X **SAFETY DATA SHEET** (INFORMATION FORM FOR CHEMICALS DATA)

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 **Eye irritation Category 2**	**H315 Causes skin irritation** **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

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℃/+32℉ to+35℃/+95℉.
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**

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

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

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

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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.