

Timolol Formulation

Signal word

Hazard statements

Precautionary statements

Versic 2.12			S Number: 98362-00014	Date of last issue: 04.04.2023 Date of first issue: 01.05.2017
1. PR	ODUCT AND COMPANY IDE	INT	IFICATION	
P	roduct name	:	Timolol Formulat	ion
N	lanufacturer or supplier's d	etai	ls	
C	Company	:	MSD	
А	ddress	:	50 Tuas West Dr Singapore - Sing	
Т	elephone	:	+1-908-740-4000)
E	mergency telephone number	:	65 6697 2111 (24	4/7/365)
E	-mail address	:	EHSDATASTEW	ARD@msd.com
R	ecommended use of the ch	em	ical and restriction	ons on use
-	ecommended use estrictions on use	:	Pharmaceutical Not applicable	
2. HA	ZARDS IDENTIFICATION			
G	HS Classification			
	pecific target organ toxicity - epeated exposure	:	Category 1 (Carc	lio-vascular system, Lungs)
G	HS label elements			
F	lazard pictograms	:		

: Danger

: H372 Causes damage to organs (Cardio-vascular system, Lungs) through prolonged or repeated exposure.

Prevention:
 P260 Do not breathe mist or vapours.
 P264 Wash skin thoroughly after handling.
 P270 Do not eat, drink or smoke when using this product.
 Response:
 P314 Get medical advice/ attention if you feel unwell.
 Disposal:



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P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-	26921-17-5	>= 0.1 -< 1
morpholino-1,2,5-thiadiazole monomaleate		

4. FIRST AID MEASURES

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.
	If inhaled In case of skin contact	:	If inhaled, remove to fresh air. Get medical attention. In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
	In case of eye contact	:	Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.
	If swallowed	:	If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.
	Most important symptoms and effects, both acute and delayed	:	Causes damage to organs through prolonged or repeated exposure.
	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).
	Notes to physician	:	Treat symptomatically and supportively.
. F	IREFIGHTING MEASURES		
	Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical None known.
	media		



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fightii	ific hazards during fire- ng irdous combustion prod-	:	Exposure to com Carbon oxides	bustion products may be a hazard to health.
ucts		•	Metal oxides Phosphorus com	pounds
Spec ods	ific extinguishing meth-	:	cumstances and Use water spray	g measures that are appropriate to local cir- the surrounding environment. to cool unopened containers. ged containers from fire area if it is safe to do
	ial protective equipment efighters	:		e, wear self-contained breathing apparatus. tective equipment.
6. ACCID	ENTAL RELEASE MEAS	SUF	RES	
tive e	onal precautions, protec- equipment and emer- y procedures	:	Follow safe hand	tective equipment. ling advice (see section 7) and personal pro- t recommendations (see section 8).
Envir	onmental precautions	:	Prevent spreadin barriers). Retain and dispo	eakage or spillage if safe to do so. g over a wide area (e.g. by containment or oil se of contaminated wash water. should be advised if significant spillages
	ods and materials for ainment and cleaning up	:	For large spills, p ment to keep may be pumped, store Clean up remaining bent. Local or national posal of this mate employed in the of mine which regul Sections 13 and	t absorbent material. rovide dyking or other appropriate contain- terial from spreading. If dyked material can a recovered material in appropriate container. ng materials from spill with suitable absor- regulations may apply to releases and dis- erial, as well as those materials and items cleanup of releases. You will need to deter- ations are applicable. 15 of this SDS provide information regarding ational requirements.
7. HANDL	ING AND STORAGE			
Loca	nical measures I/Total ventilation ce on safe handling	:	CONTROLS/PEF Use only with add Do not breathe m Do not swallow. Avoid contact wit Avoid prolonged	



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	tions for safe storage ials to avoid	practice, based of sessment Do not eat, drink Take care to pre environment. : Keep in properly Store in accorda	dance with good industrial hygiene and safety on the results of the workplace exposure as- a or smoke when using this product. Event spills, waste and minimize release to the relabelled containers. Ince with the particular national regulations. In the following product types: agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
(S)-3-[3-(tert-butylamino)-2- hydroxypropoxy]-4- morpholino-1,2,5-thiadiazole monomaleate	26921-17-5	TWA	10 µg/m3 (OEB 3)	Internal
	Further information: Eye, Skin			
		Wipe limit	100 µg/100 cm ²	Internal

Engineering measures	Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations.
Personal protective equipment	nt
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	Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous sub- stance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.
Eye protection	Wear the following personal protective equipment: Safety glasses
Skin and body protection	 Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential. Skin contact must be avoided by using impervious protective



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Hygie	ne measures	:	eye flushing syster ing place. When using do not	prons, boots, etc). nical is likely during typical use, provide ns and safety showers close to the work- eat, drink or smoke. d clothing before re-use.
9. PHYSIC	AL AND CHEMICAL P	ROF	ERTIES	
Appea	arance	:	Aqueous solution	
Colou	r	:	Colorless to pale y	vellow
Odou	r	:	No data available	
Odou	r Threshold	:	No data available	
pН		:	No data available	
Meltin	g point/freezing point	:	No data available	
Initial range	boiling point and boiling	:	No data available	
Flash	point	:	No data available	
Evapo	oration rate	:	No data available	
Flamr	nability (solid, gas)	:	Not applicable	
Flamr	nability (liquids)	:	No data available	
	r explosion limit / Upper nability limit	:	No data available	
	r explosion limit / Lower nability limit	:	No data available	
Vapo	ur pressure	:	No data available	
Relati	ve vapour density	:	No data available	
Densi	ty	:	No data available	
	ility(ies) ater solubility	:	soluble	
	on coefficient: n- ol/water	:	No data available	
	gnition temperature	:	No data available	
Decor	mposition temperature	:	No data available	



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Visco Vi	sity scosity, kinematic	: No data ava	ilable
Explosive properties		: Not explosiv	e
Oxidi	zing properties	: The substan	ce or mixture is not classified as oxidizing.
Moleo	cular weight	: Not applicab	le
Partic	cle size	: Not applicab	le

10. STABILITY AND REACTIVITY

-	::	Not classified as a reactivity hazard. Stable under normal conditions. Can react with strong oxidizing agents.
tions Conditions to avoid Incompatible materials Hazardous decomposition products	: :	

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure	:	Inhalation Skin contact
		Ingestion Eye contact

Acute toxicity

Not classified based on available information.

Components:

(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:

Acute oral toxicity :	LD50 (Rat): 1,000 mg/kg
	LD50 (Mouse): 1,140 mg/kg
Acute toxicity (other routes of : administration)	LD50 (Mouse): 300 mg/kg Application Route: Intraperitoneal
	LD50 (Mouse): 800 mg/kg Application Route: Subcutaneous

Skin corrosion/irritation

Not classified based on available information.



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Components:

(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:

Species	:	Rabbit
Method	:	Draize Test
Result	:	No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:

Species Result	-	Rabbit Mild eye irritatior	
Species	:	Dog	

Result : No eye irritation

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Components:

(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 Result: negative
Genotoxicity in vivo	:	Test Type: In vivo micronucleus test Species: Mouse Method: OECD Test Guideline 474 Result: negative

Carcinogenicity

Not classified based on available information.

Components:

(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:

Species	: Rat
Application Route	: Oral
Exposure time	: 2 Years
LOAEL	: 300 mg/kg body weight



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•	ult get Organs harks	: negative : Adrenal gland : The significan	ce of these findings for humans is not certain.
Exp LOA Res Targ	lication Route osure time \EL		
Car mer	cinogenicity - Assess- It	: Weight of evic cinogen	lence does not support classification as a car-
Not	roductive toxicity classified based on avail nponents:	able information.	
		-hydroxypropoxy]-	4-morpholino-1,2,5-thiadiazole monomaleate:
• •	cts on fertility	: Test Type: Fe Species: Rat Application Ro Fertility: NOA	rtility/early embryonic development
Effe mer	cts on foetal develop- It	Species: Rabl Developmenta Result: Some	nbryo-foetal development bit al Toxicity: LOAEL F1: 50 mg/kg body weight evidence of adverse effects on development, nal experiments.
	roductive toxicity - As- sment	: Some evidend animal experi	e of adverse effects on development, based on ments.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Causes damage to organs (Cardio-vascular system, Lungs) through prolonged or repeated exposure.

Product:

exposure.	0 0		Cardio-vascular system, Lungs Causes damage to organs through prolonged or repeated exposure.
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Components:

(S)-3-[3-(tert-butylamino)-2-	-hyd	roxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:
Target Organs Assessment		Lungs, Cardio-vascular system Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:

Species NOAEL Application Route Exposure time	:	Rat 25 mg/kg Oral 67 Weeks
Species NOAEL Application Route Exposure time Target Organs	:	Dog 10 mg/kg Oral 54 Weeks Kidney

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

<u>Produ</u>	ct	<u>:</u>	
-			

General Information	:	May cause Stomach/intestinal disorders Respiratory disorders Symptoms: Irregular cardiac activity, central nervous system
Eye contact	:	effects Symptoms: burning or stinging of the eye

Components:

(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:				
Eye contact	:	Symptoms: burning or stinging of the eye, dryness of the eyes, Headache, Nausea, Dizziness, dry mouth, changes in libido, hair loss, Allergic reactions		
Ingestion	:	Symptoms: Headache, Fatigue, Respiratory disorders, Gas- trointestinal discomfort, Allergic reactions, Rash, hair loss, altered mental status, Dizziness, changes in libido		



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12. ECOL	OGICAL INFORMATIC	N			
Ecoto	oxicity				
Com	ponents:				
	- [3-(tert-butylamino)-2 ity to fish	-hyd :		-morpholino-1,2,5-thiadiazole monomaleate ales promelas (fathead minnow)): 411 mg/l 96 h	
	Toxicity to daphnia and other : aquatic invertebrates		EC50 (Daphnia magna (Water flea)): 161 mg/l Exposure time: 48 h Method: OECD Test Guideline 202		
Toxic	Toxicity to microorganisms :		EC50: > 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition		
			EC50 (Photoba	cterium phosphoreum): > 1,800 mg/l	
Persi	stence and degradabi	ility			
Com	ponents:				
	- [3-(tert-butylamino)-2 egradability	-hyd :			
Stabi	lity in water	:	Hydrolysis: 0 %(61 d) Method: FDA 3.09		
Bioa	ccumulative potential				
Com	ponents:				
Partit	-[3-(tert-butylamino)-2 ion coefficient: n- ol/water	-hyd :		-morpholino-1,2,5-thiadiazole monomaleat	
	lity in soil ata available				
	r adverse effects ata available				
3. DISPC	SAL CONSIDERATIO	NS			
-	o sal methods e from residues	:		of waste into sewer.	



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Contaminat	ed packaging	:	 Empty containers should be taken to an approved was dling site for recycling or disposal. If not otherwise specified: Dispose of as unused produced 	
14. TRANSPOR	T INFORMATION			
Internation	al Regulations			
aircraft)	ping name risk pup ping name risk pup truction (cargo truction (passen-		Not applicable Not applicable	
IMDG-Code UN number Proper ship Class Subsidiary r Packing gro Labels EmS Code Marine pollu	ping name risk pup utant		Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable	
•	i n bulk according ble for product as			OL 73/78 and the IBC Code
	ecautions for use	•	F	

Not applicable

15. REGULATORY INFORMATION

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

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and : Not applicable



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ous S Fire S	Environmental Protection and Management (Hazard- ous Substances) Regulations Fire Safety (Petroleum and Flammable Materials) : Not applicable Regulations					
The components of this product are reported in the following inventories: AICS : not determined						
DSL		:	not determined			
IECS	С	:	not determined			
16. OTHER INFORMATION						
Revis	ion Date	:	30.09.2023			
Sourc	ter information ces of key data used to ile the Safety Data t	:		data, data from raw material SDSs, OECD arch results and European Chemicals Agen- ropa.eu/		

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 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



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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

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.

SG / EN