

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% Humudity 12-18%											
3- Intended Use	In anesthesia circle systems and respiratory therapy equipment for the purpose of removing exhaled carbon dioxide.											
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:	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 – 
10.001	SOK NO:28/A -10 ÇINAR SANAYİ SİT. ULUKENT, İZMİR Tel: + 90 232 833 42 62 & Faks: + 90 232 833 42 63 www.kngmed.com & kng.info@yahoo.com

	<u>Ürünün Adı:</u> <u>Product Name:</u>	<u>Tür/ Boyut:</u> <u>Type/ Size:</u>	<u>Ref No:</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 <table><tr><th>No</th><th>Product Types</th><th>Material</th></tr><tr><td>1</td><td>Chemical Content</td><td>CaOH, NaOH, Ethil Violet</td></tr></table> *: 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		No	Product Types	Material	1	Chemical Content
No	Product Types	Material					
1	Chemical Content	CaOH, NaOH, Ethil Violet					
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. 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. The reaction: 1) $H_2O + CO_2 \rightleftharpoons H_2CO_3$ high pH 2) $H_2CO_3 + 2 NaOH \rightleftharpoons Na_2CO_3 + 2H_2O$ high pH 3) $Na_2CO_3 + Ca(OH)_2 \rightleftharpoons CaCO_3 + 2 NaOH$ high pH also 4) $H_2CO_3 + Ca(OH)_2 \rightleftharpoons CaCO_3 + 2H_2O$ 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 CO₂ gas outlet from the patient throughout the anesthesia or ventilation machine.