

Trading name:	AZURE A, C.I. 52005				
Product code:	AA-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:	AZURE A, C.I. 52005
	EC No:	208-510-7
	Synonyms:	Methylene Azure
	Catalogue number:	AA-P-X**
	REACH registration number:	-
	CAS No:	531-53-3
	Index no.:	-
1.2.	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	For metachromatic staining of mast cells, mucins and nuclei.
	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*:
	Not identified as hazardous substance.	-
2.1.2.	Additional information	
	-	
*For full text of Hazard- and EU Hazard-statements: see Section 16		
2.2.	Label elements	

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Product identification:	AZURE A, C.I. 52005
Identification number:	-
Authorization no.:	-
Hazard pictograms:	-
Signal word:	-
Hazard statements:	-
Precautionary statements:	-
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)
531-53-3	208-510-7	-	3-amino-7-dimethylaminophenothiazin-5-ium chloride	70 - 80 %

SECTION 4. First aid measures	
4.1.	Description of first aid measures
	<p>General notes: If the suggested first aid measures do not prove sufficient, seek medical attention.</p> <p>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.</p> <p>Following skin contact: Remove contaminated clothing. Immediately wash with plenty of water and soap. Seek medical assistance if the symptoms of irritation remain.</p> <p>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.</p> <p>Following ingestion: If the afflicted person is unconscious, do not provide them with anything orally.</p> <p>Self-protection of the first aider: -</p>
4.2.	Most important symptoms and effects, both acute and delayed

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Following inhalation:	Allergic persons may display irritation after prolonged or repeated exposure.
Following skin contact:	Allergic persons may display irritation.
Following eye contact:	May cause irritation.
Following ingestion:	Swallowing may cause discomfort in abdomen and abdominal pains.
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: Carbon, nitrogen, sulfur, sodium oxides.
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 (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

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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:	-
	Industrial sector specific solutions:	-

SECTION 8. Exposure controls/personal protection		
8.1.	Control parameters	

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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

8.2. Exposure controls

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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:	powder	No information available
	Color:	dark brown	No information available
	Odour/odour threshold:	odourless	No information available
	Melting point / freezing point:	290 °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

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	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.
10.3.	Possibility of hazardous reactions:	No information available
10.4.	Conditions to avoid:	No information available
10.5.	Incompatible materials:	Strong oxidizing substances, strong acids.
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	No information available	No information available	No information available	-
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	-

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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:	Swallowing may cause discomfort in abdomen and abdominal pains.					
Dermal exposure:	Allergic persons may display irritation.					
Inhalation exposure:	Allergic persons may display irritation after prolonged or repeated exposure.					
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	-

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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	-
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:	No information available
Mutagenicity <i>in-vitro</i> :	No information available
Genotoxicity:	No information available
Mutagenicity <i>in-vivo</i> :	No information available

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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 information:		
-		

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	-
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	-

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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 available	information	No information available		-
Fresh water	No information available	No available	information	No information available		-
Air	No information available	No available	information	No information available		-
Soil	No information available	No available	information	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 K _{ow}):						
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

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

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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:	-
Further information:	-

SECTION 15. Regulatory information

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

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	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> <p>IATA: International Air Transport Association</p>

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		<p>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:	-
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

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