

ABRAXIS® Anatoxin-a/Saxitoxin Sample Diluent

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878



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

1.1. Product identifier

Product form : Mixture
Trade name : ABRAXIS® Anatoxin-a/Saxitoxins, Sample Diluent
Product code : 530010/53001L

1.2. Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses

Use of the substance/mixture : Use in either ABRAXIS® Anatoxin-a or ABRAXIS® Saxitoxin ELISA Plate Kits

Uses advised against

Restrictions on use : For research purpose only

1.3. Details of the supplier of the safety data sheet

Supplier

Gold Standard Diagnostics Horsham LLC
795 Horsham Rd
19044 Horsham, PA
T 12153573911
info.abraxis@us.goldstandarddiagnostics.com

Only Representative

Gold Standard Diagnostics Budapest Kft.
1047 Budapest
Fóti út 56, Hungary

1.4. Emergency telephone number

Emergency number : 12153573911 Monday - Friday 8:00am - 4:00pm EST

Country/Area	Organisation	Emergency number
Austria	Vergiftungsinformationszentrale. Stubenring 6 1010 Vienna.	+43 1 406 43 43
Belgium	Centre Anti-Poisons/Antigifcentrum. c/o Hôpital Militaire Reine Astrid. Rue Bruyn 1 1120 Brussels.	+32 70 245 245 Please dial: 070 245 245 for any urgent questions about intoxication (free of charge 24/7), if not accessible, dial: 02 264 96 30 (standard fee)
Bulgaria	Национален токсикологичен информационен център. Многопрофилна болница за активно лечение и спешна медицина "Н.И.Пирогов". бул. Ген. Едуард И. Тотлебен 21 1606 Sofia.	+359 2 9154 233 The phone is active 24/7 and calls to it are free
Croatia	Centar za kontrolu otrovanja. Institut za medicinska istraživanja i medicinu rada. Ksaverska Cesta 2. p.p. 291 10000 Zagreb.	+385 1 234 8342 Information available 24/7 in Croatian and English
Estonia	Mürgistusteabekeskus. Terviseamet. Paldiski mnt 81 10614.	16662 +372 7943 794 Calling the hotline is anonymous and at the cost of a local call.
Finland	Myrkytystietokeskus. Stenbäckinkatu 9. PO BOX 100 00029 Helsinki.	+358 800 147 111 +358 9 471 977 Open 24 hours a day 0800 147 111 (free of charge) 09 471 977 (normal rate call)
Germany	Klinik für Intensiv- und Notfallmedizin, Klinikum Nürnberg. Institut für Biomedizin des Alterns, Universität Erlangen-Nürnberg. Professor-Ernst-Nathan-Straße 1 90419.	+49 (0) 911 398 2451
	Giftnotruf der Charité - Universitätsmedizin Berlin. CBF, Haus VIII (Wirtschaftsgebäude), UG. Hindenburgdamm 30 12203.	+49 (0) 30 19240

ABRAXIS® Anatoxin-a/Saxitoxin Sample Diluent

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878



Country/Area	Organisation	Emergency number
Greece	Poisons Information Centre. Children's Hospital P&A Kyriakou. 11762.	+30 21 07 79 37 77
Hungary	Nemzeti Népegészségügyi Központ. Egészségügyi Toxikológiai Tájékoztató Szolgálat. Albert Flórián út 2-6 1097.	+36 80 20 11 99 +36 1 476 6464 Emergency number 1: (0-24 hours, free of charge - only from Hungary) Emergency number 2: (0-24 hours, can be called for a normal fee - also from abroad)
Ireland	National Poisons Information Centre. Beaumont Hospital. PO Box 1297. Beaumont Road 9 Dublin.	+353 1 809 2566 (Healthcare professionals-24/7) +353 1 809 2166 (public, 8am - 10pm, 7/7)
Italy	Centro Antiveleni di Bergamo. Azienda Ospedaliera Papa Giovanni XXIII. Piazza OMS - Organizzazione Mondiale della Sanità, 1 24127 Bergamo.	800 88 33 00
Latvia	Valsts ugunsdzēsības un glābšanas dienests. Toksikoloģijas un sepses klīnikas Saindēšanās un zāļu informācijas centrs. Hipokrāta 2 1038 Rīga.	112 +371 67 04 24 73 works 24 hours a day
Malta	Medicines & Poisons Info Office. Mater Dei Hospital. Msida MSD 2090 Msida.	112 +356 2545 6508
Netherlands	Nationaal Vergiftigingen Informatie Centrum (NVIC). Huispostnummer Q03.2.315. Postbus 85500 3508 GA Utrecht.	+31 88 755 80 00 Only for the purpose of informing medical personnel in cases of acute intoxications (24 hours a day, 7 days a week)
Poland	Pomorskie Centrum Toksykologii. Ul. Kartuska 4/6 80-104 Gdańsk.	+48 058 682 04 04 Biocidal product poisoning control region: Voivodeships: Pomeranian, West Pomeranian, Warmian-Masurian, Kuyavian-Pomeranian
Romania	Spitalul Clinic de Urgenta Bucuresti. Secția Clinică ATI II - Toxicologie Clinică. Calea Floreasca nr. 8. sector 1 Bucharest.	+40 21 599 23 00 (information provided in Romanian and English)
Spain	Servicio de Información Toxicológica. Instituto Nacional de Toxicología y Ciencias Forenses. Departamento de Madrid. C/José Echegaray nº4 28232 Las Rozas de Madrid.	+34 91 562 04 20 +34 91 411 26 76 (teléfono solo para médicos) (Toxicological emergencies only). Information in Spanish (24/7)
Sweden	Giftinformationscentralen. Solna Strandväg 21 171 54 Solna.	112 – begär Giftinformation

SECTION 2: Hazards identification

2.1.1 Classification of the substance or mixture (all components)

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Skin corrosion/irritation, Category 2	H315
Serious eye damage/eye irritation, Category 2	H319
Skin sensitisation, Category 1	H317
Hazardous to the aquatic environment – Chronic Hazard, Category 3	H412

Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

May cause an allergic skin reaction. Causes skin and eye irritation. May cause cancer.

ABRAXIS® Anatoxin-a/Saxitoxin Sample Diluent

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878



2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)



GHS07

Signal word (CLP)

: Warning

Contains

: ProClin

Hazard statements (CLP)

: H315 - Causes skin irritation.

H317 - May cause an allergic skin reaction.

H319 - Causes serious eye irritation.

H412 - Harmful to aquatic life with long lasting effects.

Precautionary statements (CLP)

: P261 - Avoid breathing mist, spray, vapours.

P264 - Wash hands, forearms and face thoroughly after handling.

P272 - Contaminated work clothing should not be allowed out of the workplace.

P273 - Avoid release to the environment

P280 - Wear protective gloves, protective clothing, eye protection, face protection.

P302+P352 - IF ON SKIN: Wash with plenty of soap and water.

2.3. Other hazards

Other hazards which do not result in classification : Contains material of biological origin. As with all materials of biological origin, this material should be regarded as potentially hazardous to health.

Contains no PBT and/or vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or substance(s) are not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Name	Product identifier	% in kit	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Sodium chloride 8.0%	CAS-No.: 7647-14-5 EC-No.: 231-598-3	8.0%	Eye Irrit. 2, H319
ProClin 0.1%	CAS-No.: 55965-84-9 EC-No.: 911-418-6 EC Index-No.: 613-167-00-5	0.1%	Acute Tox. 3 (Oral), H301 Acute Tox. 2 (Dermal), H310 Acute Tox. 2 (Inhalation:dust,mist), H330 Skin Corr. 1C, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 STOT RE 1, H372 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410 (M=10)

Specific concentration limits:

Name	Product identifier	Specific concentration limits (%)
ProClin	CAS-No.: 55965-84-9 EC-No.: 911-418-6 EC Index-No.: 613-167-00-5	(0.0015 $\leq$ C $\leq$ 100) Skin Sens. 1A; H317 (0.06 $\leq$ C < 0.6) Skin Irrit. 2; H315 (0.06 $\leq$ C < 0.6) Eye Irrit. 2; H319 (0.6 $\leq$ C $\leq$ 100) Skin Corr. 1C; H314 (0.6 $\leq$ C $\leq$ 100) Eye Dam. 1; H318

ABRAXIS® Anatoxin-a/Saxitoxin Sample Diluent

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878



Full text of H- and EUH-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: First aider: Pay attention to self-protection. Never give anything by mouth to an unconscious person. Give artificial respiration if necessary. Induce artificial respiration with mask fitted with one-way valve or other suitable device but, not mouth-to-mouth. If you feel unwell, seek medical advice.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing. If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. Induce artificial respiration with mask fitted with one-way valve or other suitable device; not mouth-to-mouth. If experiencing respiratory symptoms: Call a poison center or a doctor.
First-aid measures after skin contact	: Remove affected clothing and wash all exposed skin areas with mild soap and water, followed by warm water rinse. Wash contaminated clothing before reuse. Wash skin with plenty of water. Take off contaminated clothing. If skin irritation or rash occurs: Get medical advice/attention.
First-aid measures after eye contact	: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. Rinse eyes with water as a precaution.
First-aid measures after ingestion	: Rinse mouth. Do NOT induce vomiting. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Call a poison center or a doctor if you feel unwell.
Self protection of the first-aider	: First aid workers will be equipped with suitable personal protective equipment.

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

Symptoms/effects after inhalation	: May cause cancer.
Symptoms/effects after skin contact	: May cause an allergic skin reaction. Irritation (itching, redness, blistering).
Symptoms/effects after eye contact	: Causes serious eye irritation.
Symptoms/effects after ingestion	: May cause gastrointestinal irritation, nausea, vomiting and diarrhoea.
Chronic symptoms	: May cause cancer.

4.3. Indication of any immediate medical attention and special treatment needed

IF exposed or concerned: Get medical advice/attention.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Dry chemical, CO ₂ , or water spray or regular foam. Water spray. Dry powder. Foam. Carbon dioxide.
Unsuitable extinguishing media	: Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: No fire hazard.
Explosion hazard	: No direct explosion hazard.
Hazardous decomposition products in case of fire	: Toxic fumes may be released. Carbon dioxide. Carbon monoxide. Nitrogen oxides.

5.3. Advice for firefighters

Firefighting instructions	: Fight fire from safe distance and protected location. Do not enter fire area without proper protective equipment, including respiratory protection. Move containers from fire area if it can be done without personal risk. Use water spray or fog for cooling exposed containers. Prevent fire fighting water from entering the environment.
Protection during firefighting	: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

ABRAXIS® Anatoxin-a/Saxitoxin Sample Diluent

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878



SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures	: Avoid all personal contact including breathing in the mist, spray, vapours. Do not take actions involving personal risks. Absorb spillage to prevent material damage. Stop leak if safe to do so. Notify authorities if product enters sewers or public waters.
For non-emergency personnel	
Protective equipment	: Wear recommended personal protective equipment.
Emergency procedures	: Evacuate the danger area. If outdoors, move to an area upwind of the danger area. Avoid contact with skin and eyes. If possible without taking personal risks, remove ignition sources, ventilate area. Prevent other non-emergency personnel from entering the danger area.
For emergency responders	
Protective equipment	: Wear the recommended personal protective equipment. Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".
Emergency procedures	: Evacuate personnel to a safe area. Do not touch or walk on the spilled product. Stop leak if safe to do so.

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

For containment	: Contain with non-combustible inert absorbent. Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams. Stop leak without risks if possible.
Methods for cleaning up	: Take up liquid spill into absorbent material. Take up in non-combustible inert absorbent and place into container for disposal. Contaminated absorbent material may pose the same hazard as the spilt product. Decontaminate surfaces and equipment with water and detergent. Until a sufficient level of dilution is achieved, the decontamination water may pose the same hazards as the product. Dispose of collected material as soon as possible in accordance with applicable local/regional/national/international regulations.

6.4. Reference to other sections

For further information refer to section 8: "Exposure controls/personal protection". For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling	: Ensure good ventilation of the work station. Use only outdoors or in a well-ventilated area. Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid breathing mist, spray, vapours.
Hygiene measures	: Do not eat, drink or smoke when using this product. Always wash hands after handling the product. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Store in a cool, dry and well-ventilated area away from incompatible substances. Keep container closed when not in use. Store in a secure location. Keep away from heat and direct sunlight. Keep away from food, drink and animal feedingstuffs.
Incompatible materials	: Strong acids, strong bases and strong oxidants.
Packaging materials	: Always store product in container of same material as original container.

Germany

Storage class (LGK, TRGS 510)	: LGK 6.1D - Non-combustible substances of acute toxicity, category 3 / hazardous substances that are toxic or produce chronic effects
-------------------------------	--

ABRAXIS® Anatoxin-a/Saxitoxin Sample Diluent

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878



Joint storage table

LGK 1	LGK 2A	LGK 2B	LGK 3	LGK 4.1A
LGK 4.1B	LGK 4.2	LGK 4.3	LGK 5.1A	LGK 5.1B
LGK 5.1C	LGK 5.2	LGK 6.1A	LGK 6.1B	LGK 6.1C
LGK 6.1D	LGK 6.2	LGK 7	LGK 8A	LGK 8B
LGK 10	LGK 11	LGK 12	LGK 13	LGK 10-13

Joint storage not permitted for

: LGK 1, LGK 2A, LGK 4.1A, LGK 5.1A, LGK 5.1C, LGK 5.2, LGK 6.2, LGK 7

Joint storage with restrictions permitted for

: LGK 3, LGK 4.1B, LGK 4.2, LGK 4.3, LGK 5.1B

Joint storage permitted for

: LGK 2B, LGK 6.1A, LGK 6.1B, LGK 6.1C, LGK 6.1D, LGK 8A, LGK 8B, LGK 10, LGK 11, LGK 12, LGK 13, LGK 10-13

7.3. Specific end use(s)

Detection/determination of Saxitoxin concentration in a sample.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

National occupational exposure and biological limit values

ProClin (55965-84-9)	
Austria - Occupational Exposure Limits	
Local name	5-Chlor-2-methyl-2,3-dihydroisothiazol-3-on und 2-Methyl-2,3-di-hydroisothiazol-3-on (Gemisch im Verhältnis 3:1) (Kathon)
MAK (OEL TWA)	0.05 mg/m ³
Remark	Sh
Regulatory reference	BGBI. II Nr. 339/2025
Poland - Occupational Exposure Limits	
Local name	5-Chloro-2-metylo-2H-izotiazol-3-on i 2-metylo-2H-izotiazol-3-on (masa poreakcyjna 3:1)
NDS (OEL TWA)	0.2 mg/m ³
NDSch (OEL STEL)	0.4 mg/m ³
Remark	Skóra (Oznakowanie substancji notacją „skóra” oznacza, że wchłanianie substancji przez skórę może być tak samo istotne jak przy narażeniu drogą oddechową).
Regulatory reference	Dz. U. 2024 poz. 1017 wraz z późn. zm.
Sodium chloride (7647-14-5)	
Latvia - Occupational Exposure Limits	
Local name	Nātrija hlorīds
OEL TWA	5 mg/m ³
Regulatory reference	Ministru kabineta 2007. gada 15. maija noteikumiem Nr. 325 (Grozījumi Ministru kabineta 2024. gada 26. martā noteikumiem Nr. 191).
Lithuania - Occupational Exposure Limits	
Local name	Natrio chloridas
IPRV (OEL TWA)	5 mg/m ³
Regulatory reference	LIETUVOS HIGIENOS NORMA HN 23:2011 (Nr. V-695/A1-272, 2018-06-12)

ABRAXIS® Anatoxin-a/Saxitoxin Sample Diluent

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878



8.2. Exposure controls

Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station. Use general ventilation, local exhaust ventilation, or process enclosure to keep the airborne concentrations below the permissible exposure limits. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure.

Personal protection equipment

Personal protective equipment:

Personal protective equipment should be chosen according to national standards and in discussion with the supplier of the protective equipment. Wear recommended personal protective equipment.

Personal protective equipment symbol(s):



Eye and face protection

Eye protection:

Safety glasses

Skin protection

Skin and body protection:

Body protection should be chosen depending on activity and possible exposure. Long sleeved protective clothing

Hand protection:

Wear protective gloves

Respiratory protection

Respiratory protection:

In case of inadequate ventilation, wear respiratory protection.

Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Colorless
Odour	: Not available
Odour threshold	: Not available
Melting point	: Not applicable
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Non flammable
Explosive properties	: Product does not present an explosion hazard.
Oxidising properties	: Does not meet the criteria for classification as oxidising.
Lower explosion limit	: Not available
Upper explosion limit	: Not available
Flash point	: Not available
Auto-ignition temperature	: Not available
Decomposition temperature	: Not available
pH	: Not available
Viscosity, kinematic	: Not available
Solubility	: Not available
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available

ABRAXIS® Anatoxin-a/Saxitoxin Sample Diluent

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878



Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not available
Particle characteristics	: Not applicable

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions of use.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Sparks, heat, open flame and other sources of ignition. Protect from sunlight. Incompatible materials.

10.5. Incompatible materials

Strong acids, strong bases and strong oxidants.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced. Thermal decomposition generates: Carbon dioxide. Carbon monoxide. Nitrogen oxides.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation)	: Inhalation:dust,mist: Not classified (Based on available data, the classification criteria are not met).

ProClin (55965-84-9) (Antibody Solution, Standards 0-5, Control, Enzyme Conjugate, Sample Diluent Concentrate)

LD50 oral rat	66 mg/kg
LD50 dermal rat	87.12 mg/kg
LC50 Inhalation - Rat (Dust/Mist)	0.171 mg/l/4h
LC50 Inhalation - Rat (Vapours)	0.171 mg/l/4h

Sodium chloride (7647-14-5) (Microtiter Plate, Antibody Solution, Standards 0-5, Control, Enzyme Conjugate, Sample Diluent Concentrate)

LD50 oral rat	3000 mg/kg bodyweight
LD50 dermal rat	> 2000 mg/kg
LD50 dermal rabbit	> 10000 mg/kg bodyweight
LC50 Inhalation - Rat (Dust/Mist)	> 10.5 mg/l

Skin corrosion/irritation : Causes skin irritation.

ProClin (55965-84-9) (Antibody Solution, Standards 0-5, Control, Enzyme Conjugate, Sample Diluent Concentrate)

pH	3.43
----	------

ABRAXIS® Anatoxin-a/Saxitoxin Sample Diluent

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878



Sodium chloride (7647-14-5) (Microtiter Plate, Antibody Solution, Standards 0-5, Control, Enzyme Conjugate, Sample Diluent Concentrate)

Additional information	Not irritating to rabbits on cutaneous application
------------------------	--

Serious eye damage/irritation : Causes serious eye irritation.

ProClin (55965-84-9) (Antibody Solution, Standards 0-5, Control, Enzyme Conjugate, Sample Diluent Concentrate)

pH	3.43
----	------

Sodium chloride (7647-14-5) (Microtiter Plate, Antibody Solution, Standards 0-5, Control, Enzyme Conjugate, Sample Diluent Concentrate)

Serious eye damage/irritation, rabbit	Moderate eye irritant
---------------------------------------	-----------------------

Respiratory or skin sensitisation : May cause an allergic skin reaction.

ProClin (55965-84-9) (Antibody Solution, Standards 0-5, Control, Enzyme Conjugate, Sample Diluent Concentrate)

Specific concentration limits($0.0015 \leq C \leq 100$)	
---	--

Germ cell mutagenicity : Not classified (Based on available data, the classification criteria are not met)

Carcinogenicity : May cause cancer.

Reproductive toxicity : Not classified (Based on available data, the classification criteria are not met)

STOT-single exposure : Not classified (Based on available data, the classification criteria are not met)

STOT-repeated exposure : Not classified (Based on available data, the classification criteria are not met)

ProClin (55965-84-9) (Antibody Solution, Standards 0-5, Control, Enzyme Conjugate, Sample Diluent Concentrate)

LOAEL (dermal, rat/rabbit, 90 days)	0.525 mg/kg bodyweight
-------------------------------------	------------------------

NOAEL (oral, rat, 28 days)	0.4 mg/kg bw/day
----------------------------	------------------

NOAEC (inhalation, rat, 90 days)	0.34 mg/m ³
----------------------------------	------------------------

STOT-repeated exposure	Causes damage to organs through prolonged or repeated exposure.
------------------------	---

Sodium chloride (7647-14-5) (Microtiter Plate, Antibody Solution, Standards 0-5, Control, Enzyme Conjugate, Sample Diluent Concentrate)

NOAEL (oral, rat, 28 days)	2000 mg/kg bw/day
----------------------------	-------------------

NOAEL (oral, rat, 90 days)	3000 mg/kg bw/day
----------------------------	-------------------

Aspiration hazard : Not classified (Based on available data, the classification criteria are not met)

ProClin (55965-84-9) (Antibody Solution, Standards 0-5, Control, Enzyme Conjugate, Sample Diluent Concentrate)

Viscosity, kinematic	3.013 – 3.725 mm ² /s
----------------------	----------------------------------

Sodium chloride (7647-14-5) (Microtiter Plate, Antibody Solution, Standards 0-5, Control, Enzyme Conjugate, Sample Diluent Concentrate)

Viscosity, kinematic	0.876 mm ² /s
----------------------	--------------------------

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.

Hazardous to the aquatic environment, short-term (acute) : Not classified (Based on available data, the classification criteria are not met)

Hazardous to the aquatic environment, long-term (chronic) : Not classified (Based on available data, the classification criteria are not met).

ProClin (55965-84-9) (Antibody Solution, Standards 0-5, Control, Enzyme Conjugate, Sample Diluent Concentrate)

LC50 - Fish [1]	0.19 mg/l
-----------------	-----------

LC50 - Fish [2]	0.28 mg/l
-----------------	-----------

ABRAXIS® Anatoxin-a/Saxitoxin Sample Diluent

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878



ProClin (55965-84-9) (Antibody Solution, Standards 0-5, Control, Enzyme Conjugate, Sample Diluent Concentrate)

EC50 - Crustacea [1]	0.16 mg/l
ErC50 algae	27 µg/l
NOEC (chronic)	0.1 mg/l
NOEC chronic fish	0.098 mg/l
NOEC chronic crustacea	3.6 µg/l

Sodium chloride (7647-14-5) (Microtiter Plate, Antibody Solution, Standards 0-5, Control, Enzyme Conjugate, Sample Diluent Concentrate)

LC50 - Fish [1]	5840 mg/l
EC50 - Crustacea [1]	1024 mg/l
EC50 72h - Algae [1]	> 100 mg/l
LOEC (chronic)	441 mg/l
NOEC (chronic)	314 mg/l
NOEC chronic fish	252 mg/l
NOEC chronic crustacea	500 mg/l

12.2. Persistence and degradability

ABRAXIS® Anatoxin-a/Saxitoxins Sample Diluent

Persistence and degradability	Not established.
-------------------------------	------------------

ProClin (55965-84-9)

Persistence and degradability	Not rapidly degradable
-------------------------------	------------------------

Sodium chloride (7647-14-5)

Persistence and degradability	Not rapidly degradable
-------------------------------	------------------------

12.3. Bioaccumulative potential

12.4. Mobility in soil

ProClin (55965-84-9)

Mobility in soil	12.08
------------------	-------

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional waste regulation	: Disposal must be done according to official regulations.
Waste treatment methods	: Dispose of contents/container in accordance with licensed collector's sorting instructions.
Sewage disposal recommendations	: Disposal must be done according to official regulations.

ABRAXIS® Anatoxin-a/Saxitoxin Sample Diluent

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878



Product/Packaging disposal recommendations	: Disposal must be done according to official regulations. Refer to all applicable national, international and local regulations or provisions.
Additional information	: Do not re-use empty containers.
Ecological waste information	: Avoid release to the environment.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not regulated for transport				
14.2. UN proper shipping name				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information available				

14.6. Special precautions for user

Overland transport

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

Inland waterway transport

Not regulated

Rail transport

Not regulated

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

ABRAXIS® Anatoxin-a/Saxitoxin Sample Diluent

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878



SECTION 15: Regulatory information

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

EU-Regulations

REACH Annex XVII (Restriction List)

EU restriction list (REACH Annex XVII)

Reference code	Applicable on	Entry title or description
3(b)	ABRAXIS® Anatoxin-a/Saxitoxins, Sample Diluent ProClin	Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10.
3(c)	ProClin	Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard class 4.1.

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (2024/590)

Not listed on the Ozone Depletion list (Regulation EU 2024/590)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 2024/590 on substances that deplete the ozone layer)

Council Regulation (EC) for the control of dual-use items

Does not contain substances listed as dual use:

Explosives Precursors Regulation (EU 2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (EC 273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

National regulations

Not listed on the United States TSCA (Toxic Substances Control Act) inventory

Germany

Employment restrictions	: Observe restrictions according to the Act on the Protection of Working Mothers (MuSchG). Observe restrictions according to the Act on the Protection of Young People in Employment (JArbSchG).
Water hazard class (WGK)	: WGK 2, Significantly hazardous to water (Classification according to AwSV, Annex 1).
Major Accidents Ordinance (12. BImSchV)	: Is not listed in the Major Accidents Ordinance (12. BImSchV)

Netherlands

ABM category	: A(2) - toxic for aquatic organisms, may have longterm hazardous effects in aquatic environment
SZW-lijst van kankerverwekkende stoffen	: None of the components are listed
SZW-lijst van mutagene stoffen	: None of the components are listed
SZW-lijst van reprotoxische stoffen – Borstvoeding	: None of the components are listed
SZW-lijst van reprotoxische stoffen – Vruchtbaarheid	: None of the components are listed
SZW-lijst van reprotoxische stoffen – Ontwikkeling	: None of the components are listed

ABRAXIS® Anatoxin-a/Saxitoxin Sample Diluent

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878



Poland

Polish National Regulations

: Act of 25 February 2011 on chemical substances and their mixtures (J. o L. No. 63, item 322 as amended; consolidated text J. o L. 2019, item 1225).
Act of 14 December 2012 on waste (J. o L. 2013, item 322 as amended; consolidated text J. o L. 2020, item 797).
The announcement of Marshal of the Sejm of the Republic of Poland dated 19 October 2016 concerning the consolidated text announcement of the decree on the management of packaging and packaging waste (J. o L. 2016, item 1863 as amended).
Decree of the Minister of Environment of 14 December 2014 on the catalogue of waste (J. o L. 2014, item 1923).
Act of 19 August 2011 on the Carriage of Dangerous Goods (J. o L. 2011 No. 227, item 1367 as amended; consolidated text J. o L. 2020, item 154).
Regulation of the Minister of Family, Labour and Social Policy of 12 June 2018 on the highest permissible concentration and intensity of noxious agents for health at work environment (J. o L. item 1286 as amended).
The announcement of Minister of Health dated 9 September 2016 concerning the consolidated text announcement of the decree of the Minister of Health of 30 December 2004 on health and safety at work related to exposure to chemical agents at work (J. o L. of 16 September 2016, item 1488)
Regulation of the Minister of Health of 2 February 2011 on tests and measurements of the noxious agents for health at work environment (J. o L. No. 33, item 166 as amended).
Regulation of the Minister of Environment of 9 December 2003 on particularly hazardous substances to the environment (J. o L. No. 217, item 2141).
ADR Agreement: Government Statement of 13 March 2023 on the entry into force of amendments to Annexes A and B to the Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), signed in Geneva on 30 September 1957 (J. o. L. 2023, item 891)
Regulation of the Minister of Health of 25 August 2015 on the method of marking places, pipelines, and containers and tanks used for storing or containing hazardous substances or hazardous mixtures (J.o.L. 2015, item 1368 as amended)

Spain

Royal Decree 665/1997

: Is not subject to the Royal Decree 665/1997

15.2. Chemical safety assessment

No chemical safety assessment has been carried out.

SECTION 16: Other information

Abbreviations and acronyms:	
ACGIH	American Conference of Governmental Industrial Hygienists
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BLV	Biological limit value
BOD	Biochemical oxygen demand (BOD)
CAS-No.	Chemical Abstracts Service number
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
COD	Chemical oxygen demand (COD)
CSA	Chemical safety assessment
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level

ABRAXIS® Anatoxin-a/Saxitoxin Sample Diluent

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878



Abbreviations and acronyms:

EC-No.	European Community number
EC50	Median effective concentration
ED	Endocrine disruptor
EN	European Standard
EWC	European waste catalogue
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
Log Kow	Partition coefficient n-octanol/water (Log Kow)
Log Pow	Partition coefficient n-octanol/water (Log Pow)
MAK	maximum workplace concentration
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
N.O.S.	Not Otherwise Specified
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
OSHA	Occupational Safety Health Administration
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
PPE	Personal protection equipment
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
TF	Technical function
ThOD	Theoretical oxygen demand (ThOD)
TLM	Median Tolerance Limit
TWA	Time Weighted Average
VOC	Volatile Organic Compounds
vPvB	Very Persistent and Very Bioaccumulative
UFI	Unique Formula Identifier

Full text of H- and EUH-statements:

Acute Tox. 2 (Dermal)	Acute toxicity (dermal), Category 2
Acute Tox. 2 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 2

ABRAXIS® Anatoxin-a/Saxitoxin Sample Diluent

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878



Full text of H- and EUH-statements:

Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
Carc. 1A	Carcinogenicity, Category 1A
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Skin Corr. 1	Skin corrosion/irritation, Category 1
Skin Corr. 1A	Skin corrosion/irritation, Category 1, Sub-Category 1A
Skin Corr. 1C	Skin corrosion/irritation, Category 1, Sub-Category 1C
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1A	Skin sensitisation, category 1A
STOT RE 1	Specific target organ toxicity – Repeated exposure, Category 1
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation
H301	Toxic if swallowed.
H310	Fatal in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H335	May cause respiratory irritation.
H350	May cause cancer.
H372	Causes damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Skin Irrit. 2	H315	Calculation method
Eye Irrit. 2	H319	Calculation method
Skin Sens. 1	H317	Calculation method
Carc. 1A	H350	Calculation method

The classification complies with : ATP 12

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.