

according to the Hazardous Products Regulations

Buparvaquone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
4.8	09/30/2023	2091185-00014	Date of first issue: 10/17/2017

SECTION 1. IDENTIFICATION

Product name	:	Buparvaquone Formulation
Other means of identification	:	No data available

Manufacturer or supplier's details

Company name of supplier	:	Merck & Co., Inc
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@merck.com

Recommended use of the chemical and restrictions on use

Recommended use	:	Veterinary product
Restrictions on use	:	Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations

Skin irritation	:	Category 2
Eye irritation	:	Category 2A
Reproductive toxicity	:	Category 1B
Specific target organ toxicity - single exposure	:	Category 3
GHS label elements		
Hazard pictograms	:	
Signal Word	:	Danger
Hazard Statements	:	H315 Causes skin irritation. H319 Causes serious eye irritation. H335 May cause respiratory irritation. H360D May damage the unborn child.
Precautionary Statements	:	 Prevention: P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P261 Avoid breathing mist or vapors. P264 Wash skin thoroughly after handling. P271 Use only outdoors or in a well-ventilated area.

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		P280 Wear pro and face protec	tective gloves, protective clothing, eye protection ction.
		P304 + P340 + and keep comfo unwell. P305 + P351 + for several minu to do. Continue P308 + P313 IF P332 + P313 If P337 + P313 If	F ON SKIN: Wash with plenty of water. P312 IF INHALED: Remove person to fresh air ortable for breathing. Call a doctor if you feel P338 IF IN EYES: Rinse cautiously with water utes. Remove contact lenses, if present and easy rinsing. F exposed or concerned: Get medical attention. skin irritation occurs: Get medical attention. eye irritation persists: Get medical attention. ake off contaminated clothing and wash it before
		Storage: P405 Store lock	ked up.
		Disposal: P501 Dispose o disposal plant.	of contents and container to an approved waste

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

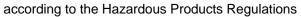
Component	S
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Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
		872-50-4	>= 30 - < 60 *
Coconut Oil	Cococ nucifera (coconut) oil	8001-31-8	>= 30 - < 60 *
Buparvaquone	No data availa- ble	88426-33-9	>= 5 - < 10 *

Actual concentration or concentration range is withheld as a trade secret

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. Get medical attention.
In case of skin contact	:	In case of contact, immediately flush skin with plenty of water





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		and shoes. Get medical att Wash clothing l				
In case of eye contact		: In case of conta for at least 15 r If easy to do, re	 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. 			
If swallowed		Get medical att	 If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water. 			
	important symptoms iffects, both acute and red	 Causes skin irritation. Causes serious eye irritation. May cause respiratory irritation. May damage the unborn child. 				
	ction of first-aiders s to physician	: First Aid respon and use the rec when the poter	nders should pay attention to self-protection, commended personal protective equipment atial for exposure exists (see section 8). atically and supportively.			

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion prod- ucts	:	Carbon oxides Nitrogen oxides (NOx)
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.
Special protective equipment for fire-fighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

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. Prevent spreading over a wide area (e.g., by containment or oil barriers). Retain and dispose of contaminated wash water.



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		Local authorities cannot be contai	should be advised if significant spillages ned.
	nods and materials for ainment and cleaning up	For large spills, p containment to k can be pumped, container. Clean up remain absorbent. Local or national disposal of this n employed in the determine which Sections 13 and	rt absorbent material. provide diking or other appropriate eep material from spreading. If diked material store recovered material in appropriate ing materials from spill with suitable regulations may apply to releases and naterial, as well as those materials and items cleanup of releases. You will need to regulations are applicable. 15 of this SDS provide information regarding ational requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures	:	See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation	:	If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling	:	Do not get on skin or clothing. Avoid breathing mist or vapors. 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. Already sensitized individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitizers. Take care to prevent spills, waste and minimize release to the environment.
Conditions for safe storage	:	Keep in properly labeled containers. Store locked up. Keep tightly closed. Keep in a cool, well-ventilated place. Store in accordance with the particular national regulations.
Materials to avoid	:	Do not store with the following product types: Strong oxidizing agents Self-reactive substances and mixtures Organic peroxides Explosives Gases



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SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of	Control parame- ters / Permissible	Basis
		exposure)	concentration	
N-Methyl-2-pyrrolidone	872-50-4	TWA	400 mg/m ³	CA ON OEL
Coconut Oil	8001-31-8	TWAEV	10 mg/m ³	CA QC OEL
		(Mist)		
Buparvaquone	88426-33-9	TWA	40 µg/m3 (OEB 3)	Internal
		Wipe limit	400 µg/100 cm ²	Internal

Biological occupational exposure limits

Components	CAS-No.	Control parameters	Biological specimen	Sam- pling time	Permissible concentra- tion	Basis
N-Methyl-2-pyrrolidone	872-50-4	5-Hydroxy- N-methyl-2- pyrrolidone	Urine	End of shift (As soon as possible after exposure ceases)	100 mg/l	ACGIH BEI
Engineering measures	tec les All des pro Co are the cor	e appropriate e hnologies to co s quick connect engineering co sign and opera- tect products, ntainment tech required to co compound to ntainment devi nimize open ha	ontrol airborn ctions). ontrols shoul ted in accord workers, and nologies sub ontrol at sour uncontrollec ces).	he concentr d be impler dance with d the enviro table for co rce and to p	ations (e.g., d nented by faci GMP principle nment. ntrolling comp revent migrati	lity s to oounds
Personal protective equ	ipment					
Respiratory protection Filter type Hand protection	exp rec	dequate local posure assess ommended gu mbined particu	ment demon iidelines, use	strates expe	osures outside / protection.	e the
Material	: Ch	emical-resista	nt gloves			
Remarks Eye protection	: We If th mis We pot	nsider double ar safety glass ne work enviro sts or aerosols ar a faceshiele ential for direc osols.	ses with side nment or act , wear the ap d or other ful	tivity involve opropriate g I face prote	es dusty condi oggles. ction if there is	sa



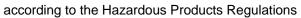
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Skin a	and body protection	task being perf disposable suit Use appropriate contaminated c	garments should be used based upon the brmed (e.g., sleevelets, apron, gauntlets, s) to avoid exposed skin surfaces. e degowning techniques to remove potentially lothing.
Hygie	ne measures	eye flushing sy working place. When using do Wash contamir The effective of engineering con appropriate deg	chemical is likely during typical use, provide stems and safety showers close to the not eat, drink or smoke. hated clothing before re-use. beration of a facility should include review of htrols, proper personal protective equipment, gowning and decontamination procedures, ne monitoring, medical surveillance and the rative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Color	:	clear, red
Odor	:	No data available
Odor Threshold	:	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
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	1 (20 °C)





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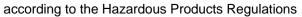
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Densi	ty	: No data availa	able	
	ility(ies) ater solubility	: No data availa	able	
	on coefficient: n- ol/water	: Not applicable		
	gnition temperature	: No data availa	able	
Deco	mposition temperature	: No data availa	able	
Visco Vis	sity scosity, kinematic	: No data availa	able	
Explo	sive properties	: Not explosive		
Oxidiz	zing properties	: The substance	e or mixture is not classified as oxidizing.	
Partic	le size	: Not applicable		

SECTION 10. STABILITY AND REACTIVITY

Reactivity Chemical stability Possibility of hazardous reac- tions	:	Not classified as a reactivity hazard. Stable under normal conditions. Can react with strong oxidizing agents.
Conditions to avoid Incompatible materials Hazardous decomposition products	::	None known. Oxidizing agents No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of Inhalation Skin contact Ingestion Eye contact	e	xposure
Acute toxicity Not classified based on available	i	nformation.
Product: Acute oral toxicity :		Acute toxicity estimate: > 2,000 mg/kg Method: Calculation method
Components:		
N-Methyl-2-pyrrolidone: Acute oral toxicity :		LD50 (Rat): 4,150 mg/kg





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	Acute in	halation toxicity	:	LC50 (Rat): > 5.1 Exposure time: 4 I Test atmosphere: Method: OECD Te	h dust/mist
	Acute de	ermal toxicity	:	LD50 (Rat): > 5,00	00 mg/kg
	Coconu	ıt Oil:			
	Acute or	ral toxicity	:	LD50 (Rat): > 5,00	00 mg/kg
	Acute de	ermal toxicity	:	LD50 (Guinea pig) Remarks: Based c): > 3,000 mg/kg on data from similar materials
	Buparva	aquone:			
	Acute or	ral toxicity	:	LD50 (Rat): > 8,00	00 mg/kg
				LD50 (Mouse): > 5 Remarks: No mort	50 mg/kg tality observed at this dose.
	Acute to administ	oxicity (other routes of tration)	:	LD50: 2.5 mg/kg Application Route:	: Intravenous
		rrosion/irritation skin irritation.			
	Compo	nents:			
	N-Methy	yl-2-pyrrolidone:			
	Result		:	Skin irritation	
	Coconu	ıt Oil:			
	Species		:	Rabbit	
	Result		:	No skin irritation	
	Buparva	aquone:			
	Species Result		:	Mouse Mild skin irritation	
		eye damage/eye irri	tati	on	
		serious eye irritation.			
	Compo				
	-	yl-2-pyrrolidone:		Dabbit	
	Species Result		:	Rabbit Irritation to eyes, r	eversing within 21 days



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Сосо	onut Oil:		
Speci	ies	: Rabbit	
Resu		: No eye irritation	
Bupa	rvaquone:		
Resu	lt	: Mild eye irritation	
Resp	iratory or skin sens	tization	
Skin	sensitization		
Not c	lassified based on av	ailable information.	
•	iratory sensitization		
Not c	lassified based on av	ailable information.	
<u>Com</u>	ponents:		
	thyl-2-pyrrolidone:		
Test		: Local lymph node assay (LLNA)	
Speci	es of exposure	: Skin contact : Mouse	
Metho		: OECD Test Guideline 429	
Resu		: negative	
Rema		: Based on data from similar materials	
Coco	onut Oil:		
Test		: Maximization Test	
	es of exposure	: Skin contact	
Speci		: Guinea pig	
Resu	It	: negative	
	cell mutagenicity		
	lassified based on av	allable information.	
	ponents:		
	thyl-2-pyrrolidone:	Toot Type: Doctorial reverse revisition access (AMES	•
Geno	toxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES Method: OECD Test Guideline 471 Result: negative)
		Test Type: In vitro mammalian cell gene mutation te	est
		Method: OECD Test Guideline 476 Result: negative	
		Test Type: DNA damage and repair, unscheduled E thesis in mammalian cells (in vitro) Result: negative	DNA sy
	toxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus te	et (in v



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				Application Route Method: OECD T Result: negative	
					: Ingestion
	Cocon	ut Oil:			
		oxicity in vitro	:	Test Type: Bacter Result: negative	ial reverse mutation assay (AMES)
		ogenicity ssified based on availa	ble	information.	
	Compo	onents:			
	N-Meth	nyl-2-pyrrolidone:			
		s ation Route ure time	:	Rat Ingestion 2 Years negative	
		s ation Route ure time	:	Rat inhalation (vapor) 2 Years negative	
	-	ductive toxicity amage the unborn child			
	Compo	onents:			
	N-Meth	yl-2-pyrrolidone:			
	Effects	on fertility	:	Test Type: Two-g Species: Rat Application Route Method: OECD T Result: negative	
	Effects	on fetal development	:	Test Type: Embry Species: Rat Application Route Method: OECD To Result: positive	
				Species: Rat	y/early embryonic development : inhalation (vapor)
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				Test Type: Embry Species: Rabbit Application Route Result: positive	vo-fetal development e: Ingestion			
	Reproductive toxicity - As- sessment STOT-single exposure May cause respiratory irritatio <u>Components:</u>		:	Clear evidence of animal experimer	f adverse effects on development, based on hts.			
			on.					
		t hyl-2-pyrrolidone: sment	:	May cause respir	atory irritation.			
		STOT-repeated exposure Not classified based on available information.						
	Repeated dose toxicity							
	Comp	Components:						
	N-Methyl-2-pyrrolidone: Species NOAEL LOAEL Application Route Exposure time Method		:	Rat, male 169 mg/kg 433 mg/kg Ingestion 90 Days OECD Test Guide	eline 408			
	Species NOAEL LOAEL Application Route Exposure time Method Species NOAEL LOAEL Application Route Exposure time		:	Rat 0.5 mg/l 1 mg/l inhalation (dust/m 96 Days OECD Test Guide				
			:	Rabbit 826 mg/kg 1,653 mg/kg Skin contact 20 Days				
	Specie NOAE Applic	L ation Route sure time rks	:	Cat 10 mg/kg Intramuscular 5 d No significant adv 5 mg/kg	verse effects were reported			



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	ication Route osure time arks	:	Intravenous 4 d No significant adv	verse effects were reported			
NOA Appl Expo	Species NOAEL Application Route Exposure time Remarks		 Mouse 50 mg/kg Oral 6 d No significant adverse effects were reported 				
-	ration toxicity classified based on availa	able	information.				
Expe	erience with human exp	osi	ire				
Com	ponents:						
	ethyl-2-pyrrolidone:						
Skin	contact	:	Symptoms: Skin i	rritation			
SECTION	I 12. ECOLOGICAL INFO	ORI	MATION				
Ecot	oxicity						
Com	ponents:						
	ethyl-2-pyrrolidone: city to fish	:	LC50 (Oncorhync Exposure time: 96	hus mykiss (rainbow trout)): > 500 mg/l ວິ h			
	city to daphnia and other tic invertebrates	:	EC50 (Daphnia m Exposure time: 24 Method: DIN 384				
Toxic plant	city to algae/aquatic s	:	ErC50 (Desmode Exposure time: 72	smus subspicatus (green algae)): 600.5 mg/l 2 h			
			EC10 (Desmodes Exposure time: 72	mus subspicatus (green algae)): 92.6 mg/l 2 h			
aqua	city to daphnia and other tic invertebrates (Chron- kicity)		NOEC (Daphnia r Exposure time: 21 Method: OECD T				
Toxid	city to microorganisms	:	EC50: > 600 mg/l Exposure time: 30 Method: ISO 8192) min			
Bup	arvaquone:						
-	city to fish	:	LC50 (Brachydan Exposure time: 96 Method: OECD T				



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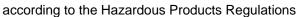
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		to daphnia and other invertebrates	:	EC50 (Daphnia m Exposure time: 48 Method: OECD Te	
	Persist	ence and degradabili	ity		
	<u>Compo</u>	nents:			
		yl-2-pyrrolidone: adability	:	Result: Readily bio Biodegradation: 7 Exposure time: 28 Method: OECD Te	73 %
	Bioacc	umulative potential			
	<u>Compo</u>	nents:			
		yl-2-pyrrolidone: n coefficient: n- /water	:	log Pow: -0.46 Method: OECD Te	est Guideline 107
	Buparv	aquone:			
	-	n coefficient: n-	:	log Pow: 6.5	
	Mobility	y in soil			
	No data	available			
	Other a	dverse effects			
	No data	available			

Disposal methods	
Waste from residues	: Do not dispose of waste into sewer. Dispose of in accordance with local regulations.
Contaminated packaging	 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

: UN 3082
: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Buparvaquone)
: 9
: III





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_	abels Inviron	mentally hazardous	:	9 yes	
U	ATA-D JN/ID I Proper	-	:	UN 3082 Environmentally h (Buparvaquone)	nazardous substance, liquid, n.o.s.
P Li P ai	abels Packing ircraft)	g group g instruction (cargo g instruction (passen-	:	9 III Miscellaneous 964 964	
g	er airc		:	yes	
U	MDG-0 JN nun Proper		:	N.O.S.	ALLY HAZARDOUS SUBSTANCE, LIQUID,
P Li E	abels mS C	g group ode pollutant	::	(Buparvaquone) 9 III 9 F-A, S-F yes	
	-	ort in bulk according	-		OL 73/78 and the IBC Code
D	omes	tic regulation	-		

TDG		
UN number	:	UN 3082
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Buparvaquone)
Class	:	9
Packing group	:	III
Labels	:	9
ERG Code	:	171
Marine pollutant	:	yes(Buparvaquone)

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.

SECTION 15. REGULATORY INFORMATION

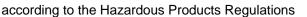
The ingredients of this product are reported in the following inventories:

AICS	:	not determined

:

DSL

not determined





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IECSC		: not determined				
SECTION 16. OTHER INFORMATION						

Full text of other abbreviations

ACGIH BEI	:	ACGIH - Biological Exposure Indices (BEI)
CA ON OEL	:	
		the Occupational Health and Safety Act.
CA QC OEL	:	Québec. Regulation respecting occupational health and safe-
		ty, Schedule 1, Part 1: Permissible exposure values for air-
		borne contaminants
CA ON OEL / TWA	:	Time-Weighted Average Limit (TWA)
CA QC OEL / TWAEV	:	Time-weighted average exposure value

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 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/



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