

<b>SAFETY DATA SHEET</b>		
In accordance with the criteria of Regulation No 1907/2006 (REACH) as amended		
<b>ASSORBIUMIDO FRUITS</b>		
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## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1. Product identifier

**ASSORBIUMDO FRUITS cd.93609006 - 93700006**

**Synonyms:** Technical calcium chloride dihydrated; calcium dichloride.

**The registration number: 01-2119494219-28-0010**

Calcium chloride has been registered as anhydrous substance. Substance in the produced form ( $\text{CaCl}_2 \cdot 2\text{H}_2\text{O}$ ) was included in the anhydrous substance dossier registration.

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

**Relevant identified uses:** Humidity absorber (hygroscopic salts) for consumer uses. A complete list of uses is listed in the attached exposure scenarios.

**Uses advised against:** This product is not recommended for all those uses not specifically identified on the label.

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

**Producer:** SARATOGA INT. SFORZA S.P.A.

**Address:** Via Edison 76 20090 Trezzano s/Naviglio (MI) - ITALY

**Telephone:** +39 02 445731

**E-mail address** of the person responsible for the SDS: trading@saratogasforza.com

### 1.4. Emergency telephone number

CAV - Ospedale Pediatrico "Bambino Gesù" - Roma - Tel. +39 06 68593726 (h24)

CAV - Azienda Ospedaliero-Universitaria Foggia - Foggia - Tel. +39 0881 732326 (h24)

CAV - Azienda Ospedaliera "A. Cardarelli" - Napoli - Tel. +39 081 7472870 (h24)

CAV - Policlinico "Umberto I" - Roma - Tel. +39 06 4450618 (h24)

CAV - Policlinico "A. Gemelli" - Roma - Tel. +39 06 3054343 (h24)

CAV - Azienda Ospedaliera "Careggi" U.O. Tossicologia Medica - Firenze - Tel. +39 055 7947819(h24)

CAV - Centro Nazionale di Informazione Tossicologica - Pavia - Tel. +39 0382 24444 (h24)

CAV - Ospedale "Niguarda Ca' Granda" - Milano - Tel. +39 02 66101029 (h24)

CAV - Azienda Ospedaliera "Papa Giovanni XXIII" - Bergamo - Tel. +39 800 883300 (h24)

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

**Classification according to Regulation 1272/2008/EC:**

**Eye Irrit. 2; H319** Causes serious eye irritation.

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## 2.2. Label elements

### Label accordance with Regulation (EC) No 1272/2008 (CLP)

#### Hazard pictograms, signal words:



#### Warning

#### Hazard statements:

H319 - Causes serious eye irritation.

H412 - Harmful to aquatic life with long lasting effects

#### Precautionary statements:

P101 - If medical advice is needed, have product container or label at hand.

P102 - Keep out of reach of children.

P261 - Avoid breathing dust.

P264 - Wash hands thoroughly after handling.

P273 - Avoid release to the environment.

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

P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+P313 - If eye irritation persists: Get medical advice/attention.

Contains: limonene. May produce an allergic reaction.

## 2.3. Other hazards

The substance does not meet the criteria of PBT or vPvB. The PBT or vPvB criteria of Annex XIII to the Regulation 1907/2008/EC does not apply to inorganic substances.

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

<b>Substance name:</b>	<b>Calcium chloride</b>
<b>Concentration [%]:</b>	≥69.5
<b>CAS Number:</b>	10043-52-4*
<b>EC Number:</b>	233-140-8
<b>Index Number:</b>	017-013-00-2
<b>Classification 1272/2008/EC:</b>	Eye Irrit. 2; H319

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Qty	Name	Identification number	Classification
0.25% - 0.5%	limonene	Index Number: 601-029-00-7 CAS: 5989-27-5 EC: 227-813-5 REACH No.: 01-2119529223 -47-000	 2.6/3 Flam. Liq. 3 H226  4.1/A1 Aquatic Acute 1 H400  4.1/C1 Aquatic Chronic 1 H410  3.2/2 Skin Irrit. 2 H315  3.4.2/1 Skin Sens. 1 H317

In section 16 stated the importance of H-phrases, abbreviations and acronyms.

\*Calcium chloride manufactured in hydrated form ( $\text{CaCl}_2 \cdot 2\text{H}_2\text{O}$ ) (CAS: 10035-04-8).

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

**Inhalation:** Move the affected person to fresh air and keep rested. Seek medical advice if necessary.

**Skin contact:** Immediately remove contaminated clothing. Flush contaminated skin with plenty of water and soap, then rinse with plenty of water. Seek medical advice if necessary.

**Eye contact:** Check for and remove any contact lenses. Immediately flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower eyelids. Avoid strong stream of water due to the risk of mechanical damage to the cornea. Seek medical advice if necessary.

**Ingestion:** Do not induce vomiting. Rinse mouth with water, and then give to drink plenty of water. Seek medical advice if necessary.

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

**Inhalation:** Prolonged inhalation of dust may cause slight irritation to the respiratory system, irritation of mucous membranes of nose and mouth, coughing.

**Eye contact:** Irritating to eyes. Significant concentrations of dust or direct ingress of substances into the eyes may cause irritation, redness, tearing, burning and conjunctivitis.

**Skin contact:** Contact with skin may cause irritation, redness, dryness, itching.

**Ingestion:** After ingestion may damage the lining of the digestive tract, stomach pain, vomiting and diarrhea.

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

Remove affected person from the contaminated product of the environment. In the event of health problems, consult your doctor or the center of toxicological concern. Provide the information contained in the SDS. If unconscious do not give anything by mouth.

## SECTION 5: Firefighting measures

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### 5.1. Extinguishing media

**Suitable extinguishing media:** Extinguishing media suitable to the burning media in the surrounding should be applied.

**Unsuitable extinguishing media:** Water jet.

### 5.2. Special hazards arising from the substance or mixture

Non-flammable substance. During combustion produce hazardous products (e.g. chlorine, hydrogen chloride). Avoid inhalation of combustion products, because they may pose a health risk.

### 5.3. Advice for firefighters

Wear full protective equipment and self-contained breathing apparatus with independent air circulation. Containers exposed to fire or high temperature cool with water and if possible remove from the danger zone. Take up mechanically. Keep out of drains, surface waters and soil against pollution. Water from fire treated as hazardous pollution and accumulate in separate containers.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

**For non-emergency personnel:** Should restrict access to non-emergency personnel to the area of failure until the completion of the disposal of the product. Wear appropriate personal protective equipment. Do not drink, eat and smoke. Provide adequate local and general ventilation. Avoid direct contact with the substance. Avoid inhalation of dust.

**For emergency responders:** Wear appropriate personal protective equipment. Do not drink, eat and smoke. Provide adequate local and general ventilation. Avoid direct contact with the substance. Avoid inhalation of dust.

### 6.2. Environmental precautions

Secure the gullies. Prevent contamination of surface water and ground. In the event of any serious pollution of the environment, notify the appropriate administrative authority, control and rescue services. Dispose of used packaging to deliver to eligible organizations.

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

Secure the gullies. Keep damaged packaging. Damaged container and place in a substitute container. Collect the spilled substance mechanically avoiding the formation of dust, transfer to a tightly sealed containers and be disposed of or recycled. Contaminated area with plenty of water.

### 6.4. Reference to other sections

Disposal - see Section 13. Personal protective equipment - see Section 8.

## SECTION 7: Handling and storage

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### 7.1. Precautions for safe handling

Do not eat, drink, smoke or take drugs at work. Remove contaminated clothing and clean before reuse. Avoid skin and eye contact. Avoid inhalation of dust. Wash your hands before break and after working with the product. The workplace should be equipped with a shower and eye wash position. Prevent against penetration into drains, surface and ground water and soil. Reaction with water is exothermic.

### 7.2. Conditions for safe storage, including any incompatibilities

Keep in properly labeled, factory tightly sealed, with a label which complies with current regulations. Store in dry, cool and well-ventilated storage room. Avoid to high temperature. Protect against moisture (substance may be lumpy). Avoid contact with oxidants and reducing agents. Corrosive to metals in the aquatic environment.

### 7.3. Specific end use(s)

The main uses of calcium chloride are as follows: as de-icing agents (de-icers), for road stabilization and dust control, for industrial processing, as additive in plastics, for calcium salt production, drainage aid for wastewater treatment etc., as accelerator in concrete, for oil and gas well fluids, miscellaneous (tire ballast, additive in fire extinguishers, admixture with starch paste, additive to control scaffolding in blast furnaces, desiccant, brine, food processing agent (e.g. coagulating agent), additives in herbicide, pH regulating agent and laboratory chemicals).

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## SECTION 8: Exposure controls/personal protection

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### 8.1. Control parameters

Substance name	TWA	STEL	BLV
Dusts	10 mg/m <sup>3</sup> (inhalable)	-	-

**Legal basis:** Ordinance on maximum permissible concentration and intensity of harmful factors in the work environment in accordance with national limit values.

EH40/2005 Workplace exposure limits, second edition, published 2011, ISBN 978 0 7176 6446 7.

**Monitoring procedures:** Use methods described in European Standards.

### Systemic effects: DNEL<sub>acute</sub> and DNEL<sub>long term</sub>

After assessment of the toxicological properties of CaCl<sub>2</sub>, it has been concluded that the substance is not expected to cause adverse systemic effects by either acute or repeated exposure. Therefore no DNELs for systemic effects by either acute or prolonged exposure have been derived either for workers or for general population for any exposure route.

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**Local effects: DNEL<sub>acute</sub> and DNEL<sub>long term</sub>**

**Dermal:**

Calcium chloride is not classified as irritating to skin; therefore DNEL not need to be determined for this route of exposure.

**Inhalation:**

Available data, albeit of poor quality, indicate that anhydrous calcium chloride may cause respiratory tract irritation due to its intense hygroscopic properties. However, available animal data are not sufficient to derive DNEL. Therefore DNELs for respiratory tract irritation by acute or long-term exposure to calcium chloride for workers have been derived by weight of evidence approach, comparing established by ACGIH (American Conference for Governmental Industrial Hygienists) limit values for occupational exposure for either Ca<sup>2+</sup> or Cl<sup>-</sup> containing substances, known to cause respiratory tract irritation.

Therefore set out:

**DNEL<sub>long-term</sub>** = 5 mg/m<sup>3</sup> (for workers)

**DNEL<sub>acute</sub>** = 10 mg/m<sup>3</sup> (for workers)

Using the recommended guidance on information requirements and chemical safety assessment for extrapolation DNEL of value to the general population, set out:

**DNEL<sub>long-term</sub>** = 2.5 mg/m<sup>3</sup> (for general population)

**DNEL<sub>acute</sub>** = 5 mg/m<sup>3</sup> (for general population)

**Oral:**

In the available acute oral toxicity studies with rabbits, several irritating local effects were revealed at gross pathology (ulceration of stomach, hemorrhagic trachea). These effects are regarded to be exaggerated by gavage administration. Taking into account that calcium and chloride are both essential nutrients for humans and a daily intake of more than 1000 mg of each of these ions is recommended, no DNEL needs to be derived for oral route of exposure.

**PNEC<sub>water</sub>:**

Because the calcium and chloride concentration varies significantly between aquatic ecosystems (0.06-210 mg/l), it is not considered useful to derive a PNEC<sub>water</sub>.

**PNEC<sub>sediment</sub>**

Data on the toxicity of sediments freshwater and marine organisms are not available. Calcium chloride is present in the environment as calcium and chloride ions, which implies that it will not adsorb on particulate matter, and it is not considered useful to derive a PNEC<sub>sediment</sub>.

**PNEC<sub>soil</sub>**

**Terrestrial organisms:**

No reliable and relevant toxicity data on terrestrial organisms are available. Calcium chloride is present in the environment as calcium and chloride ions, which implies that it will not adsorb on particulate matter, and it is not considered useful to derive a PNEC<sub>soil</sub>.

**Terrestrial plants:**

A tentative „PNEC“, a so-called „no-effect-deposition“ (NEdep) was derived for the exposure route for deposition of calcium via road salts or dust suppressors. Plants were exposed for one or more seasons. On this basis it was established value of NEdep to 150 g/m<sup>2</sup>.

PNEC, sensitive terrestrial plants: 215 mg chloride/kg (According to the Canadian Environmental Protection Act (ECHA, 2001), sensitive terrestrial plants may be affected by soil concentrations greater than about 68 mg sodium/kg and 215 mg chloride/kg.

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**PNEC<sub>atmospheric</sub>**

No data available.

**PNEC<sub>STP</sub>**

In accordance with section 1 of Annex XI of the REACH Regulation, the study does not need to be conducted as in the aquatic environment; calcium chloride is in the form of ions. Both ions originally exist in nature, and their concentrations in surface water are dependent on various factors, such as geological parameters, weathering and human activities. Therefore activated sludge is adapted to these various ion concentrations.

As the pH of the water is neutralised before entering the STP, calcium chloride is not present anymore. Bicarbonate is then present. Therefore, it is not considered useful to derive a generic PNEC<sub>STP</sub> for calcium chloride.

**PNEC<sub>oral</sub>**

In view of the nutritional aspects, the metabolism, and the mechanisms of action of calcium and chloride ions, it is not considered useful to derive a PNEC<sub>oral</sub> (secondary poisoning).

**8.2. Exposure controls****8.2.1 Appropriate engineering controls**

Mandatory general regulations on occupational health. Do not allow the crossing of the environment, the workplace concentration limits for hazardous constituents. After work, wash and clean the surface of the body and protective clothing. Do not eat, drink, smoke or take drugs at work. Remove contaminated clothing and clean before reuse. Wash hands and face before break and after working with the product. Avoid skin and eye contact. Avoid inhalation of dust. Provide adequate local and general ventilation. The workplace should be equipped with a shower and eye wash position.

**8.2.2 Individual protection measures, such as personal protective equipment**

**Eye / face protection:** Wear suitable protective glasses of goggles type, e.g. made of polycarbonate (EN 166).

**Skin Protection:** In industrial usage wear protective clothing made of natural materials (cotton) or synthetic fibers and gloves (glove materials: nitrile-, butyl-, neoprene-rubber or PVC); glove thickness: 0.5 mm, break through time:  $\geq 480$  min (EN 374).

**Respiratory protection:** In the case of high concentrations of dust, use respiratory equipment with particle filter color-coded white and the symbol P.

**Thermal Hazards:** Not required.

Used personal protective equipment should meet the requirements of local/regional/national laws. The employer must provide personal protective equipment appropriate to the type of work and meeting all requirements, including maintenance and cleaning.

Concentrations should be monitored hazardous substances in the workplace in accordance with recognized test methods. Mode, method, type and frequency of testing and measurement of harmful factors in the working environment should meet the requirements of local/regional/national laws.

**8.2.3 Environmental exposure controls**

Do not introduce the product to ground water, sewage, waste water or soil.

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## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

<b>Appearance:</b>	Solid – flakes, powder or monolithic mass, colour: White; the commercial substance could have small impurities of iron that gives light nuance coloration to the end product depending on the state of oxidation of iron itself (off-white, yellow, pink, gray) (20 °C and 101.3 kPa)
<b>Odour:</b>	According to the declared fragrance
<b>Odour threshold:</b>	-
<b>pH:</b>	8-9 (5 % water solution)
<b>Melting point/freezing point:</b>	782 °C
<b>Initial boiling point and boiling range:</b>	In accordance with column 2 of REACH Annex VII, the boiling point study does not need to be conducted, as the substance has a melting point >300 °C. However, data are available showing that calcium chloride has a boiling point >1600 °C
<b>Flash point:</b>	In accordance with column 2 of REACH Annex VII (point 7.9) a flash point study is not needed, as the substance is inorganic
<b>Evaporation rate:</b>	Negligible, because calcium chloride is an inorganic salt (vapor pressure is practically equal to 0)
<b>Flammability (solid, gas):</b>	In accordance with Annex XI of REACH the study is scientifically unjustified, as the substance is commonly known to be a stable inorganic salt. Flammability essentially reflects the ability of the substance to react with oxygen in air at elevated temperatures in a strong exothermic reaction. In CaCl <sub>2</sub> the metal cation is already present in the highest possible oxidation state and thus cannot be further oxidized by oxygen. Chloride anion cannot be oxidized by oxygen due to its high electronegativity, which is only slightly lower than that of oxygen itself. Thus, as a reaction with oxygen is not possible, calcium chloride can be considered non-flammable. The substance does not exhibit water reactivity or pyrophoric properties
<b>Upper/lower flammability or explosive limits:</b>	In accordance with Annex VII of REACH (point 7.11) studies need not be conducted. Based on the lack of chemical groups associated with explosive properties in the structure of the substance, its classification as explosive is not warranted

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<b>Vapour pressure:</b>	In accordance with column 2 of REACH Annex VII (point 7.5), a vapour pressure study does not need to be conducted as the melting point is above 300 °C. Calcium chloride is an inorganic salt, and therefore the value of the vapor pressure can be considered as negligible
<b>Vapour density:</b>	Not applicable (calcium chloride is an inorganic salt)
<b>Relative density:</b>	Density: 2.15 g/cm <sup>3</sup> at 20 °C Density: 1.8 g/cm <sup>3</sup> at 20 °C (calcium chloride dihydrate)
<b>Solubility(ies):</b>	In water: 745 g/l at 20 °C, 1590 g/l at 100 °C Solubility in other solvents: soluble in ethanol
<b>Partition coefficient: n-octanol/ water:</b>	According to REACH Regulation Annex VII (point 7.8, specific rules for adaptation) the test does not need to be conducted as calcium chloride is inorganic
<b>Auto-ignition temperature:</b>	In accordance with Annex XI of REACH the study is scientifically unjustified. The self-ignition temperature of a substance is defined as a minimum temperature at which the substance will ignite at predefined conditions. However, as the metal ion is already present in the highest possible oxidation state and chloride cannot be oxidized by oxygen at normal conditions due to its high electronegativity, the interaction with oxygen is not possible, thus the substance is essentially non-flammable. Therefore the performance of the test on auto ignition temperature is considered to be not necessary
<b>Decomposition temperature:</b>	The temperature of 175 °C CaCl <sub>2</sub> · 2H <sub>2</sub> O loses one molecule of water. At a temperature of 260°C followed by complete dehydration. No decomposition below 1600 °C
<b>Viscosity:</b>	In accordance with section 2 of Annex XI of the REACH Regulation, the test does not need to be conducted due to the properties of the substance. Calcium chloride is a solid. Viscosity is a property of liquid substances only
<b>Explosive properties:</b>	In accordance with section 1 of REACH Annex XI (point 7.11), the study does not appear scientifically necessary. Potential explosive properties are indicated by the presence of certain reactive groups in the molecule and/or by the oxygen balance. No reactive groups are present. Considering the molecular structure of the substance, explosive properties are not expected

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**Oxidising properties:**

In accordance with Column 2 of REACH Annex VII, the study does not need to be conducted, as the substance is expected to be incapable of reacting exothermically with combustible materials based on its chemical structure, e.g. on the oxidation state of the constituting element

**9.2. Other information**

In water solutions heavily corrosive for the majority of metals.

**SECTION 10: Stability and reactivity****10.1. Reactivity**

Under the conditions of storage and handling as intended - no reactivity. Product is hygroscopic. Product react exothermic with water.

**10.2. Chemical stability**

Under normal conditions of use and storage of the substance is stable. Product is hygroscopic.

**10.3. Possibility of hazardous reactions**

Not specified.

**10.4. Conditions to avoid**

High temperature, moisture (substance may be lumpy).

**10.5. Incompatible materials**

Oxidants and reducing agents. Corrosive to metals in the aquatic environment.

**10.6. Hazardous decomposition products**

Vapors of the chlorine and hydrogen chloride are generated after heating to the melting point.

**SECTION 11: Toxicological information****11.1. Information on toxicological effects****Acute toxicity:**

Based on available data, the classification criteria are not met.

**Oral:**

LD<sub>50</sub> (rat): 2301 mg/kg b.w. (Toxicological Laboratories Limited, 1987)

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**Dermal:**

LD<sub>50</sub> (New Zealand rabbits): 5000 mg/kg b.w. (Carreon *et al.*, 1981a)

**Inhalation:**

No reliable animal data on acute inhalation toxicity are available; however, human data suggest that calcium chloride is not acutely toxic by inhalation. A non-reliable acute toxicity study with rats reported signs of respiratory tract irritation at 40 and 160 mg/m<sup>3</sup>.

**Skin corrosion/irritation:**

Calcium chloride was found to be not irritating to rabbit skin in the GLP-compliant study, performed according to OECD Guideline 404 (Koopman *et al.*, 1986). No effects were noted in any of three rabbits at any observation time points (1, 24, 48 and 72 hours) following an application of the anhydrous substance under occlusive dressing for 4 hours. Based on the results of GLP-compliant guideline studies, calcium chloride does not need to be classified for skin irritation. The results of the corrosion studies indicate that the substance was not corrosive to skin.

**Serious eye damage/irritation:**

Causes serious eye irritation (H319).

In the available eye irritation study with anhydrous calcium chloride, the observed signs of irritation were not fully reversible within 21 days of observation period. This suggests that anhydrous substance should be classified as H318 (causes serious eye damage).

No examples of calcium chloride causing irreversible damage to eyes in humans have been reported, despite its long history of widespread use.

It is feasible that eye irritating properties of calcium chloride are directly related to its hygroscopic properties. Anhydrous calcium chloride is a highly hygroscopic substance, and its dissolution in water is a highly exothermic process (heat of dissolution 81.3 kJ/mol), while calcium chloride hydrates are significantly less hygroscopic and their dissolution in water is only slightly exothermic.

Available studies have been performed in accordance with OECD Guideline 401 adopted in 1981, which stated that eyes can be rinsed 24 hours post-instillation. According to the modern version of the guideline, rinsing of eyes 1 hour post-instillation is allowed. It is thus feasible that more severe effects have been observed due the longer presence of the test substance in a conjunctival sac.

**Respiratory or skin sensitization:**

Calcium chloride is not sensitizing to skin and respiratory tract. In accordance with section 1 of REACH Annex XI, testing does not appear scientifically necessary; Calcium chloride is considered not to have any sensitizing properties, based on the physiological role of both its constituent ions, as well as the fact that sensitizing effects of both ions have never been reported, despite long-term historical and wide dispersive use (e.g. via food and medication).

**Germ cell mutagenicity:**

Based on available data, the classification criteria are not met.

Calcium chloride was negative in the bacterial mutation tests and the mammalian chromosome aberration test, showing no genotoxic potential for calcium chloride. In addition, calcium chloride is already present in the tissue culture media of the *in vitro* test systems for genetic toxicity testing and needed for normal function of the cells in culture. Testing calcium chloride in vitro will affect the cellular homeostasis due to

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osmolarity and/or pH of the culture medium which might give rise to non-specific effects. Considering these aspects and taken into account that calcium chloride is a normal constituent of the body, no further genotoxicity testing is considered necessary. Based on the results of two bacterial mutation assays and an *in vitro* chromosome aberration test in Chinese hamster lung fibroblasts, calcium chloride is considered not to have a genotoxic potential.

**Carcinogenicity:**

Based on available data, the classification criteria are not met.

Calcium chloride is not genotoxic *in vivo*. Calcium and chloride are both essential nutrients for humans and a daily intake of more than 1000 mg for each of the ions is recommended. As for healthy humans, the tolerable upper intake level for calcium is set at 2500 mg per day (equivalent to 6.9 g CaCl<sub>2</sub> per day) (Standing Committee on the Scientific Evaluation of Dietary Reference Intakes, 1999). For chloride, the reference nutrient intake is set at 2500 mg/day (equivalent to 3.9 g CaCl<sub>2</sub> per day) (Department of Health, UK, 1991). The estimated intake of calcium chloride in a form of food additives (160-345 mg/day) is considerably smaller than these values. Consistent with this, the establishment of an ADI for calcium chloride has not been deemed necessary by JECFA (Joint FAO/WHO Expert Committee on Food Additives; 1974, 2001). Based on this information, it is concluded that the substance is not carcinogenic and the performance of a carcinogenicity study for calcium chloride is not indicated.

**Reproductive toxicity:**

Based on available data, the classification criteria are not met.

**Effects on fertility:** In accordance with section 1 of REACH Annex XI, testing does not appear scientifically necessary, as CaCl<sub>2</sub> will usually not reach the foetus or the male and female reproductive organs when exposed orally, dermally or by inhalation, as it does not become available systemically. As such, it is considered not useful to perform a reproduction study.

**Developmental toxicity:** It can be stated that the substance will neither reach the foetus nor reach male and female reproductive organs (as it does not become systemically available), which shows that there is no risk for developmental toxicity and no risk for toxicity to reproduction. An oral developmental study was performed in 3 species (mouse, rat and rabbit). In all three species no maternal or teratogenic effects were noted, and NOAEL 's were above highest dose given. NOAEL (oral): 169 mg/kg b.w./day.

**STOT-single exposure:**

Based on available data, the classification criteria are not met.

**STOT-repeated exposure:**

Based on available data, the classification criteria are not met.

In accordance with column 2 of REACH Annex VIII and IX, the repeated dose toxicity studies (required under section 8.6) are not needed if a substance undergoes immediate disintegration and there are sufficient data on the cleavage products. In aqueous solution calcium chloride immediately dissociates into the ions Ca<sup>2+</sup> and Cl<sup>-</sup>, which are both essential nutrients for humans and a daily intake of more than 1000 mg for each of the ions is recommended. As for healthy humans, the tolerable upper intake level for calcium is set at 2500 mg per day (equivalent to 6.9 g CaCl<sub>2</sub> per day). For chloride, the reference

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nutrient intake is set at 2500 mg/day (equivalent to 3.9 g CaCl<sub>2</sub> per day). The estimated intake of calcium chloride in a form of food additives (160-345 mg/day) is considerably smaller than these values. Consistent with this, the establishment of an ADI for calcium chloride has not been deemed necessary by JECFA. Therefore, repeated dose toxicity studies are considered (scientifically) not necessary.

**Aspiration hazard:**

Based on available data, the classification criteria are not met.

**Health effects of local exposure:**

**Inhalation:** Prolonged inhalation of dust may cause slight irritation to the respiratory system, irritation of mucous membranes of nose and mouth, coughing.

**Eye contact:** Irritating to eyes. Significant concentrations of dust or direct ingress of substances into the eyes may cause irritation, redness, tearing, burning and conjunctivitis.

**Skin contact:** Contact with skin may cause irritation, redness, dryness, itching.

**Ingestion:** After ingestion may damage the lining of the digestive tract, stomach pain, vomiting and diarrhea.

**SECTION 12: Ecological information**

**12.1. Toxicity**

The lowest L(E)C<sub>50</sub> value is >100 mg/l (48-h EC<sub>50</sub> is 2,400 mg/l in daphnids (*Daphnia magna*)) and the lowest chronic value is >0.1 mg/l (21-d EC<sub>16</sub> is 320 mg/l in daphnids (*Daphnia magna*)). Therefore calcium chloride needs not to be classified according to EU Classification, Labelling and Packaging of Substances and Mixtures (CLP) Regulation (EC) No. 1272/2008.

**Acute toxicity to fish:**

Several studies on acute toxicity to fish have been reported. The lowest 96-hour LC<sub>50</sub> value of 4630 mg/l is from a study with fathead minnow (*Pimephales promelas*) conducted under EPA guideline (Mount, D.R., Gulley, D.D., Hockett, J.R., Garrison, T.D. and Evans, J.M. (1997)). Furthermore, there are two studies with bluegill sunfish (*Lepomis macrochirus*) from Cairns and Scheier (1959) and Trama (1954) and a study with mosquitofish (*Gambusia affinis*) from Wallen *et al.* (1957) in which 96-hour LC<sub>50</sub> values between 9500 and 13400 mg/l were determined.

**Chronic toxicity to fish:**

In accordance with section 1 of REACH Annex XI, the study does not need to be conducted as in the aquatic environment; calcium chloride is easily dissociated. Both ions are essential constituents of the body of all animals.

**Acute toxicity to invertebrates:**

There are seven acute toxicity data available for *Cladocera*. Two of them were conducted according to international or national guidelines, giving the 48-hour EC<sub>50</sub> of 2400 mg/l for *Daphnia magna* (de Groot, W.A. and Groeneveld, A.H.C. (1998)) and the 48-hour LC<sub>50</sub> of

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1830 mg/l for *Ceriodaphnia* sp. (Mount *et al.*, 1997). The lowest valid 48-hour EC<sub>50</sub> was 1062 mg/l for *Daphnia magna* (Biesinger and Christensen, 1972).

The acute toxicity studies with other invertebrates showed LC<sub>50</sub> or EC<sub>50</sub> values in the range of 780-44400 mg/l. These studies were not conducted according to standard guidelines, but the test conditions were fully described and these data are acceptable.

#### **Chronic toxicity to invertebrates:**

The chronic effect of 21-day exposure on reproduction of *Daphnia magna* has been investigated as a long-term study. The methods and test conditions used in the study are fully described, and appear to be scientifically acceptable, although the study was conducted prior to the acceptance of standard guidelines for this type of study. The concentration required for 16% and 50% inhibition of reproduction (EC<sub>16</sub> and EC<sub>50</sub>) was 320 and 610 mg/l, respectively (Biesinger, K.E. and Christensen, G.M. (1972)).

#### **Algae and aquatic plants:**

There is one study with fresh water algae *Pseudokirchneriella subcapitata* (*Selenastrum capricornutum*), which was conducted according to OECD guideline 201. The 72-hour EC<sub>50</sub> and EC<sub>20</sub> obtained on the basis of biomass from the study were 2900 and 1000 mg/l, respectively (de Groot, WA (1998)).

#### **Toxicity to birds:**

In accordance with section 1 of REACH Annex XI, the study does not need to be conducted as calcium chloride is easily dissociated into calcium and chloride ions in water. The absorption, the distribution and the excretion of the ions in animals are regulated separately. Both ions are essential constituents of the body of all animals. Calcium is essential for the formation of skeletons, neural transmission, muscle contraction, coagulation of the blood, and so on. Chloride is required for regulating intracellular osmotic pressure and buffering.

### **12.2. Persistence and degradability**

#### **Degradation**

##### **Hydrolysis:**

In accordance with section 1 of REACH Annex XI, the study does not need to be conducted as in water; calcium chloride is dissociated.

##### **Biodegradation:**

In accordance with section 2 of Annex XI of the REACH Regulation, the ready biodegradability test, the simulation test on ultimate degradation in surface water, the sediment simulation test and the soil simulation test are not need to be conducted as the substance is inorganic.

### **12.3. Bioaccumulative potential**

In accordance with section 1 of REACH Annex XI, the study does not need to be conducted as in water, calcium chloride is easily dissociated into calcium and chloride ions and both ions are essential constituents of the body of all animals.

Octanol-water partition coefficient (K<sub>ow</sub>): Not applicable (calcium chloride is salt of inorganic).

Bioconcentration factor (BCF): Not applicable (calcium chloride is salt of inorganic).

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#### **12.4. Mobility in soil**

In accordance with section 1 of REACH Annex XI, the study does not need to be conducted as in water; calcium chloride is dissociated into calcium and chloride ions and chloride ions will not adsorb on particulate matter. The calcium ion may bind to soil particulate or may form stable inorganic salts with sulphate and carbonate ions, but calcium is naturally present in soil.

#### **12.5. Results of PBT and vPvB assessment**

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

#### **12.6. Other adverse effects**

No data available.

### **SECTION 13: Disposal considerations**

#### **13.1. Waste treatment methods**

During removal of waste comply with the regional / national laws.

Directive **2008/98/EC** of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives as amended.

European Parliament and Council Directive **94/62/EC** of 20 December 1994 on packaging and packaging waste as amended.

**Disposal methods for the product:** Don't introduce into the environment. Collect spilt substance to the containers. Reused or pass in a properly labeled containers for disposal to the qualifying company.

**Disposal methods for used packing:** Product and packaging disposed of as waste material; delivered to undertakings so authorized.

### **SECTION 14: Transport information**

#### **14.1. UN number**

Not applicable.

#### **14.2. UN proper shipping name**

Not applicable.

#### **14.3. Transport hazard class(es)**

Not applicable.

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#### **14.4. Packing group**

Not applicable.

#### **14.5. Environmental hazards**

Substance isn't dangerous for the environment in accordance with the UN Model Regulations criteria.

#### **14.6. Special precautions for user**

Not applicable.

#### **14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code**

Not applicable.

## **SECTION 15: Regulatory information**

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

**Regulation (EC) No 1907/2006** of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC as amended.

**Regulation (EC) No 1272/2008** of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 as amended.

**Commission Regulation (EU) 2015/830** of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

**Directive 2008/98/EC** of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives as amended.

**European Parliament and Council Directive 94/62/EC** of 20 December 1994 on packaging and packaging waste as amended.

### **15.2. Chemical safety assessment**

The Chemical Safety Report has been completed for anhydrous calcium chloride (CAS: 10043-52-4). Substance is irritating to eyes.

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## SECTION 16: Other information

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### The full text of statements H:

H319 - Causes serious eye irritation.

### Key to abbreviations and acronyms:

BLV - Biological limit values.

DNEL - Derived no-effect level.

EC<sub>50</sub> - Half maximal effective concentration.

Eye Irrit. 2 - Serious eye damage/eye irritation, Hazard Category 2.

LC<sub>50</sub> - Median lethal concentration.

LD<sub>50</sub> - Median lethal dose.

LDL<sub>0</sub> - Lethal dose low.

NOAEL - No observed adverse effect level.

NOEC - No observed effect concentration.

OECD - Organization for Economic Co-operation and Development.

PNEC - Predicted No Effect Concentration.

STEL - Short-term exposure limit.

TWA - 8 hours time-weighted average.

**Training advice:** Before use read the SDS.

**Sources of key data:** Producer SDS from 1<sup>st</sup> December 2010.

EH40/2005 Workplace exposure limits, second edition, published 2011, ISBN 978 0 7176 6446 7.

The information above is based on a current available data concerning the product, but also on the experience and knowledge in this field of the producer. They are neither a quality description of the product nor a guarantee of particular features. They are also treated as aid to safety in transport, storage and usage of the product. This does not free the user from the responsibility of improper usage of the information above also of improper compliance with the law norms in the field.

Annex to the Safety Data Sheet is the appropriate exposure scenario.

Version	Section(s)	Change(s)
1 (18.07.2013)	1.3	Producer and E-mail address
2 (16.10.2013)	headline	Document name
	16	Sources of key data and information regarding creator
3 (28.07.2014)	headline	Logo
	1.3	Name of the producer

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	2.1, 3.1	Remove classification according to Directive
	8.2.2	European standard for equipment protection to eye/face and skin
	14.7	Title according to new regulations
	15.1	Laws update
	16	Removes statements, abbreviations and acronyms "Eye Irrit. 2" explication
4 (18.08.2015)	1.1	Product identifier modification
	1.2	Relevant identified uses changed
	2.1	Removed group division of threats Removed "In section 16 stated the importance of H-phrases and symbols"
	2.2	The names of hazardous ingredients on the label removed
	2.3	Other hazards completed
	3.1	"In section 16 stated the importance of H-phrases, abbreviations and acronyms"
	3.2	Section removed
	7.1	Precautions for safe handling completed
	7.2	Conditions for safe storage, including any incompatibilities changed
	9.1	Information about vapour pressure completed Information about relative density modified
	10.1	Information about reactivity completed
	10.5	Incompatible materials changed
	10.6	Hazardous decomposition products changed
	12.1	Directive 67/548/EEC removed Information about acute toxicity to fish and invertebrates, chronic toxicity to invertebrates and toxicity to algae and aquatic plants modified
	13.1	Waste code removed
	15.1	Actualization of regulatory information
15.2	Chemical safety assessment	
16	Removed "under Sections 2 and 3"	
5 (16.05.2016)	1.1	Synonyms updated
	3.1	Information about concentration modified
	9.1	The title of the subsection changed
	9.1	Change of the record

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**Allegato alla scheda di sicurezza**

**Sezione 1. Titolo dello scenario di esposizione**

Titolo	<b>Usi di consumo del cloruro di calcio; CAS: 10043-52-4*</b>
Settori d'uso	<ul style="list-style-type: none"> <li>▪ SU21: Usi di consumo: nuclei familiari (= popolazione in generale = consumatori).</li> </ul>
Categoria del prodotto chimico	<ul style="list-style-type: none"> <li>▪ PC2: Adsorbenti;</li> <li>▪ PC4: Prodotti antigelo e prodotti per lo sbrinamento;</li> <li>▪ PC16: Fluidi per il trasferimento di calore;</li> <li>▪ PC35: Prodotti per il lavaggio e la pulizia (tra cui prodotti a base di solventi);</li> <li>PC0 - codici UCN K35100: Cemento/calcestruzzo/malta.</li> </ul>
Categorie di rilascio nell'ambiente	<ul style="list-style-type: none"> <li>▪ ERC8a: Ampio uso dispersivo indoors coadiuvanti tecnologici in sistemi aperti;</li> <li>▪ ERC8d: Wide dispersive outdoor use of processing aids in open systems.</li> </ul>
Processi, compiti, attività coperte	

**Sezione 2. Se le condizioni operative e le misure di gestione del rischio**

**2.1. Controllo dell'esposizione dei consumatori**

Forma fisica del prodotto	
Concentrazione di una sostanza in un prodotto	Copre una percentuale di sostanza nel prodotto fino al 100% [ConsOC1].
Quantità utilizzate	Per ogni caso di applicazione si riferisce all'utilizzo di quantità inferiore a 50 kg, salvo diverse indicazioni [ConsOC2].
Frequenza e durata dell'utilizzo	Include l'utilizzo in 365 giorni/anno, salvo diverse indicazioni [ConsOC3]; Include l'esposizione fino a 24 ore/incidente [ConsOC14].
Fattori umani non influenzati dalla gestione dei rischi	Dose per inalazione fino a 32,9 m <sup>3</sup> /giorno.
Altre condizioni operative che coinvolgono le esposizioni dei lavoratori	Include l'utilizzo a temperatura d'ambiente [ConsOC15]; Volume ambiente 1 m <sup>3</sup> per volume ambiente si intende lo spazio personale: una piccola area di 1 m <sup>3</sup> intorno al luogo di utilizzo. Coefficiente di scambio aria min 0,6 (1/ore). Include le applicazioni con l'area di rilascio fino a 125 m <sup>2</sup> , salvo diverse indicazioni.

**Categorie di prodotti chimici**

PC2 (adsorbenti) CaCl <sub>2</sub> utilizzato come agente idratante ad uso domestico	Condizioni d'esercizio	Non sono state definite condizioni di lavoro specifiche
	Mezzi per la gestione dei rischi	Non sono state identificate misure specifiche
PC4 (antigelo + sbrinamento) CaCl <sub>2</sub> utilizzato per prevenire la formazione del ghiaccio e il congelamento	Condizioni d'esercizio	Non sono state definite condizioni di lavoro specifiche

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	Mezzi per la gestione dei rischi	Non sono state identificate misure specifiche
PC16 (fluidi per il trasferimento di calore) Cloruro di calcio fonte di energia in un recipiente autoriscaldante	Condizioni d'esercizio	Non sono state definite condizioni di lavoro specifiche
	Mezzi per la gestione dei rischi	Non sono state identificate misure specifiche
PC35 (prodotti per il lavaggio e la pulizia) Cloruro di calcio contenente detergenti e prodotti per pulizia	Condizioni d'esercizio	<b>Attività non a spruzzo</b> - Non sono state definite condizioni di lavoro specifiche
	Mezzi per la gestione dei rischi	Non sono state identificate misure specifiche
	Condizioni d'esercizio	<b>Spruzzare</b> - Include la concentrazione fino alla saturazione (45%) [ConsOC1]; Include il tempo di nebulizzazione fino a 10 minuti/incidente Include l'utilizzo in un locale di 58 m <sup>3</sup> e altezza 2,5 m
	Mezzi per la gestione dei rischi	Nebulizzare lontano dalla gente
PC0-UCN codici K35100: (Cemento/calcestruzzo/malta) Cloruro di calcio nel Cemento/calcestruzzo/malta	Condizioni d'esercizio	Non sono state definite condizioni di lavoro specifiche
	Mezzi per la gestione dei rischi	Non sono state identificate misure specifiche

#### 2.2. Controlli dell'esposizione ambientale

Non applicabile per quanto riguarda questa applicazione, la sostanza non è pericolosa per l'ambiente.

#### Sezione 3. Stima dell'esposizione

##### 3.1. L'esposizione dei consumatori

Per valutare l'esposizione è stato impiegato il metodo ConsExpo4.1.

Categorie di processo	Esposizione prolungata per inalazione		Esposizione di breve durata per inalazione	
	Concentrazioni stimate nell'esposizione (mg/m <sup>3</sup> )	Rapporto di caratterizzazione e del rischio	Concentrazioni stimate nell'esposizione (mg/m <sup>3</sup> )	Rapporto di caratterizzazione del rischio
PC2	<0,01	<0,01	0,005	<0,01
PC4	<0,01	<0,01	0,005	<0,01
PC16	<0,01	<0,01	0,005	<0,01
PC35	<0,01	<0,01	0,005	<0,01
PC0-UCN codici K35100	<0,01	<0,01	0,005	<0,01

##### 3.2. Ambiente

Non applicabile per quanto riguarda questa applicazione, la sostanza non è pericolosa per

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l'ambiente.	
<b>Sezione 4. Guida al controllo della conformità con lo Scenario di esposizione</b>	
<b>4.1. L'esposizione dei consumatori</b>	
Istruzioni per utilizzatori a valle	<p>Si prevede che le esposizioni non superino il DN(M)EL quando sono applicate le Misure di Gestione dei Rischi/Condizioni Operative illustrate nella Sezione 2 [GC22].</p> <p>Laddove siano adottate diverse Misure di Gestione dei Rischi/Condizioni Operative, gli utilizzatori sono tenuti a garantire che i rischi siano gestiti a un livello almeno equivalente [GC23].</p> <p>Per ottenere più dettagli o informazioni sulle premesse incluse nel presente scenario d'esposizione, contattare il fornitore [ ].</p>
<b>4.2. Ambiente</b>	
Non applicabile per quanto riguarda questa applicazione, la sostanza non è pericolosa per l'ambiente.	
<b>Sezione 5.</b>	
<b>Controllo delle esposizioni dei consumatori</b>	
Mancanza.	
<b>Controllo delle esposizioni ambientali</b>	
Mancanza.	

\*Il cloruro di calcio viene prodotto in forma idratata ( $\text{CaCl}_2 \cdot 2 \text{H}_2\text{O}$ ) come CAS 10035-04-8.

Edizione	Sezione	Modifica
1 (01.08.2014)	Capitello	Logo
2 (15.09.2015)	1	Titolo dello scenario modificato
	1, 2.1, 3.1	Categorie del prodotto PC12, PC27, PC37 cancellate
	2	Campo cancellato
	3.1	E' stato indicato il metodo di valutazione dell'esposizione Modifiche nella descrizione della tabella