

Levamisole Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
4.4	28.09.2024	9374646-00009	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	:	Levamisole Formulation
1.2	Relevant identified uses of th	ie s	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	saf	ety 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)

Acute toxicity, Category 4 Reproductive toxicity, Category 2 Specific target organ toxicity - repeated exposure, Category 2 H302: Harmful if swallowed. H361d: Suspected of damaging the unborn child. H373: May cause damage to organs through prolonged or repeated exposure.

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



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



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Signal word		:	Warning	
Hazaı	rd statements	:	H302 H361d H373	Harmful if swallowed. Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure.
Preca	Precautionary statements		Prevention	:
	·		P201 P260 P270 P280	Obtain special instructions before use. Do not breathe dust. Do not eat, drink or smoke when using this prod- uct. Wear protective gloves/ protective clothing/ eye protection/ face protection.
			Response:	
				 2 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth. 3 IF exposed or concerned: Get medical advice/ attention.

Hazardous components which must be listed on the label: levamisole hydrochloride

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.

Dust contact with the eyes can lead to mechanical irritation.

Contact with dust can cause mechanical irritation or drying of the skin.

May form combustible dust concentrations in air during processing, handling or other means.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
levamisole hydrochloride	16595-80-5 240-654-6	Acute Tox. 3; H301 Repr. 2; H361d STOT RE 2; H373 (Blood, Testis) Aquatic Chronic 3; H412	>= 10 - < 20

For explanation of abbreviations see section 16.

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



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SECTION 4: First aid measures

4.1 Description of first aid meas	ures	5
General advice	:	In the case of accident or if you feel unwell, seek medical ad- vice 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. 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	:	If in eyes, rinse well with water. Get medical attention if irritation develops and persists.
If swallowed	:	If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.
4.2 Most important symptoms a	nd e	ffects, both acute and delayed
Risks	:	Harmful if swallowed. Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure.
		Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.
4.3 Indication of any immediate	mec	lical attention and special treatment needed
Treatment	:	Treat symptomatically and supportively.
SECTION 5: Firefighting mean	sure	es
5.1 Extinguishing media		

Suitable extinguishing media : Water spray Alcohol-resistant foam

Carbon dioxide (CO2)



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				Dry chemical	
	Unsuita media	able extinguishing	:	None known.	
5.2	Special	hazards arising from	the	e substance or mi	xture
	Specifi fighting		:	concentrations, and potential dust exp	dust; fine dust dispersed in air in sufficient nd in the presence of an ignition source is a losion hazard. pustion products may be a hazard to health.
	Hazarc ucts	lous combustion prod-	:	Carbon oxides	
5.3	Advice	for firefighters			
	Specia for firef	l protective equipment ighters	:		e, wear self-contained breathing apparatus. tective equipment.
	Specifi ods	c extinguishing meth-	:	cumstances and t Use water spray t	measures that are appropriate to local cir- he surrounding environment. o cool unopened containers. ged containers from fire area if it is safe to do

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.
		Retain and dispose of contaminated wash water.
		If spillage enters rivers or watercourses, inform the Environ-
		ment Agency (emergency telephone number 0800 807060).

6.3 Methods and material for containment and cleaning up

Methods for cleaning up	:	Sweep up or vacuum up spillage and collect in suitable con- tainer for disposal.
		Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
		Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are re-
		leased into the atmosphere in sufficient concentration.
		Local or national regulations may apply to releases and dis- posal of this material, as well as those materials and items

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		mine which reg Sections 13 and	e cleanup of releases. You will need to deter- ulations are applicable. d 15 of this SDS provide information regarding national requirements.		
6.4 Refere	ence to other sections	5			
See sections: 7, 8, 11, 12 and 13.					
SECTION	N 7: Handling and st	torage			
7.1 Preca	utions for safe handli	ng			
	nical measures	: Static electricity causing an expl Provide adequa	r may accumulate and ignite suspended dust losion. ate precautions, such as electrical grounding r inert atmospheres.		
	/Total ventilation e on safe handling	 Use only with a Do not breathe Do not swallow Avoid contact w Avoid prolonged 	dequate ventilation. dust.		

Technical measures	:	Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
Local/Total ventilation Advice on safe handling	::	Use only with adequate ventilation. Do not breathe dust. Do not swallow. Avoid contact with eyes. Avoid prolonged or repeated contact with skin. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as- sessment Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Do not eat, drink or smoke when using this product. 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. Wash contami- nated 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,	incl	luding any incompatibilities
Requirements for storage areas and containers	:	Keep in properly labelled containers. Store locked up. Store in accordance with the particular national regulations.
Advice on common storage	:	Do not store with the following product types: Strong oxidizing agents

7.3 Specific end use(s)

Specific use(s)	: No data available
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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

dust of any kind

10 mg/m3 Value type (Form of exposure): TWA (Inhalable) Basis: GB EH40

4 mg/m3 Value type (Form of exposure): TWA (Respirable fraction) Basis: GB EH40

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
levamisole hydro- chloride	16595-80-5	TWA	20 µg/m3 (OEB 3)	Internal
	Further information: Skin			
		Wipe limit	200 µg/100 cm ²	Internal

8.2 Exposure controls

Engineering measures

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).

Minimize open handling.

Personal protective equipment

Eye/face protection Hand 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.
Material	:	Chemical-resistant gloves
Remarks Skin and body protection	:	Consider double gloving. Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.
Respiratory protection	:	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection.



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Filter type		Equipment shou : Particulates type	uld conform to BS EN 143 e (P)
SECTION 9: Physical and chemical properties			

9.1 Information on basic physical and chemical properties

Appearance Colour Odour Odour Threshold	:	powder 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	:	Not applicable
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form combustible dust concentrations in air during pro- cessing, handling or other means.
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	Not applicable
Relative vapour density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility Partition coefficient: n- octanol/water Auto-ignition temperature	:	No data available Not applicable No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

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9.2 Other	information			
	cular weight	: No data availa	able	
Partic	cle size	: No data availa	able	

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions	: May form combustible dust concentrations in air during pro- cessing, handling or other means. Can react with strong oxidizing agents.	
10.4 Conditions to avoid		
Conditions to avoid	: Heat, flames and sparks. Avoid dust formation.	
10.5 Incompatible materials		
Materials to avoid	: Oxidizing agents	
10.6 Hazardous decompositior	products	

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Information on likely routes of exposure	:	Inhalation Skin contact Ingestion Eye contact
Acute toxicity		
Harmful if swallowed.		
Product:		
Acute oral toxicity	:	Acute toxicity estimate: 1,200 mg/kg Method: Calculation method
Components:		
levamisole hydrochloride:		
Acute oral toxicity	:	LD50 (Rat): 180 mg/kg

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		LD50 (Mous	e): 223 mg/kg
		LD50 (Rabb	it): 458 mg/kg
Acute	inhalation toxicity	: Remarks: N	o data available
Acute	dermal toxicity	: Remarks: N	o data available
-	corrosion/irritation assified based on ava	ailable information.	
<u>Comp</u>	oonents:		
levarr	nisole hydrochloride	:	
Rema	urks	: No data ava	ilable
	us eye damage/eye assified based on ava		
<u>Comp</u>	oonents:		
levar Rema	n isole hydrochloride urks	: : No data ava	ilable
Resp	iratory or skin sensi	tisation	
-	sensitisation assified based on ava	ailable information.	
-	iratory sensitisation assified based on ava		
<u>Comp</u>	oonents:		
levar Rema	n isole hydrochloride urks	: : No data ava	ilable
	cell mutagenicity assified based on ava	ailable information.	
<u>Comp</u>	oonents:		
levan	nisole hydrochloride	:	
Geno	toxicity in vitro	: Test Type: E Result: nega	Bacterial reverse mutation assay (AMES) ative
		Test Type: (Chromosome aberration test in vitro

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Carcinogenicity

Not classified based on available information.

Components:

levamisole hydrochloride:

Species Application Route Exposure time NOAEL Remarks	:	Mouse Oral 2 Years 80 mg/kg body weight No significant adverse effects were reported
Species Application Route Exposure time NOAEL Remarks	:	Rat Oral 2 Years 40 mg/kg body weight No significant adverse effects were reported

Reproductive toxicity

Suspected of damaging the unborn child.

Components:

levamisole hydrochloride:

Effects on fertility :	Test Type: Three-generation reproduction toxicity study Species: Rat Application Route: Oral Result: No significant adverse effects were reported
Effects on foetal develop- : ment	Test Type: Embryo-foetal development Species: Rat Application Route: Oral Developmental Toxicity: NOAEL: 20 mg/kg body weight Result: Fetotoxicity
	Test Type: Embryo-foetal development Species: Rabbit Application Route: Oral Developmental Toxicity: LOAEL: 40 mg/kg body weight Result: Fetotoxicity
Reproductive toxicity - As- : sessment	Some evidence of adverse effects on development, based on animal experiments.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

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ersion 4	Revision Date: 28.09.2024		OS Number: 74646-00009	Date of last issue: 06.04.2024 Date of first issue: 27.08.2021
Com	oonents:			
levan	nisole hydrochloride:			
	et Organs ssment	:	Blood, Testis May cause dama exposure.	age to organs through prolonged or repeated
Repe	ated dose toxicity			
Com	oonents:			
levan	nisole hydrochloride:			
Expos		:	Rat 2.5 mg/kg Oral 18 Months Testis	
Expos		:	Dog 20 mg/kg Oral 18 Months Blood	
		::	Dog 40 mg/kg Oral 3 Months	
•	ation toxicity lassified based on availa	ble	information.	
Expe	rience with human exp	osı	ire	
<u>Comp</u>	oonents:			
levan	nisole hydrochloride:			
Inges	-	:	Symptoms: Naus tension	sea, Vomiting, Headache, Dizziness, hypo-
ECTION	I 12: Ecological infor	ma	tion	
2.1 Toxic	city			
	oonents:			
	nisole hydrochloride: ity to fish	:	Exposure time: 9	tipes (Japanese medaka)): 37.3 mg/l 96 h Fest Guideline 203
				nagna (Water flea)): 64 mg/l

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aquat	ic invertebrates		Exposure time: 4 Method: OECD T	8 h Test Guideline 202
	stence and degradab	oility		
	ata available			
	ccumulative potential ata available			
12.4 Mobi	lity in soil			
No da	ata available			
12.5 Resu	Its of PBT and vPvB	asse	essment	
Prod	uct:			
	ssment	:	to be either persi	nixture contains no components considered stent, bioaccumulative and toxic (PBT), or nd very bioaccumulative (vPvB) at levels of
12.6 Othe	r adverse effects			
Prod	uct:			
Endo tial	crine disrupting poten-	:	ered to have end	nixture does not contain components consid- ocrine disrupting properties for environment REACH Article 57(f).
	12: Disposal cons			

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.
Contaminated packaging	 Do not dispose of waste into sewer. 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	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
ΙΑΤΑ	:	Not regulated as a dangerous good

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14.2 UN p	oroper shipping name				
ADN		: Not regulated as	s a dangerous good		
ADR		: Not regulated as	s a dangerous good		
RID		: Not regulated as	a dangerous good		
IMDO	3	: Not regulated as	a dangerous good		
ΙΑΤΑ		: Not regulated as	s a dangerous good		
14.3 Tran	sport hazard class(es				
ADN		: Not regulated as	s a dangerous good		
ADR		: Not regulated as	s a dangerous good		
RID		: Not regulated as	s a dangerous good		
IMDO	3	: Not regulated as	s a dangerous good		
ΙΑΤΑ		: Not regulated as	s a dangerous good		
14.4 Pack	ting group				
ADN		: Not regulated as	a dangerous good		
ADR		: Not regulated as	s a dangerous good		
RID		: Not regulated as	Not regulated as a dangerous good		
IMDO	3	: Not regulated as	s a dangerous good		
ΙΑΤΑ	(Cargo)	: Not regulated as	a dangerous good		
ΙΑΤΑ	(Passenger)	: Not regulated as	a dangerous good		
14.5 Envi	ronmental hazards				
Not r	egulated as a dangero	s good			
-	ial precautions for u	er			
14.7 Tran	sport in bulk accordi	•			
Rema	arks	: Not applicable for	or product as supplied.		
Remarks : Not applicable for product as supplied. SECTION 15: Regulatory information 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture					
Relevant I	EU provisions transpos	ed through retained EL	Jlaw		
UK R	EACH List of restrictio	is (Annex 17)	: Not applicable		
	EACH Candidate list c		gh : Not applicable		



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(Anne GB E Inforr	ex XIV) xport and import of ha ned Consent (PIC) Re	ces subject to authoris azardous chemicals - P egulation lazards Regulations 20 Not applicable	rior :	Not applicable Not applicable AH)

Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

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 :

DSL	:	
IECSC	:	

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 version are highlighted in the body of this document by two vertical lines.
Full text of H-Statements		
H301	:	Toxic if swallowed.
H361d	:	Suspected of damaging the unborn child.
H373	:	May cause damage to organs through prolonged or repeated exposure if swallowed.
H412	:	Harmful to aquatic life with long lasting effects.
Full text of other abbreviation	ons	5
Acute Tox.	:	Acute toxicity
Aquatic Chronic	:	Long-term (chronic) aquatic hazard
Repr.	:	Reproductive toxicity
STOT RE	:	Specific target organ toxicity - repeated exposure
GB EH40	:	UK. EH40 WEL - Workplace Exposure Limits
GB EH40 / TWA	:	Long-term exposure limit (8-hour TWA reference period)
ADN European Agreement	oon	corning 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



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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 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	:	Internal technical data, data from raw material SDSs, OECD
compile the Safety Data		eChem Portal search results and European Chemicals Agen-
Sheet		cy, http://echa.europa.eu/

Classification of the mixtur	Classification procedure:	
Acute Tox. 4	H302	Calculation method
Repr. 2	H361d	Calculation method
STOT RE 2	H373	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.

GB / EN

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