# **Material Safety Data Sheet**

Effective Date: Due Date:

Section 1 : Chemical Product Company Identification	
Product Name	Tadalafil EP Impurity C
CAT No.	KMT020015
CAS No.	NA
Identified uses	Pharmaceutical Reference Standard
Details of the Supplier Company	K. M. PHARMA SOLUTION PRIVATE LIMITED Unit No.101, Shivam Industrial park, Sarkhej-bavala NH=8A, At-Moraiya, Changodar, Ahmedabad (Gujarat), India-382213
Telephone	+91 9898822121

Section 2 : Chemical Information	
Chemical Name	(6S,12aR)-6-(1,3-Benzodioxol-5-yl)-2-methyl-2,3,6,7,12,12a-hexahydropyrazino[1',2':1,6]pyrido[3,4-b]indole-1,4-dione hydrochloride trihydrate (as per EP)
CAS No.	NA
Molecular Weight	389.4 : 36.5 : 3(18.0)
Molecular Formula	C22H19N3O4 : HCl : 3(H2O)

Section 3: Hazards Identification		
Emergency Overview:		
Appearance	NA	
Target Organs	NA	
Potential Health Effects:		
Eye	NIL	
Skin	NIL	
Ingestion	NIL	
Inhalation	NIL	
Chronic	NIL	



Section 4 : First Aid Measures	
Eye	Wash with plenty of water
Skin	Wash with plenty of water
Ingestion	Medical assistance for gastric lavage.
Inhalation	Remove to fresh air, artificial respiration or oxygen if necessary.
Notes to Physician	Tadalafil EP Impurity C can be washed with plenty of water in case of any exposure

Section 5 : Firefighting Measures	
Extinguishing Media	Carbon dioxide, dry chemical powder, foam, water.
Unusual Fire and Explosion Hazards	None indicated

Section 6 : Accidental Release Measures	
Personal Precautions	Wear self-contained breathing apparatus, avoid dust formation.
Spills/Leaks	Wash with plenty of water, provide adequate ventilation.

Section 7 : Handlings and Storage	
Handling	Wear surgical gloves
Storage	~Storage

Section 8 : Exposure Controls, Personal Protection	
Respiratory Protection	Self-contained breathing apparatus
Exposure Limits	NA
Eye Protection	Wear safety goggles
Other Protective Equipment	Protective clothing
Skin	Full sleeves apron
Clothing	Cotton
1.	

Section 9 : Physical and Chemical Properties	
Appearance	NA
Odor	NA
Melting Point	NA



рН	NA
Vapor Pressure	NA
Vapor Density	NA
Evaporation Rate	NA
Viscosity	NA
Boiling Point	NA
Decomposition Temp	NA
Auto ignition Temp.	NA
Flash Point	NA
NFPA Rating	NA
Flash Point NA  NFPA Rating NA  Explosion Limits  Lower NA	
Lower	NA
Upper	NA
Solubility	NA NA
Specific Gravity/Density	NA

Section 10 : Stability and Reactivity	
Chemical Stability	~ChemicalStability
Conditions to avoid	Direct contract to skin
Incompatibilities with other Materials	Keep away
Hazardous Decomposition Products	NIL
Hazardous Polymerization	NIL

Section 11 : Toxicological Information	
CAS	NA
LD50/LC50	>10,000 mg/kg Remarks: Behavioral:Somnolence (general depressed activity)
Carcinogenicity	NIL
Epidemiology	NIL
Teratogenicity	NIL
Reproductive Effects	NIL
Neurotoxicity	NIL



Mutagencity	NIL
Other Studies	NA

### **Section 12: Ecological Information**

Data not available

## **Section 13: Disposal Consideration**

RCRA P-Series	Can be incinerated	
RCRA U-Series	NA	2

# **Section 14: Transport Consideration**

#### **UN-Number**

ADR/RID: IMDG: IATA:

#### **UN proper shipping name**

ADR/RID: Not dangerous goods IMDG: Not dangerous goods IATA: Not dangerous goods

#### Transport hazard class(es)

ADR/RID: IATA: IMDG:

#### **Packaging Group**

ADR/RID: IMDG: IATA:

#### **Environmental hazards**

ADR/RID: No

IMDG Marine pollutant: No

IATA: No

#### Special precautions for users

#### **Further information**

# Section 15: Regulatory Information

TSCA	Attached the letter
Health & Safety Reporting List	No data available
Chemical Test Rules	Chemical analysis report is attached



# **Section 16: Additional Information**

This product is not bioactive, non-radioactive. It is for R&D use only. Not for drug, household or other uses.

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. It does not represent any guarantee of the product.



