

**ANIOSYME SYNERGY WD PLUS**

**Section: 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING**

**1.1 Product identifier**

Product name : ANIOSYME SYNERGY WD PLUS  
UFI : SC8X-1EYM-0F0Q-PUEJ  
Product code : 3040000  
Use of the Substance/Mixture : Instrument cleaner  
Substance type: : Mixture

**For professional users only.**

Product dilution information : No dilution information provided.

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

Identified uses : Medical devices . Semi-automatic process  
Recommended restrictions on use : Reserved for industrial and professional use.

**1.3 Details of the supplier of the safety data sheet**

Company : Laboratoires ANIOS  
1 rue de l'Espoir  
59260 Lezennes, France Tel. + 33 (0)3 20 67 67 67  
Fax. + 33 (0)3 20 67 67 68  
fds@anios.com

**1.4 Emergency telephone number**

Emergency telephone number : +32-(0)3-575-5555 Trans-european, German speaking, 24/7  
or +49 32 212249407 German speaking, 24/7

Poison Information Centre telephone number : +49 (0)551 38318854

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**Section: 2. HAZARDS IDENTIFICATION**

**2.1 Classification of the substance or mixture**

**Classification (REGULATION (EC) No 1272/2008)**

Corrosive to metals, Category 1 H290  
Serious eye damage, Category 1 H318

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Chronic aquatic toxicity, Category 3

H412

**2.2 Label elements****Labelling (REGULATION (EC) No 1272/2008)**

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H290 May be corrosive to metals.  
 H318 Causes serious eye damage.  
 H412 Harmful to aquatic life with long lasting effects.

Precautionary Statements : **Prevention:**  
 P273 Avoid release to the environment.  
 P280e Wear eye protection/face protection.  
**Response:**  
 P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
 P310 Immediately call a POISON CENTER/doctor.

Hazardous components which must be listed on the label:

N,N-dimethyldecylamine N-oxide

**Additional Labelling:**

Special labelling of certain mixtures : Contains: subtilisin, May produce an allergic reaction.

**2.3 Other hazards**

None known.

**Section: 3. COMPOSITION/INFORMATION ON INGREDIENTS****3.2 Mixtures****Hazardous components**

Chemical Name	CAS-No. EC-No. REACH No.	Classification REGULATION (EC) No 1272/2008	Concentration : [%]
N,N-dimethyldecylamine N-oxide	2605-79-0 220-020-5 01-2119959297-22	Acute toxicity Category 4; H302 Serious eye damage Category 1; H318 Acute aquatic toxicity Category 1; H400 Chronic aquatic toxicity Category 2; H411	>= 3 - < 5
subtilisin	9014-01-1 232-752-2 01-2119480434-38	Skin irritation Category 2; H315 Serious eye damage Category 1; H318 Respiratory sensitization Category 1; H334 Specific target organ toxicity - single exposure Category 3; H335 Acute toxicity Category 4; H302 Acute aquatic toxicity Category 1; H400 Chronic aquatic toxicity Category 2; H411	>= 0.1 - < 0.25

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		M = 1	
Substances with a workplace exposure limit :			
glycerin	56-81-5 200-289-5 01-2119471987-18	Not Classified;	>= 20 - < 25

For the full text of the H-Statements mentioned in this Section, see Section 16.

**Section: 4. FIRST AID MEASURES****4.1 Description of first aid measures**

- In case of eye contact : Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention immediately.
- In case of skin contact : Rinse with plenty of water.
- If swallowed : Rinse mouth. Get medical attention if symptoms occur.
- If inhaled : Remove to fresh air. Treat symptomatically. Get medical attention if symptoms occur.

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

See Section 11 for more detailed information on health effects and symptoms.

**4.3 Indication of immediate medical attention and special treatment needed**

- Treatment : Treat symptomatically.

**Section: 5. FIREFIGHTING MEASURES****5.1 Extinguishing media**

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Unsuitable extinguishing media : None known.

**5.2 Special hazards arising from the substance or mixture**

- Specific hazards during firefighting : Not flammable or combustible.
- Hazardous combustion products : Depending on combustion properties, decomposition products may include following materials:  
Carbon oxides  
nitrogen oxides (NOx)

**5.3 Advice for firefighters**

- Special protective equipment for firefighters : Use personal protective equipment.
- Further information : Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations. In the event of

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fire and/or explosion do not breathe fumes.

**Section: 6. ACCIDENTAL RELEASE MEASURES**

**6.1 Personal precautions, protective equipment and emergency procedures**

- Advice for non-emergency personnel : Ensure adequate ventilation. Keep people away from and upwind of spill/leak. Avoid inhalation, ingestion and contact with skin and eyes. When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. Ensure clean-up is conducted by trained personnel only. Refer to protective measures listed in sections 7 and 8.
- Advice for emergency responders : If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials.

**6.2 Environmental precautions**

- Environmental precautions : Do not allow contact with soil, surface or ground water.

**6.3 Methods and materials for containment and cleaning up**

- Methods for cleaning up : Stop leak if safe to do so. Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13). Flush away traces with water. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway.

**6.4 Reference to other sections**

- See Section 1 for emergency contact information.  
For personal protection see section 8.  
See Section 13 for additional waste treatment information.

**Section: 7. HANDLING AND STORAGE**

**7.1 Precautions for safe handling**

- Advice on safe handling : Do not get in eyes, on skin, or on clothing. Use only with adequate ventilation. Wash hands thoroughly after handling. Do not breathe spray, vapour. In case of mechanical malfunction, or if in contact with unknown dilution of product, wear full Personal Protective Equipment (PPE).
- Hygiene measures : Handle in accordance with good industrial hygiene and safety practice. Remove and wash contaminated clothing before re-use. Wash face, hands and any exposed skin thoroughly after handling. Provide suitable facilities for quick drenching or flushing of the eyes and body in case of contact or splash hazard.

**7.2 Conditions for safe storage, including any incompatibilities**

- Requirements for storage areas and containers : Absorb spillage to prevent material damage. Keep out of reach of children. Keep container tightly closed. Keep only in original packaging. Store in suitable labeled containers.

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Storage temperature : 5 °C to 25 °C

Packaging material : Suitable material: Plastic material  
Unsuitable material: Mild steel, Aluminium

**7.3 Specific end uses**

Specific use(s) : Medical devices . Semi-automatic process

**Section: 8. EXPOSURE CONTROLS/PERSONAL PROTECTION****8.1 Control parameters****Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
glycerin	56-81-5	AGW (Inhalable fraction)	200 mg/m3	TRGS 900
Further information	Y	When there is compliance with the OEL and biological tolerance values, there is no risk of harming the unborn child		

**DNEL**

Propylene glycol	:	<p>End Use: Workers Exposure routes: Inhalation Potential health effects: Long-term systemic effects Value: 168 mg/m3</p> <p>End Use: Workers Exposure routes: Inhalation Potential health effects: Long-term local effects Value: 10 mg/m3</p> <p>End Use: Consumers Exposure routes: Inhalation Potential health effects: Long-term systemic effects Value: 50 mg/m3</p> <p>End Use: Consumers Exposure routes: Inhalation Potential health effects: Long-term local effects Value: 10 mg/m3</p> <p>End Use: Consumers Exposure routes: Dermal Potential health effects: Long-term systemic effects 213 mg/kg</p> <p>End Use: Consumers Exposure routes: Ingestion Potential health effects: Long-term systemic effects Value: 85 ppm</p>
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**PNEC**

Propylene glycol	:	<p>Fresh water Value: 260 mg/l</p>
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	Marine water Value: 26 mg/l
	Intermittent use/release Value: 183 mg/l
	Fresh water sediment Value: 572 mg/kg
	Marine sediment Value: 57.2 mg/kg
	Sewage treatment plant Value: 20000 mg/l
	Soil Value: 50 mg/kg

**8.2 Exposure controls****Appropriate engineering controls**

Engineering measures : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

**Individual protection measures**

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice. Remove and wash contaminated clothing before re-use. Wash face, hands and any exposed skin thoroughly after handling. Provide suitable facilities for quick drenching or flushing of the eyes and body in case of contact or splash hazard.

Eye/face protection (EN 166) : Safety goggles  
Face-shield

Hand protection (EN 374) : No special protective equipment required.

Skin and body protection (EN 14605) : No special protective equipment required.

Respiratory protection (EN 143, 14387) : None required if airborne concentrations are maintained below the exposure limit listed in Exposure Limit Information. Use certified respiratory protection equipment meeting EU requirements(89/656/EEC, (EU) 2016/425), or equivalent, when respiratory risks cannot be avoided or sufficiently limited by technical means of collective protection or by measures, methods or procedures of work organization.

**Environmental exposure controls**

General advice : Consider the provision of containment around storage vessels.

**Section: 9. PHYSICAL AND CHEMICAL PROPERTIES****9.1 Information on basic physical and chemical properties**

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Physical state	: liquid
Colour	: clear, colourless
Odour	: slight
pH	: 9.5 - 10.5, 100 %
Particle characteristics	
Assessment	: not applicable
Particle size	: not applicable
Particle Size Distribution	: not applicable
Dustiness	: not applicable
Specific surface area	: not applicable
Surface charge/Zeta potential	: not applicable
Shape	: not applicable
Crystallinity	: not applicable
Surface treatment /Coatings	: not applicable
Flash point	: 98 °C closed cup
Odour Threshold	: Not applicable and/or not determined for the mixture
Melting point/freezing point	: Not applicable and/or not determined for the mixture
Boiling point, initial boiling point and boiling range	: Not applicable and/or not determined for the mixture
Evaporation rate	: Not applicable and/or not determined for the mixture
Flammability	: Not applicable and/or not determined for the mixture
Upper explosion limit	: Not applicable and/or not determined for the mixture
Lower explosion limit	: Not applicable and/or not determined for the mixture
Vapour pressure	: Not applicable and/or not determined for the mixture
Relative vapour density	: Not applicable and/or not determined for the mixture
Density and / or relative density	: 1.14 - 1.16
Water solubility	: soluble
Solubility in other solvents	: Not applicable and/or not determined for the mixture
Partition coefficient: n-octanol/water (log value)	: Not applicable and/or not determined for the mixture
Auto-ignition temperature	: Not applicable and/or not determined for the mixture
Thermal decomposition	: Not applicable and/or not determined for the mixture
Viscosity, kinematic	: Not applicable and/or not determined for the mixture
Explosive properties	: Not applicable and/or not determined for the mixture
Oxidizing properties	: The substance or mixture is not classified as oxidizing.

**9.2 Other information**

Not applicable and/or not determined for the mixture

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**Section: 10. STABILITY AND REACTIVITY**

**10.1 Reactivity**

No dangerous reaction known under conditions of normal use.

**10.2 Chemical stability**

Stable under normal conditions.

**10.3 Possibility of hazardous reactions**

No dangerous reaction known under conditions of normal use.

**10.4 Conditions to avoid**

None known.

**10.5 Incompatible materials**

None known.

**10.6 Hazardous decomposition products**

Depending on combustion properties, decomposition products may include following materials:

Carbon oxides

nitrogen oxides (NO<sub>x</sub>)

**Section: 11. TOXICOLOGICAL INFORMATION**

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

Information on likely routes of exposure : Inhalation, Eye contact, Skin contact

**Product**

Acute oral toxicity : Acute toxicity estimate : > 2,000 mg/kg

Acute inhalation toxicity : There is no data available for this product.

Acute dermal toxicity : There is no data available for this product.

Skin corrosion/irritation : There is no data available for this product.

Serious eye damage/eye irritation : There is no data available for this product.

Respiratory or skin sensitization : There is no data available for this product.

Carcinogenicity : There is no data available for this product.

Reproductive effects : There is no data available for this product.

Germ cell mutagenicity : There is no data available for this product.



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Teratogenicity : There is no data available for this product.

STOT - single exposure : There is no data available for this product.

STOT - repeated exposure : There is no data available for this product.

Aspiration toxicity : There is no data available for this product.

**Components**

Acute oral toxicity : N,N-dimethyldecylamine N-oxide LD50 rat: 600 mg/kg

subtilisin LD50 rat: 1,800 mg/kg

glycerin LD50 rat: 18,300 mg/kg

**Components**

Acute dermal toxicity : glycerin LD50 rabbit: 23,000 mg/kg

**Potential Health Effects**

Eyes : Causes serious eye damage.

Skin : Health injuries are not known or expected under normal use.

Ingestion : Health injuries are not known or expected under normal use.

Inhalation : Health injuries are not known or expected under normal use.

Chronic Exposure : Health injuries are not known or expected under normal use.

**Experience with human exposure**

Eye contact : Redness, Pain, Corrosion

Skin contact : No symptoms known or expected.

Ingestion : No symptoms known or expected.

Inhalation : No symptoms known or expected.

**11.2 Information on other hazards**

**Further information** : no data available

**Section: 12. ECOLOGICAL INFORMATION**

**12.1 Toxicity**

Environmental Effects : Harmful to aquatic life with long lasting effects.

**Product**

Toxicity to fish : no data available

Toxicity to daphnia and other aquatic invertebrates : no data available

Toxicity to algae : no data available

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**Components**

Toxicity to fish : N,N-dimethyldecylamine N-oxide  
96 h LC50 Danio rerio (zebra fish): 2.4 mg/l  
Test substance: Information given is based on data obtained from similar substances.

subtilisin  
96 h LC50 Oncorhynchus mykiss (rainbow trout): 8.2 mg/l

glycerin  
96 h LC50 Fish: 855 mg/l

**Components**

Toxicity to daphnia and other aquatic invertebrates : N,N-dimethyldecylamine N-oxide  
48 h EC50 Daphnia magna (Water flea): 2.63 mg/l  
Test substance: Information given is based on data obtained from similar substances.

subtilisin  
48 h EC50 Daphnia magna (Water flea): 0.868 mg/l

**Components**

Toxicity to algae : N,N-dimethyldecylamine N-oxide  
72 h EC50 Pseudokirchneriella subcapitata (green algae): 0.159 mg/l  
Test substance: Information given is based on data obtained from similar substances.

subtilisin  
72 h EC50 Pseudokirchneriella subcapitata (green algae): 1.44 mg/l

**12.2 Persistence and degradability**

**Product**

Biodegradability : The surfactants contained in the product are biodegradable according to the requirements of the detergent regulation 648/2004/EC

**Components**

Biodegradability : N,N-dimethyldecylamine N-oxide  
Result: Readily biodegradable.

subtilisin  
Result: Readily biodegradable.

glycerin  
Result: Readily biodegradable.

**12.3 Bioaccumulative potential**

no data available

**12.4 Mobility in soil**

no data available

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**12.5 Results of PBT and vPvB assessment**

**Product**

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

**12.6 Endocrine disrupting properties**

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher

**12.7 Other adverse effects**

no data available

**Section: 13. DISPOSAL CONSIDERATIONS**

Dispose of in accordance with the European Directives on waste and hazardous waste. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

**13.1 Waste treatment methods**

Product : Do not contaminate storm water drains, natural waterways or soil with chemical or used container. Where possible recycling is preferred to disposal or incineration. If recycling is not practicable, dispose of contents/container in accordance with local regulations. Dispose of wastes in an approved waste disposal facility.

Contaminated packaging : Dispose of as unused product. Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not re-use empty containers. Dispose of in accordance with local, state, and federal regulations.

Guidance for Waste Code selection : Organic wastes containing dangerous substances. If this product is used in any further processes, the final user must redefine and assign the most appropriate European Waste Catalogue Code. It is the responsibility of the waste generator to determine the toxicity and physical properties of the material generated to determine the proper waste identification and disposal methods in compliance with applicable European (EU Directive 2008/98/EC) and local regulations.

**Section: 14. TRANSPORT INFORMATION**

The shipper/consignor/sender is responsible to ensure that the packaging, labeling, and markings are in compliance with the selected mode of transport.

**Land transport (ADR/ADN/RID)**

14.1 UN number or ID number : 3267

14.2 UN proper shipping name : CORROSIVE LIQUID, BASIC, ORGANIC, N.O.S.

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(alanine, n,n-bis(carboxymethyl)-, trisodium salt)

14.3 Transport hazard class(es) : 8

14.4 Packing group : III

14.5 Environmental hazards : No

14.6 Special precautions for user : None

**Air transport (IATA)**

14.1 UN number or ID number : 3267

14.2 UN proper shipping name : Corrosive liquid, basic, organic, n.o.s.

(alanine, n,n-bis(carboxymethyl)-, trisodium salt)

14.3 Transport hazard class(es) : 8

14.4 Packing group : III

14.5 Environmental hazards : No

14.6 Special precautions for user : None

**Sea transport (IMDG/IMO)**

14.1 UN number or ID number : 3267

14.2 UN proper shipping name : CORROSIVE LIQUID, BASIC, ORGANIC, N.O.S.

(alanine, n,n-bis(carboxymethyl)-, trisodium salt)

14.3 Transport hazard class(es) : 8

14.4 Packing group : III

14.5 Environmental hazards : No

14.6 Special precautions for user : None

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**

according to Detergents Regulation EC 648/2004 : less than 5 %: Non-ionic surfactants  
Other constituents: Enzymes

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances. : Not applicable.

**National Regulations**

**Take note of Dir 94/33/EC on the protection of young people at work.**

Hazard class for water : WGK 1  
Classification according to AwSV, Annex 1

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German storage class : 10

**15.2 Chemical Safety Assessment**

Information from the chemical safety assessment of substances present in the product is included in the appropriate sections of this safety data sheet, whenever necessary.

**Section: 16. OTHER INFORMATION****Procedure used to derive the classification according to REGULATION (EC) No 1272/2008**

Classification	Justification
Corrosive to metals 1, H290	Based on product data or assessment
Serious eye damage 1, H318	Calculation method
Chronic aquatic toxicity 3, H412	Calculation method

**Full text of H-Statements**

H302	Harmful if swallowed.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.
H411	Toxic to aquatic life with long lasting effects.

**Full text of other abbreviations**

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; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan

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Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Prepared by : Regulatory Affairs

Numbers quoted in the MSDS are given in the format: 1,000,000 = 1 million and 1,000 = 1 thousand. 0.1 = 1 tenth and 0.001 = 1 thousandth

REVISED INFORMATION: Significant changes to regulatory or health information for this revision is indicated by a bar in the left-hand margin of the SDS.

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

**Annex: Exposure Scenarios**