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Trading name:	ACRIDINE ORANGE SOLUTION					
Product code:	AOA-OT-X**	Revision date:	21 Dec 2022	Version:	5	

SECTI	ON 1 Identification of the subs	tance	/mixture an	d of the company/undertaking	
1.1.	Product identifier				
	Trading name:	ACRI	DINE ORANG	GE SOLUTION	
	Chemical name:	-			
	Catalogue number:	AOA-	-OT-X**		
1.2.	Relevant identified uses of the substance or mixture and uses advised against				
	Uses:		For micros	сору.	
	Uses advised against: Only the identified uses are advised.				
	Reason why uses advised again	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 ther reason to use it for other purposes			
1.3.	Details of the supplier of the s	afety o	data sheet		
	Supplier:	Bi	oGnost Ltd.		
	Address:	М	edjugorska !	59, Zagreb	
	Telephone number:	+3	385 1 24099	97	
	Fax no.:	+3	385 1 24040	39	
	e-mail of competent person:	<u>m</u>	sds@biogno	ost.hr	
	National contact person:	_			
1.4.	Emergency telephone number	r			
	National Protection and Rescu	ıe Dire	ectorate:	112	
	Medical information:			+385 1 2348 342	
	Other information:			-	

SECTIO	ON 2. Hazards identification					
2.1.	Classification of the substance	e or mixture				
2.1.1.	Classification (REGULATION) (EC) No 1272/2008 (CLP)					
	Hazard class and category code: Hazard statements*:					
	Muta. 2 H341					
2.1.2.	Additional information					
	-					
*For fu	ll text of Hazard- and EU Hazard	d-statements: see Se	ection 16			
2.2.	Label elements					
	Product identification:	ACRIDINE O	range solution			
	Identification number:	Identification number: -				
	Authorisation number:	-				



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	Hazard pictograms:	GHS08			
	Signal word:	Warning			
	Hazard statements:	H341 Suspected of causing genetic defects			
	Precautionary statements:	P280 Wear protective gloves/protective clothing/eye protection/face protection. P308 + P313 IF exposed or concerned: Get medical advice/attention. P501 Dispose of contents/container to approved container for waste disposal.			
	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. Co	SECTION 3. Composition/information on ingredients						
CAS No	EC No:	Index no.	Identification name	Weight % content (or range)			
10127-02-3	233-353-6	-	N,N,N',N'-tetramethylacridine-3,6-diamine monohydrochloride	≤1%			

SECTI	SECTION 4. First aid measures					
4.1.	Description of first aid meas	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.				



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	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 if it comes into contact with skin.		
	Following eye contact:	Serious eye injury risk.		
	Following ingestion:	Harmful if swallowed.		
4.3.	Indication of any immediate medical attention and special treatment needed			
	-			

SECTI	CTION 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:	In case of fire, the following may occur: nitrogen oxides, hydrogen chloride gas.			
5.3.	Advice for firefighters	Advice for firefighters			
	Use a self-contained open-circuit of Cool closed containers exposed to	compressed air breathing apparatus and fireproof clothing. o fire with water spray or vapor.			
5.4.	Additional information				
	Make sure the water used for extir waters system.	nguishing fire does not contaminate water surface or underground			

SECTIO	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 proposition.					
	Emergency procedures:	Leave the hazardous area, take notice of the emergency procedures.				
6.1.2.	For emergency responders:					
	-					
6.2.	Environmental precautions:	Environmental precautions:				
	Do not allow the product enter d	rainage.				



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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 and involved materials with water.					
6.3.3.	Other information:	-					
6.4.	Reference to other sec	ctions					
	Indications about waste treatment, see Section 13.						

	ON 7. Handling and storage							
7.1.	Precautions for safe handling Protection measures							
7.1.1.	Measures to prevent fire:	Keep away from sources of ignition and heat. Do not use sparkling tools.						
	Measures to prevent aerosol and dust generation	on: 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. The	noroughly 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:	-						



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SECTION 8. Exposu	re control:	s/personal	protecti	ion						
8.1. Control para										
Substance					Occupational exposure limit values/short term values			ological limit values		
					ppm	mg/m³				
-		-			-	-		-		
Does not contain sub	ostances re	gulated by	the prof	essior	nal exposi	ure limit values	•			
Substance - name:										
EC No: -		CAS No:	_							
DNEL										
				Ind	ustrial					
Route of Acute A				Acut	e	Chron	ic	Chronic		
exposure:	effec	t local	effe	ct sys	temic	effect lo	cal	effect systemic		
Oral -			-			-		-		
Inhalation	-		-		-			-		
Dermal	-		-		-			-		
Critical physical para	meters: so	lubility, flam	nmability	, corr	osivity:					
	1		1	Con	sumer			I		
Route of		cute		Acute		Chronic		Chronic		
exposure:				ct sys	temic	effect local		effect systemic		
Oral	-		-					-		
Inhalation	_		-		_			-		
Dermal PNEC										
	ction targe	.+			PNEC					
Environmental prote	ction targe	:L								
Freshwater sediment					No information available No information available					
Marine water					No information available					
Marine sediments					No information available					
Food chain			No information available							
Microorganisms in se	ewage trea	tment			No information available					
Soil (agricultural)	errage trea				1	rmation availab				
Air						rmation availab				
					1					



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8.2.	Exposure controls							
8.2.1.	Appropriate engineering control	ls						
	Substance/mixture related meas exposure during identified uses:	•	Use personal protective equipment. Do not eat, drink or smoke in the workspace.					
	Structural measures to prevent e	exposure:	No information available					
	Organisational measures to prev	ent exposure	Organization of work in order to reduce other worker's influence during work process.					
	Technical measures for preventir	ng 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							
O.L.	Hand protection:		Gloves material: Nitrile rubber Glove thickness: 0.11 mm Break through time:> 480 min					
	Other skin protection:	such as rub spillage risl protection	circumstances use cotton clothes and adequate footwear, ober boots or shoes that cover the entire foot. In case of k use clothes made of impermeable material suitable for against liquid chemicals (Viton, PVC himex - HRN EN 465) ear made of the same material.					
8.2.2.3.	Respiratory protection:		when dust are generated. Recommended filter type: Filter P DIN 3181) for solid and liquid particles of toxic and very cances.					
8.2.2.4.	Thermal hazards:	-						
8.2.3.	Environmental exposure controls	S						
	Substance/mixture related meas prevent exposure:	ures to	See Section 6					
	Structural measures to prevent e	exposure:	Use modern equipment.					
	Organisational measures to prevexposure:	ent ent	Adapt the work process to the required working conditions of the workplace.					



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Technical measures for preventing exposure:	e Section 6
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9.1.	Information on basic physical and che	mical properties	
		Value	Method
	Physical state:	powder	No information available
	Colour:	reddish-brown	No information available
	Odour/odour threshold:	odourless	No information available
	Melting point / freezing point:	165 °C	No information available
	Boiling point or initial boiling point and boiling range:	No information available	No information available
	Flammability:	No information available	No information available
	Lower and upper explosion limit:	No information available	No information available
	Flash point:	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	рН:	No information available	No information available
	Kinematic viscosity:	No information available	No information available
	Solubility:	28 g/l (20°C)	No information available
	Partition coefficient n-octanol/water (log value):	No information available	No information available
	Vapour pressure:	No information available	No information available
	Density and/or relative density:	No information available	No information available
	Relative vapour density:	No information available	No information available
	Particle characteristics:	No information available	No information available
9.2.	Other information		

SECTIO	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				



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SECTION 11. To	xicol	ogical informati	on								
11.1. Informa	tion c	n toxicological e	ffects								
Acute to	oxicity	:	I								
Route of exposure:	Method Specie		Species	Dose LD ₅₀ /LC ₅₀		Ехрс	sure peri	od	Result		
Oral exposure:	No ava	information ilable	No availa	No informa available			information ilable	No availab	No inform available		-
Skin contact:	No ava	information ilable	No availa	No information available			information ilable	No availab	inform le	ation	-
Inhaling:	nhaling: No information No available avail			inform ble	ation		information ilable	No availab	inform le	ation	-
C:#:-	.	A	ai.a a.la		(CTC)T CI	-1.				
Specific	targe	t organ toxicity –		expost	ne (STC		arget organ			Note	
Oral exposure:	Specific effects Oral exposure: No information available				No inf		ation available	,	_	NOLE	
Skin contact:		information avai									
		information avai			No information available - No information available -						
Inhaling:	INO	illolliation avai	iabie		INO IIII	101111	ation available				
Aspirati	on ha	zard:		No in	formati	on a	vailable				
7.3рпии		zuru.		140 111	TOTTILA	OII u	valiable				
Irritatio	n and	corrosion									
		Exposure tim	ne	Sp	ecies		Evaluation	Me	thod		Note
Skin corrosion/irritation	on:	No informa	-		formati	on	-	No information available		No availa	informatio
Serious eye damage/irritation	n	No informa			information ilable		_	No information available		No availa	informatio ble
	_										
Sensitiz	ation										
Skin contact:	N	o information av	ailable								
Inhaling:	N	o information av	ailable								
Svmpto	ms re	lated to the phys	ical, ch	emical	and tox	icolo	ogical characte	eristics			
Oral exposure:		o information av					<u> </u>				
Skin contact:		o information av									
Inhaling:		o information av									



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Kepea	ted dose toxic	ity (Sul	pacute, subchror	iic, crirc	n IIC)			
	Dose		Exposure time	Specie	es	Method	Evaluation	Note
Subacute oral	No inform available	ation	No information available	No inform availa		No information available	No information available	-
Subacute dermal	No inform available	ation	No information available	No inform availa		No information available	No information available	-
Subacute inhaling toxicity	No information available		No information available	No inform availa		No information available	No information available	-
Subchronic oral	No information available		No No information available 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 inform available	ation	No No information available available			No information available	No information available	-
Chronic dermal toxicity	No inform available	ation	No No information informavailable available			No information available	No information available	-
Chronic inhalation	No inform available	ation	No information available	No inform availa		No information available	No information available	-
ı								
Specif	ic target orgar	toxici	ty – repeated ex	•				
			Specific effects			arget organ		Note
Subacute oral			formation availa			rmation availab		
Subacute derm			formation availa			rmation availab		
Subacute inhali			formation availa		ļ	rmation availab		
Subchronic ora			formation availa			rmation availab		
Subchronic der			formation availa		<u> </u>	rmation availab		
Subchronic inha	aiation		formation availa			rmation availab		
Chronic oral		No in	formation availa	ble	No into	rmation availab	ole -	



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Chronic	dermal toxicity	No inform	ation avail	able	No information available	-
Chronic	inhalation	No inform	ation avail	able	No information available	-
	CMR effects (carc	inogenicity, m	utagenicity	y, repro	ductive toxicity)	
Carcino	genicity:		No info	rmatior	n available	
Mutage	nicity <i>in-vitro</i> :		No info	rmatior	n available	
Genoto	xicity:		No info	rmatior	n available	
Mutage	nicity <i>in-vivo</i> :		No info	rmatior	n available	
Germ ce	ell mutagenicity:		Suspect	ed of c	ausing genetic defects	
Reprodu	uctive toxicity:		No info	rmatior	n available	
11.2.	Information on ot	her hazards:				
11.2.1.	Endocrine disrupt	ing properties				
	The substance/r components con disrupting prope Article 57(f) o regulation (EU) Regulation (EU) 2 higher.	sidered to ha erties accordir r Commissio 2017/2100 oi	ave endoo ng to RE n Deleg · Commis	ACH ated		
11.2.2.	Other information	۱۰				
		••				

SECTION 12. Ecologi	cal informat	tion				
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	-



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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	-
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	-

Bioaccumulative potential 12.3.

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

Value	Concentration	рН	°C	Method	Evaluation	Note
No informatio n available	No information available	-	-	No information available	No information available	No information available
	i .	1	<u> </u>	i	i	i



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V	alue		Species		Meth	od	Eva	luation		Note	
No info	rmation		information ilable	No information available		tion	No information available			No information available	
	Chronic e	cotoxi	icity								
	Value		Dose	Exposure period	S	pecies	Metho	d Eva	aluation	Note	
Chronic	toxicity or	n fish	LC ₅₀	No informati on available	No infor avail	mation able	No informa on available	info	rmation lable	-	
	toxicity or ea (Daphni		EC ₅₀	No informati on available	No infor avail	mation able	No informa on available	into	rmation lable	-	
			icted distribut	on in enviro	nmenta	ai combar	TMANTC'				
	Surface to		available			:	unches.				
		ension		Concen			Method			Note	
	Surface to	ension	:	Concen No informavailable	tration mation		Method formation	-		Note	
	Surface to Value No informati	ension	°C No information	No infor	tration mation	No in	Method formation	-		Note	
	Surface to Value No informati	on	°C No information available	No infor	tration mation	No in	Method formation	-		Note	
Transpo	Surface to Value No informati available Adsorptio	on / de	°C No information available	No infor	tration	No in	Method formation ble	Meth	nod	Note	
Transpo Soil-wat	Surface to Value No informati available Adsorption	on / de	°C No information available esorption pefficient	No informavailable	tration mation	No in availa	Method formation ble fon rate	Meth	nod		
·	Surface to Value No informati available Adsorption ort Free No available	on / de A/D co	°C No information available esorption pefficient s constant	No information available	w ation	No in availa Evaporati No info	Method formation ble fon rate rmation	Meth No info available		Note	



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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	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:	-	



Further information:

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		:				
Transport hazard	class(es):	-				
Packing group:		-				
Environmental haz	zard(s):	-				
Special precaution	ns for user:	-				_
Transport	ting/shipment by rail (R	D)				
UN number:		No	t subject to transpo	ort regulations.		
UN proper shippir	ng name:	-				
Transport hazard	class(es):	-				
Packing group:		-				
Environmental haz	zard(s):	-				
Special precaution	ns for user:	-				
Inland wa	aterway transport (ADN)					
UN number:		No	t subject to transpo	ort regulations.		
UN proper shippir	ng name:	-				
Transport hazard	class(es):	-				
Packing group:		-				
Environmental haz	zard(s):	-				
Special precaution	ns for user:	-				
Transpor	ting/shipment by sea (IN	ИDG)			
UN number:		No	t subject to transpo	ort regulations.		
UN proper shippir	ng name:	-				
Transport hazard	class(es):	-				
Packing group:		-				
Environmental haz	zard(s):	-				
Special precaution	ns for user:	-				
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code:		_				
Transporting/shipment by air (ICA			ΓΙ/IATA-DGR)			
UN number:		No	t subject to transpo	ort regulations.		
UN proper shippir	UN proper shipping name:					
Transport hazard class(es):		-				
Packing group:		-				
Environmental hazard(s):		-				
Special precautions for user:		-				



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15.1.	Safety, health and environmental regulations/legislation specific for the substance or mixture				
	EU regulations				
	Authorization and/or rest	rictions 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, amending Directive 1999/45/EC and repealing Council Regulation (EC) 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); Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VC quideline)				
	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 assessme	ent			
	None				

SECTIO	SECTION 16. Other information				
16.1.	Indication of changes:	-			
16.2.	Abbreviations and acronyms:	ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society)			



SAFETY DATA SHEET BIOGNOST ® According to Regulation (EC) No. 1907/2006 amended by Regulation (EU) No. 2020/878

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Trading name:		ACRIDINE OR	ANGE SOLUTION	-	
Product code:	AOA-OT-X**	Revision date:	21 Dec 2022	Version:	5

		DNEL: Derived No-Effect Level (UK REACH) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative
16.3.	Key literature references and source of data:	-
16.4.	Relevant H statements (numbe	r and full text)
	H: 341	Suspected of causing genetic defects
16.5.	Training advice:	-
16.6.	Further information:	** "X" in the product code marks different volumes (different packagings of the product) We are not responsible for consequences in case of failure to comply with
10.0.	Turtier information.	instructions for use or improper use of the product described in this material safety data sheet.

ANNEX:

Exposure scenario resulting to Chemical safety assessment