according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



# Crystal violet (C.I. 42555), p.a.

article number: T123 date of compilation: 10.02.2016 Version: **4.0 en** 

Revision: 02.03.2024

Replaces version of: 30.06.2021 Version: (3)

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

#### **Product identifier** 1.1

Identification of the substance Crystal violet (C.I. 42555), p.a.

Article number T123

Registration number (REACH) It is not required to list the identified uses be-

cause the substance is not subject to registration

according to REACH (< 1 t/a).

Index number in CLP Annex VI 612-204-00-2 EC number 208-953-6 CAS number 548-62-9

4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclo-Alternative name(s)

hexa-2,5-dien-1-ylidene]dimethylammonium

chloride

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

Relevant identified uses: Laboratory chemical

Laboratory and analytical use

Uses advised against: Do not use for products which come into contact

with foodstuffs. Do not use for private purposes (household). Food, drink and animal feeding-

stuffs.

1.3 Details of the supplier of the safety data sheet

> Carl Roth GmbH + Co. KG Schoemperlenstr. 3-5 D-76185 Karlsruhe

Germany

**Telephone:**+49 (0) 721 - 56 06 0 Telefax: +49 (0) 721 - 56 06 149 e-mail: sicherheit@carlroth.de Website: www.carlroth.de

Competent person responsible for the safety data 
Department Health, Safety and Environment

sheet:

e-mail (competent person): sicherheit@carlroth.de

1.4 **Emergency telephone number** 

# **SECTION 2: Hazards identification**

#### Classification of the substance or mixture 2.1

Page 1 / 19 Malta (en)

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



# Crystal violet (C.I. 42555), p.a.

article number: T123

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

Section	Hazard class	Cat- egory	Hazard class and category	Hazard statement
3.10	Acute toxicity (oral)	4	Acute Tox. 4	H302
3.3	Serious eye damage/eye irritation	1	Eye Dam. 1	H318
3.6	Carcinogenicity	2	Carc. 2	H351
4.1A	Hazardous to the aquatic environment - acute hazard	1	Aquatic Acute 1	H400
4.1C	Hazardous to the aquatic environment - chronic hazard	1	Aquatic Chronic 1	H410

For full text of abbreviations: see SECTION 16

## The most important adverse physicochemical, human health and environmental effects

Spillage and fire water can cause pollution of watercourses.

### 2.2 Label elements

# Labelling according to Regulation (EC) No 1272/2008 (CLP)

Signal word Danger

# **Pictograms**

GHS05, GHS07, GHS08, GHS09









#### **Hazard statements**

H302 Harmful if swallowed H318 Causes serious eye damage H351 Suspected of causing cancer

H410 Very toxic to aquatic life with long lasting effects

### **Precautionary statements**

# **Precautionary statements - prevention**

P273 Avoid release to the environment P280 Wear protective gloves/eye protection

### **Precautionary statements - response**

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact

lenses, if present and easy to do. Continue rinsing

P308+P313 IF exposed or concerned: Get medical advice/attention

For professional users only

Labelling of packages where the contents do not exceed 125 ml

Signal word: Danger

Symbol(s)









Malta (en) Page 2 / 19

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



# Crystal violet (C.I. 42555), p.a.

article number: T123

H318 Causes serious eye damage. H351 Suspected of causing cancer.

P280 Wear protective gloves/eye protection.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to

do. Continue rinsing.

P308+P313 IF exposed or concerned: Get medical advice/attention.

#### 2.3 Other hazards

#### Results of PBT and vPvB assessment

According to the results of its assessment, this substance is not a PBT or a vPvB.

# **Endocrine disrupting properties**

Does not contain an endocrine disruptor (ED) at a concentration of  $\geq$  0,1%.

# **SECTION 3: Composition/information on ingredients**

#### 3.1 Substances

Name of substance Crystal violet Molecular formula  $C_{25}H_{30}CIN_3$  Molar mass  $408~^g/_{mol}$  CAS No 548-62-9 EC No 208-953-6 Index No 612-204-00-2

# **Substance of Very High Concern (SVHC)**

Name of substance	CAS No	EC No	Listed in	Remarks
Crystal violet	548-62-9	208-953-6	Candidate list	Carc. A57a

Legend

Candidate Substances meeting the criteria referred to in Article 57 and for eventual inclusion in Annex XIV

Carc. A57a Carcinogenic (article 57a)

### Substance, Specific Conc. Limits, M-factors, ATE

Specific Conc. Limits	M-Factors	ATE	Exposure route
-	M-factor (acute) = 10	420 <sup>mg</sup> / <sub>kg</sub>	oral

# **SECTION 4: First aid measures**

# 4.1 Description of first aid measures



#### **General notes**

Take off contaminated clothing.

# Following inhalation

Provide fresh air. In all cases of doubt, or when symptoms persist, seek medical advice.

Malta (en) Page 3 / 19

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



# Crystal violet (C.I. 42555), p.a.

article number: T123

# Following skin contact

Rinse skin with water/shower.

# Following 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 with water (only if the person is conscious). In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

# 4.2 Most important symptoms and effects, both acute and delayed

Gastrointestinal complaints, Nausea, Vomiting, Risk of serious damage to eyes, Risk of blindness, Irritant effects, Cough, pain, choking, and breathing difficulties, Headache, Vertigo

## 4.3 Indication of any immediate medical attention and special treatment needed

none

# **SECTION 5: Firefighting measures**

# 5.1 Extinguishing media



# Suitable extinguishing media

co-ordinate firefighting measures to the fire surroundings! water, foam, alcohol resistant foam, dry extinguishing powder, ABC-powder

### Unsuitable extinguishing media

water jet

# 5.2 Special hazards arising from the substance or mixture

Combustible.

### **Hazardous combustion products**

In case of fire may be liberated: Nitrogen oxides (NOx), Carbon monoxide (CO), Carbon dioxide (CO<sub>2</sub>), Hydrogen chloride (HCl)

### 5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Do not allow firefighting water to enter drains or water courses. Fight fire with normal precautions from a reasonable distance. Wear self-contained breathing apparatus.

# SECTION 6: Accidental release measures

# 6.1 Personal precautions, protective equipment and emergency procedures



# For non-emergency personnel

Use personal protective equipment as required. Avoid contact with skin, eyes and clothes. Do not breathe dust.

Malta (en) Page 4 / 19

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



# Crystal violet (C.I. 42555), p.a.

article number: T123

# **6.2** Environmental precautions

Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it. If substance has entered a water course or sewer, inform the responsible authority.

### 6.3 Methods and material for containment and cleaning up

### Advice on how to contain a spill

Covering of drains. Take up mechanically.

# Advice on how to clean up a spill

Take up mechanically. Control of dust.

# Other information relating to spills and releases

Place in appropriate containers for disposal.

#### 6.4 Reference to other sections

Hazardous combustion products: see section 5. Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.

# **SECTION 7: Handling and storage**

# 7.1 Precautions for safe handling

Provision of sufficient ventilation. Avoid exposure. Avoid dust formation.

# Measures to prevent fire as well as aerosol and dust generation

Removal of dust deposits.

# Measures to protect the environment

Avoid release to the environment.

### Advice on general occupational hygiene

Wash hands before breaks and after work. Keep away from food, drink and animal feedingstuffs.

### 7.2 Conditions for safe storage, including any incompatibilities

Store in a dry place. Keep container tightly closed.

### **Incompatible substances or mixtures**

Observe hints for combined storage.

### Consideration of other advice:

### **Ventilation requirements**

Use local and general ventilation.

# Specific designs for storage rooms or vessels

Recommended storage temperature: 15 - 25 °C

# 7.3 Specific end use(s)

No information available.

Malta (en) Page 5 / 19

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



Crystal violet (C.I. 42555), p.a.

article number: T123

# **SECTION 8: Exposure controls/personal protection**

### 8.1 Control parameters

#### **National limit values**

# **Occupational exposure limit values (Workplace Exposure Limits)**

This information is not available.

#### **Human health values**

Relevant DNELs and other threshold levels					
Endpoint	Threshold level	Protection goal, route of exposure	Used in	Exposure time	
DNEL	1,48 mg/m³	human, inhalatory	worker (industry)	chronic - systemic effects	
DNEL	0,42 mg/kg bw/ day	human, dermal	worker (industry)	chronic - systemic effects	

#### **Environmental values**

Relevant PNECs and other threshold levels					
End- point	Threshold level	Organism	Environmental com- partment	Exposure time	
PNEC	0,002 <sup>mg</sup> / <sub>l</sub>	aquatic organisms	freshwater	short-term (single instance)	

# 8.2 Exposure controls

## Individual protection measures (personal protective equipment)

### Eye/face protection





Use safety goggle with side protection.

## Skin protection



# hand protection

Wear suitable gloves. Chemical protection gloves are suitable, which are tested according to EN 374. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. The times are approximate values from measurements at 22 ° C and permanent contact. Increased temperatures due to heated substances, body heat etc. and a reduction of the effective layer thickness by stretching can lead to a considerable reduction of the breakthrough time. If in doubt, contact manufacturer. At an approx. 1.5 times larger / smaller layer thickness, the respective breakthrough time is doubled / halved. The data apply only to the pure substance. When transferred to substance mixtures, they may only be considered as a guide.

# type of material

NBR (Nitrile rubber)

Malta (en) Page 6 / 19

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



# Crystal violet (C.I. 42555), p.a.

article number: T123

#### material thickness

>0,11 mm

# breakthrough times of the glove material

>480 minutes (permeation: level 6)

## other protection measures

Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended

# **Respiratory protection**





Respiratory protection necessary at: Dust formation. Particulate filter device (EN 143). P2 (filters at least 94 % of airborne particles, colour code: White).

### **Environmental exposure controls**

Keep away from drains, surface and ground water.

# **SECTION 9: Physical and chemical properties**

# 9.1 Information on basic physical and chemical properties

Physical state solid

Colour dark green
Odour odourless

Melting point/freezing point 198 – 250 °C (ECHA) Boiling point or initial boiling point and boiling 631,9 °C (ECHA)

range

Flammability this material is combustible, but will not ignite

readily

Lower and upper explosion limit not determined Flash point 405,1 °C (ECHA)

Auto-ignition temperature >190 °C (ECHA) (relative self-ignition temperat-

ure for solids)

Decomposition temperature not relevant

pH (value) 2,5 – 3,5 (in aqueous solution:  $10^{9}/_{l}$ ,  $20^{\circ}$ C)

Kinematic viscosity not relevant

Solubility(ies)

Water solubility  $10^{9}/_{1}$  (ECHA)

Partition coefficient

Partition coefficient n-octanol/water (log value): 1,172 (25 °C) (ECHA)

Vapour pressure 0 Pa at 25 °C

Malta (en) Page 7 / 19

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



# Crystal violet (C.I. 42555), p.a.

article number: T123

Density and/or relative density

Density 1,19 <sup>g</sup>/<sub>cm³</sub> at 20 °C

Relative vapour density Information on this property is not available.

Bulk density  $220 - 400 \, \text{kg/m}^3$ 

Particle characteristics No data available.

Other safety parameters

Oxidising properties none

9.2 Other information

Information with regard to physical hazard

classes:

hazard classes acc. to GHS (physical hazards): not relevant

Other safety characteristics:

Surface tension  $44,2 \text{ }^{\text{mN}}\text{/}_{\text{m}}$  (ECHA)

Temperature class (EU, acc. to ATEX) T4

Maximum permissible surface temperature on

the equipment: 135°C

# **SECTION 10: Stability and reactivity**

# 10.1 Reactivity

The product in the delivered form is not dust explosion capable; the enrichment of fine dust however leads to the danger of dust explosion.

#### 10.2 Chemical stability

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

### 10.3 Possibility of hazardous reactions

Violent reaction with: strong oxidiser, Strong alkali, Strong acid

#### 10.4 Conditions to avoid

There are no specific conditions known which have to be avoided.

# 10.5 Incompatible materials

There is no additional information.

### 10.6 Hazardous decomposition products

Hazardous combustion products: see section 5.

Malta (en) Page 8 / 19

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



Crystal violet (C.I. 42555), p.a.

article number: T123

# **SECTION 11: Toxicological information**

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

# Classification according to GHS (1272/2008/EC, CLP)

# **Acute toxicity**

Acuto toxicity

Harmful if swallowed.

Acute toxicity					
Exposure route	Endpoint	Value	Species	Method	Source
oral	LD50	420 <sup>mg</sup> / <sub>kg</sub>	rat		TOXNET

#### Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

# Serious eye damage/eye irritation

Causes serious eye damage.

# Respiratory or skin sensitisation

Shall not be classified as a respiratory or skin sensitiser.

# Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

# Carcinogenicity

Suspected of causing cancer.

# Reproductive toxicity

Shall not be classified as a reproductive toxicant.

#### Specific target organ toxicity - single exposure

Shall not be classified as a specific target organ toxicant (single exposure).

### Specific target organ toxicity - repeated exposure

Shall not be classified as a specific target organ toxicant (repeated exposure).

# **Aspiration hazard**

Shall not be classified as presenting an aspiration hazard.

# Symptoms related to the physical, chemical and toxicological characteristics

### If swallowed

vomiting, nausea, gastrointestinal complaints

# • If in eyes

Causes serious eye damage, risk of blindness

# • If inhaled

cough, pain, choking, and breathing difficulties

### • If on skin

Frequently or prolonged contact with skin may cause dermal irritation

#### Other information

Other adverse effects: Headache, Vertigo

Malta (en) Page 9 / 19

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



# Crystal violet (C.I. 42555), p.a.

article number: T123

# 11.2 Endocrine disrupting properties

Does not contain an endocrine disruptor (ED) at a concentration of  $\geq 0.1\%$ .

#### 11.3 Information on other hazards

There is no additional information.

# **SECTION 12: Ecological information**

# 12.1 Toxicity

Very toxic to aquatic life with long lasting effects.

Aquatic toxicity (acute)						
Endpoint	Value	Species	Source	Exposure time		
LC50	0,082 <sup>mg</sup> / <sub>l</sub>	fish	ECHA	96 h		
EC50	0,53 <sup>mg</sup> / <sub>l</sub>	aquatic invertebrates	ECHA	48 h		
ErC50	0,21 <sup>mg</sup> / <sub>l</sub>	algae	ECHA	72 h		

# 12.2 Persistence and degradability

Theoretical Oxygen Demand (without nitrification): 2,353  $^{\rm mg}/_{\rm mg}$  Theoretical Oxygen Demand (with nitrification): 2,562  $^{\rm mg}/_{\rm mg}$  Theoretical Carbon Dioxide: 2,697  $^{\rm mg}/_{\rm mg}$ 

#### 12.3 Bioaccumulative potential

Does not significantly accumulate in organisms.

n-octanol/water (log KOW)	1,172 (25 °C) (ECHA)

# 12.4 Mobility in soil

Data are not available.

#### 12.5 Results of PBT and vPvB assessment

Data are not available.

# 12.6 Endocrine disrupting properties

Does not contain an endocrine disruptor (ED) at a concentration of  $\geq$  0,1%.

# 12.7 Other adverse effects

Data are not available.

# **SECTION 13: Disposal considerations**

# Waste treatment methods



This material and its container must be disposed of as hazardous waste. Dispose of contents/container in accordance with local/regional/national/international regulations.

### Sewage disposal-relevant information

Do not empty into drains. Avoid release to the environment. Refer to special instructions/safety data

Page 10 / 19 Malta (en)

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



# Crystal violet (C.I. 42555), p.a.

article number: T123

sheets.

# Waste treatment of containers/packagings

It is a dangerous waste; only packagings which are approved (e.g. acc. to ADR) may be used. Handle contaminated packages in the same way as the substance itself. Completely emptied packages can be recycled.

# 13.2 Relevant provisions relating to waste

The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process.

# Properties of waste which render it hazardous

**HP 4** irritant - skin irritation and eye damage

**HP 6** acute toxicity

**HP7** carcinogenić

HP 14 ecotoxic

### 13.3 Remarks

Waste shall be separated into the categories that can be handled separately by the local or national waste management facilities. Please consider the relevant national or regional provisions. Non-contaminated packages may be recycled.

# **SECTION 14: Transport information**

14.1	UN	number	or ID	number
1 <del>4</del> . I	OIA	HUHHDEI	טו וט	HUHHDEI

ADR	UN 3077
IMDG-Code	UN 3077
ICAO-TI	UN 3077

### 14.2 UN proper shipping name

ADR	ENVIRONMENTALLY HAZARDOUS SUBSTANCE,

SOLID, N.O.S.

IMDG-Code ENVIRONMENTALLY HAZARDOUS SUBSTANCE,

SOLID, N.O.S.

ICAO-TI Environmentally hazardous substance, solid,

n.o.s.

Technical name Crystal violet

### 14.3 Transport hazard class(es)

ADR	9
IMDG-Code	9
ICAO-TI	9

#### 14.4 Packing group

ADR	III
IMDG-Code	III
ICAO-TI	III

# **14.5 Environmental hazards** hazardous to the aquatic environment

#### 14.6 Special precautions for user

Provisions for dangerous goods (ADR) should be complied within the premises.

Malta (en) Page 11 / 19

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



# Crystal violet (C.I. 42555), p.a.

article number: T123

# 14.7 Maritime transport in bulk according to IMO instruments

The cargo is not intended to be carried in bulk.

# 14.8 Information for each of the UN Model Regulations

# Agreement concerning the International Carriage of Dangerous Goods by Road (ADR)Additional information

Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE,

SOLID, N.O.S.

Particulars in the transport document UN3077, ENVIRONMENTALLY HAZARDOUS SUB-

STANCE, SOLID, N.O.S., (Crystal violet), 9, III, (-)

Classification code M7

Danger label(s) 9, "Fish and tree"

Environmental hazards yes (hazardous to the aquatic environment)

Special provisions (SP) 274, 335, 375, 601

Excepted quantities (EQ) E1
Limited quantities (LQ) 5 kg
Transport category (TC) 3
Tunnel restriction code (TRC) -

Hazard identification No 90

### International Maritime Dangerous Goods Code (IMDG) - Additional information

Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE,

SOLID, N.O.S.

Particulars in the shipper's declaration UN3077, ENVIRONMENTALLY HAZARDOUS SUB-

STANCE, SOLID, N.O.S., (Crystal violet), 9, III

Marine pollutant yes (hazardous to the aquatic environment), (Crystal violet)

Danger label(s) 9, "Fish and tree"





Special provisions (SP) 274, 335, 966, 967, 969

Excepted quantities (EQ) E1
Limited quantities (LQ) 5 kg
EmS F-A, S-F

Stowage category A

Malta (en) Page 12 / 19

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



# Crystal violet (C.I. 42555), p.a.

article number: T123

# International Civil Aviation Organization (ICAO-IATA/DGR) - Additional information

Proper shipping name Environmentally hazardous substance, solid,

n.o.s.

Particulars in the shipper's declaration UN3077, Environmentally hazardous substance,

solid, n.o.s., (Crystal violet), 9, III

**Environmental hazards** yes (hazardous to the aquatic environment)

Danger label(s) 9. "Fish and tree"

Special provisions (SP) A97, A158, A179, A197, A215

Excepted quantities (EQ) E1

Limited quantities (LQ) 30 kg

# SECTION 15: Regulatory information

#### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture Relevant provisions of the European Union (EU)

Restrictions according to REACH, Annex XVII

# Dangerous substances with restrictions (REACH, Annex XVII)

Name of substance	Name acc. to inventory	CAS No	Restriction	No
Crystal violet	[4-[4,4'-bis(dimethylamino) benzhy- drylidene]cyclohexa-2,5-dien-1- ylidene]dimethylammonium chloride (C.I. Basic Violet 3)	548-62-9	R72 R72_50mg	72
Crystal violet	substances in tattoo inks and permanent make-up		R75	75

#### Legend

R72 1. Shall not be placed on the market after 1 November 2020 in any of the following:

(a) clothing or related accessories;

(b) textiles other than clothing which, under normal or reasonably foreseeable conditions of use, come into contact with human skin to an extent similar to clothing;

(c) footwear; if the clothing, related accessory, textile other than clothing or footwear is for use by consumers and the substance is present in a concentration, measured in homogeneous material, equal to or greater than that specified for that substance in Appendix 12

2. By way of derogation, in relation to the placing on the market of formaldehyde [CAS No 50-00-0] in jackets, coats or upholstery, the relevant concentration for the purposes of paragraph 1 shall be 300 mg/kg during the period between 1 November 2020 and 1 November 2023. The concentration specified in Appendix 12 shall apply thereafter. 3. Paragraph 1 shall not apply to:

(a) clothing, related accessories or footwear, or parts of clothing, related accessories or footwear, made exclusively of natural leather, fur or hide;

(b) non-textile fasteners and non-textile decorative attachments;

(c) second-hand clothing, related accessories, textiles other than clothing or footwear

(d) wall-to-wall carpets and textile floor coverings for indoor use, rugs and runners.

4. Paragraph 1 shall not apply to clothing, related accessories, textiles other than clothing, or footwear within the scope of Regulation (EU) 2016/425 of the European Parliament and of the Council (\*) or Regulation (EU) 2017/745 of the European Parliament and of the Council (\*\*).

5. Paragraph 1(b) shall not apply to disposable textiles. 'Disposable textiles' means textiles that are designed to be used only once or for a limited time and are not intended for subsequent use for the same or a similar purpose.

6. Paragraphs 1 and 2 shall apply without prejudice to the application of any stricter restrictions set out in this Annex or in other applicable Union legislation.

or in other applicable offion legislation.

7. The Commission shall review the exemption in paragraph 3(d) and, if appropriate, modify that point accordingly.

(\*) Regulation (EU) 2016/425 of the European Parliament and of the Council of of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51).

(\*\*) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

R72 50 Appendix 12 (maximum concentration limits by weight in homogeneous materials): 50 mg/kg mq

Page 13 / 19 Malta (en)

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



# Crystal violet (C.I. 42555), p.a.

article number: T123

#### Legend

R75

1. Shall not be placed on the market in mixtures for use for tattooing purposes, and mixtures containing any such substances shall not be used for tattooing purposes, after 4 January 2022 if the substance or substances in question is or are present in the following circumstances:

(a) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as carcinogen category

1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight; (b) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as reproductive toxicant category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by

(c) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin sensitiser category 1, 1A or 1B, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight;

(d) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin corrosive category 1, 1A, 1B or 1C or skin irritant category 2, or as serious eye damage category 1 or eye irritant category 2, the substance is present in the mixture in a concentration equal to or greater than:

(i) 0,1 % by weight, if the substance is used solely as a pH regulator

(ií) 0,01 % by weight, in all other cases;

(e) in the case of a substance listed in Annex II to Regulation (EC) No 1223/2009 (\*1), the substance is present in the

mixture in a concentration equal to or greater than 0,00005 % by weight;

(f) in the case of a substance for which a condition of one or more of the following kinds is specified in column g (Product type, Body parts) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight:

(i) "Rinse-off products";
(ii) "Not to be used in products applied on mucous membranes";
(iii) "Not to be used in eye products";

(g) in the case of a substance for which a condition is specified in column h (Maximum concentration in ready for use preparation) or column i (Other) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration, or in some other way, that does not accord with the condition specified in that column; (h) in the case of a substance listed in Appendix 13 to this Annex, the substance is present in the mixture in a concen-

(n) in the case of a substance listed in Appendix 13 to this Annex, the substance is present in the mixture in a concentration equal to or greater than the concentration limit specified for that substance in that Appendix.

2. For the purposes of this entry use of a mixture "for tattooing purposes" means injection or introduction of the mixture into a person's skin, mucous membrane or eyeball, by any process or procedure (including procedures commonly referred to as permanent make-up, cosmetic tattooing, micro-blading and micro-pigmentation), with the aim of making a mark or design on his or her body.

3. If a substance not listed in Appendix 13 falls within more than one of points (a) to (g) of paragraph 1, the strictest concentration limit laid down in the points in question shall apply to that substance. If a substance listed in Appendix 13 also falls within one or more of points (a) to (g) of paragraph 1, the concentration limit laid down in point (h) of paragraph 1 shall apply to that substance.

as also falls within one of more of points (a) to (g) of paragraph 1, the concentration limit faid down in point (ii) of paragraph 1 shall apply to that substance.

4. By way of derogation, paragraph 1 shall not apply to the following substances until 4 January 2023:
(a) Pigment Blue 15:3 (CI 74160, EC No 205-685-1, CAS No 147-14-8);
(b) Pigment Green 7 (CI 74260, EC No 215-524-7, CAS No 1328-53-6).

5. If Part 3 of Annex VI to Regulation (EC) No 1272/2008 is amended after 4 January 2021 to classify or re-classify a substance such that the substance then becomes caught by point (a), (b), (c) or (d) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the date of application of that now or revised classification in fifty the date referred to in paragraph 1 or as the case may be paragraph. plication of that new or revised classification is after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect on the date of application of that new or revised classification.

6. If Annex II or Annex IV to Regulation (EC) No 1223/2009 is amended after 4 January 2021 to list or change the listing of a substance such that the substance then becomes caught by point (e), (f) or (g) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the

amendment takes effect after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect from the date falling 18 months after entry into force of the act by which that amendment was made.

7. Suppliers placing a mixture on the market for use for tattooing purposes shall ensure that, after 4 January 2022, the mixture is marked with the following information:

(a) the statement "Mixture for use in tattoos or permanent make-up";

(a) the statement "Mixture for use in tattoos or permanent make-up";
(b) a reference number to uniquely identify the batch;
(c) the list of ingredients in accordance with the nomenclature established in the glossary of common ingredient names pursuant to Article 33 of Regulation (EC) No 1223/2009, or in the absence of a common ingredient name, the IUPAC name. In the absence of a common ingredient name or IUPAC name, the CAS and EC number. Ingredients shall be listed in descending order by weight or volume of the ingredients at the time of formulation. "Ingredient" means any substance added during the process of formulation and present in the mixture for use for tattooing purposes. Impurities shall not be regarded as ingredients. If the name of a substance, used as ingredient within the meaning of this entry, is already required to be stated on the label in accordance with Regulation (EC) No 1272/2008, that ingredient does not need to be marked in accordance with this Regulation;
(d) the additional statement "pH regulator" for substances falling under point (d)(i) of paragraph 1;
(e) the statement "Contains nickel. Can cause allergic reactions." if the mixture contains nickel below the concentration limit specified in Appendix 13;

tion limit specified in Appendix 13

(f) the statement "Contains chromium (VI). Can cause allergic reactions." if the mixture contains chromium (VI) below the concentration limit specified in Appendix 13; (g) safety instructions for use insofar as they are not already required to be stated on the label by Regulation (EC) No 1272/2008.

The information shall be clearly visible, easily legible and marked in a way that is indelible.

The information shall be written in the official language(s) of the Member State(s) where the mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise.

Where necessary because of the size of the package, the information listed in the first subparagraph, except for point (a), shall be included instead in the instructions for use.

Before using a mixture for tattooing purposes, the person using the mixture shall provide the person undergoing the procedure with the information marked on the package or included in the instructions for use pursuant to this paragraph. 8. Mixtures that do not contain the statement "Mixture for use in tattoos or permanent make-up" shall not be used for

tattooing purposes.

Page 14 / 19 Malta (en)

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



# Crystal violet (C.I. 42555), p.a.

article number: T123

#### Legend

9. This entry does not apply to substances that are gases at temperature of 20  $^{\circ}$ C and pressure of 101,3 kPa, or generate a vapour pressure of more than 300 kPa at temperature of 50  $^{\circ}$ C, with the exception of formaldehyde (CAS No 50-00-0, EC No 200-001-8).

10. This entry does not apply to the placing on the market of a mixture for use for tattooing purposes, or to the use of a mixture for tattooing purposes, when placed on the market exclusively as a medical device or an accessory to a medical device, within the meaning of Regulation (EU) 2017/745, or when used exclusively as a medical device or an accessory to a medical device, within the same meaning. Where the placing on the market or use may not be exclusively as a medical device or an accessory to a medical device, the requirements of Regulation (EU) 2017/745 and of this Regulation shall apply cumulatively.

### List of substances subject to authorisation (REACH, Annex XIV)/SVHC - candidate list

Substance of Very Hig	Substance of Very High Concern (SVHC)					
Name acc. to invent- ory	CAS No	Listed in	Remarks	Latest application date	Sunset date	Date of in- clusion
[4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclo-hexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Violet 3) with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)	548-62- 9	Candidate list	Carc. A57a			18.06.2012

#### Legend

Candidate list Carc. A57a Substances meeting the criteria referred to in Article 57 and for eventual inclusion in Annex XIV Carcinogenic (article 57a)

### **Seveso Directive**

2012/	2012/18/EU (Seveso III)				
No	Dangerous substance/hazard categories	Qualifying quantity (tonne plication of lower and up quirements	es) for the ap- oper-tier re-	Notes	
E1	environmental hazards (hazardous to the aquatic environment, cat. 1)	100	200	56)	

### Notation

56) Hazardous to the Aquatic Environment in category Acute 1 or Chronic 1

#### **Deco-Paint Directive**

VOC content	0 %
VOC content	0 g/l

#### **Industrial Emissions Directive (IED)**

VOC content	0 %
VOC content	0 g/l

Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

not listed

Malta (en) Page 15 / 19

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



Crystal violet (C.I. 42555), p.a.

article number: T123

# Regulation concerning the establishment of a European Pollutant Release and Transfer Register (PRTR)

not listed

# **Water Framework Directive (WFD)**

List of pollutants (WFD)				
Name of substance	Name acc. to inventory	CAS No	Listed in	Remarks
Crystal violet	Organohalogen compounds and substances which may form such compounds in the aquatic envir- onment		a)	
Crystal violet	Substances and preparations, or the breakdown products of such, which have been proved to possess carcinogenic or mutagenic properties or properties which may affect steroidogenic, thyroid, reproduction or other endocrinerelated functions in or via the aquatic environment		a)	

#### Legend

a) Indicative list of the main pollutants

# Regulation on the marketing and use of explosives precursors

not listed

# **Regulation on drug precursors**

not listed

Regulation on substances that deplete the ozone layer (ODS)

not listed

Regulation concerning the export and import of hazardous chemicals (PIC)

not listed

# Regulation on persistent organic pollutants (POP)

not listed

### Other information

Directive 94/33/EC on the protection of young people at work. Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.

# **National inventories**

Country	Inventory	Status
AU	AIIC	substance is listed
CA	DSL	substance is listed
CN	IECSC	substance is listed
EU	ECSI	substance is listed
EU	REACH Reg.	substance is listed
JP	CSCL-ENCS	substance is listed
KR	KECI	substance is listed

Malta (en) Page 16 / 19

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



# Crystal violet (C.I. 42555), p.a.

article number: T123

Country	Inventory	Status	
MX	INSQ	substance is listed	
NZ	NZIoC	substance is listed	
PH	PICCS	substance is listed	
TW	TCSI	substance is listed	
US	TSCA	substance is listed (ACTIVE)	
VN	NCI	substance is listed	

#### Legend

AIIC CSCL-ENCS DSL ECSI IECSC

Australian Inventory of Industrial Chemicals
List of Existing and New Chemical Substances (CSCL-ENCS)
Domestic Substances List (DSL)
EC Substance Inventory (EINECS, ELINCS, NLP)
Inventory of Existing Chemical Substances Produced or Imported in China
National Inventory of Chemical Substances

National Inventory of Chemical Substances
KECI Korea Existing Chemicals Inventory
NCI National Chemical Inventory
NZIOC New Zealand Inventory of Chemicals
PICCS Philippine Inventory of Chemicals and Chemical Substances (PICCS)
REACH Reg. REACH registered substances
TCSI Taiwan Chemical Substance Inventory
TCCA Taiwan Chemical Substance Inventory

Toxic Substance Control Act

# 15.2 Chemical safety assessment

No Chemical Safety Assessment has been carried out for this substance.

# **SECTION 16: Other information**

# Indication of changes (revised safety data sheet)

Section	Former entry (text/value)	Actual entry (text/value)	Safety- relev- ant
2.3		Endocrine disrupting properties: Does not contain an endocrine disruptor (ED) at a concentration of ≥ 0,1%.	yes
15.1		Dangerous substances with restrictions (REACH, Annex XVII): change in the listing (table)	yes
15.1		Substance of Very High Concern (SVHC): change in the listing (table)	yes
15.1	VOC content: 0 % 0 <sup>9</sup> / <sub>l</sub>	VOC content: 0 %	yes
15.1		VOC content: 0 <sup>9</sup> / <sub>l</sub>	yes
15.1		Other information: Directive 94/33/EC on the protection of young people at work. Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.	yes
15.1		National inventories: change in the listing (table)	yes

Malta (en) Page 17 / 19

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



Crystal violet (C.I. 42555), p.a.

article number: **T123** 

# **Abbreviations and acronyms**

Abbr.	Descriptions of used abbreviations	
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concerr ing the International Carriage of Dangerous Goods by Road)	
ATE	Acute Toxicity Estimate	
Carc.	Carcinogenicity	
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances	
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures	
DGR	Dangerous Goods Regulations (see IATA/DGR)	
DNEL	Derived No-Effect Level	
EC50	Effective Concentration 50 %. The EC50 corresponds to the concentration of a tested substance causin 50 % changes in response (e.g. on growth) during a specified time interval	
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an ider fier of substances commercially available within the EU (European Union)	
ED	Endocrine disruptor	
EINECS	European Inventory of Existing Commercial Chemical Substances	
ELINCS	European List of Notified Chemical Substances	
EmS	Emergency Schedule	
ErC50	= EC50: in this method, that concentration of test substance which results in a 50 % reduction in eithe growth (EbC50) or growth rate (ErC50) relative to the control	
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations	
IATA	International Air Transport Association	
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)	
ICAO	International Civil Aviation Organization	
ICAO-TI	Technical instructions for the safe transport of dangerous goods by air	
IMDG International Maritime Dangerous Goods Code		
IMDG-Code	International Maritime Dangerous Goods Code	
index No	The Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008	
LC50	Lethal Concentration 50%: the LC50 corresponds to the concentration of a tested substance causing 50 lethality during a specified time interval	
LD50	Lethal Dose 50 %: the LD50 corresponds to the dose of a tested substance causing 50 % lethality during specified time interval	
M-factor	Means a multiplying factor. It is applied to the concentration of a substance classified as hazardous to a aquatic environment acute category 1 or chronic category 1, and is used to derive by the summation method the classification of a mixture in which the substance is present	
NLP	No-Longer Polymer	
PBT	Persistent, Bioaccumulative and Toxic	
PNEC	Predicted No-Effect Concentration	
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals	
SVHC	Substance of Very High Concern	

Malta (en) Page 18 / 19

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



# Crystal violet (C.I. 42555), p.a.

article number: T123

Abbr.	Descriptions of used abbreviations
VOC	Volatile Organic Compounds
vPvB	Very Persistent and very Bioaccumulative

# Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU.

Agreement concerning the International Carriage of Dangerous Goods by Road (ADR). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

# List of relevant phrases (code and full text as stated in section 2 and 3)

Code	Text
H302	Harmful if swallowed.
H318	Causes serious eye damage.
H351	Suspected of causing cancer.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

#### **Disclaimer**

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.

Malta (en) Page 19 / 19