

Date: 12.10.2016

Former date: 01.06.2015

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING**1.1 Product identifier****Trade name**

Medisorb EF (for sellable product names containing Medisorb EF see section 16 Other information)

Company product code

M1183655 (for sellable part numbers containing M1183655, see section 16 Other information)

Reach registration number

Not available

1.2 Relevant identified uses of the substance or mixture and uses advised against**The uses of the chemical**

Medisorb EF is CO₂ absorbent intended to be used with anesthesia systems to remove CO₂ from breathing gases when providing anesthesia in hospitals or surgery centers under constant attention of qualified professional healthcare personnel. Absorbent should only be used with air, oxygen, nitrous oxide, halothane, enflurane, isoflurane, desflurane and sevoflurane.

The sellable absorber products containing Medisorb EF are disposable packages and used with following GE Healthcare anesthesia systems: Carestation 600 series, GE Healthcare Advanced Breathing System, the GE Healthcare EZchange manifold, the GE Healthcare Compact Block and GE Healthcare Compact Block II.

Classification of economic activities (NACE)

246

Use categories (UC62)

1

The chemical can be used by the general public☐**The chemical is used by the general public only**☐**1.3 Details of the supplier of the safety data sheet****Manufacturer, importer, other undertaking**

CareFusion Finland 320 Oy

Street address

Kuortaneenkatu 2

Postcode and post office

00510 Helsinki

Post-office box**Postcode and post office****Telephone number**

+358 (0)20 7871090

Telefax**E-mail address**

@carefusion.com

Finnish Business ID (Y code)

CareFusion Finland 320 Oy 23530741

1.4 Emergency telephone number

Please contact the Emergency Centre in your own country, e.g. 112 in European Union countries or the National Chemicals Emergency Centre, 24 hour emergency number +44 (0) 1865 407333

SECTION 2: HAZARDS IDENTIFICATION**2.1 Classification of the substance or mixture:**

In accordance with the Classification, Labelling and Packaging Regulation (EC) No 1272/2008 (CLP/GHS) – see section 11	
Skin irritation Category 2	H315 Causes skin irritation
Eye irritation Category 2	H319 Causes serious eye irritation

Most important adverse effects	
Physicochemical	According to experience, the product is considered to have no adverse physicochemical properties if handled in the correct manner
Health:	Irritating to eyes and skin
Environment:	According to experience, the product is considered to have no adverse effect on the environment if handled in the correct manner

2.2 Labelling elements**Labeling in accordance with EC Regulation No 1272/2008 (CLP/GHS)**

Pictogram:	
Signal word:	WARNING

Hazard elements:

H315	Causes skin irritation
H319	Causes serious eye irritation

Precautionary statements:

P280	Wear protective gloves/protective clothing/eye protection/face protection.
P314	Get medical advice/attention if you feel unwell.
P302/352	IF ON SKIN: Wash with plenty of soap and water.
P305/351/338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332/313	If skin irritation occurs: Get medical advice/attention.

2.3 Other hazards

None known

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**Hazardous ingredients****Chemical characterisation:**

Solid bases plus additives – see section 16

The CLP classifications required in this section are related to that of the product supplier. To comply with the legislation, the classification of the relevant ingredients of the product must be outlined as if they were present at 100%. Where ingredients are present in the product at very low concentration, the level of risk to the user is reduced, therefore the classifications for the individual components and the product are different.

Name of the ingredient	CAS number	EINECS/ELINCS (EY) number	Concentration	Classification
Sodium Hydroxide	1310-73-2	215-185-5	<1%	Skin Corr. 1A: H314
Calcium Hydroxide	1305-62-0	215-137-3	>75%	Skin Irrit.2: H315 Eye damage 1: H318 WEL assigned

See section 16 for full description of H statements

SECTION 4: FIRST AID MEASURES**4.1 Description of first aid measures**

Inhalation: Remove casualty to fresh air and provide warmth and rest

Skin contact: Wash areas of affected skin immediately with soap and plenty of water. If necessary, seek medical advice.

Eye contact: Immediately wash eyes thoroughly with plenty of water until irritation subsides; consult an eye specialist/ophthalmologist.

Ingestion: Unlikely route of exposure, but if product is swallowed, do not induce vomiting. Drink plenty of water and, if necessary, seek medical advice.

4.2 Most important symptoms and effects, both acute and delayed

Skin irritation.

Eye irritation.

May cause severe effects to eyes.

Irritation in respiratory system.

No delayed symptoms or effects are known.

4.3 Indication of any immediate medical attention and special treatment needed

No need for immediate medical attention identified.

In case of eye contact consult an eye specialist/ophthalmologist after first aid described in section 4.1.

SECTION 5: FIREFIGHTING MEASURES**5.1 Extinguishing media**

Water, Foam, CO₂, powder are all suitable.

5.2 Special hazards arising from the substance or mixture

None known.

5.3 Advice for firefighters

Self-contained breathing apparatus may be needed.

SECTION 6: ACCIDENTAL RELEASE MEASURES**6.1 Personal precautions, protective equipment and emergency procedures**

Avoid inhaling dust. Avoid skin and eye contact. Wear personal protective equipment appropriate to the task. See section 8.

6.2 Environmental precautions

Do not allow to get into waste water or waterways; if this occurs, inform the relevant water authority immediately.

6.3 Methods and material for containment and cleaning up

In the event of spillage, take up mechanically (e.g. sweep or vacuum up) into tightly closed containers. Use personal protective measures. Flush any remainder with plenty of water. Label container and dispose of as prescribed.

6.4 Reference to other sections

See section 8 for personal protective equipment

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SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Handle in accordance with good hygiene and safety practice. Avoid the raising and deposition of dust.

7.2 Conditions for safe storage, including any incompatibilities

Ensure adequate ventilation of the storage area. Store in a dry environment at a temperature range 0°C/+32°F to +35°C/+95°F.

Avoid freezing and direct sunlight. Keep containers closed.

Protect the packages from physical damage and water.

7.3 Specific end use(s)

Medisorb EF is a CO₂ absorbent intended for use with anesthesia systems.

Medisorb EF should only be used with air, oxygen, heliox, nitrous oxide, halothane, enflurane, isoflurane, desflurane and sevoflurane.

Restrictions on use:

Before using other anesthetic agents, consult the manufacturer of the anesthetic agent to determine whether or not it is suitable.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

National occupational exposure limit values

Sodium Hydroxide (CAS 1310-73-2): STEL (15min): ppm 2 mg/m³

Calcium Hydroxide (CAS 1305-62-0): LTEL (8h TWA) : ppm 5 mg/m³

8.2 Exposure controls

Appropriate engineering controls

Provide adequate ventilation (e.g. local exhaust ventilation)

Personal protection

Observe normal standards for handling chemicals

Wash hands before breaks and after work

Avoid inhalation of dust if raised.

Wear personal protective equipment appropriate to the task (see below)

Eye/face protection

Safety goggles if risk of eye contamination

Skin protection

Hand protection: Suitable gloves (consider your own risk assessment; e.g. breakthrough times, rates of diffusion and degradation, tasks undertaken)

Other protection: Protective overalls if appropriate to the task

Respiratory protection

Approved dust mask or respirator (E.g. EN149:2001 FFP3) for dust if ventilation is insufficient

Thermal hazards

None.

Environmental exposure controls

None

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	Solid. White or coloured
Odour	Odourless
pH	<12,5
Melting point/freezing point	No data available
Initial boiling point and boiling range	No data available
Flash point	No data available
Evaporation rate	No data available
Flammability (solid, gas)	No data available

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Upper/lower flammability or explosive limits	No data available
Vapour pressure	No data available
Vapour density	No data available
Relative density	~0.9g/cm ³
Solubility(ies)	slight in water
Partition coefficient: n-octanol/water	No data available
Auto-ignition temperature	No data available
Auto-ignition temperature	No data available
Decomposition temperature	No data available
Viscosity	No data available
Explosive properties	No data available
Oxidising properties	No data available

9.2 Other information
None

SECTION 10: STABILITY AND REACTIVITY

- 10.1 Reactivity**
Heat is generated if exposed to acids
- 10.2 Chemical stability**
Stable under normal conditions of handling
- 10.3 Possibility of hazardous reactions**
Hazardous polymerization will not occur
- 10.4 Conditions to avoid**
Contact with air - formation of calcium and sodium carbonate
- 10.5 Incompatible materials**
Avoid contact with Chloroform or Trichloroethylene.
- 10.6 Hazardous decomposition products**
None

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity

LD/LC50 values relevant for classification:

Data for Sodium Hydroxide LD(Lo) = 500mg/kg rabbit (oral)

Data for Calcium Hydroxide LD(50) = >7000mg/kg rat (oral)

Skin corrosion/irritation

Causes skin irritation – see 11.1. Other information

Serious eye damage/irritation

Causes eye irritation — see 11.1. Other information

Respiratory or skin sensitisation

Not classified. No data available

Germ cell mutagenicity

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Not classified. No data available

Carcinogenicity

Not classified. No data available

Reproductive toxicity

Not classified. No data available

STOT-single exposure

Not classified. No data available

STOT-repeated exposure

Not classified. No data available

Aspiration hazard

No data available

Other information

Although per concentration limits of CLP, the product classification would be "corrosive", using EU official in vitro tests on the whole product, it was found to be irritating to eyes and skin, not corrosive.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not determined. Converts to naturally occurring minerals.

12.2 Persistence and degradability

Not determined. Converts to naturally occurring minerals.

12.3 Bioaccumulative potential

Not determined. Converts to naturally occurring minerals.

12.4 Mobility in soil

No data available. Converts to naturally occurring minerals.

12.5 Results of PBT and vPvB assessment

Not applicable

12.6 Other adverse effects

None known. Converts to naturally occurring minerals.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

PRODUCT:

Dispose of in accordance with national and local authority regulations. E.g. incineration.

Product tested with test methods EN 12457-3, EN 13137A and CEN/TS 14405 to meet the leaching and TOC limit value criteria of waste acceptable at landfills for non-hazardous waste. (Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste).

CONTAMINATED PACKAGING

Treat empty containers in the same way as the product. If possible wash out thoroughly and recycle.

SECTION 14: TRANSPORT INFORMATION

14.1 UN number

Not classified

14.2 UN proper shipping name

Not classified

14.3 Transport hazard class(es)

Not classified

14.4 Packing group

Not classified

14.5 Environmental hazards

The product should not be marked as marine pollutant

14.6 Special precautions for user

Not applicable

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

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Not applicable

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

The product is classified in accordance 1272/2008.

On the basis of the Administrative Regulation on the Classification of Substances hazardous to waters (VwVwS) the WGK (Water German Klasse) classification is 1 = low water hazard.

15.2 Chemical safety assessment

Not applicable

SECTION 16: OTHER INFORMATION

Further information:

Medisorb EF is packed into different packages called Medisorb EF EX, Multi Absorber Medisorb EF
Part numbers containing Medisorb EF (M1183655) are: 2079797-001, M1173311

Product contains Sodium hydroxide, but test data of EU approved in-vitro test (OECD 431, 2004) for the classification of corrosive and irritant material shows the preparation to be an irritant. Ensure all national/local regulations are observed. Before using this product in any new process or experiment, a thorough material compatibility and safety study should be carried out.

Medisorb is a trademark of CareFusion and product is labelled as manufactured by CareFusion Finland 320 Oy, who also owns the Trademarks.

This SDS has been revised in accordance with EC Regulations 1272/2008 (CLP). More products containing Medisorb EF added to this SDS.

Hazard and precautionary statements referred to in section 2 and 3:

H314 Causes severe skin burns and eye damage

H315, Causes skin irritation.

H318: Causes serious eye damage

H319, Causes serious eye irritation

P280, Wear protective gloves/protective clothing/eye protection/face protection.

P314, Get medical advice/attention if you feel unwell.

P302/P352, IF ON SKIN: Wash with plenty of soap and water.

P305/P351/P338, IF IN EYES: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

P332/313, If skin irritation occurs: Get medical advice/attention.

Sources of data:

Safety data sheet of Sofnolime Solo dated 1st of June 2015 (version number 6). Remark: Sofnolime Solo is a trademark of Molecular Products Limited

DOC1411455 rev 2, Leaching test report by Labtium Oy, Kuopio, Finland

Date of issue: 12-OCT-2016

Details given in this document are believed to be correct on our present state of knowledge. Whilst proper care has been taken in the preparation of this document, no liability for injury or damage resulting from its use is accepted.



MATERIAL SAFETY DATA SHEET

Medisorb

Date: 13 January 04

Issue No: 1

Pages: 1 of 2

1. IDENTIFICATION OF SUBSTANCE	Commercial Name Chemical Name	Medisorb Soda Lime
2. COMPOSITION	Components	%W/W CAS EINECS Supply Class
	Sodium Hydroxide	3% 1310-73-2 215-185-5 C:R34
	Calcium Hydroxide	>75% 1305-62-0 215-137-3 N/A
3. HAZARDS IDENTIFICATION		Can cause burns to eyes and skin.
4. FIRST AID MEASURE	Inhalation Skin Eyes Ingestion	Remove from exposure. Obtain medical attention. Drench with clean water. Obtain medical attention if skin becomes inflamed. Irrigate thoroughly with clean water. Obtain medical attention. Wash out mouth thoroughly. Obtain medical attention.
5. FIRE FIGHTING	Extinguishing Media Fire & Explosion Hazards Protective Measures	Water, Foam, CO ₂ , powder are all suitable. Material is non-combustible. Packaging may be combustible. Breathing apparatus may be needed.
6. ACCIDENTAL RELEASE	Personal Precautions Environmental Precautions Recovery	Avoid inhaling dust. Avoid skin and eye contact. No hazard. Contain material. Sweep or vacuum up.
7. HANDLING & STORAGE		Store in a clean, dry environment at a temperature range 0°C/+32°F to +35°C/+95°F. Avoid freezing and direct sunlight. Keep containers closed. Protect the packages from physical damage and water.
8. EXPOSURE CONTROLS	Occupational Exposure Limits (EH40)	Component TWA/ 8h STE/ 15 min
		Sodium Hydroxide 2mg/m ³
		Calcium Hydroxide 5mg/ m ³
PERSONAL PROTECTION	Respiratory Skin Eyes Hygiene	Nuisance dust mask recommended. General purpose rubber gloves. Glasses to protect against dust. Wash after skin contact.

Medisorb continued

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9. PHYSICAL & CHEMICAL PROPERTIES	Appearance Odor pH Relative Density Solubility in water	White or colored solids. None 12 - 14 2.0 g/cm ³ Slight
10. STABILITY & REACTIVITY	Material is stable. Converts to Calcium and Sodium Carbonates when exposed to air. Avoid contact with Chloroform or Trichloroethylene. Heat is generated when exposed to acids.	
11. TOXICOLOGICAL INFORMATION	Sodium Hydroxide LD(lo) = 500mg/kg rbt Calcium Hydroxide LD(50) = 7.3 g/kg rat	
12. ECOLOGICAL INFORMATION	No risk of prolonged damage to animal or plant life. Converts to naturally occurring minerals.	
13. DISPOSAL CONSIDERATIONS	Incineration or landfill in accordance with local regulations. Materials not incinerated may be alkaline.	
14. TRANSPORT INFORMATION	Transport Classification UN Number Hazard Class Packing Group	None None N/A N/A
15. REGULATORY INFORMATION	Supply Classification Risk Phrases Safety Phrases	Corrosive R34 Causes burns. S2 Keep out of reach of children. S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical attention. S37/39 Wear suitable gloves and eye/face protection. S45 In case of accident or if you feel unwell seek medical advice immediately (show the label where possible).
16. OTHER INFORMATION		Intended use Medisorb is a CO ₂ absorbent intended for use with anesthesia systems. Medisorb should only be used with air, oxygen, heliox, nitrous oxide, halothane, enflurane, isoflurane, desflurane and sevoflurane. Before using other anesthetic agents, consult the manufacturer of the anesthetic agent to determine whether or not it is suitable.
For further information contact:		Datex-Ohmeda Division Instrumentarium Corp. Teollisuuskatu 29, Helsinki FINLAND P.O.Box 900, FIN-00031 Datex-Ohmeda Tel +358 10 394 11 Fax +358 9 1463310

THE INFORMATION IN THIS SAFETY DATA SHEET IS BASED ON BEST KNOWLEDGE AVAILABLE AT THE TIME AND CURRENT NATIONAL LEGISLATION. IT PROVIDES GUIDANCE ON HEALTH, SAFETY AND ENVIRONMENTAL ASPECTS OF THE PRODUCT AND SHOULD NOT BE CONSTRUED AS ANY GUARANTEE OF TECHNICAL PERFORMANCE OR SUITABILITY FOR PARTICULAR APPLICATION. AS THE SPECIFIC CONDITIONS OF USE ARE OUTSIDE THE CONTROL OF THE SUPPLIER, THE USER IS RESPONSIBLE FOR ENSURING THAT THE PRODUCT IS USED IN A SAFE WAY AND THE REQUIREMENTS OF RELEVANT LEGISLATION ARE COMPLIED WITH.

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