

Trading name:	NIGROSINE WS, C.I. 50420				
Product code:	NGR-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:	NIGROSINE WS, C.I. 50420
	EC No:	616-852-7
	Synonyms:	Nigrosine B, Nigrosine water soluble
	Product code:	NGR-P-X**
	REACH registration number:	-
	CAS No:	8005-03-6
	Index no.:	-
1.2.	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	For use in microbiology and cytology.
	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 listed in the Registry of medical devices 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 person:	-
1.4.	Emergency telephone number	
	National Protection and Rescue Directorate:	112
	Medical information:	+385 1 2348 342
	Other information:	-

SECTION 2. Hazards identification

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 substances	-
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:	NIGROSINE WS, C.I. 50420
Identification number:	-
Authorisation number:	-
Hazard pictograms:	-
Signal word:	-
Hazard statements:	-
Precautionary statements:	-
Further information:	-

2.3. Other hazards

Endocrine Disrupting Properties:

No known endocrine disrupting properties

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

SECTION 3. Composition/information on ingredients

CAS No	EC No:	Index no.	Identification name	Weight % content (or range)
8005-03-6	616-852-7	-	Acid Black 2	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 begin rinsing with copious amounts of water for at least 15 min. 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. Drink at most two glasses of water. Seek medical assistance.
Self-protection of the first aider	-

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

Following inhalation:	Harmful if inhaled.
After skin contact:	Harmful in contact with skin.
Following eye contact:	Risk of serious damage to eyes.

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	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:	Water, foam, dry powder, CO ₂
	Unsuitable extinguishing media:	-
5.2.	Special hazards arising from the substance or mixture	
	Hazardous combustion products:	no information available
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	
	Make sure the water used for extinguishing fire does not contaminate water surface or underground waters system.	

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 breathing in dust. Avoid touching the substance. Secure proper ventilation.
	Emergency procedures:	Leave the hazardous area, take notice of the emergency procedures.
6.1.2.	For emergency responders:	
	-	
6.2.	Environmental precautions:	
	Do not allow the product enter drainage.	
6.3.	Methods and material for preventing spreading and cleaning	
6.3.1.	For creating barriers, covering and sealing:	Cover the drains. Collect, bind and pump out all the spilled material. Take notice of the possible material restriction (see Sections 7 and 10). Collect in dry form. Avoid generation of dust.
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:	-

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6.4.	Reference to other sections
	Indications about waste treatment, see Section 13.

SECTION 7. Handling and 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 sparkling tools.
	Measures to prevent aerosol and dust generation:	Secure proper ventilation.
	Environmental precautions:	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 breathing in dust. Avoid contact with skin, eyes, and clothes. Keep in tightly closed containers.
	Containers materials:	Manufacturer's original packaging.
	Requirements for storage rooms and vessels:	Keep in a tightly closed container. Keep in cool, dry and well ventilated space away from non-compatible 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	
	-	-	-	-	-
Does not contain substances regulated by the professional exposure limit values.					

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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 exposure:	No information available
Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.

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	Technical measures for preventing exposure:	Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.
8.2.2.	Personal protection equipment	
8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (preventing splashing) or visor (EN 166).
8.2.2.2.	Skin protection	
	Hand protection:	The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374 full contact: Gloves material: Nitrile rubber Glove thickness: 0.11 mm Break through time:> 480 min splash contact: Gloves material: Nitrile rubber Glove thickness: 0.11 mm Break through time:> 480 min
	Other skin protection:	In normal circumstances use cotton clothes and adequate footwear, such as rubber boots or shoes that cover the entire foot. In case of spillage risk use clothes made of impermeable material suitable for protection against liquid chemicals (Viton, PVC himex - HRN EN 465) and footwear made of 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 for preventing 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
Colour:	black	No information available

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Odour/odour threshold:	odourless/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
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:	Strong 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 period	Result

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Oral exposure:	No information available	No information available	No information available	No information available	-
Skin contact:	No information available	No information available	No information available	No information available	-
Inhaling:	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	-
Skin contact:	No information available	No information available	-
Inhaling:	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

Skin contact:	No information available
Inhaling:	No information available

Symptoms related to the physical, chemical and toxicological characteristics

Oral exposure:	No information available
Skin contact:	No information available
Inhaling:	No information available
Eye contact:	No information available

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	-

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Subacute dermal	No information available	No information available	No information available	No information available	No information available	-
Subacute inhaling toxicity	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 toxicity	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 toxicity	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 inhaling toxicity	No information available	No information available	-
Subchronic oral	No information available	No information available	-
Subchronic dermal toxicity	No information available	No information available	-
Subchronic inhalation	No information available	No information available	-
Chronic oral	No information available	No information available	-
Chronic dermal toxicity	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

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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 information:		
-		

SECTION 12. Ecological information						
12.1. Toxicity						
Acute (short-term) toxicity	Dose	Exposure period	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	-
Microorganisms	-	-	-	-	-	-
Chronic (long-term) toxicity	Dose	Exposure period	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	No information available	-

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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	-
Microorganisms	-	-	-	-	-	-

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
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 period	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

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.

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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:	-
	Transporting/shipment by rail (RID)
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-

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Environmental hazard(s):	-
Special precautions for user:	-
Inland waterway transport (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	
	Authorization and/or restrictions of use	
	Authorizations:	-
	Restrictions:	-
	Other EU regulations:	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,

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		<p>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; 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; 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; 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; 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) 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</p>
16.3.	Key literature references and source of data:	-
16.4.	Relevant H statements (number and full text)	
	H: -	-
16.5.	Training advice:	-

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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>
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<p>ANNEX: Exposure scenario resulting to Chemical safety assessment</p> <p>-</p>
