

Asenapine Formulation

Version 1.10	Revision Date: 2020/10/10		S Number:)792-00011	Date of last issue: 2020/03/23 Date of first issue: 2016/05/19	
1. PROD	UCT AND COMPANY IDE	ENT	IFICATION		
Proc	duct name	:	Asenapine Form	ulation	
Man	ufacturer or supplier's d	letai	ils		
Com	npany	:	Organon & Co.		
Addı	ress	:	JL Raya Pandaa Pandaan, Jawa	n KM. 48 Timur - Indonesia	
Tele	phone	:	551-430-6000		
Eme	ergency telephone number	:	215-631-6999		
E-ma	ail address	:	EHSSTEWARD@organon.com		
Rec	ommended use of the ch	nem	ical and restriction	ons on use	
Reco	ommended use	:	Pharmaceutical		
2. HAZA	RDS IDENTIFICATION				
GHS	S Classification				
Acut	te toxicity (Oral)	:	Category 3		
Acut	Acute toxicity (Inhalation)		Category 4		
Rep	Reproductive toxicity		Category 2		
	cific target organ toxicity - le exposure (Oral)	:	Category 1 (Cen	tral nervous system, Cardio-vascular system)	
	cific target organ toxicity - eated exposure (Oral)	:	Category 1 (Cen	tral nervous system)	
Shoi haza	rt-term (acute) aquatic ard	:	Category 1		
Long haza	g-term (chronic) aquatic ard	:	Category 1		

GHS label elements

Hazard pictograms

Signal word

Hazard statements

H301 Toxic if swallowed. H332 Harmful if inhaled. H361fd Suspected of damaging fertility. Suspected of damag-

:

:

:

Danger





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		Cardio-vascul H372 Causes through prolor	n child. damage to organs (Central nervous system, ar system) if swallowed. damage to organs (Central nervous system) nged or repeated exposure if swallowed. cic to aquatic life with long lasting effects.
Preca	autionary statements	P202 Do not h and understoc P260 Do not b P264 Wash sh P270 Do not e P271 Use only P273 Avoid re	vereathe dust. kin thoroughly after handling. eat, drink or smoke when using this product. y outdoors or in a well-ventilated area. elease to the environment. otective gloves/ protective clothing/ eye protec-
		POISON CEN P304 + P340 and keep com doctor if you fe	IF exposed or concerned: Call a POISON tor.
		Storage: P405 Store lo	cked up.
		Disposal:	of contents/ container to an approved waste

Other hazards which do not result in classification

Dust contact with the eyes can lead to mechanical irritation. Contact with dust can cause mechanical irritation or drying of the skin. May form explosive dust-air mixture during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl- 1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole male- ate	85650-56-2	>= 30 -< 60

4. FIRST AID MEASURES

General advice

: In the case of accident or if you feel unwell, seek medical ad-



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			W	e immediately. hen symptoms vice.	persist or in all cases of doubt seek medical			
	lf inhal	ed	lf r If k	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 of Re Ge Wa	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	: Ifi	n eyes, rinse w				
	lf swall	owed	: If s Ca Rii	swallowed, DO all a physician o nse mouth thore	NOT induce vomiting. r poison control centre immediately. pughly with water. ng by mouth to an unconscious person.			
		nportant symptoms ects, both acute and d	: To Ha Su Un Ca ex Co the	xic if swallowed armful if inhaled ispected of dam born child. auses damage t auses damage t posure if swallo ontact with dust e skin.	d. naging fertility. Suspected of damaging the o organs if swallowed. o organs through prolonged or repeated			
		ion of first-aiders	: Fir an wł	st Aid responde d use the recor an the potentia	ers should pay attention to self-protection, nmended personal protective equipment I for exposure exists (see section 8).			
		o physician	: Treat symptomatically and supportively.					
5. FI	REFIG	HTING MEASURES						
	Unsuita	e extinguishing media able extinguishing	Ale Ca Dr	ater spray cohol-resistant f arbon dioxide (C y chemical one known.				
	media Specifie fighting	c hazards during fire-	co po	ncentrations, ar tential dust exp	dust; fine dust dispersed in air in sufficient nd in the presence of an ignition source is a losion hazard. bustion products may be a hazard to health.			
	Hazard ucts	lous combustion prod-		arbon oxides trogen oxides (f	NOx)			
	Specifi ods	c extinguishing meth-	cu Us	mstances and t se 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			





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for fire	al protective equipment efighters		Use personal pro	e, wear self-contained breathing apparatus. tective equipment.	
6. ACCIDE	ENTAL RELEASE MEA	SUF	RES		
Personal precautions, protec- tive equipment and emer- gency procedures		:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal pro- tective equipment recommendations (see section 8).		
Enviro	onmental precautions	:	Retain and dispos	akage or spillage if safe to do so. se of contaminated wash water. should be advised if significant spillages	
	ods and materials for inment and cleaning up	:	tainer for disposa Avoid dispersal of with compressed Dust deposits sho es, as these may leased into the att Local or national posal of this mate employed in the of mine which regula Sections 13 and f	dust in the air (i.e., clearing dust surfaces	
7. HANDL	ING AND STORAGE				
Techr	nical measures	:	causing an explose Provide adequate	nay accumulate and ignite suspended dust sion. precautions, such as electrical grounding nert atmospheres.	
Local	/Total ventilation	:		tion is unavailable, use with local exhaust	
Advic	e on safe handling	:	Do not breathe du Do not swallow. Avoid contact with Avoid prolonged of Wash skin thorou Handle in accorda practice, based of sessment Keep container tig Minimize dust ger Keep container cl Keep away from h Take precautiona Do not eat, drink	n eyes. or repeated contact with skin. ghly after handling. ance with good industrial hygiene and safety n the results of the workplace exposure as-	



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Cond	ditions for safe storage	Store locked u Keep tightly cle	osed.
Mate	rials to avoid	Store in accord	, well-ventilated place. dance with the particular national regulations. ith the following product types:

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
trans-5-Chloro-2,3,3a,12b- tetrahydro-2-methyl-1H- dibenz[2,3:6,7]oxepino[4,5- c]pyrrole maleate	85650-56-2	TWA	1 μg/m3 (OEB 4)	Internal
	Further information: Skin			
		Wipe limit	10 µg/100 cm ²	Internal

Components with workplace control parameters

Engineering measures :	Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., vacuum conveying from a closed system, packout head with inflatable seal from stationary container, ventilated enclosure, etc.). All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Essentially no open handling permitted. Use closed processing systems or containment technologies.
Personal protective equipment	
Respiratory protection :	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection.
Filter type : Hand protection	Particulates type

Material	:	Chemical-resistant gloves
Remarks Eye protection	:	Consider double gloving. 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 and body protection	:	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.



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Hygie	ne measures	contaminated of If exposure to of eye flushing sy ing place. When using do Wash contamin The effective of engineering co appropriate de industrial hygie	te degowning techniques to remove potentially clothing. chemical is likely during typical use, provide estems and safety showers close to the work- o not eat, drink or smoke. nated clothing before re-use. peration of a facility should include review of ntrols, proper personal protective equipment, gowning and decontamination procedures, ene monitoring, medical surveillance and the trative controls.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Colour	:	white to off-white
Odour	:	odourless
Odour 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	:	Not applicable
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, han- dling or other means.
Flammability (liquids)	:	No data available
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	:	No data available



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	:	Not applicable	
	:	No data availat	ble
mposition temperature	:	No data availal	ble
	:	Not applicable	
osive properties	:	Not explosive	
zing properties	:	The substance	or mixture is not classified as oxidizing.
Particle size		No data availal	ble
ILITY AND REACTIVITY	Y		
nical stability	:	Stable under ne May form explo dling or other n	as a reactivity hazard. ormal conditions. osive dust-air mixture during processing, han- neans. strong oxidizing agents.
Conditions to avoid Incompatible materials Hazardous decomposition		Avoid dust forn Oxidizing agen	nation.
	TION	1	
•	f:	Inhalation Skin contact Ingestion Eye contact	
if swallowed.			
<u>uct:</u>			
e oral toxicity	:		stimate: 238.4 mg/kg ation method
e inhalation toxicity		: Acute toxicity estimate: 1.08 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method	
	2020/10/10 tion coefficient: n- hol/water lignition temperature mposition temperature osity scosity, kinematic osive properties zing properties cle size ILITY AND REACTIVITY tivity nical stability ibility of hazardous reac- litions to avoid npatible materials irdous decomposition ucts COLOGICAL INFORMA	2020/10/10690tion coefficient: n- nol/water signition temperature:ignition temperature:omposition temperature:osity scosity, kinematic:osive properties:zing properties:cle size:tivity:nical stability:ibility of hazardous reac-:litions to avoid:mpatible materials:urdous decomposition:cts:COLOGICAL INFORMATIONmation on likely routes of :suree toxicity: if swallowed. oful if inhaled.uct:	2020/10/10690792-00011iion coefficient: n- ool/water lignition temperature:Not applicable ool/water inposition temperatureiin coefficient: n- ool/water lignition temperature:No data availat oold a availatin coefficient: n- oold a availat oold a availat oold a availat oold a availat:in coefficient: n- oold a availat oold a availat oold a availat:in coefficient: n- oold a availat oold a availat:itivity nical stability ibility of hazardous reac- ibility of hazardous reac- oold avoid oold avoid oold avoid oold availat ::ititions to avoid nopatible materials rdous decomposition octs:Heat, flames an Avoid dust form oon hazardous oold :cological inFormation sure:Inhalation Skin contact Ingestion Eye contacte toxicity cif swallowed. iful if inhaled. uct::Inhalation Skin contact Ingestion Eye contact

Components:



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Acute oral toxicity		:	LD50 (Rat): 110 -	178 mg/kg
			LD50 (Dog): > 20 Remarks: No mor	0 mg/kg tality observed at this dose.
Acute	inhalation toxicity	:	LC50 (Rat): 0.5 - Exposure time: 1 Test atmosphere:	h
Acute toxicity (other routes of administration)		:		
-	corrosion/irritation lassified based on availa	ıble	information.	
Com	ponents:			
trans	-5-Chloro-2.3.3a.12b-te	etra	hvdro-2-methvl-1H	l-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole m
leate:			.,	· ····································
Rema	arks	:	No data available	
Rema Serio Not cl	ous eye damage/eye irri lassified based on availa		on	
Rema Serio Not cl <u>Comp</u> trans	ous eye damage/eye irri lassified based on availa ponents: -5-Chloro-2,3,3a,12b-te	ıble	on information.	l-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole m
Rema Serio Not cl <u>Com</u>	ous eye damage/eye irri lassified based on availa ponents: -5-Chloro-2,3,3a,12b-te	ıble	on information.	l-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole m
Rema Serio Not cl <u>Comp</u> trans leate: Rema	ous eye damage/eye irri lassified based on availa ponents: -5-Chloro-2,3,3a,12b-te	ible etra :	information. hydro-2-methyl-1H No data available	I-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole m
Rema Serio Not cl Comp trans leate: Rema Resp Skin	ous eye damage/eye irri lassified based on availa <u>ponents:</u> -5-Chloro-2,3,3a,12b-te : arks	tra : atic	information. hydro-2-methyl-1H No data available	I-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole m
Rema Serio Not cl Comp trans leate: Rema Resp Skin s Not cl	ous eye damage/eye irri lassified based on availa <u>ponents:</u> -5-Chloro-2,3,3a,12b-te arks iratory or skin sensitis sensitisation	tra : atic	information. hydro-2-methyl-1H No data available	I-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole m
Rema Serio Not cl Comp trans leate: Rema Resp Skin : Not cl Resp	ous eye damage/eye irri lassified based on availa <u>ponents:</u> -5-Chloro-2,3,3a,12b-te arks iratory or skin sensitis sensitisation lassified based on availa	ible etra : atic	information. hydro-2-methyl-1H No data available on information.	ŀ-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole m
Rema Serio Not cl Comp trans leate: Rema Resp Skin : Not cl Resp Not cl	ous eye damage/eye irri lassified based on availa ponents: -5-Chloro-2,3,3a,12b-te arks iratory or skin sensitis sensitisation lassified based on availa iratory sensitisation	ible etra : atic	information. hydro-2-methyl-1H No data available on information.	I-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole m
Rema Serio Not cl Comp trans leate: Rema Resp Skin : Not cl Resp Not cl Comp	bus eye damage/eye irri lassified based on availa ponents: -5-Chloro-2,3,3a,12b-te arks iratory or skin sensitis sensitisation lassified based on availa iratory sensitisation lassified based on availa ponents: -5-Chloro-2,3,3a,12b-te	ible tra : atic ible	information. hydro-2-methyl-1H No data available on information. information.	
Rema Serio Not cl Comp trans leate: Rema Resp Skin : Not cl Resp Not cl Comp trans	bus eye damage/eye irri lassified based on availa ponents: -5-Chloro-2,3,3a,12b-te arks iratory or skin sensitis sensitisation lassified based on availa iratory sensitisation lassified based on availa ponents: -5-Chloro-2,3,3a,12b-te ies	atic atic able able	information. hydro-2-methyl-1H No data available on information. information.	I-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole m I-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole m zer.
Rema Serio Not cl Comp trans leate: Rema Resp Skin : Not cl Resp Not cl Comp trans leate: Speci Resul	bus eye damage/eye irri lassified based on availa ponents: -5-Chloro-2,3,3a,12b-te arks iratory or skin sensitis sensitisation lassified based on availa iratory sensitisation lassified based on availa ponents: -5-Chloro-2,3,3a,12b-te ies	atic atic able able	information. hydro-2-methyl-1H No data available on information. information. hydro-2-methyl-1H Guinea pig	1-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole m

Components:



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Geno	toxicity in vitro	Result: negativ	eterial reverse mutation assay (AMES) e use Lymphoma
		Result: negativ	er chromatid exchange assay
			romosomal aberration luman lymphocytes re
Geno	toxicity in vivo	: Test Type: Mic Species: Rat Application Ro Result: negativ	ute: Oral

Carcinogenicity

Not classified based on available information.

Components:

trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole maleate:

Species Application Route Exposure time Result	:	Mouse Subcutaneous 89 - 98 weeks negative
Species Application Route Exposure time Result	:	Rat Subcutaneous 100 - 106 weeks negative

Reproductive toxicity

Suspected of damaging fertility. Suspected of damaging the unborn child.

Components:

Effects on fertility :	Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Oral Fertility: LOAEL: 1.0 mg/kg body weight Symptoms: Reduced maternal body weight gain, Reduced offspring weight gain, Effects on fertility, Effects on F1 off- spring Result: Embryotoxic effects and adverse effects on the off- spring were detected.
Effects on foetal develop- : ment	Test Type: Embryo-foetal development Species: Rabbit



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	Result: Embryote spring were dete teratogenic effect	Foxicity: LOAEL: 30 mg/kg body weight oxic effects and adverse effects on the off- ected only at high maternally toxic doses, No
	Species: Rabbit Application Rout	e: Intravenous injection Foxicity: NOAEL: 0.626 mg/kg body weight
Reproductive toxicity - As- sessment	fertility, based or	of adverse effects on sexual function and n animal experiments., Some evidence of on development, based on animal experi-

STOT - single exposure

Causes damage to organs (Central nervous system, Cardio-vascular system) if swallowed.

Components:

trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole maleate:

Exposure routes	:	Oral
Target Organs	:	Central nervous system, Cardio-vascular system
Assessment	:	Causes damage to organs.

STOT - repeated exposure

Causes damage to organs (Central nervous system) through prolonged or repeated exposure if swallowed.

Components:

trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole maleate:

Exposure routes	: Ing	estion
Target Organs	: Cei	ntral nervous system
Assessment	: Ca	uses damage to organs through prolonged or repeated
	exp	osure.

Repeated dose toxicity

Components:

Species :	Rat
LÔAEL :	0.6 mg/kg
Application Route :	Oral
Exposure time :	52 Weeks
Target Organs :	Central nervous system
Symptoms :	constriction of pupils



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Expo Symp Spec LOAE Applie Expo	EL cation Route sure time otoms ies	: Rat : 0.1 mg/kg : Intravenous : 14 Weeks : constriction c : Rat : 0.5 mg/kg : Subcutaneou : 13 Weeks : Central nervo	
LOAE Applie Expo Targe	Species:LOAEL:Application Route:Exposure time:Target Organs:Symptoms:		ks bus system of pupils, Tremors, Irritability

Aspiration toxicity

Not classified based on available information.

Components:

trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole maleate:

Not applicable

Experience with human exposure

Components:

 trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole maleate:

 Ingestion
 :

 Symptoms: restlessness, Drowsiness, Dizziness, decrease in heart rate, hypotension

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

trans-5-Chloro-2,3,3a,12b-te leate:	tra	hydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole ma-
Toxicity to fish	:	LC50 (Cyprinus carpio (Carp)): 0.53 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): 0.27 mg/l Exposure time: 72 h Method: OECD Test Guideline 201



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			mg/l Exposure time: 7	irchneriella subcapitata (green algae)): 0.08 2 h Fest Guideline 201
M-Fao icity)	ctor (Acute aquatic tox-	:	1	
	ity to fish (Chronic tox-	:	NOEC (Pimepha Exposure time: 2	les promelas (fathead minnow)): 0.04 mg/l 1 d
	ity to daphnia and other ic invertebrates (Chron- icity)	:	Exposure time: 2	magna (Water flea)): 0.00086 mg/l 1 d Fest Guideline 211
	ctor (Chronic aquatic	:	100	
toxicit Toxici	y) ity to microorganisms	:	EC50: 37 mg/l Exposure time: 3 Test Type: Resp Method: OECD 1	
			NOEC: 10 mg/l Exposure time: 3 Test Type: Resp Method: OECD 1	
	stence and degradabili ata available	ty		
Bioad	ccumulative potential			
<u>Com</u>	oonents:			
trans leate:		trał	nydro-2-methyl-1	H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole n
Bioac	cumulation	:	Species: Cyprinu Bioconcentration	is carpio (Carp) factor (BCF): 2,424
	ion coefficient: n- ol/water	:	log Pow: 4.9	
	lity in soil ata available			
	r adverse effects ata available			

Disposal methods		
Waste from residues Contaminated packaging	:	Dispose of in accordance with local regulations. 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.



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14. TRA	NSPORT INFORMATION	1			
Inte	mational Domilations				
Inte	ernational Regulations				
UN	RTDG				
UN number		:	UN 2811		
Proper shipping name		:	TOXIC SOLID, ORGANIC, N.O.S. (trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H- dibenz[2,3:6,7]oxepino[4,5-c]pyrrole maleate)		
Class Packing group Labels		:	6.1		
		:	111		
		:	6.1		
UN/	A-DGR ID No. per shipping name	:		2,3,3a,12b-tetrahydro-2-methyl-1H-	
				epino[4,5-c]pyrrole maleate)	
Clas		:	6.1 III		
	king group	:	Toxic		
Labels Packing instruction (cargo		:	677		
	raft)	•	011		
Pac	king instruction (passen- aircraft)	:	670		
IME)G-Code				
	number	:	UN 2811		
Pro	per shipping name	:		RGANIC, N.O.S. ,3,3a,12b-tetrahydro-2-methyl-1H- epino[4,5-c]pyrrole maleate)	
Cla		:	6.1	-	
	king group	:			
Lab		:	6.1		
	S Code	:	F-A, S-A		
Mai	rine pollutant	:	yes		

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

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.

15. REGULATORY INFORMATION

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





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Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minis- ter of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized Sys- tem of Classification and Labelling of Chemicals.									
Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health									
Haz	ardous substances that	must be registered	: N	lot applicable					
Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Sub- stances									
Haz	ardous substances app	roved for use	: N	lot applicable					
Prof	nibited substances		: N	lot applicable					
Res	tricted substances		: N	lot applicable					
Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials									
	Type of Hazardous Materials Restricted to Import, : Not applicable Distribution and Supervision								
The components of this product are reported in the following inventories: AICS : not determined									
DSL		: not determined							
IEC	SC	: not determined							

16. OTHER INFORMATION

Further information

Sources of key data used to compile the Safety Data Sheet	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen- cy, http://echa.europa.eu/
Date format	:	yyyy/mm/dd

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 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 con-



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centration; 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; 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

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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