Safety Data Sheet

Section 1 : Chemical Product Company Identification	
Product Name	Pregabalin Lactose Conjugate Impurity (Mixture of Isomers)
CAS No.	NA
Identified uses	Pharmaceutical Reference Standard
Details of the Supplier Company	SynZeal Research Pvt Ltd Survey No. - 355/404/407, Rajoda, Bavla, Dist. Ahmedabad - 382 220, Gujarat, INDIA
Telephone	+91-7969225400

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.	NA
Molecular Weight	465.5
Molecular Formula	C20H35NO11

Section 3 : Hazards Identification	
Emergency Overview:	
Appearance	White Solid
Target Organs	NA
Potential Health Effects:	
Eye	NA
Skin	NA
Ingestion	NA
Inhalation	NA
Chronic	NA
Label Elements:	

Pictogram		

Hazard Statement:
H302: Harmful if swallowed.
H312: Harmful in contact with skin.
H315: Causes skin irritation.
H319: Causes serious eye irritation.
H332: Harmful if inhaled.
H335: May cause respiratory irritation.
Precautionary Statement:
P261: Avoid breathing dust/fume/gas/mist/vapours/spray.
P262: Do not get in eyes, on skin, or on clothing.
P271: Use only outdoors or in a well-ventilated area.
P280: Wear protective gloves/protective clothing/eye protection/face protection.
P302 + P352:IF ON SKIN: Wash with plenty of water
P304 + P340:IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305 + P351 +P338:IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P313:IF exposed or concerned: Get medical advice/attention.

Label Elements:		
Pictogram		

Hazard Statement:
H302: Harmful if swallowed.
H312: Harmful in contact with skin.
H315: Causes skin irritation.
H319: Causes serious eye irritation.
H332: Harmful if inhaled.
H335: May cause respiratory irritation.
Precautionary Statement:
P261: Avoid breathing dust/fume/gas/mist/vapours/spray.
P262: Do not get in eyes, on skin, or on clothing.
P271: Use only outdoors or in a well-ventilated area.
P280: Wear protective gloves/protective clothing/eye protection/face protection.
P302 + P352:IF ON SKIN: Wash with plenty of water
P304 + P340:IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305 + P351 +P338:IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P313:IF exposed or concerned: Get medical advice/attention.

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	

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	
Appearance	White Solid
Odor	Odor less
Melting Point	NA
pH	Basic
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	Chloroform, Methanol
Specific Gravity/Density	NA

Section 10 : Stability and Reactivity

Chemical Stability	
Conditions to avoid	Direct contract to skin
Incompatibilities with other Materials	Keep away
Hazardous Decomposition Products	NA
Hazardous Polymerization	NA

Section 11 : Toxicological Information	
CAS	NA
LD50/LC50	NA
Carcinogenicity	NA
Epidemiology	NA
Teratogenicity	NA
Reproductive Effects	NA
Neurotoxicity	NA
Mutagencity	NA
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
Health and 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 and 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.