

## **Doxycycline Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	6105690-00010	Date of first issue: 06.07.2020

#### SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name	:	Doxycycline Formulation				
Manufacturer or supplier's details						
Company name of supplier	:	MSD				
Address	:	126 E. Lincoln Avenue				
		Rahway, New Jersey U.S.A. 07065				
Telephone	:	908-740-4000				
Emergency telephone	:	1-908-423-6000				
E-mail address	:	EHSDATASTEWARD@msd.com				
Recommended use of the cl	nical and restrictions on use					
Recommended use	:	Veterinary product				
Restrictions on use	:	Not applicable				

### **SECTION 2. HAZARDS IDENTIFICATION**

GHS Classification		Category 5
Acute toxicity (Oral)	•	Calegory 5
Skin corrosion/irritation	:	Category 1
Serious eye damage/eye irritation	:	Category 1
GHS label elements		
Hazard pictograms	:	
Signal Word	:	Danger
Hazard Statements	:	H303 May be harmful if swallowed. H314 Causes severe skin burns and eye damage.
Precautionary Statements	:	<b>Prevention:</b> P260 Do not breathe dust. P264 Wash skin thoroughly after handling. P280 Wear eye protection/ face protection.
		Response: P301 + P330 + P331 + P310 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER or doctor/ physician. P303 + P361 + P353 + P310 IF ON SKIN (or hair): Remove/ Take off immediately all contaminated clothing. Rinse skin with water/ shower. Immediately call a POISON CENTER or doctor/ physician. P304 + P340 + P310 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Imme-



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		diately call a POISON CENTER or doctor/ physician. P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/ physician. P312 Call a POISON CENTER or doctor/ physician if you feel unwell. P363 Wash contaminated clothing before reuse.		
		<b>Disposal:</b> P501 Dispose o posal plant.	of contents/ container to an approved waste dis-	
Other	• hazards			

May form explosive dust-air mixture during processing, handling or other means.

#### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture	:	Mixture	

### Components

Chemical name	CAS-No.	Concentration (% w/w)
Doxycycline Hyclate	24390-14-5	>= 50 -< 70

#### **SECTION 4. FIRST AID MEASURES**

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.
If inhaled	:	If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention immediately.
In case of skin contact	:	In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention immediately. Wash clothing before reuse. Thoroughly clean shoes before reuse.
In case of eye contact	:	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention immediately.
If swallowed	:	If swallowed, DO NOT induce voniting. If vomiting occurs have person lean forward. Call a physician or poison control center immediately. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.
Most important symptoms and effects, both acute and delayed	:	May be harmful if swallowed. Causes serious eye damage. Causes severe burns. Causes digestive tract burns.



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: First Aid respon			
and use the reco when the potent	ders should pay attention to self-protection, ommended personal protective equipment ial for exposure exists (see section 8).		
: Treat symptoma	tically and supportively.		
SURES			
: Water spray Alcohol-resistan Carbon dioxide Dry chemical			
: None known.			
concentrations, a potential dust ex	g dust; fine dust dispersed in air in sufficient and in the presence of an ignition source is a plosion hazard. nbustion products may be a hazard to health.		
: Carbon oxides			
cumstances and Use water spray	ng measures that are appropriate to local cir- d the surrounding environment. v to cool unopened containers. aged containers from fire area if it is safe to do		
	re, wear self-contained breathing apparatus. otective equipment.		
A	Remove undam so. Evacuate area. In the event of fi		

Personal precautions, protec- tive equipment and emer- gency procedures	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	:	Sweep up or vacuum up spillage and collect in suitable container 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 released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.



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CTION 7. HANDLING AND ST	TORAGE
Technical measures	<ul> <li>Static electricity may accumulate and ignite suspended dust causing an explosion.</li> <li>Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.</li> </ul>
Local/Total ventilation	<ul> <li>If sufficient ventilation is unavailable, use with local exhaust ventilation.</li> </ul>
Advice on safe handling	<ul> <li>Do not get on skin or clothing. Do not breathe dust. Do not swallow. Do not get in eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Keep container tightly closed. 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. Take care to prevent spills, waste and minimize release to the environment.</li> </ul>
Hygiene measures	<ul> <li>If exposure to chemical is likely during typical use, provide ey flushing systems and safety showers close to the working place.</li> <li>When using do not eat, drink or smoke.</li> <li>Wash contaminated clothing before re-use.</li> <li>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.</li> </ul>
Conditions for safe storage	<ul> <li>Keep in properly labeled containers.</li> <li>Store locked up.</li> <li>Keep tightly closed.</li> <li>Store in accordance with the particular national regulations.</li> </ul>
Materials to avoid	<ul> <li>Do not store with the following product types:</li> <li>Strong oxidizing agents</li> <li>Self-reactive substances and mixtures</li> <li>Organic peroxides</li> <li>Explosives</li> </ul>

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Doxycycline Hyclate	24390-14-5	TWA	OEL = 100 μg/m3 (OEB 2)	Internal



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	Engineering measures :		:	Use feasible engineering controls to minimize exposure to compound. All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.			
	Persor	nal protective equipr	nent				
	Respiratory protection Filter type		:	<ul> <li>If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside recommended guidelines, use respiratory protection.</li> <li>Particulates type</li> </ul>			
		and protection Material		Chemical-resistar	nt gloves		
	Eye 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.			
	Skin ar	nd body protection	:	Work uniform or I	aboratory coat.		
SEC	TION 9	. PHYSICAL AND CH	IEMI	CAL PROPERTIE	S		
	Appea	rance	:	powder			
	Color		:	light yellow			
	Odor		:	No data available	e		
	Odor T	hreshold	:	No data available	e		
	рН		:	1.5 - 3.5			

ρΠ	. 1.5 - 5.5
Melting point/freezing point	: No data available

- Initial boiling point and boiling : No data available range
- Flash point : Not applicable

2

Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.

Not applicable

Flammability (liquids) : Not applicable

Evaporation rate

- Upper explosion limit / Upper : No data available flammability limit
- Lower explosion limit / Lower : No data available flammability limit



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	Vapor p	pressure	:	Not applicable	
	Relative vapor density		:	Not applicable	
	Relative	e density	:	No data available	9
	Density	,	:	No data available	9
	Solubili Wat	ty(ies) er solubility	:	No data available	9
	Partition octanol	n coefficient: n-	:	Not applicable	
		nition temperature	:	No data available	9
	Decom	position temperature	:	No data available	9
	Viscosi Visc	ty cosity, kinematic	:	Not applicable	
	Explosi	ve properties	:	Not explosive	
		ng properties	:		r mixture is not classified as oxidizing.
		lar weight	:	No data available	
	Particle	size	:	No data available	9

### SECTION 10. STABILITY AND REACTIVITY

Reactivity Chemical stability Possibility of hazardous reac- tions		Not classified as a reactivity hazard. Stable under normal conditions. May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid Incompatible materials	:	Avoid dust formation. Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

### SECTION 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

Inhalation Skin contact Ingestion Eye contact

#### Acute toxicity

May be harmful if swallowed.



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Produ	ict:			
	oral toxicity	:	Acute toxicity est Method: Calculat	imate: 4,000 mg/kg ion method
Comp	onents:			
Doxyo	cycline Hyclate:			
Acute	oral toxicity	:	LD50 (Rat): 2,00	) mg/kg
			LD50 (Mouse): 1	870 mg/kg
			LD50 (Dog): 500	mg/kg
	toxicity (other routes of istration)	:	LD50 (Rat): 222 Application Route	
	corrosion/irritation			
<u>Comp</u>	onents:			
<b>Doxyo</b> Rema	<b>cycline Hyclate:</b> rks	:	No data available May irritate skin.	
	u <b>s eye damage/eye irri</b> es serious eye damage.	tati	on	
<u>Comp</u>	onents:			
Doxyo	cycline Hyclate:			
Rema	rks	:	No data available May irritate eyes.	
Respi	ratory or skin sensitiz	atio	n	
	sensitization assified based on availa	ble	information.	
•	ratory sensitization assified based on availa	ble	information.	
<u>Comp</u>	onents:			
<b>Doxyc</b> Rema	<b>cycline Hyclate:</b> rks	:		ization by skin contact. ization of susceptible persons by skir

Not classified based on available information.



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Com	ponents:		
Doxy	cycline Hyclate:		
Geno	toxicity in vitro	Test system: C Result: Weakly	romosome aberration test in vitro Chinese hamster cells v positive ed on data from similar materials
		Test system: C Result: negativ	ritro mammalian cell gene mutation test Chinese hamster cells re ed on data from similar materials
Geno	toxicity in vivo	Species: Mous Application Ro Result: negativ	ute: Oral

#### Carcinogenicity

Not classified based on available information.

#### Components:

#### **Doxycycline Hyclate:**

Species	: Rat
Application Route	: Oral
Exposure time	: 2 Years
	: 200 mg/kg body weight
Symptoms	: females
Target Organs	: Uterus (including cervix)
Remarks	: Benign tumor(s)

### Reproductive toxicity

Not classified based on available information.

### Components:

#### Doxycycline Hyclate:

Effects on fetal development	<ul> <li>Test Type: Fertility/early embryonic development</li> <li>Species: Rat, females</li> <li>Application Route: Oral</li> <li>General Toxicity Maternal: NOAEL: 250 mg/kg body weight</li> <li>Result: No adverse effects.</li> </ul>
	Test Type: Fertility/early embryonic development Species: Rat, male Application Route: Oral General Toxicity Maternal: NOAEL: 50 mg/kg body weight Symptoms: male reproductive effects
	Remarks: Fertility and developmental toxicity tests did not reveal any effect on reproduction.



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	<b>F-single exposure</b> lassified based on ava	ailable	information.				
	STOT-repeated exposure Not classified based on available information. Repeated dose toxicity						
Repe							
Com	Components:						
Spec NOAI Appli Expo		:	Rat 25 mg/kg Oral 28 d Thyroid effects				
-	ration toxicity lassified based on ava	ailable	information.				
Expe	rience with human e	xpos	ure				
Com	ponents:						
-	rcycline Hyclate: eral Information	:	May cause Target Organs:	Teeth trointestinal disturbance			
Skin	contact	:		ause photosensitization.			
Furth	ner information						
Com	ponents:						
Doxy	cycline Hyclate:						
Rema	arks	:	Well tolerated in	clinical use			
	12. ECOLOGICAL IN	IFOR	MATION				

Components:	
<b>Doxycycline Hyclate:</b> Toxicity to algae/aquatic plants	: EC10 (Anabaena flos-aquae): 0.251 mg/l End point: Growth rate Exposure time: 72 h
Ecotoxicology Assessment	

Acute aquatic toxicity	:	Very toxic to aquatic life.
Chronic aquatic toxicity	:	Toxic to aquatic life with long lasting effects.



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No da	istence and degrada ata available ccumulative potentia	-		
Com	ponents:			
Partit	rcycline Hyclate: ion coefficient: n- iol/water	: log Pow: 0.02		
	<b>lity in soil</b> ata available			
• • • • •	<b>r adverse effects</b> ata available			
SECTION	13. DISPOSAL CON	SIDERATIONS		
Disp	osal methods			

: Do not dispose of waste into sewer.
Dispose of in accordance with local regulations.
: Empty containers should be taken to an approved waste
handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

#### SECTION 14. TRANSPORT INFORMATION

### International Regulations

UN number:UN 3077Proper shipping name:ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Doxycycline Hyclate)Class:9Packing group:IIILabels:9Environmentally hazardous:yesIATA-DGRUN 3077VN/ID No.:UN 3077Proper shipping name:invironmentally hazardous substance, solid, n.o.s. (Doxycycline Hyclate)Class:9Packing group:IIILabels:9Packing instruction (cargo aircraft):Packing instruction (passen- ger aircraft):956IMDG-Code:yesIMDG-Code:UN 3077Un number::Componentally hazardous:::<	UNRTDG		
N.O.S. (Doxycycline Hyclate)Class:9Packing group:Labels:9Environmentally hazardous:VIN/ID No.:Yroper shipping name:Class:9Packing group:UN/ID No.:VIN/ID No.:Proper shipping name:Class:9Packing group:IIILabels:9Packing instruction (cargo:956aircraft)Packing instruction (passen- ger aircraft):Packing instruction (passen- ger aircraft):956IMDG-CodeUN number:UN number:	UN number	:	UN 3077
Class:9Packing group:IIILabels:9Environmentally hazardous:yesIATA-DGRUN/ID No.:UN 3077Proper shipping name:Environmentally hazardous substance, solid, n.o.s. (Doxycycline Hyclate)Class:9Packing group:IIILabels:9Packing group:IIILabels:956aircraft):956Packing instruction (passen- ger aircraft):Packing instruction (passen- ger aircraft):yesIMDG-Code:UN 3077	Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
Class:9Packing group:IIILabels:9Environmentally hazardous:yesIATA-DGRUN/ID No.:UN 3077Proper shipping name:Environmentally hazardous substance, solid, n.o.s. (Doxycycline Hyclate)Class:9Packing group:IIILabels:9Packing instruction (cargo aircraft):Packing instruction (passen- ger aircraft):956IMDG-Code:yesUN number:UN 3077			N.O.S.
Packing group : III Labels : 9 Environmentally hazardous : yes IATA-DGR UN/ID No. : UN 3077 Proper shipping name : Environmentally hazardous substance, solid, n.o.s. (Doxycycline Hyclate) Class : 9 Packing group : III Labels : Miscellaneous Packing instruction (cargo : 956 aircraft) Packing instruction (passen- : 956 ger aircraft) Environmentally hazardous : yes IMDG-Code UN number : UN 3077			(Doxycycline Hyclate)
Labels:9Environmentally hazardous:yesIATA-DGR	Class	:	9
Labels:9Environmentally hazardous:yesIATA-DGRUN 3077VN/ID No.:UN 3077Proper shipping name:Environmentally hazardous substance, solid, n.o.s. (Doxycycline Hyclate)Class:9Packing group:IIILabels:MiscellaneousPacking instruction (cargo aircraft):956Packing instruction (passen- ger aircraft):956IMDG-Code:yesUN number:UN 3077	Packing group	:	III
IATA-DGRUN 3077VN/ID No.:UN 3077Proper shipping name:Environmentally hazardous substance, solid, n.o.s. (Doxycycline Hyclate)Class:9Packing group:IIILabels:MiscellaneousPacking instruction (cargo:956aircraft):956Packing instruction (passen-:Packing instruction (passen-:ger aircraft):Packing instruction (passen-:UN number:UN number:		:	9
UN/ID No.:UN 3077Proper shipping name:Environmentally hazardous substance, solid, n.o.s. (Doxycycline Hyclate)Class:9Packing group:IIILabels:MiscellaneousPacking instruction (cargo:956aircraft):956Packing instruction (passen- ger aircraft):956IMDG-Code:yesUN number:UN 3077	Environmentally hazardous	:	yes
Proper shipping name:Environmentally hazardous substance, solid, n.o.s. (Doxycycline Hyclate)Class:9Packing group:IIILabels:MiscellaneousPacking instruction (cargo:956aircraft):956ger aircraft):956Environmentally hazardous:956ger aircraft):yesIMDG-Code:yesUN number:UN 3077	IATA-DGR		
Class:9Packing group:IIILabels:MiscellaneousPacking instruction (cargo:956aircraft):956ger aircraft):956Environmentally hazardous:yesIMDG-Code:UN 3077	UN/ID No.	:	UN 3077
Packing group:IIILabels:MiscellaneousPacking instruction (cargo:956aircraft):956Packing instruction (passen- ger aircraft):956Environmentally hazardous:yesIMDG-Code:UN 3077	Proper shipping name	:	•
Labels:MiscellaneousPacking instruction (cargo:956aircraft)	Class	:	9
Packing instruction (cargo       :       956         aircraft)       .       956         Packing instruction (passen-       :       956         ger aircraft)       .       .         Environmentally hazardous       :       yes         IMDG-Code       .       .         UN number       :       UN 3077	Packing group	:	III
aircraft) Packing instruction (passen- : 956 ger aircraft) Environmentally hazardous : yes IMDG-Code UN number : UN 3077	Labels	:	Miscellaneous
Packing instruction (passen-       :       956         ger aircraft)       :       yes         IMDG-Code       .       .         UN number       :       UN 3077		:	956
Environmentally hazardous : yes IMDG-Code UN number : UN 3077		:	956
UN number : UN 3077		:	yes
	IMDG-Code		
	UN number	:	UN 3077
Proper snipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,	Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,



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Labels EmS C Marine	code pollutant	N.O.S. (Doxycycline Hy : 9 : III : 9 : F-A, S-F : yes	/clate) RPOL 73/78 and the IBC Code		
	plicable for product as				
Domes	Domestic regulation				
UN nu Proper Class Packin	g group	N.O.S. (Doxycycline H : 9 : III	TALLY HAZARDOUS SUBSTANCE, SOLID, yclate)		
Labels <b>Speci</b> a	al precautions for use	: 9 er			
-	-				

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.

#### **SECTION 15. REGULATORY INFORMATION**

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

Federal Law for the control of chemical precursors, : Not applicable essential chemical products and machinery for producing capsules, tablets and pills.

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

#### SECTION 16. OTHER INFORMATION

Revision Date	:	30.09.2023
Date format	:	dd.mm.yyyy

#### Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for



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Standardisation; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response Guide; 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration: NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

Sources of key data used to compile the Material Safety Data Sheet

:

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8