according to Regulation (EC) No. 1907/2006 (REACH) according to Regulation (EU) No. 2020/878



Trade name: 111721 - Sodium hydrogen carbonate, NF, Ph. Eur., for

hemodialysis

**Revision date:** 24/07/2023 **Version (Revision):** 3.0.1 (3.0.0)

**Print date :** 24/07/2023

## SECTION 1: Identification of the substance/mixture and of the company/ undertaking

#### 1.1 Product identifier

Sodium hydrogen carbonate, NF, Ph. Eur., for hemodialysis (111721) Sodium hydrogen carbonate; CAS No.: 144-55-8; EC No.: 205-633-8; REACH No.: 01-2119457606-32-XXXX

# 1.2 Relevant identified uses of the substance or mixture and uses advised against

#### Relevant identified uses

For manufacturing, processing, laboratory or repacking use only.

#### Uses advised against

Uses other than those recommended.

## 1.3 Details of the supplier of the safety data sheet

# Supplier (manufacturer/importer/only representative/downstream user/distributor)

DC Fine Chemicals Ltd **Street:** 88 Hill Top

Postal code/City: NW11 6DY London United Kingdom

**Telephone:** +44 (0)20 7586 6800 **Telefax:** +44 (0)20 7504 1701

**Information contact:** info@dcfinechemicals.com

### 1.4 Emergency telephone number

(Only available during office hours; Monday-Friday; 08:00-18:00)

## SECTION 2: Hazards identification

## 2.1 Classification of the substance or mixture

## Classification according to Regulation (EC) No 1272/2008 [CLP]

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

#### 2.2 Label elements

## Labelling according to Regulation (EC) No. 1272/2008 [CLP]

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

#### 2.3 Other hazards

This substance/mixture contains no components considered to be persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

## SECTION 3: Composition/information on ingredients

## 3.1 Substances

**Substance name :** Sodium hydrogen carbonate

**EC No.:** 205-633-8

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**CAS No.:** 144-55-8 **Purity:** 100 % [mass]

## **SECTION 4: First aid measures**

#### 4.1 Description of first aid measures

Due to the composition and type of the substances present in the product, no particular warnings are necessary.

#### **Following inhalation**

Take the victim into open air; keep them warm and calm. If breathing is irregular or stops, perform artificial respiration.

#### In case of skin contact

Remove contaminated clothing.

#### After eye contact

Remove contact lenses, if present and if it is easy to do. Wash eyes with plenty of clean and cool water for at least 10 minutes while pulling eyelids up, and seek medical assistance. Dont let the person to rub the affected eye.

## Following ingestion

Keep calm. NEVER induce vomiting.

## 4.2 Most important symptoms and effects, both acute and delayed

No known acute or delayed effects from exposure to the product.

## 4.3 Indication of any immediate medical attention and special treatment needed

In case of doubt or when symptoms of feeling unwell persist, get medical attention. Never administer anything orally to persons who are unconscious.

## SECTION 5: Firefighting measures

## 5.1 Extinguishing media

### Suitable extinguishing media

Extinguisher powder or CO2. In case of more serious fires, also alcohol-resistant foam and water spray.

### Unsuitable extinguishing media

Do not use a direct stream of water to extinguish. In the presence of electrical voltage, you cannot use water or foam as extinguishing media.

## 5.2 Special hazards arising from the substance or mixture

Fire can cause thick, black smoke. As a result of thermal decomposition, dangerous products can form: carbon monoxide, carbon dioxide. Exposure to combustion or decomposition products can be harmful to your health.

#### 5.3 Advice for firefighters

Use water to cool tanks, cisterns, or containers close to the heat source or fire. Take wind direction into account.

#### **Special protective equipment for firefighters**

According to the size of the fire, it may be necessary to use protective suits against the heat, individual breathing equipment, gloves, protective goggles or facemasks, and boots.

## SECTION 6: Accidental release measures

## 6.1 Personal precautions, protective equipment and emergency procedures

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For exposure control and individual protection measures, see section 8.

## For non-emergency personnel

Follow established procedures.

#### For emergency responders

Follow established procedures.

## 6.2 Environmental precautions

Product not classified as hazardous for the environment, avoid spillage as much as possible.

### 6.3 Methods and material for containment and cleaning up

The contaminated area should be immediately cleaned with an appropriate de-contaminator. Pour the decontaminator on the remains in an opened container and let it act various days until no further reaction is produced.

#### For containment

Follow established procedures.

### For cleaning up

Follow established procedures.

#### 6.4 Reference to other sections

For exposure control and individual protection measures, see section 8. For later elimination of waste, follow the recommendations under section 13.

## SECTION 7: Handling and storage

## 7.1 Precautions for safe handling

The product does not require special handling measures, the following general measures are recommended: For personal protection, see section 8. Never use pressure to empty the containers. They are not pressure-resistant containers. In the application area, smoking, eating, and drinking must be prohibited. Follow legislation on occupational health and safety. Keep the product in containers made of a material identical to the original.

## **Protective measures**





## Measures to prevent aerosol and dust generation

No special measures are necessary.

#### **Environmental precautions**

No special measures are necessary.

#### Specific requirements or handling rules

No special measures are necessary.

### Advices on general occupational hygiene

No special measures are necessary.

## 7.2 Conditions for safe storage, including any incompatibilities

As general storage measures, sources of heat, radiation, electricity and contact with food should be avoided. Keep away from oxidising agents and from highly acidic or alkaline materials. Store according to local legislation. Observe indications on the label. The product is not affected by Directive 2012/18/EU (SEVESO III).

#### Technical measures and storage conditions

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#### Storage temperature :

Keep in a cool, well-ventilated place.

## Requirements for storage rooms and vessels

Only use containers specifically approved for the substance/product.

Hints on joint storage Storage class (TRGS 510): 13

#### 7.3 Specific end use(s)

None

## SECTION 8: Exposure controls/personal protection

#### 8.1 Control parameters

The product does NOT contain substances with Professional Exposure Environmental Limit Values. The product does NOT contain substances with Biological Limit Values.

#### 8.2 Exposure controls

Only wear fitting, comfortable and clean protective clothing.

## **Personal protection equipment**

Eye/face protection



Eye glasses EN 166

## Skin protection Hand protection

Tested protective gloves must be worn EN ISO 374 The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances.

#### **Body protection**

No special measures are necessary.

### **Respiratory protection**

No special measures are necessary.

#### Thermal hazards

No special measures are necessary.

### **Environmental exposure controls**

No information available.

## SECTION 9: Physical and chemical properties

## 9.1 Information on basic physical and chemical properties

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> Appearance: solid Safety characteristics

Melting point/freezing point: (1013 hPa) 270 °C

Initial boiling point and boiling (1013 hPa)

No data available range:

( 1013 hPa ) **Decomposition temperature:** 50

Flash point: No data available Auto-ignition temperature : No data available Lower explosion limit: No data available Upper explosion limit: No data available

Vapour pressure: (50°C) No data available Density: (20°C) 2.22 g/cm<sup>3</sup>

Solvent separation test : (20°C) not applicable Water solubility: (20°C) 96 q/I Fat solubility: No data available. (20°C)

pH: No data available

( 20 °C / 5 Weight-% ) pH: 8.6

log P O/W: No data available DIN-

Flow time: (20°C) No data available cup 4 mm

Viscosity: (20°C) No data available Relative vapour density: (20°C) No data available Evaporation rate: No data available

Flammable solids: No data available. Flammable gases: No data available. **Explosive properties:** No data available.

## 9.2 Other information

None

## SECTION 10: Stability and reactivity

## 10.1 Reactivity

The product does not present hazards by their reactivity.

## 10.2 Chemical stability

Stable under the recommended handling and storage conditions (see section 7).

#### 10.3 Possibility of hazardous reactions

The product does not present possibility of hazardous reactions.

## 10.4 Conditions to avoid

Avoid any improper handling.

## 10.5 Incompatible materials

Keep away from oxidising agents and from highly alkaline or acidic materials in order to prevent exothermic reactions.

### 10.6 Hazardous decomposition products

No decomposition if used for the intended uses.

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## SECTION 11: Toxicological information

# 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008 Acute toxicity

#### **Acute oral toxicity**

Parameter: LD50 ( Sodium hydrogen carbonate ; CAS No. : 144-55-8 )

Exposure route: Oral
Species: Rat
Effective dose: 4.22 g/kg

Acute inhalation toxicity

Parameter: LC50 ( Sodium hydrogen carbonate ; CAS No. : 144-55-8 )

Exposure route: Inhalation
Species: Rat
Effective dose: > 4.74 mg/l

Corrosion

Skin corrosion/irritation

No information available.

Serious eye damage/eye irritation

No information available.

Respiratory or skin sensitisation

No information available.

## CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

Carcinogenicity

No information available.

Germ cell mutagenicity

No information available.

Reproductive toxicity

Adverse effects on developmental toxicity

Parameter: NOAEL(C) ( Sodium hydrogen carbonate ; CAS No.: 144-55-8 )

Exposure route : Oral Species : Rat

Effective dose : > 340 mg/kg

Parameter: NOAEL(C) ( Sodium hydrogen carbonate; CAS No.: 144-55-8 )

Exposure route: Oral
Species: Rabbit
Effective dose: > 330 mg/kg

STOT-single exposure

No information available.

## **STOT-repeated exposure**

No information available.

### **Aspiration hazard**

No information available.

#### 11.2 Information on other hazards

No information available.

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## SECTION 12: Ecological information

## 12.1 Toxicity

#### **Aquatic toxicity**

#### Acute (short-term) fish toxicity

Parameter: LC50 ( Sodium hydrogen carbonate ; CAS No. : 144-55-8 )

Species: Gambusia affinis (Mosquito fish)
Evaluation parameter: Acute (short-term) fish toxicity

Effective dose: 7.5 g/l Exposure time: 96 h

Parameter: LC50 ( Sodium hydrogen carbonate ; CAS No. : 144-55-8 )

Species : Lepomis macrochirus (Bluegill)
Evaluation parameter : Acute (short-term) fish toxicity

Effective dose : 7.1 g/l
Exposure time : 96 h
Acute (short-term) toxicity to crustacea

Parameter: EC50 ( Sodium hydrogen carbonate ; CAS No. : 144-55-8 )

Species: Daphnia magna (Big water flea)
Evaluation parameter: Acute (short-term) toxicity to crustacea

Effective dose: 4.1 g/l Exposure time: 48 h

Chronic (long-term) toxicity to aquatic invertebrate

Parameter: NOEC (Sodium hydrogen carbonate; CAS No.: 144-55-8)

Species: Daphnia magna (Big water flea)

Evaluation parameter : Chronic (long-term) toxicity to aquatic invertebrate

Effective dose: > 576 mg/l Exposure time: 21 day(s)

#### 12.2 Persistence and degradability

No information available.

## 12.3 Bioaccumulative potential

No information available.

## 12.4 Mobility in soil

No information available.

### 12.5 Results of PBT and vPvB assessment

This substance does not meet the PBT/vPvB criteria of REACH, Annex XIII.

## 12.6 Endocrine disrupting properties

No information available.

### 12.7 Other adverse effects

No information available.

### SECTION 13: Disposal considerations

#### 13.1 Waste treatment methods

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Recycle according to official regulations.

## **Product/Packaging disposal**

#### Waste treatment options

Do not dump into sewers or waterways.

## Appropriate disposal / Product

Waste and empty containers must be handled and eliminated according to current local/national legislation.

## Appropriate disposal / Package

Non-contaminated packages must be recycled or disposed of. Packing which cannot be properly cleaned must be disposed of. Follow the provisions of Directive 2008/98/EC regarding waste management.

### SECTION 14: Transport information

#### 14.1 UN number

No information available.

## 14.2 UN proper shipping name

No information available.

## 14.3 Transport hazard class(es)

No information available.

## 14.4 Packing group

No information available.

#### 14.5 Environmental hazards

No information available.

## 14.6 Special precautions for user

None

## 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

No information available.

## SECTION 15: Regulatory information

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

Safety Data Sheet According to Regulation (EC) No. 1907/2006 (REACH) Classification according to Regulation (EC) No. 1272/2008 [CLP] according to Regulation (EU) No. 2020/878

#### National regulations

Water hazard class

Class: nwg (Non-hazardous to water)

#### 15.2 Chemical Safety Assessment

No information available.

## **SECTION 16: Other information**

#### 16.1 Indication of changes

15. Water hazard class

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## 16.2 Abbreviations and acronyms

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road
ASTM: ASTM International, originally known as American Society for Testing and Materials (ASTM)

EINECS: European Inventory of Existing Commercial Chemical Substances

EC50: Effective Concentration 50 (Maximum Effective Concentration for 0% of Individuals)

LC50: Lethal Concentration 50 (Lethal Concentration for 50% of Individuals)
IC50: Inhibitor Concentration 50 (Inhibitory Concentration for 50% of Individuals)

NOEL: No Observed Effect Level (Maximum dose without effect)
DNEL: Derived No Effect Level (Derived no-effect dose)

DMEL: Derived Minimum Effect Level (Derived dose of minimal effect)

CLP: Classification, Labelling and Packaging

CSR: Chemical Safety Report

LD50: Lethal Dose 50 (Lethal Dose for 50% of Individuals)

IATA: International Air Transport Association
ICAO: International Civil Aviation Organization
Codice IMDG: International Maritime Dangerous Goods code

PBT: Persistent, bioaccumulative and toxic

RID: Regulations concerning the international rail transport of Dangerous Goods

STEL: Short term exposure limit TLV: Threshold limit value TWA: Time Weighted Average

UE: European Union

vPvB: Very persistent very bioaccumulative

N.D.: Uvailable N.A.: Not applicable

VwVwS.: Text of Administrative Regulation on the Classification of Substances hazardous to waters into Water

Hazard Classes

## 16.3 Key literature references and sources for data

None

#### 16.4 Relevant H- and EUH-phrases (Number and full text)

None

## 16.5 Training advice

None

### 16.6 Additional information

None

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

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