

Vitamin B Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/07/06
8.1	2024/09/28	292436-00024	Date of first issue: 2015/10/02

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name	:	Vitamin B Formulation
Supplier's company name, a	ddr	ess and phone number
Company name of supplier	:	MSD
Address	:	Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd. Menuma factory
Telephone	:	048-588-8411
E-mail address	:	EHSDATASTEWARD@msd.com
Emergency telephone number	:	+1-908-423-6000

Recommended use of the chemical and restrictions on use

Recommended use	:	Pharmaceutical
Restrictions on use	:	Not applicable

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

Not a hazardous substance or mixture according to the Globally Harmonised System (GHS).

GHS label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

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)	ENCS No.
nicotinamide	98-92-0	>= 1 - < 10	5-736
Pyridoxine hydrochloride	58-56-0	>= 1 - < 10	9-1043 / 1-215
Thiamine hydrochloride	67-03-8	>= 1 - < 10	1-215 / 9-811



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4. FIRST AID MEASURES		
If inhaled	:	If inhaled, remove to fresh air. Get medical attention if symptoms occur.
In case of skin contact	:	Wash with water and soap as a precaution. Get medical attention if symptoms occur.
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 if symptoms occur. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	:	None known.
Protection of first-aiders Notes to physician	:	No special precautions are necessary for first aid responders. Treat symptomatically and supportively.
5. FIREFIGHTING 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) Chlorine compounds Oxides of phosphorus Metal oxides
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 firefighters	:	Wear self-contained breathing apparatus for firefighting if nec- essary. Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- :	Follow safe handling advice (see section 7) and personal pro-
tive equipment and emer-	tective equipment recommendations (see section 8).



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gency	procedures			
Enviro	nmental precautions	:	Prevent spreadin barriers). Retain and dispos	akage or spillage if safe to do so. g over a wide area (e.g. by containment or c se of contaminated wash water. should be advised if significant spillages
Methods and materials for containment and cleaning up		:	For large spills, p ment to keep man be pumped, store Clean up remaini bent. Local or national posal of this mate employed in the o mine which regula Sections 13 and	t absorbent material. rovide dyking or other appropriate contain- terial from spreading. If dyked material can a recovered material in appropriate containe 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.

Handling		
Technical measures	:	See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation	:	Use only with adequate ventilation.
Advice on safe handling	:	Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as- sessment
		Take care to prevent spills, waste and minimize release to the environment.
Avoidance of contact	:	Oxidizing agents
Hygiene measures	:	flushing systems and safety showers close to the working place.
		When using do not eat, drink or smoke.
		Wash contaminated clothing before re-use.
Storage		
Conditions for safe storage	:	Keep in properly labelled containers. Store in accordance with the particular national regulations.
Materials to avoid	:	Do not store with the following product types: Strong oxidizing agents
Packaging material	:	Unsuitable material: None known.



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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Concentra- tion standard / Permissible con- centration	Basis
Pyridoxine hydrochloride	58-56-0	TWA	OEB 3 (>= 10 < 100 µg/m3)	Internal
Thiamine hydrochloride	67-03-8	TWA	OEB 1 (>= 1000 μg/m3)	Internal

Engineering measures		dequate ventilation, especially in confined areas. workplace exposure concentrations.
Personal protective equipm	t	
Respiratory protection	sure asso	te local exhaust ventilation is not available or expo- essment demonstrates exposures outside the rec- ed guidelines, use respiratory protection.
Filter type Hand protection	Particula	res type
Remarks		nds before breaks and at the end of workday.
Eye protection	Wear the Safety gl	following personal protective equipment: asses
Skin and body protection	Skin sho	uld be washed after contact.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	:	liquid
Colour	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Boiling point, initial boiling point and boiling range	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Lower explosion limit and upper Upper explosion limit / Up- per flammability limit		xplosion limit / flammability limit No data available



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	ower explosion limit / ower flammability limit	:	No data availabl	e	
Flash	point	:	No data availabl	e	
Deco	mposition temperature	:	No data availabl	e	
pН		:	No data availabl	e	
Evap	oration rate	:	No data availabl	e	
Auto-	ignition temperature	:	No data availabl	e	
Visco Vi	sity scosity, dynamic	:	No data availabl	e	
Vi	scosity, kinematic	:	No data availabl	e	
	pility(ies) ater solubility	:	No data availabl	e	
	ion coefficient: n- ol/water	:	No data availabl	e	
Vapo	ur pressure	:	No data availabl	e	
	ity and / or relative dens elative density	ity :	No data availabl	e	
De	ensity	:	No data availabl	e	
Relat	ive vapour density	:	No data availabl	e	
Explo	osive properties	:	Not explosive		
Oxidi	zing properties	:	The substance c	or mixture is not classified as oxidizing.	
Moleo	cular weight	:	No data availabl	e	
	cle characteristics article size	:	No data availabl	e	

10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reac-	:	Can react with strong oxidizing agents.
tions		
Conditions to avoid	:	None known.



ersion 1	Revision Date: 2024/09/28		0S Number: 2436-00024	Date of last issue: 2024/07/06 Date of first issue: 2015/10/02
	npatible materials rdous decomposition cts	:	Oxidizing age No hazardous	nts decomposition products are known.
. TOXIC	OLOGICAL INFORMAT		N	
Inforn expos	nation on likely routes of sure	:	Inhalation Skin contact Ingestion Eye contact	
	e toxicity assified based on availa	ble	information.	
<u>Comp</u>	oonents:			
nicot	inamide:			
Acute	oral toxicity	:		2,500 mg/kg) Test Guideline 423 'he substance or mixture has no acute oral to:
Acute	inhalation toxicity	:	Assessment: T tion toxicity	: 4 h
Acute	dermal toxicity	:	Method: OECE	> 2,000 mg/kg) Test Guideline 402 The substance or mixture has no acute derma
Pyrid	oxine hydrochloride:			
Acute	oral toxicity	:	LD50 (Rat): 4,0	000 mg/kg
Thian	nine hydrochloride:			
	oral toxicity	:	LD50 (Rat): 3,7 Target Organs	710 mg/kg : Central nervous system, Lungs
			LD50 (Mouse):	8,224 mg/kg
-	corrosion/irritation assified based on availa	ble	information.	
Comr	oonents:			



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Specie		: Rabbit	
Metho Result		: OECD Tes : No skin irrit	t Guideline 404 tation
Pyrido	oxine hydrochloride	; :	
Specie Result		: Rabbit : No skin irrit	ation
	is eye damage/eye		
	assified based on ava onents:	ailable information.	
nicoti	namide:		
Specie		: Rabbit	
Result Metho			eyes, reversing within 7 days t Guideline 405
Metho	u	. OLOD 163	
-	oxine hydrochloride	: Rabbit	
Specie Result		: No eye irrit	ation
Respi	ratory or skin sens	itisation	
Skin s	ratory or skin sens ensitisation assified based on ava		
Skin s Not cla	ensitisation	ailable information.	
Skin s Not cla Respi	ensitisation assified based on av	ailable information.	
Skin s Not cla Respi Not cla	ensitisation assified based on ava ratory sensitisation	ailable information.	
Skin s Not cla Respin Not cla <u>Comp</u> nicotin	ensitisation assified based on aver ratory sensitisation assified based on aver onents: namide:	ailable information. ailable information.	
Skin s Not cla Respin Not cla <u>Comp</u> nicotin Test T	ensitisation assified based on avain ratory sensitisation assified based on avain onents: namide: ype	ailable information. ailable information. : Maximisatio	on Test
Skin s Not cla Respin Not cla <u>Comp</u> nicotin Test T	ensitisation assified based on avain ratory sensitisation assified based on avain onents: namide: ype ure routes	ailable information. ailable information. : Maximisation : Skin contao : Guinea pig	on Test ct
Skin s Not cla Respin Not cla <u>Comp</u> nicotin Test T Expos Specie Metho	ensitisation assified based on ava ratory sensitisation assified based on ava onents: namide: ype ure routes es d	ailable information. ailable information. : Maximisati : Skin conta : Guinea pig : OECD Tes	on Test ct
Skin s Not cla Respin Not cla <u>Comp</u> nicotin Test T Expos Specie	ensitisation assified based on ava ratory sensitisation assified based on ava onents: namide: ype ure routes es d	ailable information. ailable information. : Maximisation : Skin contao : Guinea pig	on Test ct
Skin s Not cla Respin Not cla Comp nicotin Test T Expos Specie Metho Result	ensitisation assified based on ava ratory sensitisation assified based on ava <u>onents:</u> namide: ype ure routes es d	ailable information. ailable information. : Maximisation : Skin contao : Guinea pig : OECD Tes : negative	on Test ct t Guideline 406
Skin s Not cla Respin Not cla <u>Comp</u> nicotin Test T Expos Specie Metho Result Pyrido Test T	ensitisation assified based on aver ratory sensitisation assified based on aver onents: namide: ype ure routes es d	ailable information. ailable information. : Maximisation : Skin contao : Guinea pig : OECD Tes : negative	on Test ct t Guideline 406 on Test
Skin s Not cla Respin Not cla <u>Comp</u> nicotin Test T Expos Specie Metho Result Pyrido Test T Expos	ensitisation assified based on avainatory sensitisation assified based on avainator assified based on avainator onents: namide: ype ure routes as d oxine hydrochloride ype ure routes	ailable information. ailable information. : Maximisation : Skin contao : Guinea pig : OECD Tes : negative : Naximisatio : Skin contao	on Test ct t Guideline 406 on Test ct
Skin s Not cla Respin Not cla <u>Comp</u> nicotin Test T Expos Specie Metho Result Pyrido Test T	ensitisation assified based on avainatory sensitisation assified based on avainator onents: onents: namide: ype ure routes as d oxine hydrochloride ype ure routes as d	ailable information. ailable information. : Maximisation : Skin contao : Guinea pig : OECD Tes : negative : Maximisatio : Skin contao : Guinea pig	on Test ct t Guideline 406 on Test ct

Not classified based on available information.



sion	Revision Date: 2024/09/28		Number: 436-00024	Date of last issue: 2024/07/06 Date of first issue: 2015/10/02			
Comp	oonents:						
nicoti	namide:						
	toxicity in vitro	ſ		cterial reverse mutation assay (AMES)) Test Guideline 471 re			
Geno	toxicity in vivo		cytogenetic as Species: Mous Application Ro	e ute: Intraperitoneal injection) Test Guideline 474			
Pyrid	oxine hydrochloride						
•	toxicity in vitro	: -	Fest Type: Bao Result: negativ	cterial reverse mutation assay (AMES) e			
	nogenicity assified based on ava	ilable ir	formation.				
Reproductive toxicity Not classified based on ava		ailable information.					
<u>Comp</u>	oonents:						
nicoti	namide:						
Effect ment	s on foetal develop-	: / 	Species: Rabb Application Ro	ute: Ingestion) Test Guideline 414			
Pvrid	oxine hydrochloride						
-	s on foetal develop-	: -	Test Type: Em Species: Rat Application Ro Result: negativ				
	- single exposure assified based on ava	ilable ir	formation.				
	- repeated exposure assified based on ava		formation.				
Repe	ated dose toxicity						
<u>Comp</u>	oonents:						
	namide:						



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	cation Route sure time	:	215 mg/kg Ingestion 28 Days OECD Test G	uideline 407
-	ation toxicity assified based on availa	ble	information.	
12. ECOL	OGICAL INFORMATION	N		
Ecoto	oxicity			
<u>Com</u>	oonents:			
	inamide: ity to fish	:	Exposure time	a reticulata (guppy)): > 1,000 mg/l :: 96 h D Test Guideline 203
	ity to daphnia and other ic invertebrates	:	EC50 (Daphni Exposure time	a magna (Water flea)): > 1,000 mg/l
Toxic plants	ity to algae/aquatic	:	mg/l Exposure time	desmus subspicatus (green algae)): > 1,000 e: 72 h D Test Guideline 201
			Exposure time	odesmus subspicatus (green algae)): 560 mg/l e: 72 h D Test Guideline 201
Toxic	ity to microorganisms	:	Exposure time	lomonas putida): 4,235 mg/l e: 18 h D Test Guideline 209
Pyrid	oxine hydrochloride:			
	ity to fish	:	LC50 (Oncorh Exposure time	ynchus mykiss (rainbow trout)): > 100 mg/l :: 96 h
	ity to daphnia and other ic invertebrates	:	EC50 (Daphni Exposure time	a magna (Water flea)): > 100 mg/l e: 48 h
Persi	stence and degradabili	ity		
Com	oonents:			
	inamide: gradability	:	Result: Readil Biodegradatio	y biodegradable. n: 95 %



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			Exposure time: Method: OECE	28 d) Test Guideline 301E
Pyrid	loxine hydrochloride:			
Biode	egradability	:	Biodegradation Exposure time:	
Bioa	ccumulative potential			
Com	ponents:			
Partit	inamide: ion coefficient: n- ol/water	:	log Pow: -0.38	
Pyrid	loxine hydrochloride:			
	ion coefficient: n- ol/water	:	log Pow: 4.32	
	lity in soil ata available			
	rdous to the ozone lay pplicable	er		
	r adverse effects ata available			
13. DISPC	SAL CONSIDERATIO	NS		
Dien	osal methods			
Disp				

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

14. TRANSPORT INFORMATION

International Regulations

UNRTDG UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Environmentally hazardous	:	no



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Class Subsi Packi Label Packi aircra Packi	D No. er shipping name idiary risk ng group s ng instruction (cargo	 Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable	
UN nı Prope Class Subsi	diary risk ng group	 Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable	

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

: Not applicable

: Not applicable

Not applicable for product as supplied.

National Regulations

Refer to section 15 for specific national regulation.

Special precautions for user

Not applicable

EmS Code

Marine pollutant

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law

Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture

Not applicable

Harmful Substances Required Permission for Manufacture

Not applicable

Substances Prevented From Impairment of Health

Not applicable



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on Ex	l ar concerning Info kisting Chemicals h pplicable		s having Mutagenicity - Annex 2: Informatic
		rmation on Chemicals having Mutagenicity	s having Mutagenicity - Annex 1: Informati
Not a	pplicable		
	tances Subject to b pplicable	e Notified Names	
	tances Subject to b pplicable	e Indicated Names	
Skin		ubstances for PPE Re	quirements (ISHL MO Art. 594-2)
Carci tions	nogenic Substance	s (Article 577-2 of the	Occupational Health and Safety Regula-
	nance on Preventior	n of Hazards Due to S	pecified Chemical Substances
	nance on Preventior	n of Lead Poisoning	
	nance on Preventior	n of Tetraalkyl Lead P	oisoning
	nance on Preventior	n of Organic Solvent F	Poisoning
Subs	cement Order of th tances) pplicable	e Industrial Safety an	d Health Law - Attached table 1 (Dangerou
	onous and Deleterio	ous Substances Contr	ol Law
viron			of Specific Chemical Substances in the E the Management Thereof
High	Pressure Gas Safet	y Act	
	osive Control Law		
-	pplicable		
	el Safety Law		
	egulated as a danger	ous good	
	ion Law	-	
	egulated as a danger		



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Marin	e Pollution and Sea	Disaster Preventio	n etc Law		
Bulk t	ransportation	: Not classified	Not classified as noxious liquid substance		
Pack	transportation	: Not classified	Not classified as marine pollutant		
Not ap Specil Not ap	otic or Psychotropic R pplicable fic Narcotic or Psycho pplicable e Disposal and Publ	otropic Raw Material	Import Permission) (Export / Import permission)		
	trial waste				
The c	omponents of this	product are reported	d in the following inventories:		
AICS		: not determine	ed		
DSL		: not determine	ed		
IECS	C	: not determine	ed		

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 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



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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

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.

JP / EN