

Trading name:	GENTIAN VIOLET, C.I. 42555				
Product code:	GV-P-X**	Revision date:	21 Dec 2022	Version:	5

SECTION 1. Identification of the substance/mixture and of the company/undertaking	
1.1.	Product identifier
	Substance name: GENTIAN VIOLET, C.I. 42555
	EC No: 208-953-6
	Synonyms: Crystal Violet, Methyl Violet 10B
	Catalogue number: GV-P-X**
	REACH registration number: -
	CAS No: 548-62-9
	Index no.: 612-204-00-2
1.2.	Relevant identified uses of the substance or mixture and uses advised against
	Uses: For bacterial staining according to Gram.
	Uses advised against: Only the identified uses are advised.
	Reason why uses advised against: The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes.
1.3.	Details of the supplier of the safety data sheet
	Supplier: BioGnost Ltd.
	Address: Medjugorska 59, Zagreb
	Telephone number: +385 1 2409997
	Fax no.: +385 1 2404039
	e-mail of competent person: msds@biognost.hr
	National contact: -
1.4.	Emergency telephone number
	National Protection and Rescue Directorate: 112
	Medical information: +385 1 2348 342
	Other information: -





SECTION 2. Hazards information											
2.1.	Classification of the substance or mixture										
2.1.1.	Classification according to Regulation (EC) No 1272/2008 (CLP)										
	<table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 50%; text-align: left; padding: 5px;">Hazard class and category code:</th> <th style="width: 50%; text-align: left; padding: 5px;">Hazard statements*:</th> </tr> </thead> <tbody> <tr> <td style="padding: 5px;">Acute Tox. 4</td> <td style="padding: 5px;">H302</td> </tr> <tr> <td style="padding: 5px;">Causes serious eye damage</td> <td style="padding: 5px;">H318</td> </tr> <tr> <td style="padding: 5px;">Carc. 2</td> <td style="padding: 5px;">H351</td> </tr> <tr> <td style="padding: 5px;">Aquatic Chronic 1</td> <td style="padding: 5px;">H410</td> </tr> </tbody> </table>	Hazard class and category code:	Hazard statements*:	Acute Tox. 4	H302	Causes serious eye damage	H318	Carc. 2	H351	Aquatic Chronic 1	H410
Hazard class and category code:	Hazard statements*:										
Acute Tox. 4	H302										
Causes serious eye damage	H318										
Carc. 2	H351										
Aquatic Chronic 1	H410										
2.1.2.	Additional information										

Trading name:	GENTIAN VIOLET, C.I. 42555				
Product code:	GV-P-X**	Revision date:	21 Dec 2022	Version:	5

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*For full text of Hazard- and EU Hazard-statements: see Section 16

2.2. Label elements

Product identification:	GENTIAN VIOLET, C.I. 42555
Identification number:	-
Authorization no.:	-
Hazard pictograms:	<div style="display: flex; flex-wrap: wrap; justify-content: space-around;"> <div style="text-align: center;">  GHS08 </div> <div style="text-align: center;">  GHS05 </div> <div style="text-align: center;">  GHS07 </div> <div style="text-align: center;">  GHS09 </div> </div>
Signal word:	Danger
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:	P273 Avoid release to the environment. P280 Wear protective gloves/protective clothing/eye protection/face protection. P301 + P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. 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.
Further information:	-

2.3. Other hazards

<p>Endocrine Disrupting Properties: No known endocrine disrupting properties</p> <p>Results of PBT and vPvB assessment: According to the results of its assessment, this substance is not a PBT or a vPvB.</p>

Trading name:	GENTIAN VIOLET, C.I. 42555				
Product code:	GV-P-X**	Revision date:	21 Dec 2022	Version:	5

SECTION 3. Composition/information on ingredients				
CAS No	EC No:	Index no.	Identification name	Weight % content (or range)
548-62-9	208-953-6	612-204-00-2	[4-[4,4'-bis(dimethylamino)benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride	90-100 %

SECTION 4. First aid measures	
4.1.	Description of first aid measures
	General notes: -
	Following inhalation: Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. If breathing becomes erratic or it stops, immediately apply artificial respiration (other than mouth-to-mouth) and contact a physician.
	Following skin contact: Remove contaminated clothing. Immediately wash with copious amounts of water for at least 15 minutes. Seek medical assistance if the symptoms of irritation remain.
	Following eye contact: Rinse out with plenty of water with the eyelid held wide open using clean fingers. If the symptoms remain, immediately call a physician.
	Following ingestion: DO NOT induce vomiting. If the afflicted person is unconscious, do not provide them with anything orally. Seek medical attention in case of irritation or other symptoms.
	Self-protection of the first aider: -
4.2.	Most important symptoms and effects, both acute and delayed
	Following inhalation: Harmful if swallowed.
	Following skin contact: Harmful by inhalation and in contact with skin.
	Following eye contact: Risk of serious damage to eyes.
	Following ingestion: Harmful if swallowed.
4.3.	Indication of any immediate medical attention and special treatment needed
	-

SECTION 5. Firefighting measures	
5.1.	Extinguishing media
	Suitable extinguishing media: In case of fire use water spray for cooling the jars. Use water spray, dry dust, CO ₂ , or a suitable foam.
	Unsuitable extinguishing media: -
5.2.	Special hazards arising from the substance or mixture
	Hazardous combustion products: -

Trading name:	GENTIAN VIOLET, C.I. 42555				
Product code:	GV-P-X**	Revision date:	21 Dec 2022	Version:	5

5.3.	Advice for firefighters
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing. Cool closed containers exposed to fire with water spray or vapor.
5.4.	Additional information
	-

SECTION 6. Accidental release measures	
6.1.	Personal precautions, protective equipment and emergency procedures
6.1.1.	For non-emergency personnel
	Protective equipment: Use personal protective equipment (see Section 8).
	Accident prevention methods: -
	Emergency procedures: -
6.1.2.	For emergency responders:
	-
6.2.	Environmental precautions:
	-
6.3.	Methods and material for containment and cleaning up
6.3.1.	For creating barriers, covering and sealing: -
6.3.2.	Cleaning up: Place the waste material in tightly closed impermeable containers. Store the substance in well ventilated storage rooms until disposal. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and involved materials with water.
6.3.3.	Other information: -
6.4.	Reference to other sections
	-

SECTION 7. Handling an storage	
7.1.	Precautions for safe handling
7.1.1.	Protection measures
	Measures to prevent fire: Keep away from sources of ignition and heat. Do not use tools that cause sparks.
	Measures to prevent aerosol and dust generation: Secure proper ventilation.
	Measures to protect the environment: Prevent spilling into the sewage system and waterways.
	Other measures: -

Trading name:	GENTIAN VIOLET, C.I. 42555				
Product code:	GV-P-X**	Revision date:	21 Dec 2022	Version:	5

7.1.2.	Advice on general occupational hygiene:	
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.	
7.2.	Conditions for safe storage, including any incompatibilities	
	Technical measures and storage conditions:	Wash hands thoroughly after handling. Use with appropriate ventilation. Minimize dust formation. Avoid inhaling vapor, dust, mist or gas. Avoid contact with skin, eyes and clothes. Keep in tightly closed container. Avoid swallowing and breathing.
	Packaging materials:	Manufacturer's original packaging.
	Requirements for storage rooms and vessels:	Keep container tightly closed. Keep in cool, dry and well-ventilated space, away from incompatible substances.
	Advices for storage equipment:	The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.
	Further information on storage conditions:	No information available.
7.3.	Specific end use(s)	
	Recommendations:	-
	Industrial sector specific solutions:	-

SECTION 8. Exposure controls/personal protection				
8.1.	Control parameters			
	Substance	CAS No	Occupational exposure limit values/short term values	Biological limit values
			ppm	mg/m ³
	-	-	-	-
	Substance name:	-		
	EC No:	-	CAS No:	-
DNEL				
Industrial				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	-	-
Dermal	-	-	-	-
Critical physical parameters: solubility, flammability, corrosivity:				

Trading name:	GENTIAN VIOLET, C.I. 42555				
Product code:	GV-P-X**	Revision date:	21 Dec 2022	Version:	5

Consumer				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	-	-
Dermal	-	-	-	-

PNEC	
Environmental protection target	PNEC
Fresh water	No information available
Freshwater sediments	No information available
Marine water	No information available
Marine sediments	No information available
Food chain	No information available
Microorganisms in sewage treatment	No information available
Soil (agricultural)	No information available
Air	No information available

8.2.	Exposure controls	
8.2.1.	Appropriate engineering controls	
	Substance/mixture related measures to prevent exposure during identified uses:	Use personal protective equipment. Do not eat, drink or smoke in the workspace.
	Structural measures to prevent exposure:	No information available
	Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.
	Technical measures to prevent exposure:	Use with appropriate ventilation.
8.2.2.	Personal protection equipment	
8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (preventing splashing) or visor.
8.2.2.2.	Skin protection	
	Hand protection:	In case of coming into thorough contact, use butyl rubber gloves (0.4 mm thick). In case of contact with drops, use polychlorene gloves (0.1 mm thick).
	Other skin protection:	During everyday work use cotton clothing and suitable footwear, such as rubber boots or shoes that cover the entire foot. In case of spilling hazard, use clothing made of impermeable material suitable for protection from liquid chemicals (Viton, PVC, himex) and footwear made from the same material.

Trading name:	GENTIAN VIOLET, C.I. 42555				
Product code:	GV-P-X**	Revision date:	21 Dec 2022	Version:	5

8.2.2.3.	Respiratory protection:	If the concentration level exceeds the GVI values, use full gas mask equipped with brown filter A.
8.2.2.4.	Thermal hazards:	-
8.2.3.	Environmental exposure controls	
	Substance/mixture related measures to prevent exposure:	See Section 6
	Structural measures to prevent exposure:	Use modern equipment.
	Organisational measures to prevent exposure:	Adapt the work process to the required working conditions of the workplace.
	Technical measures to prevent exposure:	See Section 6

SECTION 9. Physical and chemical properties			
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9.1.	Information on basic physical and chemical properties		
		Value	Method
	Physical state:	powder	No information available
	Color:	green	No information available
	Odour/odour threshold:	No information available	No information available
	Melting point / freezing point:	173 °C	No information available
	Boiling point or initial boiling point and boiling range:	No information available	No information available
	Flammability:	No information available	No information available
	Lower and upper explosion limit:	No information available	No information available
	Flash point:	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	pH:	2.5-3.5 (10 g/L at 20°C)	No information available
	Kinematic viscosity:	No information available	No information available
	Solubility:	50g/l (at 27°C)	No information available
	Partition coefficient n-octanol/water (log value):	No information available	No information available
	Vapour pressure:	No information available	No information available
	Density and/or relative density:	No information available	No information available
	Relative vapour density:	No information available	No information available
	Particle characteristics:	No information available	No information available
9.2.	Other information		
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Trading name:	GENTIAN VIOLET, C.I. 42555				
Product code:	GV-P-X**	Revision date:	21 Dec 2022	Version:	5

SECTION 10. Stability and reactivity		
10.1.	Reactivity:	No information available
10.2.	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using (room temperature).
10.3.	Possibility of hazardous reactions:	Violent reactions possible with: strong oxidizing agents, strong acids, oxidizing agents.
10.4.	Conditions to avoid:	No information available
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					
Acute toxicity:					
Route of exposure:	Method	Species	Dose LD ₅₀ /LC ₅₀	Exposure time	Results
Oral exposure:	No information available	rat	LD ₅₀	No information available	420 mg/kg
Dermal exposure:	No information available	No information available	No information available	No information available	-
Inhalation exposure:	No information available	No information available	No information available	No information available	-
Specific target organ toxicity – single exposure (STOT SE):					
	Specific effects	Target organ	Note		
Oral exposure:	No information available	No information available	-		
Dermal exposure:	No information available	No information available	-		
Inhalation exposure:	No information available	No information available	-		
Aspiration hazard:					
		No information available			
Irritation and corrosion					
	Exposure time	Species	Evaluation	Method	Note
Skin corrosion/irritation:	No information available	rabbit	-	No information available	No skin irritation
Serious eye damage/irritation	No information available	rabbit	-	No information available	Causes serious eye

Trading name:	GENTIAN VIOLET, C.I. 42555				
Product code:	GV-P-X**	Revision date:	21 Dec 2022	Version:	5

						damage
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Sensitization						
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Dermal exposure:	No information available					
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Inhalation exposure:	No information available					
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Symptoms related to the physical, chemical and toxicological characteristics						
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Oral exposure:	Harmful if swallowed.					
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Dermal exposure:	Harmful by inhalation and in contact with skin.					
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Inhalation exposure:	Harmful if swallowed.					
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Eye exposure:	Risk of serious damage to eyes.					
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Repeated dose toxicity (subacute, subchronic, chronic)						
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	Dose	Exposure time	Species	Method	Evaluation	Note
Subacute oral	No information available	No information available	No information available	No information available	No information available	-
Subacute dermal	No information available	No information available	No information available	No information available	No information available	-
Subacute inhalation	No information available	No information available	No information available	No information available	No information available	-
Subchronic oral	No information available	No information available	No information available	No information available	No information available	-
Subchronic dermal	No information available	No information available	No information available	No information available	No information available	-
Subchronic inhalation	No information available	No information available	No information available	No information available	No information available	-
Chronic oral	No information available	No information available	No information available	No information available	No information available	-
Chronic dermal	No information available	No information available	No information available	No information available	No information available	-

Trading name:	GENTIAN VIOLET, C.I. 42555				
Product code:	GV-P-X**	Revision date:	21 Dec 2022	Version:	5

Chronic inhalation	No information available	No information available	No information available	No information available	No information available	-
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	Specific target organ toxicity – repeated exposure (STOT RE):					
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	Specific effects	Target organ	Note
Subacute oral	No information available	No information available	-
Subacute dermal	No information available	No information available	-
Subacute inhalation	No information available	No information available	-
Subchronic oral	No information available	No information available	-
Subchronic dermal	No information available	No information available	-
Subchronic inhalation	No information available	No information available	-
Chronic oral	No information available	No information available	-
Chronic dermal	No information available	No information available	-
Chronic inhalation	No information available	No information available	-

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	CMR effects (carcinogenicity, mutagenicity, reproductive toxicity)					
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Carcinogenicity:	Suspected of causing cancer.		
Mutagenicity <i>in-vitro</i> :	No information available		
Genotoxicity:	No information available		
Mutagenicity <i>in-vivo</i> :	No information available		
Germ cell mutagenicity:	No information available		
Reproductive toxicity:	No information available		

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	Summary of evaluation of the CMR properties:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.			
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11.2.	Information on other hazards:
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11.2.1.	Endocrine disrupting properties:
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	The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.					
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11.2.2.	Other informations:
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Trading name:	GENTIAN VIOLET, C.I. 42555				
Product code:	GV-P-X**	Revision date:	21 Dec 2022	Version:	5

SECTION 12. Ecological information						
12.1. Toxicity						
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	Pimephales promelas (fathead minnow)	No information available	0.13 mg/l	-
Crustacea:	EC ₅₀	48 hours	Daphnia magna	No information available	0.24 – 0.5 mg/l	-
Algae/aquatic plants	IC ₅₀	72 hours	Pseudokirchneriella subcapitata (green algae)	No information available	0.2 – 0.8 mg/l	-
Other organisms	-	-	-	-	-	-
Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	No information available	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants	IC ₅₀	72 hours	No information available	No information available	No information available	-
Other organisms	-	-	-	-	-	-
12.2. Persistence and degradability						
Abiotic degradation						
	Degradation half-lives	Method		Evaluation	Note	
Marine water	No information available	No information available		No information available	-	
Fresh water	No information available	No information available		No information available	-	
Air	No information available	No information available		No information available	-	
Soil	No information available	No information available		No information available	-	
Biodegradation						
% Degradation	Time (days)	Method		Evaluation	Note	

Trading name:	GENTIAN VIOLET, C.I. 42555				
Product code:	GV-P-X**	Revision date:	21 Dec 2022	Version:	5

3.6 %	28 d	No information available	No information available	Not readily biodegradable.
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12.3. Bioaccumulative potential

Partition coefficient: n-octanol/water (log Kow):

Value	Concentration	pH	°C	Method	Evaluation	Note
No information available	No information available	-	-	No information available	No information available	No information available

Bioconcentration factor (BCF)

Value	Species	Method	Evaluation	Note
No information available	No information available	No information available	No information available	No information available

Chronic ecotoxicity

Value	Dose	Exposure time	Species	Method	Evaluation	Note
Chronic toxicity on fish	LC ₅₀	No information available	No information available	No information available	No information available	-
Chronic toxicity on crustacea (<i>Daphnia</i>)	EC ₅₀	No information available	No information available	No information available	No information available	-

12.4. Mobility in soil

Known or predicted distribution in environmental compartments:

No information available

Surface tension:

Value	°C	Concentration	Method	Note
No information available	No information available	No information available	No information available	-

Trading name:	GENTIAN VIOLET, C.I. 42555				
Product code:	GV-P-X**	Revision date:	21 Dec 2022	Version:	5

Adsorption / desorption					
Transport	A/D coefficient Henry's constant	log Kow	Evaporation rate	Method	Note
Soil-water	No information available	No information available	No information available	No information available	-
Water-air	No information available	No information available	No information available	No information available	-
Soil-air	No information available	No information available	No information available	No information available	-

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

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

12.7. Other adverse effects

No information available

SECTION 13. Disposal considerations

13.1. Waste treatment methods

13.1.1. Product/Packaging disposal:

Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.

13.1.2. Waste codes/waste designations according to Law:

No information available

13.1.3. Waste treatment – relevant information:

No information available

13.1.4. Sewage disposal – relevant information:

Waste must not be disposed of into the sewage system.

Trading name:	GENTIAN VIOLET, C.I. 42555				
Product code:	GV-P-X**	Revision date:	21 Dec 2022	Version:	5

13.1.5.	Other disposal recommendations:
	Do not dispose of the product's remains into the sewage system. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the packaging to the collectors authorized by the ministry in charge. Do not dispose of in places where ignition may occur.
13.1.6.	Relevant Community provisions:
	-

SECTION 14. Transport information

Transporting/shipment by road (ADR)	
UN number:	3077
UN proper shipping name:	Environmentally hazardous substance, solid, n.o.s. (hexamethylene pararosanyl chloride)
Transport hazard class(es):	9
Packing group:	III
Environmental hazard(s):	yes
Special precautions for user:	-
Transporting/shipment by rail (RID)	
UN number:	3077
UN proper shipping name:	Environmentally hazardous substance, solid, n.o.s. (hexamethylene pararosanyl chloride)
Transport hazard class(es):	9
Packing group:	III
Environmental hazard(s):	yes
Special precautions for user:	-
Transporting/shipment by inland waterways (ADN)	
UN number:	3077
UN proper shipping name:	Environmentally hazardous substance, solid, n.o.s. (hexamethylene pararosanyl chloride)
Transport hazard class(es):	9
Packing group:	III
Environmental hazard(s):	yes
Special precautions for user:	-
Transporting/shipment by sea (IMDG)	
UN number:	3077
UN proper shipping name:	Environmentally hazardous substance, solid, n.o.s. (hexamethylene pararosanyl chloride)
Transport hazard class(es):	9

Trading name:	GENTIAN VIOLET, C.I. 42555				
Product code:	GV-P-X**	Revision date:	21 Dec 2022	Version:	5

Packing group:	III
Environmental hazard(s):	yes
Special precautions for user:	-
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code:	-
Transporting/shipment by air (ICAO-TI/IATA-DGR)	
UN number:	3077
UN proper shipping name:	Environmentally hazardous substance, solid, n.o.s. (hexamethylene pararosanil chloride)
Transport hazard class(es):	9
Packing group:	III
Environmental hazard(s):	yes
Special precautions for user:	-
Further information: Packages smaller than or equal to 5 kg /L, not dangerous goods of Class 9.	

SECTION 15 REGULATORY INFORMATION

15.1.	Safety, health and environmental regulations/legislation specific for the substance or mixture	
	EU regulations	
	Authorization and/or restrictions of use	
	Authorizations:	-
	Restrictions:	-
	Other EU regulations:	<p>Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC;</p> <p>Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC;</p> <p>Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work;</p> <p>Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006;</p> <p>REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);</p>
	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline)	

Trading name:	GENTIAN VIOLET, C.I. 42555				
Product code:	GV-P-X**	Revision date:	21 Dec 2022	Version:	5

National legislation:	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Sustainable Waste Management Act, Transport of Hazardous Substances Act
15.2. Chemical safety assessment	None

SECTION 16. Other information	
16.1. Indication of changes:	-
16.2. Abbreviations and acronyms:	ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) DNEL: Derived No-Effect Level (UK REACH) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative
16.3. Key literature references and source of data:	-
16.4. Relevant H statements (number and full text)	
H:	302 Harmful if swallowed. 318 Causes serious eye damage. 351 Suspected of causing cancer. 410 Very toxic to aquatic life with long lasting effects.
16.5. Training advice:	-
16.6. Further information:	** "X" in the product code marks different volumes (different packagings of the product) We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.

ANNEX:
EXPOSURE SCENARIO RESULTING TO CHEMICAL SAFETY ASSESSMENT
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