

KNGMED Medical Co. Ltd.	Sodalime TDS Product #: PrSL05-20	Form #: 132 Issued Date: 01.06.2010 Page: 1/1
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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% Humidity 12-18%											
3-Intended Use	<i>In anesthesia circle systems and respiratory therapy equipment for the purpose of removing exhaled carbon dioxide.</i>											
4- CO₂ Capacity	26% (120 lt) According to USP Methodology											
5- Hardness	75,8 (Shore A)											
6- Particle Distribution	<table><tr><th>Particle Size</th><th>Rate (%)</th></tr><tr><td>> 4 mm</td><td>1</td></tr><tr><td>4-2 mm</td><td>85</td></tr><tr><td>2-0,60mm</td><td>13</td></tr><tr><td>600 µm</td><td>1</td></tr></table>		Particle Size	Rate (%)	> 4 mm	1	4-2 mm	85	2-0,60mm	13	600 µm	1
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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Created: On 01.06.2010 by HVK.

Company Profile:	<p>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.</p> <p>It has 14 employees and capital 2 billion USD.</p>
Executive Summary Product	<p>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.</p> <p>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.</p> <p>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.</p> <p>DEVICE DESCRIPTION</p> <p>Product Name: CARBON DIOXIDE ABSORBER (SODALIME)</p> <p>Brand Name: KNGMED</p> <p>Product Models- Photos –</p> 
10.001	<p>SOK NO:28/A -10 ÇINAR SANAYİ SİT. ULUKENT, İZMİR</p> <p>Tel: + 90 232 833 42 62 & Faks: + 90 232 833 42 63</p> <p>www.kngmed.com & kng.info@yahoo.com</p>

<u>Ürünün Adı:</u>	<u>Tür/ Boyut:</u>	<u>Ref No:</u>
<u>Product Name:</u>	<u>Type/ Size:</u>	<u>Ref No:</u>
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** according to 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:	<p>The product is connected to the anesthesia and ventilation machines. The input gas is flow through the tubes and reach to the patient. After 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 CO₂ absorber to remove the excess CO₂ content in the expiration gas. The chemical content of the product reacts with the CO₂ and neutralizes its specifications by absorbing the compound.</p> <p>The reaction:</p> <p>1) $H_2O + CO_2 \rightleftharpoons H_2CO_3$ high pH</p> <p>2) $H_2CO_3 + 2 NaOH \rightleftharpoons Na_2CO_3 + 2H_2O$ high pH</p> <p>3) $Na_2CO_3 + Ca(OH)_2 \rightleftharpoons CaCO_3 + 2 NaOH$ high pH also</p> <p>4) $H_2CO_3 + Ca(OH)_2 \rightleftharpoons CaCO_3 + 2H_2O$ high pH</p>
Intended Use :	<p>Sodalime is used for the absorption 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.</p> <p>It is used to provide absorption of CO₂ gas outlet from the patient throughout the anesthesia or ventilation machine.</p>