

Trading name:	XYLIDINE PONCEAU, C.I. 16150		
Product code:	XP-P-X**	Revision date:	21 Dec 2022
		Version:	4


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

1.1. Product identifier	
Substance name:	XYLIDINE PONCEAU, C.I. 16150
EC No:	223-178-3
Synonyms:	Ponceau 2R, Ponceau de Xylidine
Catalogue number:	XP-P-X**
REACH registration number:	-
CAS No:	3761-53-3
Index no.:	-
1.2. Relevant identified uses of the substance or mixture and uses advised against	
Uses:	For Masson trichrome staining.
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)	
Hazard class and category code:	Hazard statements*:
Carc. 2	H351
2.1.2. Additional information	
-	
*For full text of Hazard- and EU Hazard-statements: see Section 16	
2.2. Label elements	

Trading name:	XYLIDINE PONCEAU, C.I. 16150			
Product code:	XP-P-X**	Revision date:	21 Dec 2022	Version: 4

Product identification:	XYLIDINE PONCEAU, C.I. 16150
Identification number:	-
Authorization no.:	-
Hazard pictograms:	 GHS08
Signal word:	Warning
Hazard statements:	H351 Suspected of causing cancer.
Precautionary statements:	P201 Obtain special instructions before use. P281 Use personal protective equipment as required. P308 + P313 IF exposed or concerned: Get medical advice/attention
Supplemental hazard information (EU):	-

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>

SECTION 3. Composition/information on ingredients				
CAS No	EC No:	Index no.	Identification name	Weight % content (or range)
3761-53-3	223-178-3	-	Disodium 1-(2,4-dimethylphenylazo)-2-hydroxynaphthalene-3,6-disulphonate	90 %

SECTION 4. First aid measures		
4.1.	Description of first aid measures	
General notes:	If the suggested first aid measures do not prove sufficient, seek medical attention.	
Following inhalation:	Remove from exposure to fresh air immediately. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical aid.	
Following skin contact:	Get medical aid. Wash clothing before reuse. Flush skin with plenty of soap and water. Destroy contaminated shoes. Get medical attention if irritation develops or persists.	
Following eye contact:	Flush with plenty of water for at least 15 minutes, occasionally lifting the upper and lower eyelids. Get medical aid.	

Trading name:	XYLIDINE PONCEAU, C.I. 16150		
Product code:	XP-P-X**	Revision date:	21 Dec 2022
		Version:	4

	Following ingestion:	If victim is conscious and alert, give 2-4 cupfuls of milk or water. NEVER give anything by mouth to an unconscious person. Get medical aid. Do NOT induce vomiting.
	Self-protection of the first aider:	-
4.2.	Most important symptoms and effects, both acute and delayed	
	Following inhalation:	May cause respiratory tract irritation.
	Following skin contact:	May cause skin irritation. May cause skin sensitization, an allergic reaction, which becomes evident upon re-exposure to this material.
	Following eye contact:	May cause eye irritation.
	Following ingestion:	May cause gastrointestinal irritation with nausea, vomiting and diarrhea. Low hazard for usual industrial handling.
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 to cool fire expose containers. Use water, dry chemical, chemical foam, or alcohol-resistant foam, or appropriate foam. Use agent most appropriate to extinguish fire.
	Unsuitable extinguishing media:	No information available
5.2.	Special hazards arising from the substance or mixture	
	Hazardous combustion products:	No information available
5.3.	Advice for firefighters	
	As in any fire, wear a self-contained breathing apparatus in pressure-demand, MSHA/NIOSH approved or equivalent, and full protective gear. During a fire, irritating and highly toxic gases may be generated by thermal decomposition or combustion. Dust can be an explosion hazard when exposed to heat or flame.	
5.4.	Additional information	
	Remove sources of heat and ignition. Do not contaminate the environment with extinguishing media.	

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:	Avoid inhaling dust. Avoid contact with the substance. Secure proper ventilation.
	Emergency procedures:	Mark the area using proper signs.
6.1.2.	For emergency responders:	
	Use protective equipment; in case of inadequate ventilation use adequate airways protective equipment	

Trading name:	XYLIDINE PONCEAU, C.I. 16150				
Product code:	XP-P-X**	Revision date:	21 Dec 2022	Version:	4

	(see Section 8).	
6.2.	Environmental precautions:	
	Do not dispose of in sewage, drainage system or waterways.	
6.3.	Methods and material for containment and cleaning up	
6.3.1.	For creating barriers, covering and sealing:	Cap the drains. Collect, bundle and pump out everything that got spilled. Pay attention to the possible material restrictions (see Sections 7 and 10). Collect in dry form.
6.3.2.	Cleaning up:	Vacuum or sweep, then store in a tightly closed container. Prevent formation of dust. Ventilate the room
6.3.3.	Other information:	-
6.4.	Reference to other sections	
	For indications of waste processing see Section 13.	

SECTION 7. Handling and storage		
7.1.	Precautions for safe handling	
7.1.1.	Protection measures	
	Measures to prevent fire:	-
	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:	-
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:	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:	-

Trading name:	XYLIDINE PONCEAU, C.I. 16150				
Product code:	XP-P-X**	Revision date:	21 Dec 2022	Version:	4

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:

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

Trading name:	XYLIDINE PONCEAU, C.I. 16150				
Product code:	XP-P-X**	Revision date:	21 Dec 2022	Version:	4

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:	Nitrile rubber protective gloves, 0.11 mm thick
Other skin protection:	Cotton clothing and adequate closed footwear.
8.2.2.3. Respiratory protection:	Suitable mask or half mask equipped with "A" filter used when concentration levels exceed GVI.
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

9.1. Information on basic physical and chemical properties			
		Value	Method
Physical state:	solid (crystals)		No information available
Color:	dark red - bordeaux		No information available
Odour/odour threshold:	No information available		No information available
Melting point / freezing point:	No information available		No information available
Boiling point or initial boiling point and boiling range:	No information available		No information available

Trading name:	XYLIDINE PONCEAU, C.I. 16150				
Product code:	XP-P-X**	Revision date:	21 Dec 2022	Version:	4

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:	No information available	No information available
Kinematic viscosity:	No information available	No information available
Solubility:	No information available	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	
	-	

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:	No information available.
10.4.	Conditions to avoid:	Incompatible materials, excess heat.
10.5.	Incompatible materials:	Strong oxidizing agents.
10.6.	Hazardous decomposition products:	Carbon monoxide, oxides of sulfur, carbon dioxide, nitrogen oxides, nitrogen.

SECTION 11. Toxicological information
--

Trading name:	XYLIDINE PONCEAU, C.I. 16150				
Product code:	XP-P-X**	Revision date:	21 Dec 2022	Version:	4

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	15.200 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	No information available	-	No information available	No information available
Serious eye damage/irritation	No information available	No information available	-	No information available	No information available

Sensitization

Dermal exposure:	No information available
Inhalation exposure:	No information available

Symptoms related to the physical, chemical and toxicological characteristics

Oral exposure:	May cause gastrointestinal irritation with nausea, vomiting and diarrhea. Low hazard for
----------------	--

Trading name:	XYLIDINE PONCEAU, C.I. 16150				
Product code:	XP-P-X**	Revision date:	21 Dec 2022	Version:	4

	usual industrial handling.
Dermal exposure:	May cause skin irritation. May cause skin sensitization, an allergic reaction, which becomes evident upon re-exposure to this material.
Inhalation exposure:	May cause respiratory tract irritation.
Eye exposure:	May cause eye irritation.

--	--	--	--	--	--	--

Repeated dose toxicity (subacute, subchronic, chronic)						
--	--	--	--	--	--	--

	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	-
Chronic inhalation	No information available	No information available	No information available	No information available	No information available	-

--	--	--	--	--	--	--

Specific target organ toxicity – repeated exposure (STOT RE):						
---	--	--	--	--	--	--

	Specific effects	Target organ	Note
Subacute oral	No information available	No information available	-
Subacute dermal	No information available	No information available	-

Trading name:	XYLIDINE PONCEAU, C.I. 16150				
Product code:	XP-P-X**	Revision date:	21 Dec 2022	Version:	4

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	-

CMR effects (carcinogenicity, mutagenicity, reproductive toxicity)

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

Summary of evaluation of the CMR properties:	No information available
--	--------------------------

11.2. Information on other hazards:

11.2.1. 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.

11.2.2. Other informations:

-

SECTION 12. Ecological information

12.1. Toxicity

Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	No information available	-

Trading name:	XYLIDINE PONCEAU, C.I. 16150					
Product code:	XP-P-X**	Revision date:	21 Dec 2022	Version:	4	

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	-	-	-	-	-	-
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
No information available	No information available	No information available	No information available	-

12.3. Bioaccumulative potential

Partition coefficient: n-octanol/water (log Kow):						
Value	Concentration	pH	°C	Method	Evaluation	Note
No	No information	-	-	No information	No information	No information

Trading name:	XYLIDINE PONCEAU, C.I. 16150				
Product code:	XP-P-X**	Revision date:	21 Dec 2022	Version:	4

information available	available		available	available	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 (Daphnia)	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	-

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	-

Trading name:	XYLIDINE PONCEAU, C.I. 16150				
Product code:	XP-P-X**	Revision date:	21 Dec 2022	Version:	4

	available	available	available	available	
Soil-air	No information available	No information available	No information available	No information available	-
12.5. Results of PBT and vPvB assessment					
	No information available				
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.
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)

Trading name:	XYLIDINE PONCEAU, C.I. 16150		
Product code:	XP-P-X**	Revision date:	21 Dec 2022
		Version:	4

UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazard(s):	-
Special precautions for user:	-

Transporting/shipment by rail (RID)

UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazard(s):	-
Special precautions for user:	-

Transporting/shipment by inland waterways (ADN)

UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazard(s):	-
Special precautions for user:	-

Transporting/shipment by sea (IMDG)

UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazard(s):	-
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:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazard(s):	-
Special precautions for user:	-

Trading name:	XYLIDINE PONCEAU, C.I. 16150		
Product code:	XP-P-X**	Revision date:	21 Dec 2022
		Version:	4

Further information:	-
----------------------	---

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)	
	National legislation:	<p>Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Transport of Hazardous Substances Act</p>
15.2.	Chemical safety assessment	
	None	

SECTION 16. Other information

16.1.	Indication of changes:	-
16.2.	Abbreviations and acronyms:	<p>ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)</p> <p>IMDG: International Maritime Code for Dangerous Goods</p>

Trading name:	XYLIDINE PONCEAU, C.I. 16150				
Product code:	XP-P-X**	Revision date:	21 Dec 2022	Version:	4

		<p>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</p>
16.3.	Key literature references and source of data:	-
16.4.	Relevant H statements (number and full text)	
	H: 351	Suspected of causing cancer.
16.5.	Training advice:	-
16.6.	Further information:	<p>** "X" in the product code marks different volumes (different packaging of the product)</p> <p>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.</p>

ANNEX:
EXPOSURE SCENARIO RESULTING TO CHEMICAL SAFETY ASSESSMENT
-