

Benzylpenicillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
4.3	08.12.2023	9374126-00009	Date of first issue: 27.08.2021

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

1.1 Product identifier

Trade name : Benzylpenicillin Formulation

Other means of identification : Duplocillin LA (A004183) Depocillin (A004256)

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

Use of the Sub- stance/Mixture	:	Veterinary product
Recommended restrictions on use	:	Not applicable

1.3 Details of the supplier of the safety data sheet

Company	:	MSD Walton Manor, Walton MK7 7AJ Milton Keynes - United Kingdom
Telephone	:	+1-908-740-4000
E-mail address of person responsible for the SDS	:	EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Respiratory sensitisation, Category 1	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin sensitisation, Category 1	H317: May cause an allergic skin reaction.
Short-term (acute) aquatic hazard, Cate- gory 1	H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Cat- egory 3	H412: Harmful to aquatic life with long lasting effects.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



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2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Hazard pictograms	:	
Signal word	:	Danger
Hazard statements	:	 H317 May cause an allergic skin reaction. H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled. H410 Very toxic to aquatic life with long lasting effects.
Precautionary statements	:	Prevention:P273Avoid release to the environment.P280Wear protective gloves.
		Response:P304 + P340IF INHALED: Remove person to fresh air and keep comfortable for breathing.P333 + P313If skin irritation or rash occurs: Get medical advice/ attention.P342 + P311If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.P391Collect spillage.

Hazardous components which must be listed on the label: Benzylpenicillin

2.3 Other hazards

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.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No.	Classification	Concentration
	EC-No.		(% w/w)
	Index-No.		
	Registration number		
Benzylpenicillin	61-33-6	Resp. Sens. 1A;	>= 30 - < 50
	200-506-3	H334	
		Skin Sens. 1B;	
		H317	
		Aquatic Acute 1;	

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			H400 Aquatic Chronic 3; H412 M-Factor (Acute aquatic toxicity): 1

For explanation of abbreviations see section 16.

SECTION 4: First aid measur	es
4.1 Description of first aid meas	sures
General advice	 In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.
Protection of first-aiders	: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
If inhaled	 If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
In case of skin contact	 In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
In case of eye contact	: Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.
If swallowed	: If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.
4.2 Most important symptoms a	nd effects, both acute and delayed
Risks	 May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficul- ties if inhaled.

Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).



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4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media		
Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.
5.2 Special hazards arising from	the	e substance or mixture
Specific hazards during fire- fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion prod- ucts	:	Carbon oxides Metal oxides
5.3 Advice for firefighters		
Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
Specific extinguishing meth- ods	:	Use extinguishing measures that are appropriate to local cir- cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal pro- tective equipment recommendations (see section 8).
6.2 Environmental precautions		
Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. If spillage enters rivers or watercourses, inform the Environ- ment Agency (emergency telephone number 0800 807060).



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6.3 Methods and material for containment and cleaning up

Methods for cleaning up	<u> </u>
	: Soak up with inert absorbent material. For large spills, provide dyking or other appropriate contain- ment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absor- bent.
	Local or national regulations may apply to releases and dis- posal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter- mine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures	: See Engineering measures under EXPOSURE
	CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation	: Use only with adequate ventilation.
Advice on safe handling	: Do not get on skin or clothing.
	Avoid breathing mist or vapours.
	Do not swallow.
	Avoid contact with eyes.
	Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as- sessment
	Keep container tightly closed.
	Already sensitised individuals, and those susceptible
	to asthma, allergies, chronic or recurrent respiratory disease,
	should consult their physician regarding working with respira- tory irritants or sensitisers.
	Take care to prevent spills, waste and minimize release to the environment.
Hygiene measures	: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before re-use.
	The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage	:	Keep in properly labelled containers. Keep tightly closed.
areas and containers		Store in accordance with the particular national regulations.



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Advice on common storage		:	: Do not store with the following product types: Strong oxidizing agents Gases	
7.3 Specific end use(s) Specific use(s)			No data available	

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No. Value type (Form		Control parameters	Basis
		of exposure)		
Benzylpenicillin 61-33-6		TWA	600 µg/m3 (OEB 2)	Internal
	Further inform	ation: RSEN, DSEN		
		Wipe limit	100 µg/100 cm2	Internal

Predicted No Effect Concentration (PNEC):

Substance name	Environmental Compartment	Value
Benzylpenicillin	Water	0.014 mg/l

8.2 Exposure controls

Engineering measures

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Laboratory operations do not require special containment.

Personal protective equipment

Eye/face protection	:	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Hand protection Material	:	Chemical-resistant gloves
Skin and body protection Respiratory protection	:	Work uniform or laboratory coat. If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Equipment should conform to BS EN 143
Filter type	:	Particulates type (P)

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SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

9.1 Information on basic physical Appearance Colour Odour Odour Threshold	an : : :	suspension white No data available No data available
рН	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility Partition coefficient: n- octanol/water	::	soluble Not applicable No data available
Auto-ignition temperature		
Decomposition temperature	:	No data available
Viscosity Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
9.2 Other information Flammability (liquids)	:	No data available

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ts.				
: None known.				
Materials to avoid : Oxidizing agents				

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Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

Respiratory or skin sensitisation

Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Components:

Benzylpenicillin:

Test Type Exposure routes Species Result	:	Local lymph node assay (LLNA) Dermal Mouse Weak sensitizer
Test Type Exposure routes Species Result Remarks		Maximisation Test Dermal Guinea pig positive Based on data from similar materials
Result Remarks	:	Strong sensitizer Based on human experience.

Germ cell mutagenicity

Not classified based on available information.

Components:

Benzylpenicillin:

Germ cell mutagenicity- As-	:	Weight of evidence does not support classification as a germ
sessment		cell mutagen.

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

Components:

Benzylpenicillin:

Effects on fertility

: Test Type: Fertility Species: Mouse Result: No effects on fertility

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		Test Type: Fert Species: Rat Result: No effec	
		Test Type: Fert Species: Rabbi Result: No effe	t
Effect ment	ts on foetal develop-	: Test Type: Dev Species: Mouse Result: No effe	
		Test Type: Dev Species: Rat Result: No effe	elopment cts on foetal development
		Test Type: Dev Species: Rabbi	elopment
	Γ - single exposure lassified based on avai	lable information.	
	F - repeated exposure lassified based on avai	lable information.	
•	ration toxicity lassified based on avai	lable information.	
Expe	rience with human ex	posure	
<u>Com</u>	ponents:		
Benz Inhala	ylpenicillin: ation	: Symptoms: Alle chospasm, skin	ergic reactions, Abdominal pain, bron- rash
ECTION	N 12: Ecological info	ormation	
2.1 Toxic	city		
Com	ponents:		
	ylpenicillin: ity to fish	: LC50 (Oncorhy	nchus mykiss (rainbow trout)): > 100 mg/l

		Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 3.6 mg/l Exposure time: 48 hrs Method: OECD Test Guideline 202

Exposure time: 96 hrs

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	Toxicity to algae/aquatic : plants		idocelis subcapitata (freshwater green alga)): > ne: 72 hrs CD Test Guideline 201	
		mg/l Exposure tir	hidocelis subcapitata (freshwater green alga)): 50 ne: 72 hrs CD Test Guideline 201	
		Exposure tir	green algae): 0.74 mg/l ne: 72 hrs CD Test Guideline 201	
		Exposure tir	-green algae): 0.14 mg/l ne: 72 hrs CD Test Guideline 201	
M-Fa icity)	ctor (Acute aquatic tox-	: 1		
Toxic	ity to microorganisms	: EC50 : > 50 Exposure tir Test Type: F Method: OE		
		Exposure tir Test Type: F	NOEC : 5 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209	
12.2 Pers	istence and degradabi	ity		
<u>Com</u>	ponents:			
	ylpenicillin: egradability	Biodegradat Exposure tir	dily biodegradable. ion: 70.10 % ne: 28 d CD Test Guideline 301B	
	ccumulative potential ata available			
	ility in soil ata available			
12.5 Resu	ults of PBT and vPvB a	ssessment		
Prod	uct:			
Asse	ssment		nce/mixture contains no components considered persistent, bioaccumulative and toxic (PBT), or	

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0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment

: 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

13.1 Waste treatment methods

Product	:	Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.
Contaminated packaging	:	Empty containers should be taken to an approved waste han- dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

ADN	:	UN 3082
ADR	:	UN 3082
RID	:	UN 3082
IMDG	:	UN 3082
ΙΑΤΑ	:	UN 3082
14.2 UN proper shipping name		
ADN	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Benzylpenicillin)
ADR	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Benzylpenicillin)
RID	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.

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				(Benzylpenicillin)	
	IMDG		:	ENVIRONMENTA N.O.S. (Benzylpenicillin)	ALLY HAZARDOUS SUBSTANCE, LIQUID,
	ΙΑΤΑ		:	Environmentally h (Benzylpenicillin)	nazardous substance, liquid, n.o.s.
14.3	8 Transp	oort hazard class(es)			
				Class	Subsidiary risks
	ADN		:	9	
	ADR		:	9	
	RID		:	9	
	IMDG		:	9	
	ΙΑΤΑ		:	9	
14.4	Packir	ng group			
	Classif	g group ication Code I Identification Number	:	III M6 90 9	
	Classif Hazard Labels	g group ication Code I Identification Number restriction code	:	III M6 90 9 (-)	
	Classif	g group ication Code I Identification Number	:	III M6 90 9	
	IMDG Packing Labels EmS C	g group ode	:	III 9 F-A, S-F	
	aircraft Packin Packin	g instruction (cargo	:	964 Y964 III	
	Labels		:	Miscellaneous	
		Passenger) g instruction (passen- craft)	:	964	
	Packin	g instruction (LQ)	:	Y964	

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	Packing group ∟abels	: III : Miscellaneous	
14.5	Environmental hazards		
-	ADN Environmentally hazardous	: yes	
	ADR Environmentally hazardous	: yes	
-	RID Environmentally hazardous	: yes	
-	MDG Marine pollutant	: yes	
	ATA (Passenger) Environmentally hazardous	: yes	
	ATA (Cargo) Environmentally hazardous	: yes	

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

: Not applicable for product as supplied.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks

SECTION 15: Regulatory information

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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17)	:	Conditions of restriction for the fol- lowing entries should be considered: Number on list 3
		Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the condi- tions in corresponding Regulation to determine whether an entry is appli- cable to the placing on the market or not.
UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation	:	Not applicable
The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain)	:	Not applicable



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•	lation (EC) No 1005/20 the ozone layer	009 on substances that	de- :	Not applicable	
		es subject to authorisa	tion :	Not applicable	
· ·	ex XIV)			Net en elle ele le	
	ned Consent (PIC) Reg	zardous chemicals - Pr	ior :	Not applicable	
Control of Major Accident Hazards Regulations 2015 (COMAH)					
	,	0	,	Quantity 1	Quantity 2
E1		ENVIRONMEN HAZARDS	ΓAL	100 t	200 t

Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

The components of this product are reported in the following inventories:

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information	Items where changes have been made to the previous ve are highlighted in the body of this document by two vertic lines.			
Full text of H-Statements				
H317	May cause an allergic skin reaction.			
H334	May cause allergy or asthma symptoms or breathing diffi ties if inhaled.	icul-		
H400	Very toxic to aquatic life.			
H412	Harmful to aquatic life with long lasting effects.			
Full text of other abbreviations				
Aquatic Acute	Short-term (acute) aquatic hazard			
Aquatic Chronic	Long-term (chronic) aquatic hazard			
Resp. Sens.	Respiratory sensitisation			
Skin Sens.	Skin sensitisation			
ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland				

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - 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



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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 Chemical Substance Inventory; TECI -Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

Sources of key data used to compile the Safety Data Sheet	eChem Portal search re	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen- cy, http://echa.europa.eu/	
Classification of the mixture	:	Classification procedure:	
Resp. Sens. 1	H334	Calculation method	
Skin Sens. 1	H317	Calculation method	
Aquatic Acute 1	H400	Calculation method	
Aquatic Chronic 3	H412	Calculation method	

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 is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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