TECHNICAL DATA SHEET

SODALIME

Manufacturer Name & Address:	KNGMED Medical Co. Ltd. 10.001 St. No: 28/A-10 Cinar San. Sit. Ulukent, Izmir, TURKIYE 35630	Ph: +902328334262 Fax: +902328334263 Web: www.kngmed.com
1- Chemical Product Information:	Product Name : Sodalime, (KNGSORB - CO2 absorber – CO2 absorbent) Chemical Name : Sodalime (Medical Carbon dioxide absorbent)	
2- Composition & Ingredients:	Sodium Hydroxide (CAS# 1310-73-2) 2-4% Calcium Hydroxide (CAS# 1305-62-0) >75% Humudity 12-18%	
3-Intended Use	*In anesthesia circle systems and respiratory therapy equipment for the purpose of removing exhaled carbon dioxide.*	
4- CO_2 Capacity	*26% (120 lt) According to USP Methodology*	
5- Hardness	75,8 (Shore A)	

6- Particle Distribution

Particle Size	***Rate (%)***
> 4 mm	*1*
4-2 mm	*85*
2-0,60mm	*13*
600 µm	*1*

7- Reaction (Indication)	White to Violet
Please Contact:	KNGMED Medical Co. Ltd. 10.001 St. No: 28/A-10 Cinar San. Sit. Ulukent, Izmir, TURKIYE 35630 Ph: +902328334262 Fax: +902328334263 E-mail: info@kngmed.com & kng.info@yahoo.com

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Company Profile:	Kngmed Medical was established in 2008 manufactures of whole products in product range. Headquarter is in Izmir, Turkey. It has lots of dealers both Turkey and Abroad. It has 14 employees and capital 2 billion USD.
Executive Summary Product	Sodalime; is a mixture of chemicals, used in granular form in closed breathing environments, absorbs carbon dioxide (CO2) in anesthesia closed circle systems and respiratory therapy equipment. Sodalime; in the close circuits of anesthesia systems, used to absorb CO2 from breathing gases to prevent CO2retention. During the administration of general anaesthesia, the gases expired by a patient, which contain carbon dioxide, are passed through an anaesthetic machine breathing circuit filled with soda lime granules. Production of Sodalime is done newest technology Pelletizer (semi- automatic) and manuel processes. Newly developed automatic systems and technologies are followed and will be applied when the sale quantities and production scale increases. **DEVICE DESCRIPTION** **Product Name:** CARBON DIOXIDE ABSORBER (SODALIME) **Brand Name:** KNGMED **Product Models- Photos –** 

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Ürünün Adı: *Product Name:*	***Tür/ Boyut:*** *Type/ Size:*	***Ref No:*** *Ref No:*
Sodalime	**1 Kg**	**7600064-1**
	5 Kg	**7600064-5**
	20 Kg	**7600064-20**

Product MDD Classification and Rule

The product class is determined as **Class II A** accordingt o the **Rule 3 of 93/42/EEC -Annex V** Classification Rules, which is

Class II A Rule 3 Annex V

Medical Device Directive Annex V

The devices are **Class IIa** according to council directive 93/42/EEC, **Annex V, Rule 3** ("This Non-invasive device, modifies chemical composition, which intended for filtrates CO2 breathing circuits of anesthesia devices" classification route is considered).

Biocompatibility Evaluation
N/A Product has no direct or indirect contact with the patient.

Conformity Assessment Method

Medical Devices Directive 93/42/EEC Annex IX .

Product GMDN Code and Description

GMDN Code : **36051**
Category : 02 - Anesthesia and Breathing Devices, 10 – Disposable Devices
Definition : An absorbent material (e.g., granules of treated soda lime) that is placed into an anesthesia system, to remove carbon dioxide (CO2) from the exhaled gases in a patient breathing circuit by chemical reaction. This is a single-use device.
Product Performance Criteria

The performance criteria of our product are determined according to market and user requirements. The requirement controls are based on the 93/42/EEC Medical Devices Directive Annex I Essential Requirements, and Applicable Standards. According to this, determined performance criteria is below:

Criteria	Claim
Capacity of CO2 Absorbation	23% - 28%
Color Change	White to Violet
Grannula Sizes	4mm R:2mm

Critical Materials

Raw Materials / Components

No	Product Types	Material
1	***Chemical Content***	CaOH, NaOH, Ethil Violet

**: Indicates critical components and raw materials for the product*

Product Storage Information

Non Sterile products are storage under 0 – 50 °C ± 10 temperature and low humidity (30-70%Rh) conditions before being shipped to the customer. Storage conditions are determined in RP 4.3.2.2 Stability Validation

Marketing History:

Annual Sale Figures
2010 Report of Sodalime
Product Code: Product Name: Sale Amount:
7600064 Sodalime 6.515
2011 Report of Sodalime
Product Code: Product Name: Sale Amount:
7600064 Sodalime 18.892
2012 Report of Sodalime
Product Code: Product Name: Sale Amount:
7600064 Sodalime 35.986
2013 Report of Sodalime
Product Code: Product Name: Sale Amount:
7600064 Sodalime 57.496
2014 Report of Sodalime

	Product Code: Product Name: Sale Amount: 7600064 Sodalime 93.984 **2015 Report of Sodalime** **Product Code: Product Name: Sale Amount:** 7600064 Sodalime 79.205 **2016 Report of Sodalime** **Product Code: Product Name: Sale Amount:** 7600064 Sodalime 76.612 **2017 Report of Sodalime** **Product Code: Product Name: Sale Amount:** 7600064 Sodalime 87.541
Work Mechanism:	The product is connected to the anesthesia and ventilation machines. The input gas is flow through the tubes and reach to the patient. Afther the respiration occurs the gas outlet (expiration) reaches to the machine through the tubes. The gas mixture coming from the patient is directly given into the CO_2 absorber to remove the excess CO_2 content in the expiration gas. The chemical content of the product reacts with the CO_2 and neutralizes its specifications by absorbing the compound. **The reaction:** 1) $H_2O + CO_2 ====> H_2CO_3$ high pH 2) $H_2CO_3 + 2\ NaOH ====> Na_2CO_3 + 2H_2O$ high pH 3) $Na_2CO_3 + Ca(OH)_2 ====> CaCO_3 + 2\ NaOH$ high pH also 4) $H_2CO_3 + Ca(OH)_2 ====> CaCO_3 + 2H_2O$ high pH
Intended Use :	Sodalime is used for the absorbation of carbondioxide gas sourcing from the expiration of the patient who is connected to an anesthesia, ventilation or breathing machine. It doesn't have direct contact with the patient. It is used to provide absorbation of CO_2 gas outlet from the patient throughout the anesteshia or ventilation machine.

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sodalime

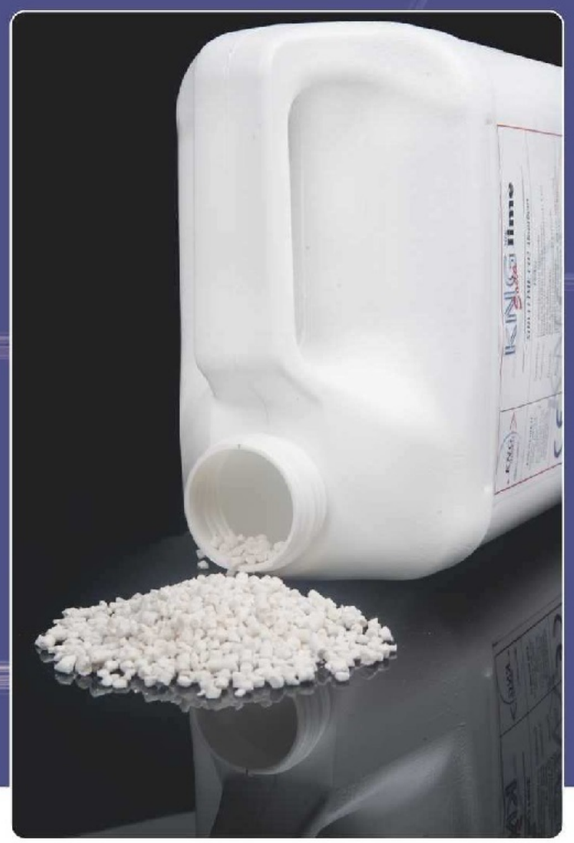
Medical Soda Lime Carbon Dioxide Absorbent

sodalime

(CO_2 absorbent)

Soda lime is essential for CO_2 absorption in inhalation anesthesia machines with rebreathing systems.

With the irregular shape, minimises the amount of dust produced during transit allowing the product to reach you in perfect condition for use.



KNGSORB does not contain potassium Hydroxide or Barium Hydroxide and only low level of Sodium Hydroxide.
High CO2 absorption capacity pellet form prevents channel formation, uniform utilization reducing your costs through longer life time Little dust generation creating a safer environment for your personnel and protects your equipment.
Additional safety for patients Reduction of undesirable reaction products when accidentally dried out

Raw material
- NaOH less than 4%
- KOH free formula
- 14-19% H2O

Design
- Optimum air flow and absorption 4x2 mm granule form

Features
- 97% hardness
- Color indicator shows usable life changes from white to violet

Usage
- Suitable for all close circuit anesthesia devices

Package
- 5kg and 20kg plastic can
- Light proof, opaque package
- Leakage proof, sealedlid

sodalime

(CO_2 absorbent)

KNGSORB CO_2 Absorbents (Sodalime) are safely and efficiently removing CO_2 from anesthesia systems, respiratory systems, and hyperbaric chambers.

KNGSORB is a medical soda lime manufactured from mixture of Calcium and Sodium Hydroxides It is supplied in the form of hard, porous regular rounded pellets which have been specifically processed to absorption CO_2 capacity. One kilogram of KNGSORB will absorb a minimum of 130 litres of CO_2

Characteristic:
- Particle size: 4x2 mm
- Hardness: 97%
- Moisture: 12%-18%
- CO Absorbation: min 130 L/kg
- CO2 Activity: min 26%
- Indicator:White to Violet
- No KOH

Packages:
- 5 Kg
- 20 Kg plastic can

Storage information

Store the absorbent in original closed container only.
Use within one month of opening the container.
Keep container away from direct heat and sunlight to prevent drying out or over-heating of the absorbent.
Do not freeze; if frozen, absorbent must be completely thawed before use.
Do not subject to excessive loads.
When stored correctly, unopened containers will maintain their absorption capability for at least five years.

Safety information

Risk of serious damage to eyes
Irritating to eye, respiratory system and skin In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
Wear suitable gloves and eye/face protection

1. Sodalime 5kg - item no: #7600064-5
2. Sodalime 20kg (item no: #7600064-20

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