SAFETY DATA SHEET

According to Regulation (EC). No.1272/2008[CLP]

Document No.: SDS/ FM/ 0068 Version No.: 1.0 Effective Date: 13 Feb 2023

SECTION 1: CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

1.1 PRODUCT IDENTIFIERS

Product Name : Sitagliptin and Metformin HCl tablets 50 mg/500 mg

Synonyms : --

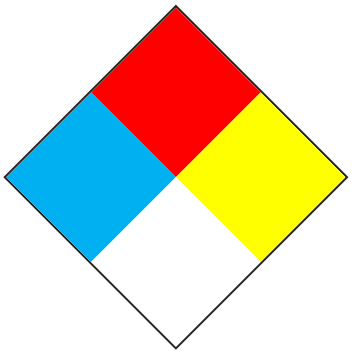
CAS No. : --

Molecular Weight : --

Molecular Formula : --

NFPA Rating

Health (Blue);
Flammability (Red);
Reactivity (Yellow);
Specific (White);



NFPA RATING			
Rating	NFPA-Blue	NFPA-Red	NFPA-Yellow
0	None	None	None
1	Very Low	Very Low	Very Low
2	Low	Low	Low
3	High	High	High
4	Very High	Very High	Very High
White (symbol & nature)			
OXY - Oxidizer		₩ - Use No Water	
ACID - Acid		☢ - Radiation Hazard	
ALK - Alkali		SA - Simple Asphyxiant	
COR - Corrosive		-- - Not Applicable	

1.2 CONTACT INFORMATION

Corporate Office : Laurus Labs Limited, 2nd Floor, Serene Chambers, Road No # 7, Banjara Hills, Hyderabad-500034. Telangana, India. Tel: 040-39804333

Registered Office : Laurus Labs Limited, Plot No. 21, J N Pharma City, Parawada, Anakapalli-531021. Andhra Pradesh, India. Tel: 0891 3061222

SECTION 2: HAZARDS IDENTIFICATION

2.1 CLASSIFICATION OF THE SUBSTANCE OR MIXTURE:

Not a hazardous substance or mixture according to Regulation (EC) No: 1272/2008. This substance is not classified as dangerous according to Directive 67/ 548/ EEC.

2.2 LABEL ELEMENTS:

Not a hazardous substance or mixture according to Regulation (EC) No: 1272/2008. The product does not need to be labelled in accordance with EC directives or respective national laws.

2.3 OTHER HAZARDS:

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: COMPOSITION/ INFORMATION ON INGREDIENTS

CAS #	Chemical name	Percent
486460-32-6	Sitagliptin hydrochloride monohydrate	4.36 – 7.98
1115-70-4	Metformin hydrochloride	70.42 – 77.27
9003-39-8	Polyvinyl pyrrolidone (Kollidon-30)	2.61 – 2.86
9004-34-6	Microcrystalline Cellulose (Pharmacel 102)	9.87 – 12.33
7757-93-9	Dicalcium phosphate anhydrous (A-tab)	2.52 - 4.61
74811-65-7	Croscarmellose sodium (Vivasol GF LM)	0.31 -0.56

9004-82-4	Sodium lauryl sulfate (Kolliphor SLS)	0.5
557-04-0	Magnesium stearate (Ligamed MF-2-V)	1.00
Not assigned	Opadry II Pink 85F540445	3.0

SECTION 4: FIRST AID MEASURES

4.1 DESCRIPTION OF NECESSARY FIRST-AID MEASURES:

Eye contact:

Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. Get medical attention immediately.

Skin contact:

In case of contact, immediately flush skin with plenty of water. Cover the irritated skin with an emollient / Remove contaminated clothing and shoes. Cold water may be used. Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention.

Inhalation:

If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Ingestion:

Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately / Loosen tight clothing such as a collar, tie, belt or waistband.

4.2 MOST IMPORTANT SYMPTOMS/ EFFECTS - ACUTE AND DELAYED:

Causes serious eye irritation. Contact with dust can cause mechanical irritation or drying of the skin.

4.3 INDICATION OF IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED:

Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1 EXTINGUISHING MEDIA:

Suitable extinguishing media: Water,Foam (AFFF),ABC Powder,Carbon Dioxide,DCP (Dry Chemical Powder)

Unsuitable extinguishing media: For this substance/ mixture no limitations of extinguishing agents are given.

5.2 SPECIFIC HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE:

carbon oxides (COx), nitrogen oxides (NOx), and, gaseous hydrogen chloride (HCl).

5.3 ADVICE FOR FIRE FIGHTERS:

Wear self contained breathing apparatus for firefighting if necessary.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 PERSONAL PRECAUTIONS PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES:

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.

6.2 ENVIRONMENTAL PRECAUTIONS:

Ensure adequate ventilation. Use personal protective equipment. Avoid dust formation. Keep people away from and upwind of spill/leak. Evacuate personnel to safe areas.

6.3 METHODS AND MATERIALS FOR CONTAINMENT AND CLEANING UP:

Do not flush into surface water or sanitary sewer system. Do not allow material to contaminate ground water system.

SECTION 7: HANDLING AND STORAGE

7.1 PRECAUTIONS FOR SAFE HANDLING:

During handling wear personal protective equipment. Ensure adequate ventilation. Avoid contact with skin eyes and clothing. Avoid ingestion and inhalation.

7.2 CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES:

Store in well closed containers at 15 to 30°C.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

8.1 CONTROL PARAMETERS:

No Data available

8.2 EXPOSURE CONTROLS:

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

8.3 PERSONAL PROTECTIVE EQUIPMENT :



Eye & Face protection:

Use personal protective equipment Nose mask, goggles & gloveless as described by the Indian standard and other international standard.

Skin & Body protection:

Long sleeved clothing. Gloves must be inspected prior to use

Respiratory protection:

For nuisance exposures use respirator cartridges. Use respirators and components tested and approved under appropriate government standards

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES:

Physical state & Appearance	:	capsule shaped, film-coated tablet
Colour	:	Light pink
Odor	:	No data available
Odour threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Boiling point / range	:	No data available
Flash point	:	No data available
Flammability (solid, gas)	:	No data available
Flammability or explosive limits - Upper	:	No data available
Flammability or explosive limits - Lower	:	No data available
Evaporation rate	:	No data available

Vapour pressure	:	No data available
Vapour density	:	No data available
Relative density	:	No data available
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Special gravity	:	No data available
Oxidizing properties	:	No data available
Viscosity	:	No data available

SECTION 10: STABILITY AND REACTIVITY

10.1 REACTIVITY:

No data available

10.2 CHEMICAL STABILITY:

Stable under normal conditions.

10.3 POSSIBILITY OF HAZARDOUS REACTIONS:

May form explosive dust-air mixture during processing, handling or other means.

10.4 CONDITIONS TO AVOID:

Heat, flames and sparks. Avoid dust formation

10.5 INCOMPATIBLE MATERIALS:

None

10.6 HAZARDOUS DECOMPOSITION PRODUCTS:

Hazardous decomposition products formed under fire conditions: carbon oxides (COx), nitrogen oxides (NOx), and, gaseous hydrogen chloride (HCl).

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS:

Acute Toxicity:

Type	Species	Value	Unit	Any other
LD50, Oral	Rat	> 3,000	mg/kg	Sitagliptin
LD50, Oral	Rat (Male)	1770	mg/kg	Metformin Hydrochloride
	Rat (Female)	1770	mg/kg	Metformin Hydrochloride

Skin corrosion/irritation:

No data available

Serious eye damage/eye irritation:

No data available

Respiratory or skin sensitization:

No data available

Germ cell mutagenicity:

No data available

Carcinogenicity:

IARC: No component of this product presents at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC. To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Reproductive toxicity:
No data available
Specific target organ toxicity - single exposure:
No data available
Specific target organ toxicity - repeated exposure:
No data available
Aspiration hazard:
No data available

11.2 ADDITIONAL INFORMATION:
The toxicological properties have not been fully investigated.

SECTION 12: ECOLOGICAL INFORMATION

12.1 ECO-TOXICITY:
No data available
Toxicity to algae:
No data available

12.2 PERSISTENCE AND DEGRADABILITY:
Biodegradability:
No data available

12.3 BIOACCUMULATIVE POTENTIAL:
No data available

12.4 MOBILITY IN SOIL:
No data available

12.5 OTHER ADVERSE EFFECTS:
No data available

SECTION 13: DISPOSAL CONSIDERATIONS

Waste Disposal methods -Waste must be segregated, stored and disposed of in accordance with central, state and local environmental control regulations.

SECTION 14: TRANSPORT INFORMATION

	TRANSPORT	ADR/RID	IMDG	IATA
14.1	UN NUMBER	--	--	--
14.2	UN PROPER SHIPPING NAME	Not dangerous goods	Not dangerous goods	Not dangerous goods
14.3	TRANSPORT HAZARD CLASS(ES)	--	--	--
14.4	PACKING GROUP	--	--	--
14.5	ENVIRONMENTAL HAZARD	No	No	No
14.6	SPECIAL PRECAUTIONS FOR USER	--	--	--
14.7	SYMBOL	--		

SECTION 15: REGULATORY INFORMATION

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

This safety datasheet complies with the requirements of Regulation (EC) No. 1272/2008.

SECTION 16: OTHER INFORMATION

DISCLAIMER:

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product.

Revision log:

Revision No.	Reason for Revision	Effective Date
0.0	First issue	23 Oct 2019
1.0	Changed into new template and Sections 1,3,7 & 9 modified	13 Feb 2023

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END OF SAFETY DATA SHEET

----- This is an electronically generated SDS, and hence need not be signed -----