According to Regulation (EC) No 1907/2006

Issue date: September 17., 1999 Revision # 4, date: March 20, 2020

1: Identification of the substance / mixture and of the company / undertaking 1.1 Identification of the substance : Trade name: Sodium hydrogencarbonate sodium hydrogen carbonate, sodium bicarbonate, sodium acid Chemical name: carbonate Identification number: CAS No: 144-55-8 Registration number: 01-2119457606-32-0010 1.2 Use of the substance : feed material, food additive, medicinal products, medical devices, cosmetic ingredient, Identified uses: special applications Unrecommended uses: Not identified

1.3 Company/undertaking identification:

Macco Organiques, s. r.o.

Zahradní 46c, 792 01 Bruntál, Czech Republic IČ: 26819210, phone: +420 – 555 – 530 334

SDS provider's contact: Jaroslav Zavadil, phone: +420 - 555 - 530 340, jaroslav.zavadil@macco.cz

1.4 Emergency telephone:

The first aid details may be consulted with toxicological information centre (TIS): Job-related illness clinic, Na Bojišti 1, 128 08 Praha 2, tel. 2 24 91 92 93 or 2 24 91 54 02. Permanent poisoning informations.

2: Hazard identification

The substance is NOT classified as dangerous according to Directive 1272/2008/ES.

2.1 Classification of the substance:

Acc. to Directive 1272/2008/ES --

The most important adverse physicochemical, human health and environmental effects and symptoms :

High concentrations of dust may cause coughing and sneezing. May cause skin irritation. Repeated or prolonged exposure may cause drying and cracking of the skin. Contact with eye may cause mild irritation, redness, and pain. Extremely large oral doses may cause gastrointestinal disturbances.

No ecological problems are to be expected when the substance is handled and used with due care and attention.

2.2 Information on the label:

Hazard pictogram		Signal word	
Hazard statements		i - · g · · · · · · · · ·	
Precautionary statements			
Additional information on label	none		

2.3 Other dangerousness:

The PBT or vPvB criteria of Annex XIII to the Regulation does not apply to inorganic substances.

3: Composition / information on ingredients

3.1 Substance

3.1.1 Constituent

Chemical identity	Index No.	CAS	EINECS	concentration	classification list number
Sodium hydrogencarbonate	none	144-55-8	205-633-8	99 - 100%	So far none

3.1.2 Impurities, stabilizers,

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Chemical identity	Index No.	CAS	EINECS	concentration	classification list number
none					

4: First aid measures

In all cases provide the physical and mental rest and avoid of getting chilled. In case of health problems or doubts inform physician and provide him with the information contained in this safety data sheet. Never pass a medication to a unconscious person. Maintain personal safeness during rescue operation.

4.1 First aid description:

If inhaled:

Stop exposition, move the afflicted person to the fresh air, keep him warm and at rest. If symptoms persist seek medical attention. In case of unconsciousness start with resuscitation (artificial respiration, cardiac massage) and call for medical attention.

In the event of skin contact:

Remove contaminated clothes and footwear. Wash of any skin contamination with cool water and soap. Launder clothes before re-use. In case of persisting irritation contact physician .

In the event of eye contact:

Remove contact lenses if present. Immediately flush with plenty of lukewarm water for at least 15 minutes. Avoid strong stream of water due to the risk of mechanical damage to the cornea. Eyelids should be held away from the eyeball to ensure thorough rinsing. Seek medical attention.

Do not use neutralization solution!

If swallowed:

Wash out mouth with water and give plenty of water to drink (at least 300 ml). Do not induce vomiting. Seek medical attention. When vomiting, maintain supervision until the help arrives. Obtain medical advice if symptoms persist.

4.2 The most important acute and belated symptoms and effects:

By the big concentrations of dust may cause mechanical skin, eyes and respiratory tracts irritation. After oral intake of big amounts nausea, vomiting may occur.

4.3 Immediate medical help instruction and special treatment:

The workplace should be equipped with a shower and eye wash position.

5: Fire fighting measures

5.1 Extinguishing media:

Suitable extinguishing media:

Non-combustible substance. All extinguishing media are allowed, select the appropriate extinguishing media depending on the surrounding fire and environment.

Not suitable extinguishing media:

Strong water jet

5.2 Specific hazards:

During the fire carbon oxides (CO, CO₂) may be formed.

5.3 Special protective actions for fire-fighters:

Put on gas-tight protective clothing and breathing apparatus functioning independently of the ambient air.

6: Accidental release measures

6.1 Personal precautions:

Use personal safety working clothes – section 8. Prevent from skin and eye contact. Do not inhale dust. Well ventilate areas. Prevent from dust making. Other safety precautions – section 7.

6.2 Environmental precautions:

Prevent from escape to watercourses and soil and from their contamination. If there is no way to avoid it, immediately inform appropriate authority (police and firemen).

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6.3 Methods for cleaning up:

Clean up contamination/spillages as soon as they occur. Collect as much as possible in a suitable clean container, preferably for re-use, otherwise for disposal (according section 13). Avoid generation of dust. Wash the spillage area with large quantities of water. When packaging is damaged, replace the amount into a new packaging with proper marking.

6.4 Other sections references:

Also follow the regulations in sections 8 and 13 of this safety data sheet.

7: Handling and storage

7.1 Handling:

Use the personal safety tools (section 8). Ensure fresh water for the first aid. Maintain the cleanness and tidiness on the working area. Provide basic employee training to prevent / minimize exposures and to report any healthy problems that may develop. Do not eat, drink or smoke during work. Avoid contact with skin and eyes. Wash hands duly with soap and water, take a shower. Use a body lotion.

7.2 Storage:

Store at a dry and well ventilated place, not above normal room temperature. Store in tightly closed packages.

7.3 Specific uses:

Industrial chemical, component of food supplements

8: Exposure controls / personal protection

8.1 Exposure limit values

8.1.1 Exposure limits

Total dust: OEL 10 mg/m³

8.1.2 Biological limit values:

- not specified

8.1.3 DNEL and PNEC values:

DNEL Long-term

For the determination of a DNEL long-term, no reliable repeated-dose studies were available (from which normally a critical effect NOAEL is used to derive a DNEL). After assessment of the physicochemical, toxicocinetic and the normal physiological role of sodium bicarbonate, it is concluded that these studies are not required. Therefore, the DNEL long term cannot be established and is considered not necessary.

DNEL Acute

A DNEL acute should be established for substances if an acute toxicity hazard (leading to classification and labelling) has been identified and a potential for high peak exposures exists. Since sodium bicarbonate has not been classified for any toxicological property, there is no need to look at the exposure scenarios.

In addition, in the acute studies (oral and inhalation) no signs for local irritation effects were noted, nor were any other critical systemic effects described (LD50 derived were close or above the highest given doses). Therefore, sodium bicarbonate is considered to be of no toxicological concern, which renders a DNEL derivation not necessary.

PNECwater

Because the natural pH, bicarbonate and sodium concentration (and also their fluctuations in time) varies significantly between aquatic ecosystems, it is not considered useful to derive a generic PNEC or PNEC_{added}.

PNECsediment

No toxicity data on sediment organisms are available. Sodium bicarbonate is present in the environment as sodium and bicarbonate ions, which implies that it will not adsorb on particulate matter, and it is not considered useful to derive a PNEC_{sediment}.

PNEC_{soil}

Toxicity tests that determined the effect of sodium bicarbonate on terrestrial organisms are not available. Calculation of a PNEC_{soil} is not necessary because exposure of the soil compartment is unlikely, sodium bicarbonate is naturally present in soil and the toxicity for terrestrial organisms is expected to be low.

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PNECatmospheric

Solid sodium bicarbonate has a negligible vapour pressure and for this reason it will not be distributed to the atmosphere, it is therefore not considered useful to derive a PNEC_{atmospheric}.

PNEC_{STP}

Because the natural pH, bicarbonate and sodium concentration (and also their fluctuations in time) varies significantly between aquatic ecosystems, it is not considered useful to derive a generic PNEC_{STP} or PNEC_{STP-added}. The toxicity of sodium bicarbonate to micro-organisms is expected to be low because the substance is naturally present in water.

PNECoral secondary poisoning

Since sodium bicarbonate is an important extracellular buffer in vertebrates and is readily regulated in the body, it is not considered useful to derive a PNEC_{oral secondary poisoning}.

8.2 Exposure control

8.2.1 Occupational exposure control:

Operate in a well-ventilated area, avoid inhalation of dusts or mists (for liquids). Ensure shower and area for eyes rinsing. The mentioned personal safety instruments should be in compliance with EN standards.

Personal protective equipment:

Respiratory protection:	In the case of high dust levels wear suitable respiratory protective equipment, ie. dust mask or respirator conforming to EN standards. Recommended filter = particle filter,P2.
Hand protection:	Wear suitable chemical resistant protective gloves for frequent or prolonged operations tested to EN374 with an acceptable permeation test. Suitable materials include neoprene (chloroprene), PVC and nitrile rubber. Break through time is > 480 min. Contaminated gloves should be carefully rinsed with water before reuse. Non suitable materials: Leather gloves.
Eye / face protection:	Wear suitable eye/face protection. Most materials for protective googles and face visors will probably be suitable eg. polycarbonate.
Skin and body protection:	Normal working clothes is suitable.

Occupational safety: General regulations on occupational safety are in force. Do not allow exceeding standards for occupational exposure limits for hazardous components at the work – places. After finishing the work take off contaminated clothing. Before breaks during the work wash the hands and face. After the work wash thoroughly the whole body. Do not drink, eat and smoke by handling and use.

8.2.2 Environmental exposure controls:

Prevent from escape to environment.

9: Physical and chemical properties

9.1 General information:

Physical state (at 20 °C):	Solid – powder or fine crystals
Colour:	White
Odour (fragrance):	odourless
Treshold odour value:	odourless
9.2 Important health, safety and	l environmental information :
рН (at 20 °C):	8,6(5 % solution at 20 °C)
Melting point:	Decomposition starts before melting. Therefore a melting point can not be determined
Boiling point:	Decomposition starts before boiling
Flash point:	Not applicable, incombustible matter
E	NetPII-

		determined	
Boiling point:		Decomposition starts before boiling	
Flash point:		Not applicable, incombustible matter	
Evaporation rate:		Not applicable	
Flamability (solid, g	gas):	The substance is non-flammable	
Evologion limits	lower:	Not available, non-explosive matter	
Explosion limits	upper:	Not available, non-explosive matter	
Vapour pressure:		irrelevant	
Vapour density:		irrelevant	
Relative density:		2,21 – 2,23 g/cm ³	
Water solubility (a	t 20 °C) :	9,3 g / 100 ml	
	Flash point: Evaporation rate: Flamability (solid, g Explosion limits Vapour pressure: Vapour density: Relative density:	Flash point: Evaporation rate: Flamability (solid, gas): Explosion limits lower: upper: Vapour pressure: Vapour density:	

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Solubility in solvents:	Not available
Partition coefficient n-octanol/water:	Not applicable
Self-ignition temperature:	Not applicable
Decomposition temperature:	When heated over 50 °C the release of CO ₂ , H ₂ O and Na ₂ CO ₃ starts, resulting in total decomposition at 270 °C.
Viscosity:	Not applicable
Explosive properties:	The substance is non-explosive
Oxidizing properties:	The substance is non-oxidizing
9.3 Other information:	
Fat solubility:	Not available
Conductivity:	Not available
Gas group:	Not applicable

10: Stability and reactivity

Stable under recommended storage and handling conditions.

10.1 Conditions to avoid:

High temperature (decomposition). Moisture (substance may be lumpy).

10.2 Materials to avoid:

Alkali metals, acids.

10.3 Hazardous decomposition products:

None at normal use. At temperatures over 50 °C decomposition occurs with release of gaseous CO and CO₂.

11: Toxicological information

Acute toxicity:	
- LD ₅₀ oral, rat (mg.kg ⁻¹):	> 4 000
- LD ₅₀ dermal, rabbit (mg.kg ⁻¹):	Not specified
 LC₅₀ inhalation, rat, for aerosols or particles (mg.l⁻¹): 	Not specified
Skin irritation:	No irritation
Eye irritation:	No irritation
Sensitisation:	Substance does not have sensitive effects on skin and respiratory system
Carcinogenicity:	Not carcinogenic substance
Mutagenicity:	Not mutagenic substance
Toxicity for reproduction:	Not toxic substance for reproduction
Toxicity for specific target body – single exposition	Substance does not have toxic effects within single exposition
Toxicity for specific target body – repeated exposition:	Substance does not have toxic effects within repeated exposition
Irritation if inhaled:	Substance does not have irritable effects
Other information: none	

12: Ecological information

12.1 Ecotoxicity:	
- LC ₅₀ 96 hr., fish (mg.l ⁻¹):	7 100
- EC ₅₀ 48 hr., daphnia (mg.l ⁻¹):	3 100
- EC₅₀ 72 hr. algae (mg.l ⁻¹):	Not available
- EC ₅₀ 30 min. bacteria (mg.l ⁻¹):	Not available
12.2 Mobility :	Not specified
12.3 Persistence and degradability:	Not specified (not relevant for inorganic substances)
12.4 Bioacumulative potential:	Not specified
12.5 Results of PBT assessment:	Substance is not classified as PBT or vPvB.

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12.6 Other adverse effects:

Not specified.

13: Disposal considerations

13.1 Product:

If recycling or reuse is not practical then the product must be disposed of by authorized personnel in accordance with local, state or national regulations. Never dispose by flushing into the drainage! Waste former is responsible for its sorting and disposal.

Special safety precaution for recommended waste treatment:

Preferably dispose in independent container.

13.2 Packaging:

If recycling or reuse is not practical then packaging must be disposed of by authorized personnel in accordance with local, state or national regulations. Clean packaging with water and dispose of washings in accordance to local regulations. Packaging can be passed to a packaging return system after the cleaning.

13.3 Legal waste regulations:

Directive 2008/98/ES

National or regional provisions may be in force!

14: Transport information

14.1 ADR/RID (Land Transport) :	Not classified as hazardous for transportation.
14.2 ADN/ADNR (Inland Waterway Transport):	Not classified as hazardous for transportation.
14.3 IMDG (Marine Transport):	Not classified as hazardous for transportation.
14.4 ICAO/IATA (Air Transport):	Not classified as hazardous for transportation.

15: Regulatory Information

15.1 Health, safety and environmental information

on the label: ---

15.2 Chemical Safety Assessment:

Not available.

15.3 National legislation:

Regulation (EC) No. 1907 / 2006 / ES, REACH Regulation (EC) No. 1272 / 2008 / ES, CLP National laws or provisions may be in force!

16: Other information

Changes made in Safety Data Sheet in terms of revision:

Revision of Safety data sheet in terms of avoidance of Directive 67/548/EHS.

Key or explanation for abbreviations:

DNEL Derived No Effect Level (derived concentration of substance, at which no unfavourable effects occure)
PNEC Predicted No Effect Concentration (prediction of substance concentration, at which no unfavourable

effects occure)

PEL Acceptable exposure limit, long-term (8 hours)

Important literature references and data sources:

SDS of other producers, special literature, ECHA web. site http://apps.echa.europa.eu/registered/registered-sub.aspx)

Training instructions:

According to Safety Data Sheet.

Recommended restrictions of use:

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Not specified

Other:

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