

		SAFETY DATA SHEET conforms to Regulation EC No. 1907/2006 (REACH), Regulation EC No. 1272/2008 (CLP) and Commission Regulation EU No. 2015/830		
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SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1	Product identifier	
	Product name:	Mr. Bacteria No. 2
	Other means of identification:	not available
	Registration number:	not required, the product is a mixture, not a compound
1.2	Relevant identified uses of the substance or mixture and uses advised against	
	Identified uses:	bioenzymatic cleaner for small sewage treatment plants (STP) - powder of naturally occurring bacteria decomposing organic matter
	Uses advised against:	not set
1.3	Details of the supplier of the safety data sheet	
	Distributor: (responsible for marketing)	EXPORT TEAM s.r.o. Bodická ulica 162/2 - Bodice Liptovský Mikuláš 031 01 Slovak Republic infoline: +421 907 840 000
	Competent person responsible for the safety data sheet: PharmDr. Vladimír Végh, PHARMIS, info@pharmis.sk	
1.4	Emergency telephone number	
	National Toxicological Information Centre (NTIC), FNŠP, Limbová 5, 833 05 Bratislava 37, Slovak Republic, tel.: 00421 (0)2 5477 4166 ; tel.: 00421 (0) 2 5477 4605, (24 h non-stop), www.ntic.sk	

SECTION 2: HAZARDS IDENTIFICATION

General classification of the mixture: the mixture **is not** classified as hazardous in compliance with Regulation (EC) 1272/2008. The mixture does not contain substances presenting a health or environmental hazard within the meaning of Regulation (EC) No. 1272/2008, with assigned a Community workplace exposure limit, classified as PBT/vPvB nor included in the Candidate List of Substances of very high Concerns (SVHC).

Compilation of the Safety Data Sheet is not required for this mixture; however this Safety Data Sheet provides important information on safety at work, storage, transport and other manipulation.

	Important health effects:	The mixture is not classified as hazardous for human health. No adverse effects for human health are expected for the mixture under normal conditions of usage. Direct contact with eyes may cause temporary eye irritation. Prolonged or repeated contact with unprotected skin may cause removal of natural fat from the skin resulting and mild irritation. Inhalation of loosen dust in high concentration may irritate moderately respiratory system and mucous membranes. Swallowing of larger amount can lead to stomachache, vomiting, diarrhea or other gastrointestinal problems. Contains non-pathogenic viable microorganisms; however, these should not contaminate open wounds.
	Important environmental effects:	The mixture is not classified as hazardous for the environment. No adverse effects in the environment are expected for the mixture under normal conditions of usage. Within the environment the mixture underlies biological decomposition (fully biodegradable).
2.1	Classification of the substance or mixture	
	Classification in accordance with 1272/2008/EC:	not classified as hazardous
2.2	Label elements	
	Contains:	not required

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Hazard pictograms:	not required			
Signal word:	not required			
Hazard statements:	not required			
Supplemental hazard information:	not required			
Supplemental label elements for certain mixtures:	not required			
Precautionary statements:	not required			
Other required labeling:	not required			

- 2.3 Other hazards**
Results of PBT and vPvB assessment: The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII; no substances of the mixture in the amount of ≥ 0.1 % are included in the Candidate List of Substances of very high concerns (SVHC).

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

	Mixture of dry bacterial cultures with additives on natural carrier. All bacteria are naturally occurring bacteria and were not genetically modified.
3.1 Substances	does not apply
3.2 Mixtures	Substances presenting a health or environmental hazard within the meaning of Regulation (EC) No. 1272/2008, assigned a Community / national workplace exposure limit, classified as PBT/vPvB or included in the Candidate List: not included

Substance <i>REACH Registration number</i>	Content (% w/w)	EC Number CAS Number Index Number	Classification 1272/2008/EC*	Exposure limits
-	-	-	-	-

* For full wording of used classification abbreviations and Hazard Statements (H-phrases) see Section 16.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures	Health hazard is no minimal, being neither irritating, corrosive, volatile, nor toxic. Effects of over exposure: There are no hazards under normal use conditions. Observe all user considerations and safety measures stated on the packaging. In case of any health problem or uncertainty seek medical attention and provide information from this Material Safety Data Sheet. Unconscious persons place in the stabilized position and observe the breathing. Never give any fluids to unconscious persons.	
Inhalation:	No adverse effects are expected under normal conditions of use. Dust or aerosols in high concentration can cause airway irritation. In this case remove the affected persons to a fresh air. For those providing assistance, avoid exposure to yourself or others. Use adequate respiratory protection. If respiratory irritation, dizziness, nausea, or unconsciousness occurs, seek immediate medical assistance. If breathing has stopped, assist ventilation with a mechanical device or use mouth-to-mouth resuscitation. Call immediately medical emergency.	
Skin contact:	No adverse effects are expected under normal conditions of use - no special requirements needed. Wash contaminated skin with water and soap. When needed, use regenerative cream / ointment. If problems persist, call a physician.	
Eye contact:	No adverse effects are expected under normal conditions of use - no special requirements needed. Dust or aerosols may cause temporary eye irritation. Seek medical advice if the eye irritation persists.	

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Ingestion:	In cases of intended use rinse mouth with water and allow affected person to drink some water or milk (however, only if the person is conscious). Do not induce vomiting! In case of spontaneous vomiting avoid aspiration of the vomits. In case of persistent problems get medical attention and show this Safety Data Sheet or product label!
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- 4.2 Most important symptoms and effects, both acute and delayed**
The mixture **is not** classified as hazardous for human health. No adverse effects for human health are expected for the mixture under normal conditions of usage. Direct contact with eyes may cause temporary eye irritation. Prolonged or repeated contact with unprotected skin may cause removal of natural fat from the skin resulting and mild irritation. Inhalation of loosen dust in high concentration may irritate moderately respiratory system and mucous membranes. Swallowing of larger amount can lead to stomachache, vomiting, diarrhea or other gastrointestinal problems.
Contains non-pathogenic viable microorganisms; however, these should not contaminate open wounds.

- 4.3 Indication of any immediate medical attention and special treatment needed**
No specific therapy known. Use supportive and symptomatic treatment.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media	
Suitable extinguishing media:	Foam, Water, Carbon dioxide (CO ₂), Dry chemical, Alcohol resistant foams are preferred if available. General-purpose synthetic foams (including AFFF) or protein foams may function, but much less effectively.
Unsuitable extinguishing media:	direct water stream - could spread fire
5.2 Special hazards arising from the substance or mixture	No special hazards are known. In case of fire incomplete combustion and thermolysis may produce toxic, irritating and flammable decomposition products (such as carbon monoxide, carbon dioxide, sooth, aldehydes and other products of organic compounds decomposition). Do not inhale smokes.
5.3 Advice for fire-fighters	<u>Fire Fighting Procedures:</u> Keep people away. Isolate fire and deny unnecessary entry. Use water spray to cool fire exposed containers and fire affected zone until fire is out and danger of re-ignition has passed. Fight fire from protected location or safe distance. Move container from fire area if this is possible without hazard. If possible, avoid leaked water to enter sewage system or environment. <u>Special Protective Equipment for Firefighters:</u> Wear positive-pressure self-contained breathing apparatus (SCBA) and protective firefighting clothing (includes firefighting helmet, coat, trousers, boots, and gloves). Avoid contact with this material during firefighting operations. If contact is likely, change to full chemical resistant firefighting clothing with self-contained breathing apparatus. For protective equipment in post-fire or non-fire clean-up situations, refer to the relevant sections 6 and 8.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures	No special requirements are needed. Observe all user considerations and safety measures. Avoid contact with skin, eyes and mucous membranes. See Section 8.2 for advice on the minimum requirements for personal protective equipment (protective goggles, clothes, gloves etc.). All unprotected persons should be restraint. Dust from the product represents a potential explosion hazard and as such it must be continuously removed. Ensure appropriate ventilation of closed rooms. Additional protective measures may be necessary, depending on the specific circumstances and/or the expert judgment of the emergency responders.
6.2 Environmental precautions	No special requirements are needed. Avoid entering soil, surface- and ground-waters, drains, cellars or other closed rooms. In case of serious leakage inform appropriate authorities.
6.3 Methods and materials for containment and cleaning up	Collect mechanically to appropriate containers with lids. All containers with waste should be appropriately labeled. Avoid dusting during disposal. Dispose according to valid legislation; send to wastes treatment facility according to local regulations (see Section 13). Clean up affected areas with large amount of water and appropriate detergent.
6.4 Reference to other sections	Adhere to instructions in the section 8 and 13.

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SECTION 7: HANDLING AND STORAGE

7.1	Precautions for safe handling Avoid contact with eyes and mucous membranes; prevent prolonged contact with skin. Do not eat, drink or smoke when manipulating with the product. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. See Section 8 for advice on the minimum requirements for personal protective equipment. Do not inhale whirled dust - avoid dusting. Dust from the product represents a potential explosion hazard and as such it must be continuously removed. Use only with adequate ventilation. Do not expose to temperatures above 38°C. Do not use with disinfectants, biocides, acids or hydroxides.
7.2	Conditions for safe storage, including any incompatibilities Store in tightly closed original packages or in appropriately labelled reserve containers. Store in dry, bunded areas, protected from weather conditions. Keep away from direct sunlight and excessive heat. Protect from moisture. Store away from oxidative compounds and strong acids / alkalis. Keep out of the reach of children. Store at temperatures not exceeding 38°C.
7.3	Specific end uses not specified

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1

Control parameters

Indicative occupational exposure limit EC: not set

CAS	Substance name	Indicative occupational exposure limit
-	-	-

National work-place / occupational exposure limits (only selected lands are displayed): not set

CAS	Substance name	Occupational exposure limits
-	-	-

Indicative biological limits: not set

Other recommended values: not set

CAS	Substance name	OEL - equivalents
-	-	-

DNEL: not available for the mixture.

PNEC: not available for the mixture.

8.2

Exposure controls

Appropriate engineering controls:

Avoid contact with skin, eyes and mucous membranes. Avoid prolonged or repeated contact with skin. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. Discard contaminated clothing and footwear that cannot be cleaned. Personal protective equipment selections vary based on potential exposure conditions such as applications, handling practices, concentration and ventilation. Information on the selection of protective equipment for use with this material, as provided below, is based upon intended, normal usage.

Individual protection measures, such as personal protective equipment:

a) Eye / face protection

No special requirements are needed under normal conditions of usage. Avoid contact with eyes. If risk of eye contact exists (dusting / emergency situation), use safety glasses with side shields (EN 166).

b) Skin protection:

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No special requirements are needed under normal conditions of usage. Where long-term hand contact with the product may occur the use of gloves approved to relevant standards (e.g. Europe: EN374) made from the following materials may provide suitable chemical protection: PVC, neoprene or nitrile rubber ≥ 0.1 mm, permeation time > 30 min.. Suitability and durability of a glove is dependent on CEN standards EN 420 and EN 374 provide general requirements and lists of glove types. Glove suitability and breakthrough time will differ depending on the specific use conditions. Because of the lack of specific tests, the breakthrough time should be twice the expected contact time. Contact the glove manufacturer for specific advice on glove selection and breakthrough times for your use conditions. Inspect and replace worn or damaged gloves.

Note: Glove suitability and breakthrough time will differ depending on the specific use conditions, such as other chemicals, physical factors (risk of cutting / tearing, thermal damage). Contact the glove manufacturer for specific advice on glove selection and breakthrough times for your use conditions. Inspect and replace worn or damaged gloves.

c) Respiratory protection:

Not needed under general / typical use. Do not inhale dust. Ensure appropriate ventilation or exhaustion at the workplace. In case of dust formation use face mask with particle filter (P2, STN EN 14387+A1) or self-contained breathing apparatus. Respirator selection, use, and maintenance must be in accordance with regulatory requirements, if applicable. European Committee for Standardization (CEN) standards EN 136, 140 and 405 provide respirator masks and EN 149 and 143 (STN EN 14387+A1) provide filter recommendations.

d) Thermal hazards:

No such risk when normally used.

Environmental exposure controls:

Comply with applicable environmental regulations limiting discharge to air, water and soil. Protect the environment by applying appropriate control measures to prevent or limit emissions. All storage and manipulation are have to be equipped for the sanation of possible leakage. See information in sections 6 and 12.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Properties	value	method / condition
Appearance:	solid powder	20°C
Colour:	grey / brown	-
Odour:	slight yeast smell	-
Odour threshold:	information not available	-
pH:	information not available	-
Melting point/freezing point:	information not available	-
Initial boiling point and boiling range:	information not available	-
Flash point:	information not available	-
Evaporation rate:	information not available	-
Flammability (solid, gas)	not flammable	-
Upper/lower flammability or explosive limits:	information not available	-
Vapour pressure:	information not available	-
Vapour density:	information not available	-
Relative density:	cca 1 g/cm ³	25°C
Solubility/ies:	information not available	-
Partition coefficient: n-octanol/water:	information not available	-
Auto-ignition temperature:	information not available	-
Decomposition temperature:	information not available	-

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	Viscosity:	information not available	-
	Explosive properties:	information not available	-
	Oxidising properties:	no oxidative properties	-
9.2	Other information		
	-	-	-

SECTION 10: STABILITY AND REACTIVITY

10.1	Reactivity No specific test data related to reactivity available for this product or its ingredients. Not reactive under normal conditions of storage and manipulation.
10.2	Chemical stability Mixture is chemically stable under normal conditions of storage and manipulation. Disinfectants, biocides, acids or hydroxides may affect the viability of contained bacteria.
10.3	Possibility of hazardous reactions Under normal conditions of storage and use, no hazardous reactions are known.
10.4	Conditions to avoid Stable under normal conditions. Keep away from direct sunlight, heat sources. Protect from moisture. Do not expose to temperatures above 38°C.
10.5	Incompatible materials Disinfectants, biocides, antibiotics, acids or hydroxides, strong oxidative / reductive compounds.
10.6	Hazardous decomposition products Material does not decompose at ambient temperatures. In case of fire incomplete combustion and thermolysis may produce toxic, irritating and flammable decomposition products (such as carbon monoxide, carbon dioxide, soot, aldehydes and other products of organic compounds decomposition).

SECTION 11: TOXICOLOGICAL INFORMATION

11.1	Information on toxicological effects The mixture contains microorganisms selected from natural sources. These microorganisms are not pathogens to human, animals or plants.
a)	<i>Acute toxicity</i> Based on available data, the classification criteria are not met. No toxicology data for the mixture. Based on the composition the mixture has very low acute toxicity. Swallowing of larger amounts may lead to nausea, stomachache, vomiting or diarrhea.
b)	<i>Skin corrosion/irritation</i> Based on available data, the classification criteria are not met. Prolonged or repeated contact with unprotected skin may cause temporal removal of natural fat from the skin and dry skin. However, these effects are not a reason for classification.
c)	<i>Serious eye damage/irritation</i> Based on available data, the classification criteria are not met. Can cause mild and transient eye irritation upon direct contact. However, these effects are not a reason for classification.
d)	<i>Respiratory or skin sensitisation</i> Based on available data, the classification criteria are not met. Compounds do not have known sensitizing potential.
e)	<i>Germ cell mutagenicity</i> Based on available data, the classification criteria are not met. Compounds have no potential for mutagenicity.
f)	<i>Carcinogenicity</i> Based on available data, the classification criteria are not met. Compounds have no potential for carcinogenicity.
g)	<i>Reproductive toxicity</i> Based on available data, the classification criteria are not met. Compounds have no potential for reproductive toxicity.

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- | | |
|----|---|
| h) | <i>STOT-single exposure</i>
Based on available data, the classification criteria are not met. Inhalation of loosened dust in high concentration can cause irritation of airways. However, these effects are not a reason for classification. |
| i) | <i>STOT-repeated exposure</i>
Based on available data, the classification criteria are not met. |
| j) | <i>Aspiration hazard</i>
Based on available data, the classification criteria are not met. |

SECTION 12: ECOLOGICAL INFORMATION

	The mixture is not classified as hazardous for the environment. No adverse effects in the environment are expected for the mixture under normal conditions of usage. Within the environment the mixture underlies biological decomposition (fully biodegradable).
12.1	Toxicity No experimental data measured for the mixture. No adverse effects in the environment are expected for the mixture.
12.2	Persistence and degradability No experimental data measured for the mixture. Within the environment the mixture is expected to underlie full biological decomposition (biodegradable).
12.3	Bioaccumulative potential The mixture has no bioaccumulative potential.
12.4	Mobility in soil No data for the mixture. Soluble / miscible in water; however, mobility in soil is not expected.
12.5	Results of PBT and vPvB assessment Results of PBT and vPvB assessment: The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII; no substances of the mixture in the amount of ≥ 0.1 % are included in the Candidate List of Substances of very high concerns (SVHC).
12.6	Other adverse effects not known

SECTION 13: DISPOSAL CONSIDERATIONS

13.1	Waste treatment methods It is recommended to dispose all rests in authorized dangerous waste facility. Disposal has to comply all local legal requirements on wastes. <u>Substance or mixture disposal methods:</u> Dispose in accordance with the valid waste legislation. Do not dispose as a common household waste. Dispose in a certified waste facility / recycle. According to the European Waste Catalogue waste codes are not specific for product, but for its use. Therefore, appropriate waste code should assign final user according to his specific use. Proposed waste classification, based on the most common use: 02 Wastes from agriculture, horticulture, aquaculture, forestry, hunting and fishing, food preparation and processing 02 01 Wastes from agriculture, horticulture, aquaculture, forestry, hunting and fishing Waste type name: agrochemical waste other than those mentioned in 02 01 08 Waste catalog code: 02 01 09 Hazardous waste: no (category O)
	<u>Packages disposal methods:</u> Recycle empty packages. Proposed waste classification, based on the most common use: 15 Waste packaging; absorbents, wiping cloths, filter materials and protective clothing not otherwise specified 15 01 packaging (including separately collected municipal packaging waste) Waste type name: paper and card board packaging / plastic packaging Waste catalog code for empty package: 15 01 01 / 15 01 02 Dangerous waste: no (category O)

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SECTION 14: TRANSPORT INFORMATION

The substance **is not** classified as dangerous for transport according to ADR/RID/IMDG/ICAO/IATA.

14.1	UN Number: -			
14.2	UN proper shipping name			
	<i>Road transport ADR</i>	<i>Rail transport RID</i>	<i>Int. maritime trans. IMDG</i>	<i>Air transport ICAO/IATA</i>
	-	-	-	-
14.3	Transport hazard class(es)			
	<i>Road transport ADR</i>	<i>Rail transport RID</i>	<i>Int. maritime trans. IMDG</i>	<i>Air transport ICAO/IATA</i>
	-	-	-	-
	Classification code			
	-	-	-	-
	Hazard identification number (Kemler)			
	-	-	-	-
	Labels			
	-	-	-	-
	Other remarks			
	-	-	-	-
14.4	Packing group			
	<i>Road transport ADR</i>	<i>Rail transport RID</i>	<i>Int. maritime trans. IMDG</i>	<i>Air transport ICAO/IATA</i>
	-	-	-	-
14.5	Environmental hazards: no			
14.6	Special precautions for user: not required			
14.7	Transport in bulk according to Annex II of MARPOL and the IBC Code: not transported			

SECTION 15: REGULATORY INFORMATION

15.1	Safety, health and environmental regulations/legislation specific for the substance or mixture <u>Relevant legislation European Union:</u> - Regulation (EC) No 1907/2006 of the European Parliament and of the , concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) - Regulation EC No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 - Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) - Commission Directive 2000/39/EC of 8 June 2000 establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work - Commission Directive 2006/15/EC of 7 February 2006 establishing a second list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Directives 91/322/EEC and 2000/39/EC - Commission Directive 2009/161/EU of 17 December 2009 establishing a third list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Commission Directive 2000/39/EC - Commission Directive (EU) 2017/164 of 31 January 2017 establishing a fourth list of indicative occupational exposure limit values pursuant to Council Directive 98/24/EC - Commission Directive (EU) 2019/1831 of 24 October 2019 establishing a fifth list of indicative occupational exposure limit values pursuant to Council Directive 98/24/EC and amending Commission Directive 2000/39/EC
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	- Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work - European Waste Catalogue - Council Directive 1999/13/EC of 11 March 1999 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain activities and installations - Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products Text with EEA relevance - Regulation (EU) No 526/2013 of the European Parliament and of the Council of 21 May 2013 concerning the European Union Agency for Network and Information Security (ENISA) and repealing Regulation (EC) No 460/2004
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Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles: none	
<i>Designation of the substance, of the group of substances or of the mixture</i>	<i>Conditions of restriction</i>
-	-

15.2	Chemical safety assessment Chemical safety assessment not carried yet
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SECTION 16: OTHER INFORMATION

a)	<i>Changes made to the previous version of the safety data sheet</i> Not applicable, first edition - version 1.0
	<i>Key or legend to abbreviations and acronyms used in the safety data sheet</i> Exp. lim. Exposure limit NPEL The highest permissible exposure limit (Slovak Republic) PEL The highest permissible exposure limit (Czech Republic) OEL Occupational exposure limit PBT Substances persistent, bioaccumulative and toxic vPvB Substances very persistent and very bioaccumulative VOC Volatile organic compound DNEL Derived No Effect Level PNEC Predicted No Effect Concentration BW Body weight LD50 Median lethal Dose LC50 Median lethal concentration EC50 Half maximal effective concentration IC50 Half maximal inhibitory concentration ADR European Agreement concerning the International Carriage of Dangerous Goods by Road RID International Rule for Transport of Dangerous Substances by Railway IMDG International Maritime Dangerous Goods Code ICAO International Civil Aviation Organization IATA International Air Transport Association
c)	<i>Key literature references and sources for data</i> No information
d)	<i>Methods of evaluating information used for the purpose of classification</i> The substance was classified by expert judgment and conventional calculations methods in accordance with the Regulation EC No. 1272/2008 (CLP).
e)	<i>Full wording of used Hazard Statements (H-phrases)</i> not used
f)	<i>Advice on any training appropriate for workers</i> Before handling, storing or using the present substance for the first time, employees must be informed - common training for handling chemicals, occupational safety training.

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g) Other information

Safety Data Sheet (SDS) is compiled in accordance with the Regulation EC No. 1907/2006 (REACH), Regulation EC No. 1272/2008 (CLP) and Commission Regulation EU No. 2015/830; and contains information on safety use, occupational health protection, and environmental protection. The information contained herein is given in good faith and is accurate to the best of knowledge at the date indicated above. This particular information applies on the product as supplied and may not be valid in mixtures with other substances. If used for other purposes as identified in this SDS, the distributor is not liable for any damage.

The information given herein in no way dispenses the user from knowing and applying all provisions regulating his activity. The user bears sole liability for the precautions required when using the product. The regulatory texts indicated herein are intended to aid the user to fulfill his obligations. This list is not to be considered complete and exhaustive. It is the user's responsibility to ensure that he is subject to no other obligations than those mentioned.

Compiled: PharmDr. Vladimír Végh, PHARMIS, www.pharmis.cz