

SAFETY DATA SHEET

Document No.: SDS/BO01.00

Product : BARETab ODT

Review On : 18.08.2022

01 IDENTIFICATION:

Product identifier:

Product Name: BARETab ODT

[Premix of Microcrystalline Cellulose USP-NF/Ph. Eur. (MCC), Mannitol, Croscarmellose Sodium USP-NF/ Ph. Eur. (CCS)]

Trade name: BareTab™ ODT

Grade : 50M / 90M

Article number: Not available

CAS (Chemical Abstract Services) Number: Given in point no. 3 for each individuals

EC number: Not available

Recommended Use of the chemical: As excipient in drug products , As food additive in food preparations.

Supplier Details: Manufacturer & Supplier: **M/s. SIGACHI INDUSTRIES LIMITED.**

Head Office:

4th Floor, Kalyan's Tulsiram Chambers,
Madinaguda, Hyderabad
Telangana (India) – 500 049

Manufacturing Unit:

Plot no. Z-16, Dahej SEZ Part I,
Dahej, Dist. Bharuch – 392130
Gujarat state (india)
e-mail: qa.dahej@sigachi.com
Information department: Product safety department

Emergency telephone number: 02641 291951, 9392259755

02 HAZARD(Z) IDENTIFICATION :

Classification of the substance or mixture

EC Regulation No. 1272/2008 : Not Applicable

Classification according to Directive 67/548/EEC or Directive 1999/45/EC : None listed as hazardous

Information concerning particular hazards for human and environment : Not applicable.

Label elements : Not applicable

GHS label elements : Not applicable

Hazard pictograms – None required

Signal word : None required

Hazard statements: May cause respiratory irritation if dusting inhaled.

Precautionary statements: If medical advice is needed have product container or label at hand. Keep out of reach of children. Read label before use. Avoid breathing dust. IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a doctor/physician if you feel unwell. Store in a well-ventilated place. Keep container tightly closed. Dispose of contents/container in accordance with local/regional/national/international regulations.

03 COMPOSITION / INFORMATION ON INGREDIENTS

- Chemical characterization : White, crystalline free flowing powder and sweet in taste.
- Synonyms : Not applicable
- Therapeutic Category : Drug excipient (Tablet and Capsule diluents),
- Compositions

Material	CAS No.	E Number	Reference
Microcrystalline Cellulose	9004-34-6	E 460	USP-NF/Ph.Eur
Mannitol	69-65-8	E 421	NF
Croscarmellose Sodium	74811-65-7	E 468	USP-NF/Ph.Eur

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#229/1 & 90, 4th Floor, Kalyan's Tulasiram Chamber's, Madinaguda, Hyderabad -500 049, Telangana State, India.

Tel.: +91-40-40114874 / 75 / 76, Email : customercare@sigachi.com, website: www.sigachi.com

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04	FIRST AID MEASURES
	Description of first aid measures General information : No special measures required. After inhalation : Supply fresh air; consult doctor in case discomfort occurs and persists. After skin contact : Wash with plenty of water. Use soap solution if required. After eye contact : Rinse opened eye for several minutes under running water. Consult doctor if irritation occurs and persists. After swallowing : Have a person sip a glass of water. If any discomfort persists consult doctor. Information for doctor: Most important symptoms and effects, both acute and delayed. No further relevant information available. Indication of any immediate medical attention and special treatment needed No further relevant information available.
05	FIRE FIGHTING MEASURES
	Suitable extinguishing agents: CO₂, any media suitable for extinguishing or water spray. Special hazards arising from the substance or mixture : No further relevant information available. Advice for firefighters: Use protective equipment against the hazard of heat. Do not breathe smoke/gas generated.
06	ACCIDENTAL RELEASE MEASURES
	Personal precautions, protective equipment and emergency procedures: Evacuate personnel to safe area. Provide adequate ventilation. Environmental precautions : Reduce airborne dust and prevent scattering by moistening with water. Methods and material for containment and cleaning up : Pick up mechanically. Sweep up the spilled material. Wash spilled area with soap and water. Reference to other sections : See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.
07	HANDLING AND STORAGE
	Handling: Precautions for safe handling : To be handled as per labeled instruction Information about protection against explosions and fires : No special measures required. Conditions for safe storage, including any incompatibilities: Storage : Store in a dry and ventilated area. Requirements to be met by storerooms and receptacles : Keep unexposed Information about storage in one common storage facility : No special measures required. Further information about storage conditions : Store protected from light and moisture Specific end use(s) : As food additive, pharma excipient
08	Exposure controls / personal protection
	Additional information about design of technical systems : No further data; See item 7. Control parameters Exposure limit: Microcrystalline cellulose – 10 mg/m³, Mannitol-NA Croscarmellose Sodium - NA Exposure controls : Prevent from dusting.

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	Personal protective equipment : Nose mask, safety glasses, Gloves General protective and hygienic measures: The usual precautionary measures for handling chemicals should be followed. Breathing equipment : Nose mask to prevent inhale of dusting. Protection of hands : Gloves should be used. Replace the gloves considering the penetration times, rates of diffusion and the degradation Material of gloves : The glove material has to be impermeable and resistant to the substance. Penetration time of glove material The exact break through time has to be decided by the user of the protective gloves and has to be observed. Eye protection: Use safety glasses while handling.
09	PHYSICAL AND CHEMICAL PROPERTIES
	Information on basic physical and chemical properties General Information Appearance : White, crystalline, free flowing powder and sweet in taste. Form : Crystalline, free flowing Powder Color : White Odor : Odorless Odor threshold : Not determined. pH-value at 20 °C (68 °F) : Between 5 and 7.5 Residue on Ignition : NMT 2.0%
	Change in condition Melting point/Melting range : 165 – 170°C Boiling point/Boiling range : Undetermined. Flash point : Not applicable. Flammability (solid, gaseous) : Product is not flammable. Ignition temperature : Not applicable Decomposition temperature : Not applicable Auto igniting : Not determined. Danger of explosion : Product does not present an explosion hazard. Explosion limits: - Lower : Not determined. - Upper : Not determined. - Vapor pressure : Not applicable. Density : 0.40 – 0.55 g/ml Relative density : Not determined. Vapour density : Not applicable. Evaporation rate : Not applicable. Solubility in / Miscibility with Water : Practically insoluble in water and in solvents Partition coefficient (n-octanol/water): Not determined. Viscosity : Dynamic : Not applicable. Kinematic : Not applicable. Organic solvents : 0.0 % Solids content : 100.0 % Other information: No further relevant information available.

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10	STABILITY AND REACTIVITY
	Reactivity : No information known Chemical stability : Stable under recommended storage condition Thermal decomposition / conditions to be avoided : No decomposition. Possibility of hazardous reactions : No dangerous reactions known. Conditions to avoid : Avoid exposure to light and moisture Incompatible materials : Strong oxidizers, water Hazardous decomposition products : May emit toxic fumes under fire conditions.
11	TOXICOLOGICAL INFORMATION
	Information on toxicological effects Acute toxicity: Data No available Primary irritant effect: - On the skin : No irritant effect. - On the eye : No irritating effect. - Sensitization : No sensitizing effects known. Additional toxicological information: No adverse human effects are known. Carcinogenic categories - IARC (International Agency for Research on Cancer) : Substance is not listed. - NTP (National Toxicology Program) : Substance is not listed.
12	ECOLOGICAL INFORMATION
	Toxicity Aquatic toxicity : No further relevant information available. Persistence and degradability : No further relevant information available. Behavior in environmental systems: Bioaccumulative potential : No further relevant information available. Mobility in soil : Easily biodegradable Additional ecological information: Results of PBT and vPvB assessment : PBT (Persistent, bioaccumulative and toxic) : Not applicable. vPvB (Very persistent and Very bioaccumulative) : Not applicable. Other adverse effects : No further relevant information available.
13	DISPOSAL CONSIDERATION
	Waste treatment methods - Recommendation : Dispose of waste in compliance with all applicable local laws. Un-cleaned packaging: - Recommendation : Disposal must be made according to official regulations. Recommended cleansing agent: Water, if necessary with cleansing agents. Disposal Method : No special disposal methods are suggested. It is the user's responsibility to comply with all applicable local, state, and federal laws, rules, regulations and standards.

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14	TRANSPORT INFORMATION
	DOT: Non-Hazardous for Transport: This substance is considered to be non-hazardous for transport. IATA: Non-Hazardous for Air Transport. IMDG : Not a dangerous good. Environmental hazards : Marine pollutant : No Special precautions for user : Not applicable. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code : Not applicable. UN "Model Regulation": ---
15	REGULATORY INFORMATION
	Safety, health and environmental regulations/legislation specific for the substance or mixture SARA (Safety analysis risk assessment) Section 355 (extremely hazardous substances) : Substance is not listed. Section 313 (Specific toxic chemical listings) : Substance is not listed. E numbers : Refer point No. 3 Proposition 65 Chemicals known to cause cancer : Substance is not listed. Chemicals known to cause reproductive toxicity for females : Substance is not listed. Chemicals known to cause reproductive toxicity for males : Substance is not listed. Chemicals known to cause developmental toxicity : Substance is not listed. Carcinogenic categories EPA (Environmental Protection Agency) : Substance is not listed. TLV (Threshold Limit Value established by ACGIH) : Substance is not listed. NIOSH-Ca (National Institute for Occupational Safety and Health): Substance is not listed. OSHA-Ca (Occupational Safety & Health Administration) : Substance is not listed. Substances of very high concern (SVHC) according to the REACH regulations EC 1907/2006 for the manufacturing, placing on the market and use must be observed. : Substance is not listed. TSCA (Toxic Substances Control Act) : On inventory list GHS label elements : Refer to Point No. 02. Chemical safety assessment: A Chemical Safety Assessment has not been carried out.
16	OTHER INFORMATION
	This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship. Department issuing SDS : QA Date of preparation / last revision : 25.05.2020 / 25.05.2020 Abbreviations and acronyms: Given at the place ADR : European Agreement concerning the International Carriage of Dangerous Goods by Road ACGIH : American Conference of Governmental Industrial Hygienists

For Sigachi Industries Limited, Dahej.



Sunil Kumar Mohanty.
Manager – Quality Assurance



Date :-09.06.2023

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