, Category 2, H341

> 32-XXXX Acute toxicity, Category 3, H331 Acute toxicity, Category 3, H311

Acute toxicity, Category 3, H301

Specific target organ toxicity - repeated exposure,

Category 2, H373

Skin corrosion, Category 1B, H314

For the full text of the H-Statements mentioned in this Section, see Section 16.

SECTION 4. First aid measures

4.1 Description of first aid measures

After inhalation: fresh air.

In case of skin contact: Take off immediately all contaminated clothing. Rinse skin with water/ shower.

After eye contact: rinse out with plenty of water. Remove contact lenses.

After swallowing: make victim drink water (two glasses at most). Consult doctor if feeling unwell.

4.2 Most important symptoms and effects, both acute and delayed

irritant effects, respiratory paralysis, Dermatitis, Dizziness, narcosis, inebriation, euphoria, Nausea, Vomiting

Drying-out effect resulting in rough and chapped skin.

4.3 Indication of any immediate medical attention and special treatment needed

No information available.

SECTION 5. Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Water, Foam, Carbon dioxide (CO2), Dry powder

Unsuitable extinguishing media

For this substance/mixture no limitations of extinguishing agents are given.

5.2 Special hazards arising from the substance or mixture

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^{*)} A registration number is not available for this substance as the substance or its use are exempted from registration according to Article 2 REACH Regulation (EC) No 1907/2006, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.

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Product name Gram's crystal violet solution for the Gram staining method

Mixture with combustible ingredients.

Development of hazardous combustion gases or vapours possible in the event of fire.

Vapours are heavier than air and may spread along floors.

Forms explosive mixtures with air at elevated temperatures.

5.3 Advice for firefighters

Special protective equipment for firefighters

In the event of fire, wear self-contained breathing apparatus.

Further information

Remove container from danger zone and cool with water. Prevent fire extinguishing water from contaminating surface water or the ground water system.

SECTION 6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel: Do not breathe vapours, aerosols. Ensure adequate ventilation. Keep away from heat and sources of ignition. Evacuate the danger area, observe emergency procedures, consult an expert.

Advice for emergency responders:

Protective equipment see section 8.

6.2 Environmental precautions

Do not let product enter drains. Risk of explosion.

6.3 Methods and materials for containment and cleaning up

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up with liquid-absorbent material (e.g. Chemizorb®). Dispose of properly. Clean up affected area.

6.4 Reference to other sections

Indications about waste treatment see section 13.

SECTION 7. Handling and storage

7.1 Precautions for safe handling

Advice on safe handling

Observe label precautions.

Advice on protection against fire and explosion

Keep away from open flames, hot surfaces and sources of ignition. Take precautionary measures against static discharge.

Hygiene measures

Change contaminated clothing. Wash hands after working with substance.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions

Keep container tightly closed in a dry and well-ventilated place. Keep away from heat and sources of ignition.

according to Regulation (EC) No. 1907/2006

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Product name Gram's crystal violet solution for the Gram staining method

Recommended storage temperature see product label.

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

SECTION 8. Exposure controls/personal protection

8.1 Control parameters

Derived No Effect Level (DNEL)

ethanol ((64-17-5)

CC., C., C., T.	/			
Worker DNEL, acute	Local effects	inhalation	1900 mg/m ³	
Worker DNEL, longterm	Systemic effects	dermal	343 mg/kg Body weight	
Worker DNEL, longterm	Systemic effects	inhalation	950 mg/m ³	
Consumer DNEL, acute	Local effects	inhalation	950 mg/m ³	
Consumer DNEL, longterm	Systemic effects	dermal	206 mg/kg Body weight	
Consumer DNEL, longterm	Systemic effects	inhalation	114 mg/m³	
Consumer DNEL, longterm	Systemic effects	oral	87 mg/kg Body weight	
Phenol (108-95-2)				
Worker DNEL, longterm	Systemic effects	inhalation	8 mg/m ³	
Worker DNEL,	Systemic effects	dermal	1,23 mg/kg Body weight	

Predicted No Effect Concentration (PNEC)

ethanol (64-17-5)	
PNEC Fresh water	0,96 mg/l
PNEC Marine water	0,79 mg/l
PNEC Fresh water sediment	3,6 mg/kg
PNEC Soil	0,63 mg/kg
PNEC Aquatic intermittent release	2,75 mg/l
PNEC Sewage treatment plant	580 mg/l
PNEC oral	720 mg/kg

Phenol	(108-	95-21
PHEHOL	I LUO-	ココ ース 1

longterm

Phenol (108-95-2) PNEC Fresh water	0,0077 mg/l
PNEC Marine water	0,00077 mg/l
PNEC Fresh water sediment	0,0915 mg/kg
PNEC Marine sediment	0,00915 mg/kg
PNEC Soil	0,136 mg/kg
PNEC Sewage treatment plant	2,1 mg/l

8.2 Exposure controls

according to Regulation (EC) No. 1907/2006

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Product name Gram's crystal violet solution for the Gram staining method

Engineering measures

Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.

See section 7.1.

Individual protection measures

Protective clothing needs to be selected specifically for the workplace, depending on concentrations and quantities of the hazardous substances handled. The chemical resistance of the protective equipment should be enquired at the respective supplier.

Eye/face protection Safety glasses

Hand protection

full contact:

Glove material: butyl-rubber
Glove thickness: 0,7 mm
Break through time: 480 min

splash contact:

Glove material: Nitrile rubber Glove thickness: 0,40 mm
Break through time: 120 min

The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374, for example KCL 898 Butoject® (full contact), KCL 730 Camatril® -Velours (splash contact).

The breakthrough times stated above were determined by KCL in laboratory tests acc. to EN374 with samples of the recommended glove types.

This recommendation applies only to the product stated in the safety data sheet, supplied by us and for the designated use. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN374 please contact the supplier of CE-approved gloves (e.g. KCL GmbH, D-36124 Eichenzell, Internet: www.kcl.de).

Other protective equipment

Flame retardant antistatic protective clothing.

Respiratory protection

required when vapours/aerosols are generated.

Recommended Filter type: filter ABEK

The entrepeneur has to ensure that maintenance, cleaning and testing of respiratory protective devices are carried out according to the instructions of the producer.

These measures have to be properly documented.

Environmental exposure controls

Do not let product enter drains. Risk of explosion.

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Product name Gram's crystal violet solution for the Gram staining method

SECTION 9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Form liquid

Colour blue

Odour phenol-like

Odour Threshold No information available.

pH No information available.

Melting point No information available.

Boiling point No information available.

Flash point 47 °C

Evaporation rate No information available.

Flammability (solid, gas) No information available.

Lower explosion limit No information available.

Vapour pressure No information available.

Relative vapour density No information available.

Density 0,99 g/cm3

at 20 °C

Relative density No information available.

Water solubility at 20 °C

soluble

Partition coefficient: n-

octanol/water

No information available.

Auto-ignition temperature No information available.

Decomposition temperature No information available.

Viscosity, dynamic No information available.

Explosive properties Not classified as explosive.

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Oxidizing properties none

9.2 Other data

none

SECTION 10. Stability and reactivity

10.1 Reactivity

Vapour/air-mixtures are explosive at intense warming.

10.2 Chemical stability

The product is chemically stable under standard ambient conditions (room temperature) .

10.3 Possibility of hazardous reactions

Violent reactions possible with:

The generally known reaction partners of water.

10.4 Conditions to avoid

Heating.

10.5 Incompatible materials

no information available

10.6 Hazardous decomposition products

no information available

SECTION 11. Toxicological information

11.1 Information on toxicological effects Mixture

Acute oral toxicity

Acute toxicity estimate: > 2.000 mg/kg

Calculation method

Symptoms: Nausea, Vomiting

Acute inhalation toxicity

Acute toxicity estimate: > 20 mg/l; 4 h; vapour

Calculation method

Symptoms: Possible damages:, mucosal irritations

Acute dermal toxicity

Acute toxicity estimate: > 2.000 mg/kg

Calculation method

Skin irritation

Possible damages: Drying-out effect resulting in rough and chapped skin.

Eye irritation

This information is not available.

according to Regulation (EC) No. 1907/2006

Catalogue No. 109218

Product name Gram's crystal violet solution for the Gram staining method

Sensitisation

This information is not available.

Germ cell mutagenicity

This information is not available.

Carcinogenicity

This information is not available.

Reproductive toxicity

This information is not available.

Teratogenicity

This information is not available.

Specific target organ toxicity - single exposure

This information is not available.

Specific target organ toxicity - repeated exposure

This information is not available.

Aspiration hazard

This information is not available.

11.2 Further information

Property that must be anticipated on the basis from the components of the mixture: Long-term feeding studies in rats and mice revealed an increased incidence of tumours in different target organs.

The results of the long-term studies available suggest that exposure to crystal violet/gentian violet may lead to irreversible damage. The positive in-vitro genetic toxicity findings also point in a negative direction. However, the data available do not suffice to classify the dye as carcinogenic in humans.

Systemic effects:

euphoria

After absorption of large quantities:

Dizziness, inebriation, narcosis, respiratory paralysis

However, when the product is handled appropriately, hazardous effects are unlikely to occur.

Handle in accordance with good industrial hygiene and safety practice.

Components

ethanol

Acute oral toxicity LD50 Rat: 10.470 mg/kg OECD Test Guideline 401

Acute inhalation toxicity

LC50 Rat: 124,7 mg/l; 4 h; vapour

OECD Test Guideline 403

Skin irritation

Rabbit

Result: No skin irritation OECD Test Guideline 404

Eye irritation

Result: Eye irritation OECD Test Guideline 405

according to Regulation (EC) No. 1907/2006

Catalogue No. 109218

Product name Gram's crystal violet solution for the Gram staining method

Sensitisation

Local lymph node assay (LLNA) Mouse

Result: negative

Method: OECD Test Guideline 429

Germ cell mutagenicity Genotoxicity in vitro Ames test

Salmonella typhimurium

Result: negative

Method: OECD Test Guideline 471

In vitro mammalian cell gene mutation test

Mouse lymphoma test Result: negative

Method: OECD Test Guideline 476

Reproductive toxicity
Application Route: Oral

Mouse

Method: OECD Test Guideline 416

Hexamethylpararosaniline chloride (crystal violet)

Acute oral toxicity LD50 Rat: 420 mg/kg

(RTECS)

Phenol

Acute dermal toxicity LD50 Rat: 660 mg/kg OECD Test Guideline 402

Skin irritation
In vitro study
Result: Causes by

Result: Causes burns. OECD Test Guideline 431

Eye irritation Rabbit Result: Corrosive

OECD Test Guideline 405

Sensitisation

Sensitisation test: Guinea pig

Result: negative

(IUCLID)

Germ cell mutagenicity Genotoxicity in vitro

Mutagenicity (mammal cell test): chromosome aberration.

Result: positive

Method: OECD Test Guideline 473

Mutagenicity (mammal cell test): micronucleus.

Result: positive

Method: OECD Test Guideline 487

according to Regulation (EC) No. 1907/2006

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SECTION 12. Ecological information

Mixture

12.1 Toxicity

No information available.

12.2 Persistence and degradability

No information available.

12.3 Bioaccumulative potential

No information available.

12.4 Mobility in soil

No information available.

12.5 Results of PBT and vPvB assessment

Substance(s) in the mixture do(es) not meet the criteria for PBT or vPvB according to Regulation (EC) No 1907/2006, Annex XIII, or a PBT/vPvB assessment was not conducted.

12.6 Other adverse effects

Discharge into the environment must be avoided.

Components

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ethanol
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Toxicity to fish

flow-through test EC50 Pimephales promelas (fathead minnow): 15.300 mg/l; 96 h

Analytical monitoring: yes

US-EPA

Toxicity to daphnia and other aquatic invertebrates

EC50 Daphnia magna (Water flea): 9.268 - 14.221 mg/l; 48 h

(IUCLID)

Toxicity to algae

IC5 Scenedesmus quadricauda (Green algae): 5.000 mg/l; 7 d

(Lit.)

Toxicity to bacteria

EC5 Pseudomonas putida: 6.500 mg/l; 16 h

(IUCLID)

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

semi-static test NOEC Daphnia magna (Water flea): 9,6 mg/l; 9 d

(ECHA)

Biodegradability

94 %

OECD Test Guideline 301E

Readily biodegradable

Biochemical Oxygen Demand (BOD)

930 - 1.670 mg/g (5 d)

(Lit.)

Theoretical oxygen demand (ThOD)

2.100 mg/g

(Lit.)

according to Regulation (EC) No. 1907/2006

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Product name Gram's crystal violet solution for the Gram staining method

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Ratio COD/ThBOD
     90 %
     (Lit.)
     Partition coefficient: n-octanol/water
     log Pow: -0,31
     (experimental)
     (Lit.) Bioaccumulation is not expected.
     Substance does not meet the criteria for PBT or vPvB according to Regulation (EC) No 1907/2006,
     Annex XIII.
Hexamethylpararosaniline chloride (crystal violet)
     Toxicity to fish
     LC50 S.gairdnerii: 0,7 mg/l; 96 h
     (External MSDS)
     Toxicity to daphnia and other aquatic invertebrates
     static test EC50 Daphnia magna (Water flea): > 0,24 - < 0,5 mg/l; 48 h
     OECD Test Guideline 202
     Toxicity to algae
     EC50 Pseudokirchneriella subcapitata (green algae): 0,42 mg/l; 72 h
     OECD Test Guideline 201
     Toxicity to bacteria
     EC50 Bacteria: 10 - 100 mg/l
     (External MSDS)
     Biodegradability
     3,6 %; 28 d; aerobic
     OECD Test Guideline 301F
     Not readily biodegradable.
     Partition coefficient: n-octanol/water
     log Pow: 1,172 (25 °C)
     OECD Test Guideline 107
     Bioaccumulation is not expected.
     M-Factor
Phenol
     Toxicity to fish
     LC50 Oncorhynchus mykiss (rainbow trout): 5,0 mg/l; 96 h
     (ECOTOX Database)
     Toxicity to daphnia and other aquatic invertebrates
     static test EC50 Ceriodaphnia dubia (water flea): 3,1 mg/l; 48 h
     US-EPA
     Toxicity to algae
     IC5 Scenedesmus quadricauda (Green algae): 7,5 mg/l; 8 d
     (IUCLID) (maximum permissible toxic concentration)
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static test EC50 Pseudokirchneriella subcapitata (algae): 61,1 mg/l; 96 h

US-EPA

according to Regulation (EC) No. 1907/2006

Catalogue No. 109218

Product name Gram's crystal violet solution for the Gram staining method

Toxicity to bacteria

EC50 activated sludge: 766 mg/l; 3 h

OECD Test Guideline 209

Toxicity to fish (Chronic toxicity)

semi-static test NOEC Poecilia reticulata (guppy): 4 mg/l; 14 d

OECD Test Guideline 204

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) semi-static test EC10 Daphnia magna (Water flea): 0,46 mg/l; 16 d

(ECHA)

Biodegradability 100 %; 6 d OECD Test Guideline 302B Easily eliminable.

85 %; 14 d OECD Test Guideline 301C Readily biodegradable

Biochemical Oxygen Demand (BOD) 1.680 mg/g (5 d) (IUCLID)

Chemical Oxygen Demand (COD) 2.300 mg/g (IUCLID)

Partition coefficient: n-octanol/water log Pow: 1,47 (30 °C) (ECHA) Bioaccumulation is not expected.

Substance does not meet the criteria for PBT or vPvB according to Regulation (EC) No 1907/2006, Annex XIII.

Surface tension 71,3 mN/m at 20 °C

according to Regulation (EC) No. 1907/2006

Catalogue No. 109218

Product name Gram's crystal violet solution for the Gram staining method

SECTION 13. Disposal considerations

Waste treatment methods

See www.retrologistik.com for processes regarding the return of chemicals and containers, or contact us there if you have further questions.

SECTION 14. Transport information

Land transport (ADR/RID)

14.1 UN number UN 1993

14.2 Proper shipping FLAMMABLE LIQUID, N.O.S. (ETHANOL)

name

14.3 Class 3 **14.4 Packing group** III **14.5 Environmentally** --

hazardous

14.6 Special precautions yes

for user

Tunnel restriction code D/E

Inland waterway transport (ADN)

Not relevant

Air transport (IATA)

14.1 UN number UN 1993

14.2 Proper shipping FLAMMABLE LIQUID, N.O.S. (ETHANOL)

name

14.3 Class314.4 Packing groupIII14.5 Environmentally--

hazardous

14.6 Special precautions no

for user

Sea transport (IMDG)

14.1 UN number UN 1993

14.2 Proper shipping FLAMMABLE LIQUID, N.O.S. (ETHANOL)

name

14.3 Class 3 **14.4 Packing group** III **14.5 Environmentally** --

hazardous

14.6 Special precautions yes

for user

EmS F-E S-E

according to Regulation (EC) No. 1907/2006

Catalogue No. 109218

Product name Gram's crystal violet solution for the Gram staining method

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not relevant

SECTION 15. Regulatory information

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

EU regulations

Major Accident Hazard

SEVESO III

Legislation

FLAMMABLE LIQUIDS

P5c

Quantity 1: 5.000 t Quantity 2: 50.000 t

Occupational restrictions

Take note of Dir 94/33/EC on the protection of young

people at work.

Regulation (EC) No 1005/2009 on substances not regulated

that deplete the ozone layer

Regulation (EC) No 850/2004 of the

not regulated

European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC

Substances of very high concern (SVHC)

This product does not contain substances of very high concern according to Regulation (EC) No 1907/2006 (REACH), Article 57 above the respective regulatory concentration limit of \geq 0.1 %

(w/w).

National legislation

Storage class 3

15.2 Chemical safety assessment

For this product a chemical safety assessment was not carried out.

according to Regulation (EC) No. 1907/2006

Catalogue No. 109218

Product name Gram's crystal violet solution for the Gram staining method

SECTION 16. Other information

Full text of H-Statements referred to under sections 2 and 3.

H225	Highly flammable liquid and vapour.
H226	Flammable liquid and vapour.
H301	Toxic if swallowed.
H302	Harmful if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H331	Toxic if inhaled.
H341	Suspected of causing genetic defects.
H351	Suspected of causing cancer.
H373	May cause damage to organs through prolonged or
	repeated exposure.
H400	Very toxic to aquatic life.

Training advice

Provide adequate information, instruction and training for operators.

Key or legend to abbreviations and acronyms used in the safety data sheet

Used abbreviations and acronyms can be looked up at www.wikipedia.org.

Regional representation

This information is given on the authorised Safety Data Sheet for your country.

The information contained herein is based on the present state of our knowledge. It characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of any properties of the product.

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