



SAFETY DATA SHEET

Product: **Nexodyn™ Antimicrobial Wound Care Solution**

Rev. 1

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Section 1 Identification

Product Name	Manufacturer	Emergency Contact
Nexodyn™ Antimicrobial Wound Care Solution	APR Applied Pharma Research S.A. Balerna Switzerland	Angelini Pharma Inc. 8322 Helgerman Court Gaithersburg, MD 20877, USA Phone: 301-330-7597 Fax: 301-330-6432

Section 2 Hazards Identification

Classification of the mixture

This product is not hazardous by the OSHA Hazard Communication Standard (HCS) (29 CFR 1910.1200).

Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication

Hazard Class	Hazard category	Hazard statement
Not classified		
Hazard Pictograms		None
Signal Word		None
Hazard Statements		None
Safety statements		None
- <i>Response</i>		None
- <i>Storage</i>		None
- <i>Disposal</i>		None
Other information		None

Section 3 Composition & Information on Ingredients

Name	EC number	CAS number	%*
Hypochlorous acid**	232-232-5	7790-92-3	< 0.01
Chlorine**	231-959-5	7782-50-5	< 0.01
Water	231-791-2	7732-18-5	≈100

The product has a maximum content of Chloride of 200ppm. This chloride content is due to the presence of low quantity of Hydrogen chloride and Sodium chloride.


*There is batch-to-batch variation.

** The combination of the equilibrium species molecular chlorine, hypochlorous acid, and the hypochlorite ion in chlorinated water is defined Free Chlorine.

Section 4 First Aid Measures

Description of first aid measures

EYES:	Under normal circumstances, the product has no harmful effect. Irrigate copiously with clean, fresh water. Get medical advice if adverse symptoms appear.
SKIN:	Under normal circumstances, the product has no harmful effect. Wash with plenty of water. Get medical advice if adverse symptoms appear.
INHALATION:	Under normal circumstances, the product has no harmful effect. Get medical advice if adverse symptoms appear.
INGESTION:	Rinse mouth with water. Do not induce vomiting. Do not give alcohol. Get medical advice if adverse symptoms appear.

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Most important symptoms and effects, both acute and delayed

For symptoms and effects see Section 11.

Indication of any immediate medical attention and special treatment needed

Not foreseen.

Section 5 Fire-fighting Measures**Extinguishing media****SUITABLE EXTINGUISHING MEDIA**

The extinction equipment should be of the conventional kind: carbon dioxide, foam, powder. For product leaks and spills that didn't caught fire, nebulized water may be used to disperse the flammable vapors and protect the people involved in stopping the leak.

EXTINGUISHING MEDIA WHICH SHALL NOT BE USED FOR SAFETY REASONS

Not known.

Special hazards arising from the substance or mixture**HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE**

Excess pressure may form in containers exposed to fire with explosion hazard. Do not breathe combustion products (carbon oxide, toxic pyrolysis products, etc.).

Advice for firefighters**GENERAL INFORMATION**

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Hardhat with visor, fireproof clothing (fireproof jacket and trousers with straps around arms, legs and waist), work gloves (fireproof, cut proof and antistatic), a depressurized mask with facemask covering the whole of the operator's face or a self-respirator (self-protector).

Section 6 Accidental Release Measures**Personal precautions, protective equipment and emergency procedures**

Block the leakage if there is no risk.

Wear suitable protective equipment (including personal protective equipment referred to in Section 8 of the data sheet) to prevent contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.

Remove unequipped persons. Eliminate all sources of ignition (cigarettes, flames, sparks, etc..) or heat from the area in which the leakage occurred.

Environmental precautions

The product must not penetrate the sewers, surface water, ground water and neighboring areas.

Methods and material for containment and cleaning up

Confine using earth or inert material. Collect as much material as possible and eliminate the rest using jets of water. Ensure adequate ventilation of the area affected by the leakage. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

Section 7 Handling & Storage**Precautions for safe handling**

Keep away from heat, sparks and open flames, do not smoke, use matches or lighters. Avoid dispersal into the environment.

Conditions for safe storage, including any incompatibilities

Store in original container. Store in a cool, well-ventilated area away from heat sources, open flames, sparks and other sources of ignition. Store containers away from any incompatible materials, verifying Section 10.

Nexodyn™ Antimicrobial Wound Care Solution should be stored in a dry place, protected from light and heat, in its original sealed bottle and carton between 41 °F and 77 °F (5 °C and 25 °C). Nexodyn™ Antimicrobial Wound Care Solution is non-flammable.

Special storage precautions are not needed. After use, the container should be closed before storing.

Specific end use

Wound rinsing solution.



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Reference to other sections

Any information on personal protection and disposal is given in Sections 8 and 13.

Section 8 Exposure Controls/ Personal Protection

Control parameters

Name	Type	TWA/8h		STEL/15min	
		mg/m ³	ppm	mg/m ³	ppm
Chlorine (CAS 7782-50-5)	ACGIH	1.5	0.5	2.9	1
	NIOSH	-	-	1.42 Ceiling	0.5 Ceiling
	OSHA	-	-	3	1

DNEL (Derived No-Effect Level)

Name	Long-term exposure - inhalation - local effects	Long-term exposure - inhalation - systemic effects
Chlorine (CAS 7782-50-5)	0.75 mg/m ³	0.75 mg/m ³

ACGIH BIOLOGICAL EXPOSURES INDICES (BEI): Not defined.

Exposure controls

For those who handles large amount of product:

The use of adequate technical equipment must always take priority over personal protection equipment, ensure good ventilation at the workplace through effective local aspiration.

Recommended monitoring procedures: Personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment.

Engineering controls need to keep gas, vapor or dust concentrations below any lower explosive limits.

Hygiene measures: Ensure that eyewash stations and safety showers are close to the workstation location. Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period.

Personal protection

Observance of safety measures used in handling chemical substances.

Hand protection

In healthcare sector follow the good hygienic practices.

For those who handles large amount of product: protect hands with work gloves, such as those in PVC, neoprene, nitril or equivalent.

The following should be considered when choosing work glove material: degradation, breakage times and permeation. Work glove resistance to preparations should be checked before use, as it can be unpredictable. Gloves` limit depends on the duration of exposure.

Skin protection

In healthcare sector follow the good hygienic practices.

For those who handles large amount of product: wear work clothes with long sleeves and safety footwear for professional use.

Wash with soap and water after removing protective clothing.



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Eye protection

In healthcare sector follow the good hygienic practices.

For those who handles large amount of product: wear protective goggles. Provide a system for eye wash.

Respiratory protection

In healthcare sector follow the good hygienic practices.

For those who handles large amount of product: in case of exceeding the threshold value (if available) of one or more of the substances present in the product wear a mask with type A filter or universal type filter, the class (1, 2 or 3) should be chosen according to the limit concentration of use. The use of respiratory protection equipment is necessary in absence of technical measures limiting worker exposure.

Environmental exposure controls

Emissions from productive processes, including those from ventilation should be controlled in order to comply with regulations for environmental protection.

Section 9 Physical & Chemical Properties

Information on basic physical and chemical properties

Appearance:	Liquid
Colour:	Colorless
Odour:	Characteristic
Odour threshold:	Data not available
pH:	2.50 – 3.00 (Mettler Toledo SevenMulti pHMeter mV/ORP Potentiometric
Melting or freezing point:	Determination)
Initial boiling point:	Data not available
Boiling range:	Data not available
Flash point”	Data not available
Evaporation Rate:	Data not available
Flammability of solids and gases:	Data not available
Lower inflammability limit:	Data not available
Upper inflammability limit:	Data not available
Lower explosive limit:	Data not available
Upper explosive limit:	Data not available
Vapor pressure”	Data not available
Vapor density:	Data not available
Relative density:	Data not available
Solubility:	Data not available
Partition coefficient: n-octanol/water:	Data not available
Autoignition temperature:	Data not available
Decomposition temperature:	Data not available
Viscosity:	Data not available

Other information

OxidoReductive Potential ORP (mV):	1000 - 1200 (as is at 25° C by Mettler Toledo SevenMulti combination redox electrode (P/N 51343200) Potentiometric Titration)
Free Chlorine Assay (mg/l or ppm):	40.0 - 70.0 (Internal Method M37-07 Spectrophotometric Method source APAT IRS CNR HandBook Volume 2 - Ref 4080)
Total Chlorine Assay (mg/l or ppm):	40.0 - 70.0 (Internal Method M37-07 Spectrophotometric Method source APAT IRSA CNR HandBook Volume 2 - Ref 4080)
Total Chlorine Assay (mg/l or ppm):	40.0 - 70.0 (Internal Method M37-07 Iodometric Method source APAT IRSA CNR HandBook Volume 2 - Ref 4080)



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Chloride Assay (mg/l or ppm): < 200.0 (Internal Method M05-08 Spectrophotometric Method source APAT IRSA CNR HandBook Volume 2 - Ref 4090)

Section 10 Stability & Reactivity

Reactivity

There are no particular risks of reaction with other substances in normal conditions of use.

Chemical stability

The product is stable in normal conditions of use and storage.

Stability of the unused solution is assured for 30 days after first opening if the bottle is kept closed with the screw cap or spray cap when not in use.

Possibility of hazardous reactions

No hazardous reactions are foreseeable in normal conditions of use and storage.

Conditions to avoid

None in particular, however the usual precautions used for chemical products should be respected.

Incompatible materials

Information not available.

Hazardous decomposition products

In the event of thermal decomposition or fire, vapors potentially dangerous to health may be released.

Section 11 Toxicological Information

Information on toxicological effects

In absence of experimental toxicological data on the product itself, the possible health hazards of the product were evaluated based on the properties of substances according to the criteria prescribed by OSHA Hazard Communication Standard (HCS) (29 CFR 1910.1200).

Delayed, immediate or chronic effects from short- and long-term exposure for each route of exposure:

Dermal: Under normal circumstances, the product has no harmful effect.

Ingestion: Ingestion may cause irritation to the gastrointestinal mucous membranes.

Inhalation: Under normal circumstances, the product has no harmful effect.

Contact with eyes: Under normal circumstances, the product has no harmful effect.

Toxicological properties:

Acute toxicity:

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Oral: Data not available

Dermal: Data not available

Inhalation: Data not available

Chlorine

Oral: Data not available

Dermal: Data not available

Inhalation: LD₅₀ (rat): 293ppm/1h as gas

Corrosion/Irritation:

Nexodyn™ Antimicrobial Wound Care Solution

Nexodyn™ Antimicrobial Wound Care Solution has been shown to be non-irritating for skin and eyes.

Dermal: Acute skin irritation test has been performed on White Zealand rabbits, and the test product Nexodyn™ Antimicrobial Wound Care Solution has been used as is on a shaved area of the back of the animals. The application lasted 4 hours, and the skin reaction has been evaluated at 1, 24, 48 and 72 hours after the beginning of the treatment. No signs of erythema or oedema were observed during the study. The test product results not skin irritant according to ISO 10993-10:2002/AMD 1:2006.



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Eye contact: In the primary ocular irritation test, Nexodyn™ Antimicrobial Wound Care Solution has been applied on the ocular tissues of 3 healthy New Zealand White Rabbits. The eyes were examined at 1, 24, 48 and 72 hours post-treatment using a fluorescein staining lamp. The observation times were -24, +1, +24, +28, + 72 hours since dosing. No signs of irritation were noted in any of the test or control eyes of any of the animals at any of the observation points, according to the classification system for grading ocular lesions and the fluorescein staining grading scale. The test product results not eye irritant according to ISO 10993-10:2002, as amended 2006.

Oral: In the acute oral irritation study the test product has been evaluated to produce primary buccal irritation following a single exposure (minimum of 5 min per hour for four consecutive hours) to the cheek pouches of healthy female Golden Syrian Hamsters. Based on the criteria of the protocol, the test article has been considered to be non-irritant to the oral tissues. The test product results not oral irritant according to ISO 10993-10:2002, as amended 2006.

Sensitization:

Dermal:

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In the test for delayed-type hypersensitivity, the test product used as such results not sensitizing according to ISO 10993-10:2002/AMD 1:2006.

Respiratory: Data not available

Specific Target organ toxicity – Single exposure:**Chlorine**

Exposure to Chlorine causes irritation to the upper airways.

Specific Target organ toxicity – Repeated exposure:**Nexodyn™ Antimicrobial Wound Care Solution**

The skin irritation test has been conducted for repeated exposure; 2 consecutive applications of the test product were performed each day (5 days a week) for 4 weeks. Physiological solution was used as control. Patches were removed 1 hour after the application, and skin reaction was observed before and after each application. Treated sites and one control site for each animal – at the end of the study - were macroscopically observed. No signs of erythema or oedema were observed; microscopically, there were no signs of inflammatory processes. The test product results not skin irritant according to ISO 10993-10:2002/AMD 1:2006. The test article was also evaluated for its potential to produce and advance an irritation effect on the ocular tissue of rabbits, when administered as a 30-day repeat dose application. The animals were treated daily by instilling 0.1 ml of the test article in the left eye of each animal; eyes were examined daily for 30 days one hour after each dosing. No signs of irritation were noted. The test product results not ocular irritant according to ISO 10993-10:2002.

Chlorine

For repeated dose toxicity, in a two year study, the LOAEL for respiratory irritation has been determined to be 0.4 ppm (1.2 mg/m³) for rats and mice: an NOAEL for inhalation route could not be established. In none of the available studies any systemic effect was observed. A NOAEL of 950 ppm available chlorine (59.5 mg/kg bw/day) can be derived from a 13-week rat study with sodium hypochlorite in drinking water. A NOAEL of 14 mg/kg bw/day for rats and a NOAEL of 22.5 mg/kg bw/day for mice can be derived from a two year study with sodium hypochlorite in drinking water. There are many detailed studies reported for human exposure. An inhalation acute NOEL of 0.5 ppm (1.5 mg/m³) which excludes tissue lesions and impairment of the pulmonary function can be derived by human experience and control studies in volunteers.

CMR effects:

Germinal cell mutagenicity:

Nexodyn™ Antimicrobial Wound Care Solution

Genotoxicity studies have been conducted on the test product (Nexodyn™ Antimicrobial Wound Care Solution) in order to evaluate its genotoxic potential, using the Salmonella typhimurium reverse mutation assay, also called “Ames test”. The test has been performed on five mutant strains of S. typhimurium: TA 1535, TA 1537, TA98, TA100, TA102. The presumed mutagenic activity has been determined by comparing the number of reverting colonies with the number of reverting colonies in the control cultures. The direct plate



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incorporation method has been used both in the presence and absence of an enzymatic system for metabolic activation (S9 Mix). The test substance has been prepared as a WFI solution, as described in OECD Test Guideline 471, equivalent to 50 mg/ml. Afterwards, the following dilutions have been performed: 1:10, 1:100, 1:1000 and 1:10.000. On the basis of the results, the test substance has been proved to be non-mutagenic, either in the presence or absence of metabolic activation.

Carcinogenicity:

Some studies report a genetic activity of HClO (Pullar et al., 2000; Stanley et al. 2010). HClO is effective as an anti-microbial agent because of its reactivity and ability to damage biological systems critical to the normal replication of microorganisms. The genotoxic capabilities of HClO, as well as other agents with similar mode of action, appear to be limited to some in vitro assays and pose no risk in vivo. Normal tissues provide sufficient antioxidant capacities to detoxify excessive concentrations of ROS.

Chlorine

IARC (International Agency for Research on Cancer): Not listed

NTP (National Toxicology Program): Not listed

OSHA carcinogenic classification: Not listed

Hypochlorous acid

IARC (International Agency for Research on Cancer): Not listed

NTP (National Toxicology Program): Not listed

OSHA carcinogenic classification: Not listed

Reproductive toxicity:

Chlorine

The absence of reproductive toxic effects was clearly shown up to 5 mg/kg (maximum dose tested) in a one generation oral study in rats. Although limited data are available in animals, there is no evidence of adverse developmental effects. Moreover, epidemiological studies in humans did not show evidence of toxic effects on fetal development.

Aspiration hazard:

An aspiration hazard is not expected, taking into account the use of the solution.

Section 12 Ecological Information

Use this product according to good working practices. If the product should reach waterways or sewers or contaminate soil or vegetation, inform the competent authorities.

Toxicity**Chlorine**

Fish	LC ₅₀ <i>Onchohynchus mykiss</i> 132 µg/L for 96 hr.
Aquatic invertebrates	LC ₅₀ <i>Daphnia magna</i> = 0.15mg/l/48h
Algae and aquatic plants	Data not available

Persistence and degradability

Information not available.

Bioaccumulative potential

Chlorine: A potential for bioaccumulation or bioconcentration of active chlorine species can be disregarded, because of their water solubility and their high reactivity.

Mobility in soil

Information not available.

Results of PBT and vPvB assessment

Information not available.



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Other adverse effects

Information not available.

Section 13 Waste Disposal Considerations**Waste treatment methods**

Dispose of empty bottles and/or unused solution in accordance with local regulations or guidelines for expired medical products.
CONTAMINATED PACKAGING

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

Section 14 Transport Information

Not classified in accordance with ADR/RID, IMDG, IATA and DOT regulations.

Section 15 Regulatory Information**U.S. Federal regulations**

All components in this product are listed on or exempt from reporting under the US Toxic Substances Control Act (TSCA).

Clean Water Act (CWA) 307

No component listed

Clean Air Act Section 112(b) Hazardous Air Pollutants (HAPs)

CHLORINE

Clean Air Act Section 602 Class I Substances

No component listed

Clean Air Act Section 602 Class II Substances

No component listed

EPA List of Lists

Regulatory Name	CAS Number/313 Category Code ^I	EPCRA 302 EHS TPQ ^{II}	EPCRA 304 EHS RQ ^{III}	CERCLA RQ ^{IV}	EPCRA 313 TRI ^V	RCRA Code ^{VI}	CAA 112(r) RMP TQ ^{VII}
CHLORINE	7782-50-5	100	10	10	313	-	2500

^I**313 Category Code:** Emergency Planning and Community Right-to Know Act Section 313 Category Code

^{II}**EPCRA 302 EHS TPQ:** Extremely Hazardous Substance Threshold Planning Quantity (Emergency Planning and Community Right-to-Know Act Section 302 Category Code)

^{III}**EPCRA 304 EHS RQ:** Extremely Hazardous Substance Reportable Quantity (Emergency Planning and Community Right-to-Know Act Section 304 Category Code)

^{IV}**CERCLA RQ:** Reportable Quantity (Comprehensive Environmental Response, Compensation, and Liability Act)

^V**EPCRA 313 TRI:** Toxics Release Inventory (Emergency Planning and Community Right-to Know Act Section 313 Category Code)

^{VI}**RCRA Code:** Resource Conservation and Recovery Act Code

^{VII}**CAA 112(r) RMP TQ:** Risk Management Plan Threshold Quantity (Clean Air Act Section 112(r))

State	Components listed	Note
Massachusetts	CHLORINE	Extraordinarily hazardous
New York	CHLORINE	Acutely hazardous
New Jersey	CHLORINE	-
Pennsylvania	CHLORINE	Environmental hazard

List of Hazardous Substances prepared by the Director pursuant to Labor Code Section 6380. The substances on this list are subject to the provisions of Labor Code Sections 6360 through 6399.7 and Section 5194 in Title 8 of the California Code of Regulations.

CHLORINE
(CAS 7782-50-5)

California Prop. 65



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Ingredient name	Cancer	Reproductive	NSRL* or MADL** (µg/day)
No component listed			

*NSRL = No Significant Risk Level

**MADL = Maximum Allowable Dose Level

Section 16 Other Information

REVISIONS:

- Edition n.01 dated 11/03/2015
- Revision n. 00

LEGEND:

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE NUMBER: Identifier in ESIS (European archive of existing substances)
- CLP: EC Regulation 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX NUMBER: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as Reach Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: EC Regulation 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA STEL: Short-term exposure limit
- TWA: Time-weighted average exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative

Classification and procedure used to derive the classification for mixtures according to Hazard Communication Standard, 29 CFR 1910.1200 (HCS) :

Classification:	Classification procedure
Not classified	-

GENERAL BIBLIOGRAPHY



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1. Hazard Communication Standard (HCS 2012)
2. NTP. 2011. Report on Carcinogens, Twelfth Edition. Research Triangle Park, NC: U.S. Department of Health and Human Services, Public Health Service, National Toxicology Program.
3. OSHA website
4. NIOSH - Registry of Toxic Effects of Chemical Substances
5. IARC website
6. Clean Water Act, P.L. 92-500 Section 307 (33 U.S.C. 1317), Toxic and pretreatment effluent standards
7. Clean Air Act, P.L. 88-206
8. Emergency Planning and Community Right-to Know Act (EPCRA) commonly known as SARA Title III.
9. Superfund Amendments and Reauthorization Act (SARA)
10. Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)
11. Controlled Substances Act, 21 U.S.C. § 802, Definition 34 (list I) and 35 (list II).
12. LIST OF LISTS - Consolidated List of Chemicals Subject to the Emergency Planning and Community Right-To-Know Act (EPCRA), Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) and Section 112(r) of the Clean Air Act
13. The Merck Index. - 10th Edition
14. Handling Chemical Safety
15. INRS - Fiche Toxicologique (toxicological sheet)
16. Patty - Industrial Hygiene and Toxicology
17. N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
18. ECHA website
19. ACGIH 2014 Threshold Limit Values for Chemical Substances and Physical Agents & Biological Exposure Indices
20. GESTIS International Limit Values
21. GESTIS Substance database
22. ChemIDplus Lite, online
23. HSDB database, online.

Note for users:

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.