

**Sitagliptin / Metformin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 10/01/2022
5.0	04/04/2023	27095-00022	Date of first issue: 10/31/2014

**SECTION 1. IDENTIFICATION**

Product name : Sitagliptin / Metformin Formulation  
Other means of identification : No data available

**Manufacturer or supplier's details**

Company name of supplier : Merck & Co., Inc  
Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065  
Telephone : 908-740-4000  
Emergency telephone : 1-908-423-6000  
E-mail address : EHSDATASTEWARD@merck.com

**Recommended use of the chemical and restrictions on use**

Recommended use : Pharmaceutical  
Restrictions on use : Not applicable

**SECTION 2. HAZARDS IDENTIFICATION****GHS classification in accordance with the Hazardous Products Regulations**

Acute toxicity (Oral) : Category 4

**GHS label elements**

Hazard pictograms :



Signal Word : Warning

Hazard Statements : H302 Harmful if swallowed.

Precautionary Statements : **Prevention:**  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
**Response:**  
P301 + P312 + P330 IF SWALLOWED: Call a doctor if you feel unwell. Rinse mouth.  
**Disposal:**  
P501 Dispose of contents and container to an approved waste disposal plant.

**Other hazards**

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.

# Sitagliptin / Metformin Formulation

Version 5.0      Revision Date: 04/04/2023      SDS Number: 27095-00022      Date of last issue: 10/01/2022  
 Date of first issue: 10/31/2014

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
metformin hydrochloride	No data available	1115-70-4	$\geq 60 - < 80$ *
Sitagliptin	No data available	654671-77-9	$\geq 5 - < 10$ *
Cellulose	No data available	9004-34-6	$\geq 1 - < 5$ *
Titanium dioxide	Titanic anhydride	13463-67-7	$\geq 0.1 - < 1$ *

\* Actual concentration or concentration range is withheld as a trade secret

## SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice 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 unless directed to do so by medical personnel.  
 Get medical attention.  
 Rinse mouth thoroughly with water.  
 Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed : Contact with dust can cause mechanical irritation or drying of the skin.  
 Dust contact with the eyes can lead to mechanical irritation.  
 Harmful if swallowed.

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.

## SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray  
 Alcohol-resistant foam  
 Carbon dioxide (CO<sub>2</sub>)  
 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

**Sitagliptin / Metformin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 10/01/2022
5.0	04/04/2023	27095-00022	Date of first issue: 10/31/2014

- potential dust explosion hazard.  
Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides  
Nitrogen oxides (NO<sub>x</sub>)  
Metal oxides
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances 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 fire-fighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

**SECTION 6. ACCIDENTAL RELEASE MEASURES**

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective 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 container 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 determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

**SECTION 7. HANDLING AND STORAGE**

- Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.  
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- 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.  
Wash skin thoroughly after handling.

## Sitagliptin / Metformin Formulation

Version 5.0      Revision Date: 04/04/2023      SDS Number: 27095-00022      Date of last issue: 10/01/2022  
 Date of first issue: 10/31/2014

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment

Minimize dust generation and accumulation.

Keep container closed when not in use.

Keep away from heat and sources of ignition.

Take precautionary measures against static discharges.

Do not eat, drink or smoke when using this product.

Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage : Keep in properly labeled containers.  
 Store in accordance with the particular national regulations.  
 Materials to avoid : Do not store with the following product types:  
 Strong oxidizing agents

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

## Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
metformin hydrochloride	1115-70-4	TWA	1 mg/m <sup>3</sup> (OEB 1)	Internal
Sitagliptin	654671-77-9	TWA	0.5 mg/m <sup>3</sup> (OEB 2)	Internal
Cellulose	9004-34-6	TWA	10 mg/m <sup>3</sup>	CA AB OEL
		TWA (Total dust)	10 mg/m <sup>3</sup>	CA BC OEL
		TWA (respirable dust fraction)	3 mg/m <sup>3</sup>	CA BC OEL
		TWAEV (total dust)	10 mg/m <sup>3</sup>	CA QC OEL
		TWA	10 mg/m <sup>3</sup>	ACGIH
Titanium dioxide	13463-67-7	TWA	10 mg/m <sup>3</sup>	CA AB OEL
		TWA (Total dust)	10 mg/m <sup>3</sup>	CA BC OEL
		TWA (respirable dust fraction)	3 mg/m <sup>3</sup>	CA BC OEL
		TWAEV (total dust)	10 mg/m <sup>3</sup>	CA QC OEL
		TWA (Respirable particulate matter)	2.5 mg/m <sup>3</sup> (Titanium dioxide)	ACGIH

This substance(s) is not bioavailable and therefore does not contribute to a dust inhalation hazard.

Titanium dioxide

Engineering measures : Use feasible engineering controls to minimize exposure to compound.

**Sitagliptin / Metformin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 10/01/2022
5.0	04/04/2023	27095-00022	Date of first issue: 10/31/2014

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

**Personal protective equipment**

Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type	:	Particulates type
Hand protection	:	
Material	:	Chemical-resistant gloves
Eye protection	:	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Skin and body protection	:	Work uniform or laboratory coat.
Hygiene measures	:	If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance	:	powder
Color	:	No data available
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	:	No data available

**Sitagliptin / Metformin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 10/01/2022
5.0	04/04/2023	27095-00022	Date of first issue: 10/31/2014

---

Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	Not applicable
Relative vapor density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle size	:	No data available

---

**SECTION 10. STABILITY AND REACTIVITY**

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	May form explosive dust-air mixture during processing, handling 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.

**Sitagliptin / Metformin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 10/01/2022
5.0	04/04/2023	27095-00022	Date of first issue: 10/31/2014

**SECTION 11. TOXICOLOGICAL INFORMATION****Information on likely routes of exposure**

Inhalation  
Skin contact  
Ingestion  
Eye contact

**Acute toxicity**

Harmful if swallowed.

**Product:**

Acute oral toxicity : Acute toxicity estimate: 1,380 mg/kg  
Method: Calculation method

**Components:****metformin hydrochloride:**

Acute oral toxicity : LD50 (Rat): 1,000 mg/kg  
LD50 (Mouse): 1,450 - 3,500 mg/kg  
LD50 (Monkey): 463 mg/kg  
LD50 (Rabbit): 350 mg/kg  
LD50 (Guinea pig): 500 mg/kg

**Sitagliptin:**

Acute oral toxicity : LD50 (Rat): > 3,000 mg/kg  
LD50 (Mouse): 3,000 mg/kg

**Cellulose:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Acute inhalation toxicity : LC50 (Rat): > 5.8 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

**Titanium dioxide:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Acute inhalation toxicity : LC50 (Rat): > 6.82 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Assessment: The substance or mixture has no acute inhalation toxicity

**Sitagliptin / Metformin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 10/01/2022
5.0	04/04/2023	27095-00022	Date of first issue: 10/31/2014

---

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****metformin hydrochloride:**

Species	: Rabbit
Result	: Mild skin irritation

**Sitagliptin:**

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

**Titanium dioxide:**

Species	: Rabbit
Result	: No skin irritation

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****metformin hydrochloride:**

Species	: Rabbit
Result	: Mild eye irritation

**Sitagliptin:**

Species	: Rabbit
Result	: Irritating to eyes.
Method	: Draize Test

**Titanium dioxide:**

Species	: Rabbit
Result	: No eye irritation

**Respiratory or skin sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Components:****Sitagliptin:**

Test Type	: Local lymph node assay (LLNA)
Species	: Mouse
Method	: OECD Test Guideline 429
Result	: Not a skin sensitizer.

**Sitagliptin / Metformin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 10/01/2022
5.0	04/04/2023	27095-00022	Date of first issue: 10/31/2014

**Titanium dioxide:**

Test Type	: Local lymph node assay (LLNA)
Routes of exposure	: Skin contact
Species	: Mouse
Result	: negative

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****metformin hydrochloride:**

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative  Test Type: in vitro test Test system: mouse lymphoma cells Result: negative  Test Type: Chromosomal aberration Test system: Human lymphocytes Result: negative
Genotoxicity in vivo	: Test Type: Micronucleus test Species: Mouse Application Route: Oral Result: negative

**Sitagliptin:**

Genotoxicity in vitro	: Test Type: Ames test Result: negative  Test Type: Chromosome aberration test in vitro Test system: Chinese hamster ovary cells Result: negative  Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro) Test system: rat hepatocytes Result: negative
Genotoxicity in vivo	: Test Type: Micronucleus test Species: Mouse Application Route: Oral Result: negative

**Cellulose:**

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative  Test Type: In vitro mammalian cell gene mutation test Result: negative
-----------------------	---

**Sitagliptin / Metformin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 10/01/2022
5.0	04/04/2023	27095-00022	Date of first issue: 10/31/2014

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

**Titanium dioxide:**

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
-----------------------	--

Genotoxicity in vivo	: Test Type: In vivo micronucleus test Species: Mouse Result: negative
----------------------	--

**Carcinogenicity**

Not classified based on available information.

**Components:****metformin hydrochloride:**

Species	: Mouse
Exposure time	: 91 weeks
Dose	: 1500 mg/kg body weight
Result	: negative

Species	: Rat, male
Application Route	: Oral
Exposure time	: 104 weeks
Dose	: 900 mg/kg body weight
Result	: negative

Species	: Rat, female
Application Route	: Oral
Exposure time	: 104 weeks
LOAEL	: 900 mg/kg body weight
Result	: negative
Target Organs	: Uterus (including cervix)
Remarks	: The mechanism or mode of action may not be relevant in humans.

**Sitagliptin:**

Species	: Mouse
Application Route	: Oral
Exposure time	: 2 Years
Result	: negative

Species	: Rat
Application Route	: oral (drinking water)
Exposure time	: 2 Years
Result	: positive
Target Organs	: Liver
Remarks	: Significant toxicity observed in testing

**Sitagliptin / Metformin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 10/01/2022
5.0	04/04/2023	27095-00022	Date of first issue: 10/31/2014

Carcinogenicity - Assessment : Weight of evidence does not support classification as a carcinogen

**Cellulose:**

Species : Rat  
Application Route : Ingestion  
Exposure time : 72 weeks  
Result : negative

**Titanium dioxide:**

Species : Rat  
Application Route : inhalation (dust/mist/fume)  
Exposure time : 2 Years  
Method : OECD Test Guideline 453  
Result : positive  
Remarks : The mechanism or mode of action may not be relevant in humans.  
This substance(s) is not bioavailable and therefore does not contribute to a dust inhalation hazard.

Carcinogenicity - Assessment : Limited evidence of carcinogenicity in inhalation studies with animals.

**Reproductive toxicity**

Not classified based on available information.

**Components:****metformin hydrochloride:**

Effects on fertility : Test Type: Fertility  
Species: Rat  
Application Route: Oral  
Fertility: NOAEL: 600 mg/kg body weight  
Result: No effects on fertility.

Effects on fetal development : Test Type: Development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: NOAEL: 600 mg/kg body weight  
Result: No teratogenic effects.

Test Type: Embryo-fetal development  
Species: Rabbit  
Application Route: Oral  
Embryo-fetal toxicity: NOAEL: 140 mg/kg body weight  
Result: No teratogenic effects.

**Sitagliptin:**

Effects on fertility : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Oral  
Fertility: NOAEL Parent: 1,000 mg/kg body weight

**Sitagliptin / Metformin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 10/01/2022
5.0	04/04/2023	27095-00022	Date of first issue: 10/31/2014

	Result: Animal testing did not show any effects on fertility.
Effects on fetal development	: Test Type: Embryo-fetal development Species: Rat Application Route: Oral Teratogenicity: LOAEL: 250 mg/kg body weight Result: Embryotoxic effects and adverse effects on the offspring were detected., No teratogenic effects.
	Test Type: Embryo-fetal development Species: Rabbit Teratogenicity: NOAEL: 125 mg/kg body weight Result: No teratogenic effects.

**Cellulose:**

Effects on fertility	: Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative
Effects on fetal development	: Test Type: Fertility/early embryonic development Species: Rat Application Route: Ingestion Result: negative

**STOT-single exposure**

Not classified based on available information.

**STOT-repeated exposure**

Not classified based on available information.

**Repeated dose toxicity****Components:****metformin hydrochloride:**

Species	: Rat
NOAEL	: 125 mg/kg
Application Route	: Oral
Exposure time	: 1 year
Remarks	: No significant adverse effects were reported
Species	: Rabbit
NOAEL	: 100 mg/kg
Application Route	: Oral
Exposure time	: 1 Year
Remarks	: No significant adverse effects were reported
Species	: Dog
NOAEL	: 50 mg/kg
Application Route	: Subcutaneous
Exposure time	: 2 year
Remarks	: No significant adverse effects were reported

**Sitagliptin / Metformin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 10/01/2022
5.0	04/04/2023	27095-00022	Date of first issue: 10/31/2014

---

**Sitagliptin:**

Species	: Mouse
NOAEL	: 500 mg/kg
LOAEL	: 1,000 mg/kg
Application Route	: Oral
Exposure time	: > 2 y
Target Organs	: Kidney

Species	: Rat
NOAEL	: 500 mg/kg
LOAEL	: 1,000 mg/kg
Application Route	: Oral
Exposure time	: 14 Weeks
Target Organs	: Liver, Kidney, Heart, Teeth

Species	: Dog
NOAEL	: 10 mg/kg
LOAEL	: 50 mg/kg
Application Route	: Oral
Exposure time	: 53 Weeks
Target Organs	: Central nervous system
Symptoms	: Loss of balance
Remarks	: The mechanism or mode of action may not be relevant in humans.

Species	: Dog
NOAEL	: 2 mg/kg
LOAEL	: 10 mg/kg
Application Route	: Oral
Exposure time	: 27 Weeks
Target Organs	: Skeletal muscle, Central nervous system
Symptoms	: Loss of balance
Remarks	: The mechanism or mode of action may not be relevant in humans.

Species	: Monkey
NOAEL	: 100 mg/kg
Application Route	: Oral
Exposure time	: 14 Weeks
Remarks	: No significant adverse effects were reported

**Cellulose:**

Species	: Rat
NOAEL	: >= 9,000 mg/kg
Application Route	: Ingestion
Exposure time	: 90 Days

**Titanium dioxide:**

Species	: Rat
NOAEL	: 24,000 mg/kg
Application Route	: Ingestion
Exposure time	: 28 Days

**Sitagliptin / Metformin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 10/01/2022
5.0	04/04/2023	27095-00022	Date of first issue: 10/31/2014

Species	: Rat
NOAEL	: 10 mg/m <sup>3</sup>
Application Route	: inhalation (dust/mist/fume)
Exposure time	: 2 y

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Components:****metformin hydrochloride:**

Skin contact	: Remarks: May irritate skin.
Eye contact	: Remarks: May irritate eyes.
Ingestion	: Symptoms: Diarrhea, Nausea, Vomiting, Gastrointestinal discomfort, flatulence, asthenia, Fatigue, Headache

**Sitagliptin:**

Inhalation	: Symptoms: upper respiratory tract infection, pharyngitis, Headache
Ingestion	: Symptoms: upper respiratory tract infection, nasopharyngitis, Headache, Nausea, Abdominal pain, Diarrhea

**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****metformin hydrochloride:**

Toxicity to algae/aquatic plants	: EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201  NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to fish (Chronic toxicity)	: NOEC (Pimephales promelas (fathead minnow)): 10 mg/l Exposure time: 33 d Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC (Daphnia magna (Water flea)): 40 mg/l Exposure time: 21 d Method: OECD Test Guideline 211
Toxicity to microorganisms	: EC50: > 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209

**Sitagliptin:**

## Sitagliptin / Metformin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10/01/2022
5.0	04/04/2023	27095-00022	Date of first issue: 10/31/2014

Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 60 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): > 39 mg/l Exposure time: 96 h Method: OECD Test Guideline 201  NOEC (Pseudokirchneriella subcapitata (green algae)): 2.2 mg/l Exposure time: 96 h Method: OECD Test Guideline 201
Toxicity to fish (Chronic toxicity)	:	NOEC (Pimephales promelas (fathead minnow)): 9.2 mg/l Exposure time: 33 d Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 9.8 mg/l Exposure time: 21 d Method: OECD Test Guideline 211
Toxicity to microorganisms	:	EC50: > 150 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209  NOEC: 150 mg/l Exposure time: 3 h Test Type: Respiration inhibition

**Cellulose:**

Toxicity to fish	:	LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l Exposure time: 48 h Remarks: Based on data from similar materials
------------------	---	--

**Titanium dioxide:**

Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	EC50 (Skeletonema costatum (marine diatom)): > 10,000 mg/l Exposure time: 72 h
Toxicity to microorganisms	:	EC50: > 1,000 mg/l Exposure time: 3 h Method: OECD Test Guideline 209

**Sitagliptin / Metformin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 10/01/2022
5.0	04/04/2023	27095-00022	Date of first issue: 10/31/2014

---

**II****Persistence and degradability****Components:****metformin hydrochloride:**

Biodegradability	:	Result: rapidly degradable Biodegradation: 50 % Exposure time: 2 hrs
------------------	---	--

**Sitagliptin:**

Biodegradability	:	Result: not rapidly degradable Biodegradation: 39.7 % Exposure time: 28 d Method: OECD Test Guideline 314
Stability in water	:	Hydrolysis: 50 %(401 d) Method: OECD Test Guideline 111

**Cellulose:**

Biodegradability	:	Result: Readily biodegradable.
------------------	---	--------------------------------

**Bioaccumulative potential****Components:****metformin hydrochloride:**

Partition coefficient: n-octanol/water	:	log Pow: -2
--	---	-------------

**Sitagliptin:**

Partition coefficient: n-octanol/water	:	log Pow: -0.03
--	---	----------------

**Mobility in soil****Components:****metformin hydrochloride:**

Distribution among environmental compartments	:	log Koc: 4.3 Method: OECD Test Guideline 106
---	---	---

**Sitagliptin:**

Distribution among environmental compartments	:	log Koc: 4.37
---	---	---------------

**Other adverse effects**

No data available

---

**SECTION 13. DISPOSAL CONSIDERATIONS****Disposal methods**

Waste from residues	:	Dispose of in accordance with local regulations.
---------------------	---	--

**Sitagliptin / Metformin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 10/01/2022
5.0	04/04/2023	27095-00022	Date of first issue: 10/31/2014

**II**  
Contaminated packaging : Do not dispose of waste into sewer.  
Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

**SECTION 14. TRANSPORT INFORMATION****International Regulations****UNRTDG**

Not regulated as a dangerous good

**IATA-DGR**

Not regulated as a dangerous good

**IMDG-Code**

Not regulated as a dangerous good

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

Not applicable for product as supplied.

**Domestic regulation****TDG**

Not regulated as a dangerous good

**Special precautions for user**

Not applicable

**SECTION 15. REGULATORY INFORMATION****The ingredients of this product are reported in the following inventories:**

AICS : not determined

DSL : not determined

IECSC : not determined

**SECTION 16. OTHER INFORMATION****Full text of other abbreviations**

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
CA AB OEL	:	Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)
CA BC OEL	:	Canada. British Columbia OEL
CA QC OEL	:	Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
ACGIH / TWA	:	8-hour, time-weighted average
CA AB OEL / TWA	:	8-hour Occupational exposure limit
CA BC OEL / TWA	:	8-hour time weighted average
CA QC OEL / TWA EV	:	Time-weighted average exposure value

**Sitagliptin / Metformin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 10/01/2022
5.0	04/04/2023	27095-00022	Date of first issue: 10/31/2014

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; TECL - 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

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Revision Date : 04/04/2023  
Date format : mm/dd/yyyy

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

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.

CA / Z8