

ABRAXIS® Patulin Positive Control Solution for Strip Test

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® Patulin Positive Control Solution for Strip Test
Product code : 500140

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

Relevant identified uses

Use of the substance/mixture : A known concentration of Patulin for use with ABRAXIS® Patulin Strip Test 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)
France	ORFILA	+33 1 45 42 59 59 This number automatically directs calls to the nearest poison control center, based on the caller's location. These poison and toxicovigilance centers provide free medical assistance (excluding call costs), 24 hours a day, 7 days a week.

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Country/Area	Organisation	Emergency number
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
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. Classification of the substance or mixture

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

Not classified

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

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

No labelling applicable

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2.3. Other hazards

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

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH Annex II

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	: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms: Call a poison center or a doctor.
First-aid measures after skin contact	: Wash skin with plenty of water. If skin irritation occurs: Get medical advice/attention. Wash contaminated clothing before reuse.
First-aid measures after eye contact	: Rinse eyes with water as a precaution. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
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.

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

Symptoms/effects after inhalation	: Not expected to present a significant inhalation hazard under anticipated conditions of normal use.
Symptoms/effects after skin contact	: Not expected to present a significant skin hazard under anticipated conditions of normal use.
Symptoms/effects after eye contact	: Not expected to present a significant eye contact hazard under anticipated conditions of normal use.
Symptoms/effects after ingestion	: Not expected to present a significant ingestion hazard under anticipated conditions of normal use.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Use extinguishing agent suitable for surrounding fire.
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.
Hazardous decomposition products in case of fire	: No hazardous decomposition products known.

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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.

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. 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 unnecessary personnel. 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 if safe to do so.
- Methods for cleaning up : Take up in non-combustible inert absorbent and place into container for disposal. Decontaminate surfaces and equipment with water. 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. Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid breathing mist, spray, vapours. Take precautionary measures against static discharge.
- Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Store in a dry, cool and well-ventilated place.
- Incompatible materials : None known.

Germany

- Storage class (LGK, TRGS 510) : LGK 12 - Non-combustible liquids

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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 6.2, LGK 7

Joint storage with restrictions permitted for

: LGK 4.1A, LGK 4.3, LGK 5.1C

Joint storage permitted for

: LGK 2A, LGK 2B, LGK 3, LGK 4.1B, LGK 4.2, LGK 5.1A, LGK 5.1B, LGK 5.2, 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)

A known concentration of Patulin for use with ABRAXIS® Patulin Strip Test Kits.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station. Handle in accordance with good industrial hygiene and safety procedures. 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:

Wear safety glasses which protect from splashes

Skin protection

Skin and body protection:

No special clothing/skin protection equipment is recommended under normal conditions of use

Hand protection:

Wear protective gloves

Respiratory protection

Respiratory protection:

No respiratory protection needed under normal use conditions. In case of insufficient ventilation, wear suitable respiratory equipment

Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment. Take measures to reduce or limit air emissions and releases to soil and the aquatic environment.

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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 available
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Non flammable
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
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

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

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

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Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met)
Serious eye damage/irritation	: Not classified (Based on available data, the classification criteria are not met)
Respiratory or skin sensitisation	: Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)
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)
Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

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)

12.2. Persistence and degradability

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Persistence and degradability	Not established.
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12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

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.
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.

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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

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)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

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)

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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

Germany

VOC ordinance (ChemVOCFarbV)

:

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 1, Slightly hazardous to water (Classification according to AwSV, Annex 1).

Override matching entry (12. BImSchV)

: Is not subject to the Major Accidents Ordinance (12. BImSchV)

Netherlands

ABM category

: A(4) - low hazard for aquatic organisms, may have longterm hazardous effects in aquatic environment

SZW List of Carcinogenic Substances

: None of the components are listed

SZW List of Mutagenic Substances

: None of the components are listed

SZW List of Reprotoxic Substances – Breastfeeding

: None of the components are listed

SZW List of Reprotoxic Substances – Fertility

: None of the components are listed

SZW List of Reprotoxic Substances – Development

: None of the components are listed

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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).

15.2. Chemical safety assessment

No additional information available

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
EC-No.	European Community number

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Abbreviations and acronyms:

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

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.