

Trading name:	AURAMINE O, C.I. 41000		
Product code:	AU-P-X**	Revision date:	26.07.2019. Version: 3

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

1.1. Product identifier	
Substance name:	AURAMINE O, C.I. 41000
EC No:	219-567-2
Synonyms:	Basic Yellow 2
Catalogue number:	AU-P-X**
REACH registration number:	-
CAS No:	2465-27-2
Index no.:	-
1.2. Relevant identified uses of the substance or mixture and uses advised against	
Uses:	For microscopy.
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*:
Acute Tox. 4	H302
Acute Tox. 3	H311
Carc. 2	H351
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:	AURAMINE O, C.I. 41000
Identification number:	-
Authorization no.:	-
Hazard pictograms:	  GHS06 GHS08
Signal word:	Danger
Hazard statements:	H302 Harmful if swallowed. H311 Toxic in contact with skin. H351 Suspected of causing cancer.
Precautionary statements:	P280 Wear protective gloves/protective clothing/eye protection/face protection. P302+P352 IF ON SKIN: Wash with plenty of water and soap. P308 + P313 IF exposed or concerned: Get medical advice/attention.
Further information:	-
2.3. Other hazards	
	-

SECTION 3. Composition/information on ingredients				
CAS No	EC No:	Index no.	Identification name	Weight % content (or range)
2465-27-2	219-567-2	-	Auramine O	~ 80 %

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.

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	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 suitable foam.
	Unsuitable extinguishing media:	-
5.2.	Special hazards arising from the substance or mixture	
	Hazardous combustion products:	-
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

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		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 and storage		
7.1.	Precautions for safe handling	
7.1.1.	Protection measures	
	Measures to prevent fire:	Heat sources.
	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:	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
			Biological limit values

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		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	
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	No information available

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	exposure:	
	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.
8.2.2.3.	Respiratory protection:	Required when dust are generated. Recommended filter type: Filter P 3 (acc. to DIN 3181) for solid and liquid particles of toxic and very toxic substances.
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:	yellow	No information available
	Odor:	No odor	No information available
	Odor threshold:	No information available	No information available
	pH:	6 -7 (10g/l at 20°C)	No information available
	Melting point / freezing point;	>250 °C	No information available
	Initial boiling point and boiling range:	No information available	No information available

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Flash point:	No information available	No information available
Evaporation rate:	No information available	No information available
Flammability (solid, gas):	No information available	No information available
Upper/lower flammability or explosive limits:	No information available	No information available
Vapor pressure:	No information available	No information available
Vapor density:	No information available	No information available
Relative density:	No information available	No information available
Bulk density:	No information available	No information available
Solubility(ies):	soluble in alcohol and mildly soluble in water	No information available
Partition coefficient: n-octanol/water (log Kow):	No information available	No information available
Auto-ignition temperature:	No information available	No information available
Decomposition temperature:	265 °C	No information available
Viscosity:	No information available	No information available
Explosive properties:	No information available	No information available
Oxidising properties:	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.
10.5.	Incompatible materials:	Strongly oxidizing media.
10.6.	Hazardous decomposition products:	Reaction in contact with nitrates, nitric acid and nitrate gases may liberate carcinogenic nitrosamines.

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	mouse	LD ₅₀ =480 mg/kg	No information available	-

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Dermal exposure:	No information available	mouse	LD ₅₀ =300 mg/kg	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:	Harmful if swallowed.
Dermal exposure:	Harmful by inhalation and in contact with skin.
Inhalation exposure:	Harmful if swallowed.
Eye exposure:	Risk of serious damage to eyes.

Repeated dose toxicity (subacute, subchronic, chronic)

	Dose	Exposure time	Species	Method	Evaluation	Note
Subacute oral	No information	No	No	No	No information	-

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	available	information available	information available	information available	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	-
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	-

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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
Germ cell mutagenicity:	No information available
Reproductive toxicity:	No information available

Summary of evaluation of the CMR properties:	No information available
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11.2. Practical experiences:

Remarks relevant for classification:	No information available
Other remarks:	No information available

11.3. General notes:

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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	No information	No information	-

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			available	available	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 K_{ow}):

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

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		available	available	available	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. Other adverse effects

No information available					
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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:

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	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:	2811
UN proper shipping name:	Toxic solid, organic, n.o.s. (4,4'-carbonimidoylbis (N, N-dimethylaniline) monohydrochloride)
Transport hazard class(es):	6.1
Packing group:	III
Environmental hazard(s):	-
Special precautions for user:	-
	Transporting/shipment by rail (RID)
UN number:	2811
UN proper shipping name:	Toxic solid, organic, n.o.s. (4,4'-carbonimidoylbis (N, N-dimethylaniline) monohydrochloride)
Transport hazard class(es):	6.1
Packing group:	III
Environmental hazard(s):	-
Special precautions for user:	-
	Transporting/shipment by inland waterways (ADN)
UN number:	2811
UN proper shipping name:	Toxic solid, organic, n.o.s. (4,4'-carbonimidoylbis (N, N-dimethylaniline) monohydrochloride)
Transport hazard class(es):	6.1
Packing group:	III
Environmental hazard(s):	-
Special precautions for user:	-

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Transporting/shipment by sea (IMDG)	
UN number:	2811
UN proper shipping name:	Toxic solid, organic, n.o.s. (4,4'-carbonimidoylbis (N, N-dimethylaniline) monohydrochloride)
Transport hazard class(es):	6.1
Packing group:	III
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:	2811
UN proper shipping name:	Toxic solid, organic, n.o.s. (4,4'-carbonimidoylbis (N, N-dimethylaniline) monohydrochloride)
Transport hazard class(es):	6.1
Packing group:	III
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
	Authorization and/or restrictions of use
	Authorizations: -
	Restrictions: -
Other EU regulations:	<p>EC Regulation No. 1906/2007 and EC Regulation No. 1272/2008 of the European Parliament and the European Council;</p> <p>The European Commission Regulation No. 453/2006 of 2010 on changes and amendments to the Regulation (EC) No. 1907/2006 of the European Parliament and Council on registration, evaluation, authorization and restriction of chemical substances (REACH);</p> <p>EC Regulation No. 2037/2000 of the European Parliament and Council from 29 June 2000 on substances that damage the ozone layer;</p> <p>EC Regulation No. 689/2008 of the European Parliament and Council from 17 June 2008 concerning the export and import of dangerous chemicals;</p> <p>EC Regulation No. 850/2004 of the European Parliament and Council from 29 April 2004 about persistent organic pollutants;</p> <p>Directive 2008/98/EC of the European Parliament and Council of 19 November 2008 on waste and repealing certain Directives</p>

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	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline)
National legislation:	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
15.2.	Chemical safety assessment
	None

SECTION 16. Other information											
16.1.	Indication of changes: -										
16.2.	Abbreviations and acronyms: <table border="0" style="width: 100%;"> <tr> <td style="width: 150px;">PBT</td> <td>Stable, bioaccumulative and toxic</td> </tr> <tr> <td>vPvB</td> <td>Strongly stable and strongly bioaccumulative.</td> </tr> <tr> <td>LD₅₀</td> <td>Lethal dose, 50%</td> </tr> <tr> <td>LC₅₀</td> <td>Lethal concentration, 50%</td> </tr> <tr> <td>STOT-SE</td> <td>Specific target organ toxicity - single exposure</td> </tr> </table>	PBT	Stable, bioaccumulative and toxic	vPvB	Strongly stable and strongly bioaccumulative.	LD ₅₀	Lethal dose, 50%	LC ₅₀	Lethal concentration, 50%	STOT-SE	Specific target organ toxicity - single exposure
PBT	Stable, bioaccumulative and toxic										
vPvB	Strongly stable and strongly bioaccumulative.										
LD ₅₀	Lethal dose, 50%										
LC ₅₀	Lethal concentration, 50%										
STOT-SE	Specific target organ toxicity - single exposure										
16.3.	Key literature references and source of data: -										
16.4.	Relevant H statements (number and full text) <table border="0" style="width: 100%;"> <tr> <td style="width: 150px;">H302</td> <td>Harmful if swallowed.</td> </tr> <tr> <td>H: H311</td> <td>Harmful in contact with skin.</td> </tr> <tr> <td>H351</td> <td>Suspected of causing cancer.</td> </tr> </table>	H302	Harmful if swallowed.	H: H311	Harmful in contact with skin.	H351	Suspected of causing cancer.				
H302	Harmful if swallowed.										
H: H311	Harmful in contact with skin.										
H351	Suspected of causing cancer.										
16.5.	Training advice: -										
16.6.	Further information: <p>** "X" in the product code marks different volumes (different packagings 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
-