Material Safety Data Sheet

Effective Date: 09/02/2026 **Due Date:** 08/02/2029

Section 1 : Chemical Product Company Identification

Product Name	Pregabalin Impurity Mixture of PD0312236 & PD0312237
CAT No.	KMP004098
CAS No.	Not Available
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	(S)-1-(((2R,3R,4S,5R)-2,3-dihydroxy-5-(hydroxymethyl)-4-(((2S,3R,4S,5R,6R)-3,4,5-trihydroxy-6-(hydroxymethyl)tetrahydro-2H-pyran-2-yl)oxy)tetrahydrofuran-2-yl)methyl)-4-isobutylpyrrolidin-2-one compound with (S)-4-isobutyl-1-(((2R,3S,4R,5R)-2,3,5-trihydroxy-4-(((2S,3R,4S,5R,6R)-3,4,5-trihydroxy-6-(hydroxymethyl)tetrahydro-2H-pyran-2-yl)oxy)tetrahydro-2H-pyran-2-yl)methyl)pyrrolidin-2-one (1:1)
CAS No.	Not Available
Molecular Weight	465.5
Molecular Formula	C20H35NO11

Section 3 : Hazards Identification

Emergency Overview:	
Appearance	Off White Solid
Target Organs	NA
Potential Health Effects:	
Eye	NIL
Skin	NIL
Ingestion	NIL

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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	Pregabalin Lactose Conjugate Impurity (Mixture of Isomers) 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

Section 9 : Physical and Chemical Properties

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Appearance	Off White Solid
Odor	NA
Melting Point	NA
pH	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
Explosion Limits	
Lower	NA
Upper	NA
Solubility	Water
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

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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

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: IMDG: IATA:

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

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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.

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