

Omarigliptin Formulation

7.0 2024/09/28 402494-00019 Date of first issue: 2016/01/07	Version 7.0	Revision Date: 2024/09/28	SDS Number: 402494-00019	Date of last issue: 2024/04/06 Date of first issue: 2016/01/07
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1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name	:	Omarigliptin 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 chemica Specific target organ toxicity - repeated exposure (Oral)	product Category 2 (Stomach, Blood, Kidney)
GHS label elements	
Hazard pictograms	
Signal word	Warning
Hazard statements	H373 May cause damage to organs (Stomach, Blood, Kidney) through prolonged or repeated exposure if swallowed.
Precautionary statements	Prevention: P260 Do not breathe dust.
	Response:
	P314 Get medical advice/ attention if you feel unwell.
	Disposal:
	P501 Dispose of contents/ container to an approved waste disposal plant.



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Other hazards which do not result in classification

Important symptoms and out- lines of the emergency as- sumed	:	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, han-
		dling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture	:	Mixture
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Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Cellulose	9004-34-6	>= 10 - < 20	
Omarigliptin	1226781-44-7	>= 10 - < 20	

4. FIRST AID MEASURES

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	:	If inhaled, remove to fresh air. Get medical attention if symptoms occur.
In case of skin contact	:	Wash with water and soap. Get medical attention if symptoms occur.
In case of eye contact	:	If in eyes, rinse well with water. 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	:	May cause damage to organs through prolonged or repeated exposure if swallowed. Contact with dust can cause mechanical irritation or drying of
Protection of first-aiders	:	the skin. Dust contact with the eyes can lead to mechanical irritation. First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment
Notes to physician	:	when the potential for exposure exists (see section 8). Treat symptomatically and supportively.
5. FIREFIGHTING MEASURES		
Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
l la suite bla suite suis bis s	_	New elements

Unsuitable extinguishing : None known.



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med	lia				
Spe figh	cific hazards during fire- ting	:	concentrations, ar potential dust exp	dust; fine dust dispersed in air in sufficient nd in the presence of an ignition source is a losion hazard. oustion products may be a hazard to health.	
Haz ucts	ardous combustion prod-	:	Carbon oxides Metal oxides		
Spe ods	cific extinguishing meth-	:	cumstances and t Use water spray to	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	
	Special protective equipment for firefighters		In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.		
6. ACCII	DENTAL RELEASE MEAS	SUF	RES		
tive	sonal precautions, protec- equipment and emer- cy procedures	:		ective equipment. ing advice (see section 7) and personal pro- recommendations (see section 8).	
Env	ironmental precautions	:	 Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained. 		
	hods and materials for tainment and cleaning up	:	tainer for disposal Avoid dispersal of with compressed Dust deposits sho es, as these may leased into the atr Local or national r posal of this mate employed in the c mine which regula Sections 13 and 1	dust in the air (i.e., clearing dust surfaces	

7. HANDLING AND STORAGE

Handling



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Tech	nnical measures	:	causing an explose Provide adequate	nay accumulate and ignite suspended dust sion. e precautions, such as electrical grounding nert atmospheres.
	al/Total ventilation ce on safe handling	::	Use only with ade Do not breathe du Do not swallow. Avoid contact with Avoid prolonged of Handle in accorda practice, based of sessment Minimize dust gen Keep container of Keep away from Take precautiona	equate ventilation. ust.
	dance of contact ene measures	:	flushing systems place. When using do no	emical is likely during typical use, provide eye and safety showers close to the working ot eat, drink or smoke. ed clothing before re-use.
Stor	age			
Con	ditions for safe storage	:		abelled containers.
Mate	erials to avoid	:		the following product types:
Pack	kaging material	:	Unsuitable mater	al: None known.

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
Cellulose	9004-34-6	TWA	10 mg/m3	ACGIH
Omarigliptin	1226781-44- 7	TWA	10 µg/m3	Internal
		Wipe limit	100 µg/100 cm ²	Internal

Engineering measures

: Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations. Apply measures to prevent dust explosions. Ensure that dust-handling systems (such as exhaust ducts, Version



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			signed in a mar	vessels, and processing equipment) are de- iner to prevent the escape of dust into the there is no leakage from the equipment).		
Pers	onal protective equip	nent				
Fi	iratory protection	:	sure assessme	al exhaust ventilation is not available or expo- nt demonstrates exposures outside the rec- delines, use respiratory protection. e		
Hand	I protection					
М	aterial	:	Chemical-resist	ant gloves		
R	Remarks		Choose gloves to protect hands against chemicals depend on the concentration and quantity of the hazardous sub- stance and specific to place of work. Breakthrough time is r determined for the product. Change gloves often! For speci 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 p	protection	:		ing personal protective equipment:		
Skin	and body protection	:		washed after contact.		
). PHYSIC	CAL AND CHEMICAL F	PRO	PERTIES			
Phys	ical state	:	tablet			
Color	ur	:	yellow			
Odou	ır	:	No data availal	ble		
Odou	ur Threshold	:	No data availal	ble		
Melti	ng point/freezing point	:	No data availal	ble		
	ng point, initial boiling and boiling range	:	No data availal	ble		
Flam	mability (solid, gas)	:	May form explo dling or other n	osive dust-air mixture during processing, han- neans.		
Flam	mability (liquids)	:	No data availal	ble		
U	er explosion limit and up pper explosion limit / Up er flammability limit					
1.	wor ovelogion limit /					



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ammability limit ion temperature rate n temperature	: : : :	No data available No data available No data available No data available	
ion temperature rate n temperature	::	No data available No data available	
rate n temperature	: : : :	No data available No data available	
rate n temperature	::	No data available	
n temperature	:		
n temperature	:	No data available	
	:		
		No data available	
r, dynamic	:	No data available	
, kinematic	:	No data available	
s) Iubility	:	No data available	
efficient: n- er	:	No data available	
sure	:	No data available	
/ or relative densit	: у :	No data available	
oour density	:	No data available	
roperties	:	Not explosive	
operties	:	The substance or	mixture is not classified as oxidizing.
eight	:	No data available	
racteristics	:	No data available	
	/ or relative densit our density operties operties	/ or relative density our density : operties : operties : eight : racteristics	 / or relative density i No data available our density i No data available operties i Not explosive operties i The substance or eight i No data available

10. STABILITY AND REACTIVITY

Reactivity Chemical stability Possibility of hazardous reac- tions	: S : N	Not classified as a reactivity hazard. Stable under normal conditions. May form explosive dust-air mixture during processing, han- dling or other means. Can react with strong oxidizing agents.
Conditions to avoid		Heat, flames and sparks. Avoid dust formation.
Incompatible materials	-	Oxidizing agents



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Hazar produ	dous decomposition cts	:	No hazardous c	ecomposition products are known.
1. TOXIC	OLOGICAL INFORMAT	101	N	
Inform expos	nation on likely routes of ure	:	Inhalation Skin contact Ingestion Eye contact	
	toxicity			
	assified based on availa conents:	ble	information.	
Cellul				
	oral toxicity	:	LD50 (Rat): > 5,0	000 mg/kg
Acute	inhalation toxicity	:	LC50 (Rat): > 5. Exposure time: 4 Test atmosphere	ŀh ¯
Acute	dermal toxicity	:	LD50 (Rabbit): >	2,000 mg/kg
Omar	igliptin:			
	oral toxicity	:	LD50 (Rat): 750	mg/kg
	corrosion/irritation			
	assified based on availa	ble	information.	
-	oonents:			
Resul	igliptin: t	:	No skin irritation	
	us eye damage/eye irri assified based on availa			
	oonents:	DIE		
	igliptin:			
Specie	es	:	Bovine cornea No eye irritation	
		•		
Respi	ratory or skin sensitis	atic	n	
Skin s	sensitisation			



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Not c	Firatory sensitisation lassified based on ava ponents:		
	rigliptin:		
Test Spec	Type ies ssment	: Mouse	node assay (LLNA) se skin sensitisation.
Germ	n cell mutagenicity		
Not c	lassified based on ava	ilable information.	
Com	ponents:		
	llose: otoxicity in vitro	: Test Type: Ba Result: negat	acterial reverse mutation assay (AMES) ive
		Test Type: In Result: negat	vitro mammalian cell gene mutation test ive

Genotoxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Ingestion Result: negative
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Omarigliptin:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
	Test Type: Chromosome aberration test in vitro Test system: Chinese hamster ovary cells Result: negative
Genotoxicity in vivo	: Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis) Species: Rat Application Route: Intraperitoneal injection Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Cellulose:

Species	:	Rat
Application Route	:	Ingestion



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Expo: Resu	sure time It		72 weeks negative	
Omai	rigliptin:			
Speci Applie	ies cation Route sure time	:	Rat Oral 2 Years 20 mg/kg bod negative	y weight
Speci Applic Expos Resu	cation Route sure time	:	Mouse Oral 2 Years 20 mg/kg bod negative	y weight
Not c	oductive toxicity lassified based on avai ponents: lose:	lable i	nformation.	
Effect	ts on fertility	:	Species: Rat	e-generation reproduction toxicity study oute: Ingestion ve
Effect ment	ts on foetal develop-	:	Species: Rat	rtility/early embryonic development oute: Ingestion ve
Omai	rigliptin:			
	ts on fertility	:	Species: Rat Application Ro	EL: 100 mg/kg body weight
Effect ment	ts on foetal develop-	:	Species: Rabl Developmenta	nbryo-foetal development bit al Toxicity: NOAEL: > 50 mg/kg body weigh ects on foetal development



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П		es.	
II			
	T - single exposure classified based on ava	ilable information	
STO	T - repeated exposure	9	
	cause damage to orga allowed.	ns (Stomach, Blo	od, Kidney) through prolonged or repeated exposure
Com	ponents:		
Oma	rigliptin:		
Targ	osure routes et Organs essment		Blood, Kidney e damage to organs through prolonged or repeated
••		oxpoouro.	
Repe	eated dose toxicity		
<u>Com</u>	ponents:		
	ulose:		
Spec NOA		: Rat : >= 9,000 r	na/ka
Appli	ication Route	: Ingestion	
Expo	osure time	: 90 Days	
	rigliptin:		
Spec NOA		: Rat : 100 mg/kg	
Appli	ication Route	: Oral	
Expo Rem	osure time arks	: 90 Days : No signific	ant adverse effects were reported
Spec		: Rat	·
NOA	EL	: 10 mg/kg	
LOA	EL ication Route	: 100 mg/kg : Oral	1
Expo	sure time	: 180 Days	
Targ	et Organs	: Blood, Kid	Iney
Spec		: Dog	
NOA LOA		: 10 mg/kg : 75 mg/kg	
Appli	ication Route	: Oral	
	osure time et Organs	: 40 Days : Stomach	
Spec		: Dog	
NOA		: 10 mg/kg : 75 mg/kg	
		. , o mg/kg	



ersion 0	Revision Date: 2024/09/28	-	0S Number: 2494-00019	Date of last issue: 2024/04/06 Date of first issue: 2016/01/07
Expos	cation Route sure time t Organs	:	Oral 270 Days Stomach	
	EL cation Route sure time	:	Monkey 9 mg/kg Oral 90 Days No significant ac	lverse effects were reported
-	ation toxicity assified based on availa	ble	information.	
Expe	rience with human exp	osı	ire	
<u>Comp</u>	oonents:			
Omar Ingest	igliptin: tion	:		dache, stomach discomfort, Dizziness, Tireo flu-like symptoms, Back pain, Vomiting, chi
	DGICAL INFORMATION	N		
	oonents:			
Cellu				
	ty to fish	:	Exposure time: 4	atipes (Japanese medaka)): > 100 mg/l 48 h I on data from similar materials
	igliptin:			
Toxici	ty to daphnia and other ic invertebrates	:	Exposure time: 4	magna (Water flea)): > 100 mg/l ł8 h Test Guideline 202
			Exposure time: 9	nysis): > 100 mg/l 96 h A OPPTS 850.1035
Toxici plants	ty to algae/aquatic	:	mg/l Exposure time: 7	rchneriella subcapitata (green algae)): > 100 72 h Test Guideline 201
			NOEC (Pseudok mg/l Exposure time: 7 Method: OECD	



/ersion 7.0	Revision Date: 2024/09/28		S Number: 2494-00019	Date of last issue: 2024/04/06 Date of first issue: 2016/01/07
Toxic icity)	city to fish (Chronic tox-	:	Exposure time	phales promelas (fathead minnow)): 11 mg/ e: 32 d D Test Guideline 210
aqua	city to daphnia and other tic invertebrates (Chron- kicity)	:	Exposure time	nia magna (Water flea)): 11 mg/l e: 21 d D Test Guideline 211
Toxic	city to microorganisms	:		
Pers	istence and degradabili	ty		
<u>Com</u>	ponents:			
Cellu	llose:			
Biode	ilose: egradability	:	Result: Readi	ly biodegradable.
	rigliptin:			
Biode	egradability	:	Biodegradation	
	ccumulative potential			
<u>Com</u>	ponents:			
Oma	rigliptin:			
	tion coefficient: n- nol/water	:	log Pow: 0.52	25
Mobi	ility in soil			
<u>Com</u>	ponents:			
Oma	rigliptin:			
	ibution among environ- al compartments	:	log Koc: 4.01 Method: OEC	D Test Guideline 106
	ardous to the ozone laye applicable	er		



ects DERATIONS s es table CRMATION ulations ame table	Do not dispose Empty contained dling site for re- If not otherwise Not applicable Not applicable Not applicable	ccordance with local regulations. of waste into sewer. ers should be taken to an approved waste har cycling or disposal. e specified: Dispose of as unused product.			
s es : kaging : DRMATION ulations	Do not dispose Empty contained dling site for re- If not otherwise Not applicable Not applicable Not applicable	e of waste into sewer. ers should be taken to an approved waste har cycling or disposal.			
es : kaging : DRMATION ulations	Do not dispose Empty contained dling site for re- If not otherwise Not applicable Not applicable Not applicable	e of waste into sewer. ers should be taken to an approved waste har cycling or disposal.			
kaging : DRMATION ulations	Do not dispose Empty contained dling site for re- If not otherwise Not applicable Not applicable Not applicable	e of waste into sewer. ers should be taken to an approved waste har cycling or disposal.			
DRMATION ulations	dling site for re If not otherwise Not applicable Not applicable Not applicable	cycling or disposal.			
ulations	Not applicable Not applicable				
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National Regulations

Refer to section 15 for specific national regulation.



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Special precautions for user

Not applicable

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

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

Substances Subject to be Notified Names

Not applicable

Substances Subject to be Indicated Names

Not applicable

Skin and Eye Damage Substances for PPE Requirements (ISHL MO Art. 594-2) Not applicable

Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)

Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

Ordinance on Prevention of Lead Poisoning

Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable





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	nance on Prevention	of Organic Solvent F	Poisoning
	cement Order of the tances)	e Industrial Safety an	d Health Law - Attached table 1 (Dangerou
Not a	pplicable		
	onous and Deleterio pplicable	us Substances Contr	ol Law
viron			of Specific Chemical Substances in the E the Management Thereof
-	Pressure Gas Safet	y Act	
•	pplicable		
	el Safety Law egulated as a dangero	ous good	
	ion Law egulated as a dangere	ous good	
Marin	e Pollution and Sea	Disaster Prevention	etc Law
Bulk t	ransportation	: Not classified a	as noxious liquid substance
Pack	transportation	: Not classified a	as marine pollutant
Narco Not aj Speci	pplicable	aw Material (Export / I	mport Permission) Export / Import permission)
	e Disposal and Pub trial waste	lic Cleansing Law	
The c	components of this	product are reported	in the following inventories:
AICS		: not determined	3
DSL		: not determined	1
IECS	<u>_</u>	: not determined	4

Further information



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Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format : yyyy/mm/dd

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, time-weighted average

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

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.