

## **Omarigliptin Formulation**

Vers 2.1	ion	Revision Date: 2023/09/30		S Number: 2472-00017	Date of last issue: 2023/04/04 Date of first issue: 2016/01/07		
1. PI	1. PRODUCT AND COMPANY IDENTIFICATION						
	Product	name	:	Omarigliptin Forr	nulation		
	Manufa	cturer or supplier's d	letai	ls			
	Compa	ny	:	MSD			
	Address	5	:	126 E. Lincoln Av Rahway, New Je	venue rsey U.S.A. 07065		
	Telepho	one	:	908-740-4000			
	Emerge	ency telephone number	·:	1-908-423-6000			
	E-mail a	address	:	EHSDATASTEW	ARD@msd.com		
	Recom	mended use of the cl	nem	ical and restriction	ons on use		
	Recom	mended use	:	Pharmaceutical			
	Restrict	ions on use	:	Not applicable			
2. H	AZARD	S IDENTIFICATION					
	GHS CI	assification					
		: target organ toxicity - d exposure (Oral)	:	Category 2 (Ston	nach, 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	:	<b>Prevention:</b> P260 Do not breathe dust.
		Response: P314 Get medical advice/ attention if you feel unwell.
		<b>Disposal:</b> P501 Dispose of contents/ container to an approved waste disposal plant.



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#### 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
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Components

Chemical name	CAS-No.	Concentration (% w/w)
Cellulose	9004-34-6	>= 10 -< 30
Omarigliptin	1226781-44-7	>= 10 -< 30

#### **4. FIRST AID MEASURES**

<ul> <li>If inhaled</li> <li>If inhaled</li> <li>If inhaled, remove to fresh air. Get medical attention if symptoms occur.</li> <li>In case of skin contact</li> <li>Wash with water and soap. Get medical attention if symptoms occur.</li> <li>In case of eye contact</li> <li>If swallowed</li> <li>If swallowed</li> <li>If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.</li> <li>Most important symptoms and effects, both acute and delayed</li> <li>Protection of first-aiders</li> <li>If standard</li> <li>If symptoms are constant of the symptoms of the symptoms</li></ul>	5. FIREFIGHTING MEASU	RES
<ul> <li>Vice immediately.</li> <li>When symptoms persist or in all cases of doubt seek meradvice.</li> <li>If inhaled</li> <li>If inhaled, remove to fresh air. Get medical attention if symptoms occur.</li> <li>In case of skin contact</li> <li>Wash with water and soap. Get medical attention if symptoms occur.</li> <li>In case of eye contact</li> <li>If in eyes, rinse well with water. Get medical attention if irritation develops and persists.</li> <li>If swallowed</li> <li>If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.</li> <li>May cause damage to organs through prolonged or repeater exposure if swallowed. Contact with dust can cause mechanical irritation or dryin the skin. Dust contact with the eyes can lead to mechanical irritation or dryin the skin.</li> <li>Protection of first-aiders</li> <li>First Aid responders should pay attention to self-protectic and use the recommended personal protective equipmer</li> </ul>	Notes to physician	
<ul> <li>If inhaled</li> <li>If inhaled</li> <li>If inhaled, remove to fresh air. Get medical attention if symptoms occur.</li> <li>In case of skin contact</li> <li>Wash with water and soap. Get medical attention if symptoms occur.</li> <li>In case of eye contact</li> <li>If swallowed</li> <li>If swallowed</li> <li>If swallowed</li> <li>If swallowed</li> <li>If swallowed</li> <li>Most important symptoms and effects, both acute and delayed</li> <li>If an advice.</li> <li>If swallowed.</li> <li>Contact with dust can cause mechanical irritation or dryin the skin.</li> </ul>	Protection of first-aide	s : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment
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vice immediately.         When symptoms persist or in all cases of doubt seek meradvice.         If inhaled       :         If inhaled       :	In case of skin contac	: Wash with water and soap.
vice immediately. When symptoms persist or in all cases of doubt seek me	If inhaled	
General advice . In the case of accident or if you feel unwell, seek medical	General advice	When symptoms persist or in all cases of doubt seek medical

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire- fighting	:	Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a

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potential dust explosion hazard. Exposure to combustion products may be a hazard to healt         Hazardous combustion products       : Carbon oxides 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         Special protective equipment       : In the event of fire, wear self-contained breathing apparatus Use personal protective equipment.         6.ACCIDENTAL RELEASE MEASURES       : Use personal protective equipment. Follow safe handling advice (see section 7) and personal pr gency procedures         Environmental precautions, protec- tive equipment and emer- gency procedures       : Use personal protective equipment. Follow safe handling advice (see section 7) and personal pr tective equipment tecommendations (see section 8).         Environmental precautions       : Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of containment and values water. Local authorities should be advised if significant spillages cannot be contained.         Methods and materials for containment and cleaning up       : Sweep up or vacuum up spillage and collect in suitable con tainer for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surface es, as these may form an explosive mixture if they are re- leased into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposive mixture which regulations are applicable. Sections 13 and 15 of this SDS provide information regar	2.1	2023/09/30		2472-00017	Date of first issue: 2023/04/04 Date of first issue: 2016/01/07
Exposure to combustion products may be a hazard to healt         Hazardous combustion prod- ucts       Carbon oxides Metal oxides         Specific extinguishing meth- ods       : Use extinguishing measures that are appropriate to local cit curstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to so. Evacuate area.         Special protective equipment       : In the event of fire, wear self-contained breathing apparatus Use personal protective equipment.         6. ACCIDENTAL RELEASE MEASURES         Personal precautions, protec- tive equipment and emer- gency procedures       : Use personal protective equipment. Follow safe handling advice (see section 7) and personal pr tective equipment recommendations (see section 8).         Environmental 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.         Methods and materials for containment and cleaning up to the deposite should be advised if significant spillages cannot be contained.       : Sweep up or vacuum up spillage and collect in suitable con tainer for disposal. Dust deposite should be allowed to accumulate on surfa es, as these may form an explosive mixture if they are re- leased into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and dis- posal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter mine which regulations are applicable. Sections 13 and 15 of this SDS provide information regardit certain local or					
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ods       cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to so.         Special protective equipment for firefighters       In the event of fire, wear self-contained breathing apparatus Use personal protective equipment.         S. ACCIDENTAL RELEASE MEASURES         Personal precautions, protec- tive equipment and emer- gency procedures       Use personal protective equipment. Follow safe handling advice (see section 7) and personal pr tective equipment recommendations (see section 8).         Environmental 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.         Methods and materials for containment and cleaning up containment and cleaning up       :       Sweep up or vacuum up spillage and collect in suitable con tainer for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfa es, as these may form an explosive mixture if they are re- leased into the atmosphere in sufficient concentration. Local or national regulations may apply to releases. You will need to deter mine which regulations are applicable. Sections 13 and 15 of this SDS provide information regardii certain local or national requirements.         t       HANDLING AND STORAGE         Technical measures       :       Static electricity may accumulate and ignite suspended dus causing an explosion. Provide adequate ventillation. Advice on safe handling <td></td> <td></td> <td>:</td> <td></td> <td></td>			:		
Special protective equipment in the event of fire, wear self-contained breathing apparatus Use personal protective equipment.         6. ACCIDENTAL RELEASE MEASURES         Personal precautions, protective equipment and emergency procedures       : Use personal protective equipment. Follow safe handling advice (see section 7) and personal precetive equipment recommendations (see section 8).         Environmental 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.         Methods and materials for containment and cleaning up       : Sweep up or vacuum up spillage and collect in suitable con tainer for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determ ine which regulations are applicable. Sections 13 and 15 of this SDS provide information regardin certain local or national requirements.         7. HANDLING AND STORAGE       : Static electricity may accumulate and ignite suspended dus causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. Avoid prolonged or repeated contact with skin.	•	cific extinguishing meth-	:	cumstances and Use water spray Remove undama	the surrounding environment. to cool unopened containers.
Personal precautions, protective equipment and emergency procedures       :       Use personal protective equipment.         Follow safe handling advice (see section 7) and personal prective equipment recommendations (see section 8).         Environmental 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.         Methods and materials for containment and cleaning up       :       Sweep up or vacuum up spillage and collect in suitable con tainer for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are re-leased into the atmosphere in sufficient concentration. Local or national regulations may apply to releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.         Technical measures       :       Static electricity may accumulate and ignite suspended dus causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. Use only with adequate ventilation. Advice on safe handling         Local/Total ventilation Advice on safe handling       :       Use only with adequate ventilation. Do not swallow. Avoid oronact with eyes. Avoid prolonged or repeated contact with skin.			:	In the event of fir	
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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.         Methods and materials for containment and cleaning up       Sweep up or vacuum up spillage and collect in suitable con tainer for disposal.         Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).       Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.         Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter mine which regulations are applicable.         Sections 13 and 15 of this SDS provide information regardin certain local or national requirements.         7. HANDLING AND STORAGE         Local/Total ventilation Advice on safe handling       Static electricity may accumulate and ignite suspended dus causing an explosion.         Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.       Use only with adequate ventilation.         Advice on safe handling       Do not breathe dust.       Do not swallow.         Avoid prolonged or repeated contact with skin.       Avoid prolonged or repeated contact with skin.	tive	equipment and emer-	:	Follow safe hand	lling advice (see section 7) and personal pro-
containment and cleaning uptainer for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfa es, as these may form an explosive mixture if they are re- leased into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and dis- posal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter mine which regulations are applicable. Sections 13 and 15 of this SDS provide information regardli certain local or national requirements.r. HANDLING AND STORAGE:Static electricity may accumulate and ignite suspended dus causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.Local/Total ventilation Advice on safe handling:Use only with adequate ventilation. Do not breathe dust. Do not swallow. Avoid contact with eyes. Avoid prolonged or repeated contact with skin.	Envi	ronmental precautions	:	Prevent further le Retain and dispo Local authorities	eakage or spillage if safe to do so. se of contaminated wash water. should be advised if significant spillages
<ul> <li>Technical measures</li> <li>Static electricity may accumulate and ignite suspended dus causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.</li> <li>Use only with adequate ventilation.</li> <li>Do not breathe dust. Do not swallow. Avoid contact with eyes. Avoid prolonged or repeated contact with skin.</li> </ul>			:	tainer for disposa Avoid dispersal of with compressed Dust deposits sh es, as these may leased into the a Local or national posal of this mate employed in the mine which regul Sections 13 and	al. of dust in the air (i.e., clearing dust surfaces air). ould not be allowed to accumulate on surfac- form an explosive mixture if they are re- tmosphere in sufficient concentration. regulations may apply to releases and dis- erial, as well as those materials and items cleanup of releases. You will need to deter- lations are applicable. 15 of this SDS provide information regarding
<ul> <li>causing an explosion.</li> <li>Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.</li> <li>Local/Total ventilation</li> <li>Use only with adequate ventilation.</li> <li>Do not breathe dust.</li> <li>Do not swallow.</li> <li>Avoid contact with eyes.</li> <li>Avoid prolonged or repeated contact with skin.</li> </ul>	7. HAND	LING AND STORAGE			
Local/Total ventilation: Use only with adequate ventilation.Advice on safe handling: Do not breathe dust. Do not swallow. Avoid contact with eyes. Avoid prolonged or repeated contact with skin.	Tech	nnical measures	:	causing an explo Provide adequate	sion. e precautions, such as electrical grounding
3/15			:	Use only with ad Do not breathe d Do not swallow. Avoid contact with	equate ventilation. ust. h eyes.
0710				3 / 15	

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	itions for safe storage rials to avoid	practice, based sessment Minimize dust g Keep container Keep away from Take precaution Take care to pr environment. Keep in properl Store in accord	rdance with good industrial hygiene and safety on the results of the workplace exposure as- generation and accumulation. closed when not in use. n heat and sources of ignition. nary measures against static discharges. event spills, waste and minimize release to the y labelled containers. ance with the particular national regulations. th the following product types: g agents

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Cellulose	9004-34-6	NAB	10 mg/m3	ID OEL
		TWA	10 mg/m3	ACGIH
Omarigliptin	1226781-44- 7	TWA	10 µg/m3	Internal
		Wipe limit	100 µg/100 cm <sup>2</sup>	Internal
Engineering measures	Minimize worl Apply measur Ensure that d dust collector signed in a m work area (i.e	<pre>xplace exposure res to prevent du ust-handling sys s, vessels, and p anner to prevent</pre>	especially in confined concentrations. ist explosions. tems (such as exhau processing equipment the escape of dust in kage from the equipr	st ducts, t) are de- nto the
		aal aybayat yaa	filation is not available	
Respiratory protection	sure assessm	ient demonstrate uidelines, use re	tilation is not available as exposures outside spiratory protection.	
Hand protection	i antiodiatoo tj	,00		
Material	Chemical-res	stant gloves		
Remarks	on the concer stance and sp determined fo	ntration and quan becific to place o r the product. Cl	ds against chemicals ntity of the hazardous f work. Breakthrough hange gloves often! F clarifying the resistan	s sub- time is not For special

#### Components with workplace control parameters



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Skin a	protection and body protection one measures	glove manufact end of workday : Wear the follow Safety goggles : Skin should be : If exposure to d eye flushing sy ing place. When using do	ving personal protective equipment:

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	tablet
Colour	:	yellow
Odour	:	No data available
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	:	No data available
Evaporation rate	:	No data available
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	:	No data available
Relative vapour density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility	:	No data available



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octa	tition coefficient: n- anol/water p-ignition temperature	: No data ava : No data ava	
	composition temperature	: No data ava	ilable
١	cosity /iscosity, dynamic	: No data ava	ilable
	/iscosity, kinematic losive properties	: No data ava : Not explosiv	
	dizing properties	·	nce or mixture is not classified as oxidizing.
	ecular weight	: No data ava	
Part	ticle size	: No data ava	ilable

#### **10. STABILITY AND REACTIVITY**

Reactivity Chemical stability Possibility of hazardous reac- tions		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
Hazardous decomposition products	•	No hazardous decomposition products are known.

#### 11. TOXICOLOGICAL INFORMATION

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

#### Acute toxicity

Not classified based on available information.

#### Components:

#### Cellulose:

Acute oral toxicity	:	LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): > 5.8 mg/l Exposure time: 4 h



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		Test	atmospher	e: dust/mist
Acute	dermal toxicity	: LD50	0 (Rabbit): >	> 2,000 mg/kg
Omar	igliptin:			
Acute	oral toxicity	: LD50	0 (Rat): 750	mg/kg
-	corrosion/irritation assified based on av	ailable inforn	nation.	
<u>Com</u>	ponents:			
Omar Resul	r <b>igliptin:</b> t	: No s	kin irritation	
Not cl	us eye damage/eye assified based on av ponents:		nation.	
-	igliptin:			
Speci Resul	es		ne cornea eye irritation	
Resp	iratory or skin sens	tisation		
-	sensitisation assified based on av	ailable inforn	nation.	
-	iratory sensitisation			
	assified based on av	ailable inforn	nation.	
	oonents:			
Omar Test Speci		: Loca : Mou		le assay (LLNA)
	ssment	: Doe: : nega		skin sensitisation.
	cell mutagenicity	ailable inforn	nation.	
	oonents:			
Cellu	lose:			
Geno	toxicity in vitro		Type: Bact ult: negative	erial reverse mutation assay (AMES)
			Type: In vit ult: negative	ro mammalian cell gene mutation tes



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Geno	toxicity in vivo		pe: Mammalian erythrocyte micronucleus test (in v etic assay)
		Species Applicat	: Mouse ion Route: Ingestion negative
Omar	igliptin:		
Geno	toxicity in vitro		pe: Bacterial reverse mutation assay (AMES) negative
		Test sys	be: Chromosome aberration test in vitro stem: Chinese hamster ovary cells negative
Geno	toxicity in vivo	cytogen Species Applicat	
		Result: I	ion Route: Intraperitoneal injection negative
	<b>nogenicity</b> assified based on av		negative
Not cl			negative
Not cl	assified based on av		negative
Not cl Comp Cellu Speci	assified based on av ponents: lose: es	ailable information	on.
Not cl <u>Comp</u> Cellu Speci Applic	assified based on av <u>conents:</u> lose: es cation Route	ailable informatio : Rat : Ingestio	negative on.
Not cl <u>Comp</u> Cellu Speci Applic	assified based on av <u>conents:</u> lose: es cation Route sure time	ailable information	negative on. n «s
Not cl Comp Cellu Speci Applic Expos Resul	assified based on av <u>conents:</u> lose: es cation Route sure time	ailable information : Rat : Ingestio : 72 week	negative on. n «s
Not cl <u>Comp</u> <u>Cellu</u> Speci Applic Expos Resul Omar Speci	assified based on av <u>conents:</u> lose: es cation Route sure time t rigliptin: es	ailable informatio : Rat : Ingestio : 72 week : negative : Rat	negative on. n «s
Not cl Comp Cellu Speci Applic Expos Resul Omar Speci Applic	assified based on av <u>conents:</u> lose: es cation Route sure time t rigliptin: es cation Route	ailable information : Rat : Ingestio : 72 week : negative : Rat : Oral	negative on. n ks e
Not cl Comp Cellu Speci Applic Expos Resul Omar Speci Applic	assified based on av <u>conents:</u> lose: es cation Route sure time t rigliptin: es	ailable information : Rat : Ingestio : 72 week : negative : Rat : Oral : 2 Years	negative on. n (S e
Not cl Comp Cellu Speci Applic Expos Resul Omar Speci Applic	assified based on av <u>conents:</u> lose: es cation Route sure time t rigliptin: es cation Route sure time	ailable information : Rat : Ingestio : 72 week : negative : Rat : Oral : 2 Years	negative on. n ks e
Not cl Comp Cellu Speci Applic Expos Resul Omar Speci Applic Expos	assified based on av <u>conents:</u> lose: es cation Route sure time t rigliptin: es cation Route sure time t	ailable information : Rat : Ingestio : 72 week : negative : negative : Cral : 2 Years : 20 mg/k	negative on. n ks e
Not cl Comp Cellu Speci Applic Expos Resul Speci Applic Expos Resul Speci Applic	assified based on av <u>conents:</u> lose: es cation Route sure time t rigliptin: es cation Route sure time t es cation Route sure time	ailable information : Rat : Ingestio : 72 week : negative : Rat : Oral : 2 Years : 20 mg/k : negative : Mouse : Oral	n on. n ks e g body weight
Not cl Comp Cellu Speci Applic Expos Resul Speci Applic Expos Resul Speci Applic	assified based on av <u>conents:</u> lose: es cation Route sure time t <b>igliptin:</b> es cation Route sure time t t es	ailable information : Rat : Ingestio : 72 week : negative : Rat : Oral : 2 Years : 20 mg/k : negative : Mouse : Oral : 2 Years : Oral : 2 Years	n on. n ks e g body weight e
Not cl Comp Cellu Speci Applic Expos Resul Speci Applic Expos Resul Speci Applic	assified based on av <u>conents:</u> lose: es cation Route sure time t rigliptin: es cation Route sure time t es cation Route sure time t	ailable information : Rat : Ingestio : 72 week : negative : Rat : Oral : 2 Years : 20 mg/k : negative : Mouse : Oral : 2 Years : Oral : 2 Years	negative on. n ks e g body weight e

Not classified based on available information.



### **Omarigliptin Formulation**

ersion 1	Revision Date: 2023/09/30	SDS Number: 402472-00017	Date of last issue: 2023/04/04 Date of first issue: 2016/01/07
<u>Com</u>	oonents:		
Cellu	lose:		
Effect	ts on fertility	Species: Rat	Route: Ingestion
Effect ment	ts on foetal develop-	Species: Rat	Route: Ingestion
Omar	rigliptin:		
Effect	ts on fertility	Species: Rat Application R	Route: Oral AEL: 100 mg/kg body weight
Effect ment	ts on foetal develop-	Species: Rat Developmen	mbryo-foetal development obit tal Toxicity: NOAEL: > 50 mg/kg body weight ffects on foetal development
		Species: Rat Application R Developmen Result: Redu food consum	

Not classified based on available information.

#### STOT - repeated exposure

May cause damage to organs (Stomach, Blood, Kidney) through prolonged or repeated exposure if swallowed.

#### Components:

#### Omarigliptin:

Exposure routes	:	Ingestion
Target Organs	:	Stomach, Blood, Kidney
Assessment	:	May cause damage to organs through prolonged or repeated exposure.



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	peated dose toxicity mponents:		
Sp NC Ap	<b>Ilulose:</b> ecies DAEL plication Route posure time	: Rat : >= 9,000 mg/k : Ingestion : 90 Days	g
Sp	narigliptin: ecies DAEL	: Rat : 100 mg/kg	
Ap Ex	plication Route posure time marks	: Oral : 90 Days	adverse effects were reported
NC LO Ap Ex	ecies DAEL AEL plication Route posure time rget Organs	: Rat : 10 mg/kg : 100 mg/kg : Oral : 180 Days : Blood, Kidney	
NC LO Ap Ex	ecies DAEL AEL plication Route posure time rget Organs	: Dog : 10 mg/kg : 75 mg/kg : Oral : 40 Days : Stomach	
NC LO Ap Ex	ecies DAEL AEL plication Route posure time rget Organs	: Dog : 10 mg/kg : 75 mg/kg : Oral : 270 Days : Stomach	
NC Ap Ex	ecies DAEL plication Route posure time marks	: Monkey : 9 mg/kg : Oral : 90 Days : No significant	adverse effects were reported

#### Aspiration toxicity

Not classified based on available information.

#### Experience with human exposure

#### **Components:**

Omarigliptin:



## **Omarigliptin Formulation**

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	stion	:		ache, stomach discomfort, Dizziness, Tired- lu-like symptoms, Back pain, Vomiting, chills
12. ECU	LOGICAL INFORMATION	N		
Eco	toxicity			
<u>Con</u>	ponents:			
	ulose: city to fish	:	Exposure time: 48	ipes (Japanese medaka)): > 100 mg/l } h on data from similar materials
Oma	arigliptin:			
	city to daphnia and other atic invertebrates	:	EC50 (Daphnia m Exposure time: 48 Method: OECD Te	
			EC50 (Americamy Exposure time: 96 Method: US-EPA	
Toxi plan	city to algae/aquatic ts	:	EC50 (Pseudokiro mg/l Exposure time: 72 Method: OECD To	
			NOEC (Pseudokir mg/l Exposure time: 72 Method: OECD Te	
Toxi icity)	city to fish (Chronic tox-	:	NOEC (Pimephale Exposure time: 32 Method: OECD Te	
aqua	city to daphnia and other atic invertebrates (Chron- xicity)	:	NOEC (Daphnia r Exposure time: 21 Method: OECD Te	
Тохі	city to microorganisms	:	EC50: > 1,000 mg Exposure time: 3 Test Type: Respir Method: OECD Te	h ation inhibition
			NOEC: 0.1 mg/l Exposure time: 3 Test Type: Respir Method: OECD To	ation inhibition



## **Omarigliptin Formulation**

ersion .1	Revision Date: 2023/09/30	-	OS Number: 2472-00017	Date of last issue: 2023/04/04 Date of first issue: 2016/01/07
Pers	istence and degradabi	lity		
Com	ponents:			
Cellu	ulose:			
Biode	egradability	:	Result: Readily b	biodegradable.
Oma	rigliptin:			
	egradability		Result: Not read	ily biodegradable.
Diou	ograduomty	•	Biodegradation:	
			Exposure time: 1	11 d
			Method: OECD	Test Guideline 314
Bioa	ccumulative potential			
<u>Com</u>	ponents:			
Oma	rigliptin:			
Parti	tion coefficient: n- nol/water	:	log Pow: 0.525	
Mob	ility in soil			
<u>Com</u>	ponents:			
Oma	rigliptin:			
	ibution among environ-	:	log Koc: 4.01	
	al compartments			Test Guideline 106
Othe	er adverse effects			
No d	ata available			
3. DISPO	OSAL CONSIDERATIO	NS		
Disp	osal methods			
-	te from residues	:	Do not dispose o	of waste into sewer.
_			Dispose of in ac	cordance with local regulations.
Cont	aminated packaging	:		s should be taken to an approved waste har
				ycling or disposal. specified: Dispose of as unused product.
4. TRAN	ISPORT INFORMATION	١		
Inter	notional Degulations			
	national Regulations			
	TDG number		Not applicable	
	er shipping name	÷	Not applicable	
Class	S	:	Not applicable	
	idiary risk	:	Not applicable	
Pack	ina aroup	•	Not applicable	

: Not applicable

Packing group



rsion I	Revision Date: 2023/09/30		DS Number: 2472-00017	Date of last issue: 2023/04/04 Date of first issue: 2016/01/07
Label	S	:	Not applicable	
IATA	DGR			
UN/IE	) No.	:	Not applicable	
Prope	er shipping name	:	Not applicable	
Class		:	Not applicable	
	diary risk	:	Not applicable	
	ng group	:	Not applicable	
Label	-	:	Not applicable	
Packi aircra	ng instruction (cargo ft)	:	Not applicable	
	ng instruction (passen- rcraft)	:	Not applicable	
IMDG	-Code			
-	umber		Not applicable	
_	er shipping name		Not applicable	
Class		÷	Not applicable	
	diary risk	÷	Not applicable	
	ng group	÷	Not applicable	
Label			Not applicable	
EmS	Code	:	Not applicable	
Marin	e pollutant	:	Not applicable	
Trans	port in bulk according	ı to	Annex II of MAR	POL 73/78 and the IBC Code
	oplicable for product as			
Spec	ial precautions for use	r		
-	oplicable			

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

# Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered : Not applicable

#### Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

Hazardous substances approved for use	:	Not applicable
Prohibited substances	:	Not applicable
Restricted substances	:	Not applicable



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# Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials

Type of hazardous materials subject to distribution and : Not applicable control, Annex I

Type of hazardous materials subject to distribution and : Not applicable control, Annex II

#### The components of this product are reported in the following inventories:

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

#### **16. OTHER INFORMATION**

Revision Date	:	2023/09/30		
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 Agency, http://echa.europa.eu/		
Date format	:	yyyy/mm/dd		
Full text of other abbreviations				
ACGIH ID OEL	:	USA. ACGIH Threshold Limit Values (TLV) Indonesia. Occupational Exposure Limits		
ACGIH / TWA ID OEL / NAB	:	8-hour, time-weighted average Long term exposure limit		

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



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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.

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