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Mfg. Bulk Drug

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MATERIAL SAFETY DATA SHEET

1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product Identifier:

Calcite Powder			
CHEMICAL NAMES	SYNONYMS		
Calcite Powder	Calcii Carbonas		

1.2 Relevant , identified uses of the substance/ preparation and uses which are not recommended.

Identified uses of the substance /preparation: Manufacture of CaCO₃ Not recommended uses of the substance/ preparation: None

1.3 Details of the supplier, who provides the Safety Data Sheet

Manufacturer SBF PHARMA Block No. 265, Santej Vadasar Road, B/H Kitchen Express, Ta- Kalol, Dis- Gandhinagar, Gujarat-382721 Phone: +91 9879522397 Information Contact: 9879522397

E-mail: <u>info@sbfpharma.com</u> Website: <u>www.sbfpharma.com</u>

1.4 Dept. responsible for information: - Department Regulatory Affairs

2.0 HAZARDS IDENTIFICATION

2.1 Classification of the substance/preparation

This mixture is classified as) not hazardous according to Regulation (EC) 1272/2008(GHS).\

There is no obligatory labelling requirement according to the Directive covering preparations 1999/45/EC.

2.2 Labelling according to Regulation (EC) No 1272/2008

Hazard pictograms:

Signal word: - Non Hazardous H

- phrases: ---
- P phrases: 102 Keep out of reach of children
 - 260 Do not breathe dust/fume/gas/mist/vapour/spray.
 - 270 Do no eat, drink or smoke when using this product.

2.3 Labelling according to Directive 67/548/EEC

- Hazard symbols:
 - R phrases :-
 - **S phrases** :- 2 Keep out of the reach of children.

13 Keep away from food, drink and animal feeding stuffs. 20/21

- When using do not eat, drink or smoke.
- 22 Do not breathe dust.
- **2.4** Additional critical hazard to man and environment: No risks worthy of mention.

3 COMPOSITION / INFORMMATION ON INDREDIENTS

- 3.1 Chemical characterization:-, Calcite PowderGround, natural Calcite Powder (CaCO₃₎
- 3.2 Composition of the substance / preparation

Chemical name	CAS. No.	Einecs No.	EC Index-No.	Concentration	Classification
Calcite Powder	471-34-1	207-439-9	215-279-6	Min. 98.5%	-

3.3 Additional information:- None

Revision No.: 4th

<u>4.</u>

FIRST AID MEASURES

4.1	Description of the first aid measures
	General Information : In case of accident or if you feel unwell, seek medical advice immediately (show
	safety data sheet if possible)
	Following Inhalation: Provide fresh air. In case of irritation of the respiratory tract seek medical advice. After
	contract with skin, wash immediately with plenty of water and soap. In case of skin irritation, seek medical treatment.
	Following eye contact: In case of contact with eyes, rinse immediately with plenty of following water for 10 to
	15 minutes holding eyelids apart. Subsequently consult an ophthalmologist.
	After Ingestion: Rinse mouth immediately and drink large quantity of water. No
	administration in cases of unconsciousness or cramps. Do not induce
	vomiting. Seek medical attention if problems persist.
	Self protection:- No special measures are necessary.
4.2	Major acute and delayed occurring symptoms and dangers
	Symptoms : Milk-alkali syndrome. Calcite Powder syndrome.
	Nature of Hazard, Humanalezamia, Alkalacia, Banal durfunction
	Nature of Hazard: Hypercalcaemia, Alkalosis. Renal dysfunction.
4.3	Information on emergency aid or special treatment
	Emergency aid: Let water be swallowed in little sips, vomiting.
	Treatment: Treat symptomatically.
<u>5.</u>	FIRE FIGHTING MEASURES
5.1	General information:- Extinguisher materials should be selected according to the surrounding area. The product itself is not combustible.
5.2	Extinguishing Media:- Suitable: Water fog. High power water jet. Carbon dioxide (CO3). Foam. Dry extinguishing
0.2	powder.
	Unsuitable: None
5.3	Special exposure hazards arising from the substance/ preparation:- Releases: Carbon Dioxide, Calcium Oxide.
5.4	Instruction for fire fighting
	Special protective equipment for fire –fighters.
	Wear a self contained breathing apparatus and chemical resistant suit.
	Additional information
	Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.
<u>6.</u>	ACCIDENTAL RELEASE MEASURES
6.1	Personal precautions, protective equipment and emergency procedures
0.1	Provided adequate ventilation, wear personal protection equipment. See protective measure under point 7 and
	8.
6.2	Environmental precautions:- Do not empty into drains or the aquatic environment.
6.3	Methods and materials for retention and cleaning up
0.0	Remove mechanically, placing in appropriate containers for disposal. Treat the assimilated material according to the section
	on waste disposal. Avoid generation of dust. Clear contaminated area thoroughly. Wash with generous amount of water.

6.4 Reference to other section:- Absorb wet solids or soak them up.

HANDLING AND STORAGE

7.1 Safety measures for safe handling

Information of safe handling: - Avoid generation of dust. Do not breath dust.

Technical measures: - Provide for sufficient ventilation and punctiform suction at critical points.

Precautions against fire and explosion:-No special fire protection measures are necessary.

Additional Information: - None

7.2 Conditions for safe storage

Technical measure and storage conditions:- Ensure adequate ventilation of the storage area.

Packing materials: - Keep/store only in original container.

Requirements for store rooms and containers:-Keep containers tightly closed and in a well ventilated place.

Information about storing together in the storage facility:-Do not store together with acid, oxidizing agents,

aluminium, magnesium. Keep away from food, drink and animal feeding stuffs.

Further information concerning storage conditions:-None. Storage

class: 13 non-combustible solids.

7.3 Specific use(s):- Observe instructions for use.

<u>8.</u>

Exposure controls/Personal protection equipment

8.1 Parameters to control Exposure limit values

Calcite Powder

CAS-No.: 471-34-1

Source: TRGS 900-Common dust limit (01/2006) Occupational exposure limit value: 3 mg/m³ A or 1 mg/m³ E Limitation of exposure peaks: 2(II)

Remark: AGS

A: Alveolar dust fraction E: respirable dust fraction AGS Committee on Hazardous Substances

Control-Banding:-None

8.2 Exposure controls Occupational exposure controls Recommended monitoring procedures: Flame-AAS

Chemical handling

Do not eat, drink, smoke or sneeze at the workplace. Wash hands before breaks and at the end of work. Apply skin care products after work. Wash contaminated clothing prior to re-use.

Personal protection equipment:-None

Respiratory protection:-With correct and proper use, and under normal conditions, breathing protection is not required.

Respiratory protection required in case of: exceeding critical value:-Suitable respiratory protective equipment: particulates filter device (DIN EN 143)

Hand protection:-Hand protection: not required. Eye

protection:-Tightly sealed safety glasses. Skin

protection:-Skin protection: not required

<u>7.</u>

Environmental exposure controls:-Refer to chapter 7. No further action is necessary.

Consumer exposure controls:-Refer to chapter 7. No further action is necessary.

<u>9.</u>

Physical and Chemical properties

9.1 Information on the basic physical and chemical properties

Appearance

Status of matter: Solid: Powder Colour:

White to off white

Odour: Odourless

Odour threshold: None Safety relevant basis data

	Parameter	value	unit	Remark.
Density:	at 20°C	2.71	g/cm ³	measurement
Package density:		400-700	kg/cm ³	literature (GESTIS)
pH:	at 100 g/l	9.4		measurement
Melting point/range:			825°C	slow decomposition
Boiling temperature/range:				not applicable
Flash point:				no flash point
Flammability:				not applicable
Lower flammability limit:				not applicable
Upper flammability limit:				not applicable
Explosion hazard:				not applicable
Lower explosion hazard				not applicable
Upper explosion hazard				not applicable
Ignition temperature:				not applicable
Decomposition temperature:		>800°C		not applicable
Oxidizing characteristics:				not oxidizing
Vapour pressure:				not applicable
Relative vapour density:				not applicable
Speed of				
Vaporization/evaporation rate:				not applicable
Solubility in water:	at 20°C	0.3%		measurement
Fat solubility:				insoluble
Solubility in				not applicable
log P O/W (n-octanol/water):				not applicable
Viscosity:				not applicable
Solvent separation test:				not applicable
Solvent content:				not applicable

9.2 Other Information:-CaCO3 dissolves in strong acids, releasing CO2

10. Stability and reactivity

10.1 Reactivity:-None.

 $10.2 \ Chemical stability: \hbox{-} Decomposition takes place from temperature above 825 ^{\circ}C$

10.3 Possible reactions:-Violent reaction with: Acid, Formation of: Carbon dioxide.

10.4 Conditions to avoid:-None

- 10.5 Materials to avoid:-Acid, Oxidizing agents, strong Aluminium, Magnesium.
- **10.6 Hazardous decomposition products:-**Calcium oxide, calcium dioxide.
- 10.7 Additional information:- None

11. Toxicological information

11.1 Information on toxicological effects:-Data apply to the principal component. Acute

toxicity

Calcite Powder CAS No.: 471-34-1 Toxicological information acute toxicity, oral LD50:6450 mg/kg (Rat) **Specific**

symptoms in Laboratory animals:-No information Available.

11.2 Irritation and etching

Irritant effect on the skin:-Not an irritant. Irritant on the eye:-Mild irritant. Irritant effect on the respiratory tract:-Mild irritant. Etaching:-Not corrosive

11.3 Sensitization:- No danger of sensitization.

- 11.4 Repeated dose toxicity:-Danger of cumulative effects. Milk-alkali- or Calcite Powder – syndrome.(4-60 g/d orally)
- 11.5 CMR effects Carcinogenicity:-None Mutagenicity:-None Reproductive toxicity:-None
- 11.6 General remarks:-None Practical experience:-None Other observations:-None Additional information :-None

<u>12.</u>

ECOLOGICAL INFORMATION

12.1 Information on ecological effects:- No information available.

- 12.2. Persistence and Biodegradation :- No information available.
- 12.3 Bio accumulative potential:- No information available.
- **12.4 Mobility:-** No information available.
- 12.5 Results of PBT and vPvB assessments:-This substance does not meet the criteria for classification as PBT or vPvB.
- 12.6 Other harmful effects:- None
- 12.7 Further ecological information:-Do not empty into drain or the aquatic environment.
- 12.8 Further details :-None

<u>13.</u>

DISPOSAL CONSIDERATIONS

13.1 Appropriate disposal

Appropriate disposal/ Products:-Waste disposal according to EC directive 75/442/EEC and 91/689/EEC on waste and hazardous waste in their latest versions.

Appropriate disposal/packaging:-Cleaned containers may be recycled. Handle contaminated packaging in the same way as the substance itself.

Control report for waste code/ waste marking according to EAKV:-According to EAKV, allocation of waste identity numbers/ waste description must be carried out in a specific way for every industry and process.

Waste key product: 02 04 02 or 03 03 09 Waste key packaging: 02 04 02 or 03 03 09

Remarks:-Waste disposal according to official state regulations.

TRANSPORT INFORMATION

<u>4.</u> 1/1 Overlan

 14.1 Overland transport (ADR/RID)

 Proper shipping Calcite Powder,

 ALL QUALITIES

 UN No.:

 Label:
 Packing Group:

 Classification code: - Remarks:

 Not a hazardous material with respect to these transportation regulations.

14.2 Transport by sea (IMDG)

Proper Shipping name Calcite Powder ALL QUALITIES UN No.: - ---

 Label:
 - Packing Group: Classification code: --

 EmS No.
 -- MFAG: -- Marine pollutant: No

 Special Provisions: keep away from food, drink and animal feeding stuffs.

Remark: not a hazardous material with respect to these transportation regulations.

14.3 Air transport (ICAO-TI/IATA-DGR)

Proper Shipping name CALCITE POWDER, ALL QUALITIES UN/ID-No.: ----Label: ----

packing group: ---

Remark: Not a hazardous material with respect to these transportation regulations.

14.4 Mail

<u>15.</u>

Not a hazardous material with respect to these transportation regulations.

REGULATORY INFORMATION

15.1 Labelling

Hazardous component(s) for labelling:-Calcite Powder, Special labelling of particular preparations :-Safety data sheet available for professional user on request.

15.2 Regulations for the safety, health and environmental protection as well as specific Legislation for the substance/preparation

EU-Regulations

Directive 1999/13/EC on the limitation of emissions of volatile organic compounds (VOC-RL):-None Regulation (EC) No 2037/2000 on substances that deplete the ozone layer:-None Regulation (EC) No 850/2004 on persistent organic pollutants:-None

Regulation (EC) No 689/2008 concerning the export and import of dangerous chemicals:-None

Regulations (EC) No 648/2004 (Detergents regulation):-None

Restrictions under Title VIII of Regulation (EC) No 1907/2006:-None National

regulations :- Moreover, national legislation has to be observed! Informations

on working limitations:-None

Major Accidents Ordinance :- None

Storage class according to VCL:-13 Non-combustible solids

Water Hazard Class according to VwVwS:-0 not a water pollutant

Technical instructions on Air Quality Control (TA-Luft):-Total dust emission levels shall not be exceeded (see paragraph 5.2.1).

Further regulations, limitations and legal requirements:-None

<u>14.</u>

15.3 Chemical safety assessment

For this preparation, a chemical safety assessment has been carried out: For this substance a chemical safety assessment is not required.

<u>16.</u>

OTHER INFORMATION

- 16.1 Wording of the H and R-phrases under paragraph 3 Regulation (EC) No 1272/2008:- ----Directive e67/548/EEC:----
- 16.2 Training instructions: None
- 16.3 Recommended restrictions of use:- Refer to chapter 1

16.4 Further remarks

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information can not be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the made-up material.

- 6.5 Documentation of changes:-None
- $16.6 \hspace{0.1 cm} \text{Data sources:-} \text{Data arise from reference works and literature}$
- 16.7 Key and definition:-None