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



#### Calciumchloride-dihydraat CELLPURE® ≥99 %, CELLPURE®

article number: **HN04** Version: **3.0 en** Replaces version of: 2021-03-23 Version: (2)

date of compilation: 2016-09-14 Revision: 2024-03-03

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

**CELLPURE**®

600-075-5

10035-04-8

01-2119494219-28-xxxx

Laboratory chemical

Laboratory and analytical use

HN04

#### 1.1 Product identifier

Identification of the substance

Article number

**Registration number (REACH)** 

EC number

CAS number

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

Relevant identified uses:

Uses advised against:

Do not use for private purposes (household). Food, drink and animal feedingstuffs.

Calciumchloride-dihydraat CELLPURE® ≥99 %,

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

Carl Roth GmbH + Co. KG Schoemperlenstr. 3-5 D-76185 Karlsruhe Germany

**Telephone:**+49 (0) 721 - 56 06 0 **Telefax:** +49 (0) 721 - 56 06 149 **e-mail:** sicherheit@carlroth.de **Website:** www.carlroth.de

Competent person responsible for the safety data Department Health, Safety and Environment sheet:

#### e-mail (competent person):

#### sicherheit@carlroth.de

#### 1.4 Emergency telephone number

Name	Street	Postal code/city	Telephone	Website
National Poisons Information Centre Beaumont Hospital	Beaumont Road	Dublin 9	+353 1 809 2166	https:// www.poisons.ie/

## **SECTION 2: Hazards identification**

#### 2.1 Classification of the substance or mixture

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

Section	Hazard class	Cat- egory	Hazard class and category	Hazard statement
3.3	Serious eye damage/eye irritation	2	Eye Irrit. 2	H319

For full text of abbreviations: see SECTION 16

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



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#### 2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 (CLP)

Warning
s
Causes serious eye irritation
tements
tements - prevention
Wear protective gloves/eye protection
tements - response
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
where the contents do not exceed 125 ml



#### 2.3 Other hazards

#### Results of PBT and vPvB assessment

According to the results of its assessment, this substance is not a PBT or a vPvB.

#### **Endocrine disrupting properties**

Does not contain an endocrine disruptor (ED) at a concentration of  $\ge 0,1\%$ .

## **SECTION 3: Composition/information on ingredients**

### 3.1 Substances

Name of substance	Calciumchloride-dihydraat
Molecular formula	$CaCl_2 \cdot 2 H_2O$
Molar mass	147 <sup>g</sup> / <sub>mol</sub>
REACH Reg. No	01-2119494219-28-xxxx
CAS No	10035-04-8
EC No	600-075-5

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



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

#### 4.1 Description of first aid measures



#### **General notes**

Take off contaminated clothing.

#### **Following inhalation**

Provide fresh air. In all cases of doubt, or when symptoms persist, seek medical advice.

#### Following skin contact

Rinse skin with water/shower. In all cases of doubt, or when symptoms persist, seek medical advice.

#### Following eye contact

Irrigate copiously with clean, fresh water for at least 10 minutes, holding the eyelids apart. In case of eye irritation consult an ophthalmologist.

#### **Following ingestion**

Rinse mouth. Call a doctor if you feel unwell.

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

Irritation, Gastrointestinal complaints, Nausea, Vomiting

**4.3 Indication of any immediate medical attention and special treatment needed** none

## **SECTION 5: Firefighting measures**

#### 5.1 Extinguishing media



#### Suitable extinguishing media

co-ordinate firefighting measures to the fire surroundings! water, foam, alcohol resistant foam, dry extinguishing powder, ABC-powder

#### Unsuitable extinguishing media

water jet

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

Non-combustible.

#### Hazardous combustion products

In case of fire may be liberated: Hydrogen chloride (HCl)

#### 5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Fight fire with normal precautions from a reasonable distance. Wear self-contained breathing apparatus.

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



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## **SECTION 6: Accidental release measures**

6.1 Personal precautions, protective equipment and emergency procedures



#### For non-emergency personnel

Avoid contact with skin, eyes and clothes. Do not breathe dust.

#### 6.2 Environmental precautions

Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it.

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

#### Advice on how to contain a spill

Covering of drains. Take up mechanically.

#### Advice on how to clean up a spill

Take up mechanically. Control of dust.

#### Other information relating to spills and releases

Place in appropriate containers for disposal.

#### 6.4 Reference to other sections

Hazardous combustion products: see section 5. Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.

### **SECTION 7: Handling and storage**

#### 7.1 Precautions for safe handling

Avoid dust formation.

#### Advice on general occupational hygiene

Wash hands before breaks and after work. Keep away from food, drink and animal feedingstuffs.

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

Store in a dry place. Keep container tightly closed.

#### Incompatible substances or mixtures

Observe hints for combined storage.

#### Consideration of other advice:

#### Specific designs for storage rooms or vessels

Recommended storage temperature: 15 - 25 °C

#### 7.3 Specific end use(s)

No information available.

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



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## **SECTION 8: Exposure controls/personal protection**

8.1 Control parameters

#### **National limit values**

#### **Occupational exposure limit values (Workplace Exposure Limits)**

This information is not available.

#### 8.2 Exposure controls

#### Individual protection measures (personal protective equipment)

#### **Eye/face protection**



Use safety goggle with side protection.

#### **Skin protection**



#### hand protection

Wear suitable gloves. Chemical protection gloves are suitable, which are tested according to EN 374. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. The times are approximate values from measurements at 22 ° C and permanent contact. Increased temperatures due to heated substances, body heat etc. and a reduction of the effective layer thickness by stretching can lead to a consider-able reduction of the breakthrough time. If in doubt, contact manufacturer. At an approx. 1.5 times larger / smaller layer thickness, the respective breakthrough time is doubled / halved. The data apply only to the pure substance. When transferred to substance mixtures, they may only be considered as a guide.

#### • type of material

NBR (Nitrile rubber)

#### material thickness

>0,11 mm

#### • breakthrough times of the glove material

>480 minutes (permeation: level 6)

#### other protection measures

Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended.

#### **Respiratory protection**



Respiratory protection necessary at: Dust formation. Particulate filter device (EN 143). P1 (filters at least 80 % of airborne particles, colour code: White).

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



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#### Environmental exposure controls

Keep away from drains, surface and ground water.

## **SECTION 9: Physical and chemical properties**

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

Physical state	solid
Form	crystalline
Colour	white
Odour	odourless
Melting point/freezing point	176 °C at 1.013 hPa (Release of crystal water)
Boiling point or initial boiling point and boiling range	not determined
Flammability	non-combustible
Lower and upper explosion limit	not determined
Flash point	not applicable
Auto-ignition temperature	not determined
Decomposition temperature	176 °C (Release of crystal water)
pH (value)	4,5 – 8,5 (in aqueous solution: 50 <sup>g</sup> / <sub>l</sub> , 20 °C)
Kinematic viscosity	not relevant
Solubility(ies)	
Water solubility	~ 147 <sup>g</sup> / <sub>l</sub> at 20 °C
Partition coefficient	
Partition coefficient n-octanol/water (log value):	not relevant (inorganic)
Vapour pressure	not determined
Density and/or relative density	
Density	1,85 <sup>g</sup> / <sub>cm³</sub> at 20 °C
Relative vapour density	Information on this property is not available.
Particle characteristics	No data available.
Other safety parameters	
Oxidising properties	none
Other information	
Information with regard to physical hazard classes:	hazard classes acc. to GHS (physical hazards): not relevant

9.2

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



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Other safety characteristics:

There is no additional information.

## **SECTION 10: Stability and reactivity**

#### 10.1 Reactivity

This material is not reactive under normal ambient conditions.

#### 10.2 Chemical stability

Hygroscopic solid.

#### 10.3 Possibility of hazardous reactions

Exothermic reaction with: Strong acid, Water

#### 10.4 Conditions to avoid

Keep away from heat. Decompostion takes place from temperatures above: 176 °C. Protect from moisture.

#### **10.5** Incompatible materials

There is no additional information.

#### 10.6 Hazardous decomposition products

Hazardous combustion products: see section 5.

## **SECTION 11: Toxicological information**

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

Classification according to GHS (1272/2008/EC, CLP)

#### Acute toxicity

Shall not be classified as acutely toxic.

## Acute toxicity

Exposure route	Endpoint	Value	Species	Method	Source
oral	LD50	2.120 <sup>mg</sup> / <sub>kg</sub>	rat	anhydrous	ECHA
dermal	LD50	>5.000 <sup>mg</sup> / <sub>kg</sub>	rabbit	anhydrous	ECHA

#### Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

#### Serious eye damage/eye irritation

Causes serious eye irritation.

#### Respiratory or skin sensitisation

Shall not be classified as a respiratory or skin sensitiser.

#### Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

#### Carcinogenicity

Shall not be classified as carcinogenic.

#### **Reproductive toxicity**

Shall not be classified as a reproductive toxicant.

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



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#### Specific target organ toxicity - single exposure

Shall not be classified as a specific target organ toxicant (single exposure).

#### Specific target organ toxicity - repeated exposure

Shall not be classified as a specific target organ toxicant (repeated exposure).

#### Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

#### Symptoms related to the physical, chemical and toxicological characteristics

#### • If swallowed

vomiting, nausea, gastrointestinal complaints

#### • If in eyes

Causes serious eye irritation

#### • If inhaled

Data are not available.

#### • If on skin

Frequently or prolonged contact with skin may cause dermal irritation

#### Other information

none

#### **11.2** Endocrine disrupting properties

Does not contain an endocrine disruptor (ED) at a concentration of  $\ge 0,1\%$ .

#### 11.3 Information on other hazards

There is no additional information.

## **SECTION 12: Ecological information**

#### 12.1 Toxicity

Shall not be classified as hazardous to the aquatic environment.

Aquatic toxicity (acute)						
Endpoint	Value	Species	Source	Exposure time		
LC50	4.630 <sup>mg</sup> / <sub>l</sub>	fish	ECHA	96 h		
ErC50	>4.000 <sup>mg</sup> / <sub>l</sub>	algae	ECHA	72 h		
Aquatic toxicity (ch	Aquatic toxicity (chronic)					
Endpoint	Value	Species	Source	Exposure time		
EC50	900 <sup>mg</sup> / <sub>l</sub>	aquatic invertebrates	ECHA	21 d		

#### 12.2 Persistence and degradability

Data are not available.

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



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#### 12.3 Bioaccumulative potential

Data are not available.

- **12.4 Mobility in soil** Data are not available.
- **12.5 Results of PBT and vPvB assessment** Data are not available.
- **12.6** Endocrine disrupting properties Does not contain an endocrine disruptor (ED) at a concentration of  $\ge 0,1\%$ .

#### 12.7 Other adverse effects

Data are not available.

## **SECTION 13: Disposal considerations**

#### 13.1 Waste treatment methods



This material and its container must be disposed of as hazardous waste. Dispose of contents/container in accordance with local/regional/national/international regulations.

#### Sewage disposal-relevant information

Do not empty into drains.

#### Waste treatment of containers/packagings

Handle contaminated packages in the same way as the substance itself. Completely emptied packages can be recycled.

#### 13.2 Relevant provisions relating to waste

The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process.

#### Properties of waste which render it hazardous

HP 4 irritant - skin irritation and eye damage

#### 13.3 Remarks

Waste shall be separated into the categories that can be handled separately by the local or national waste management facilities. Please consider the relevant national or regional provisions. Non-contaminated packages may be recycled.

## **SECTION 14: Transport information**

- 14.1 UN number or ID number
- 14.2 UN proper shipping name
- 14.3 Transport hazard class(es)
- 14.4 Packing group
- 14.5 Environmental hazards

#### 14.6 Special precautions for user

There is no additional information.

- not subject to transport regulations
- not assigned
- none
- not assigned

non-environmentally hazardous acc. to the dangerous goods regulations

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



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Maritime transport in bulk according to IMO instruments 14.7 The cargo is not intended to be carried in bulk.

#### 14.8 Information for each of the UN Model Regulations

International Maritime Dangerous Goods Code (IMDG) - Additional information Not subject to IMDG.

International Civil Aviation Organization (ICAO-IATA/DGR) - Additional information Not subject to ICAO-IATA.

## SECTION 15: Regulatory information

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

**Relevant provisions of the European Union (EU)** 

#### **Restrictions according to REACH, Annex XVII**

#### Dangerous substances with restrictions (REACH, Annex XVII)

Name of substance	Name acc. to inventory	CAS No	Restriction	No
Calciumchloride-dihydraat	substances in tattoo inks and perman- ent make-up		R75	75

Leaend R75

1. Shall not be placed on the market in mixtures for use for tattooing purposes, and mixtures containing any such sub-stances shall not be used for tattooing purposes, after 4 January 2022 if the substance or substances in question is or are present in the following circumstances

(a) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as carcinogen category 1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;
(b) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as reproductive toxicant

category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight;

(c) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin sensitiser category 1, 1A or 1B, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight:

(d) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin corrosive category 1, 1A, 1B or 1C or skin irritant category 2, or as serious eye damage category 1 or eye irritant category 2, the substance is present in the mixture in a concentration equal to or greater than:

(i) 0,1 % by weight, if the substance is used solely as a pH regulator;
(ii) 0,01 % by weight, in all other cases;
(e) in the case of a substance listed in Annex II to Regulation (EC) No 1223/2009 (\*1), the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;
(f) in the case of a substance for which a condition of one or more of the following kinds is specified in column g (Product type, Body parts) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;
(f) in the case of a substance for which a condition of one or more of the following kinds is specified in column g (Product type, Body parts) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight:

(i) "Rinse-off products";
(ii) "Not to be used in products applied on mucous membranes";
(iii) "Not to be used in eye products";
(g) in the case of a substance for which a condition is specified in column h (Maximum concentration in ready for use preparation) or column i (Other) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration, or in some other way, that does not accord with the condition specified in that column; (h) in the case of a substance listed in Appendix 13 to this Annex, the substance is present in the mixture in a concen-tration equal to or greater than the concentration limit specified for that substance in that Appendix. 2. For the purposes of this entry use of a mixture "for tattooing purposes" means injection or introduction of the mix-ture into a person's skin, mucous membrane or eyeball, by any process or procedure (including procedures com-monly referred to as permanent make-up, cosmetic tattooing, micro-blading and micro-pigmentation), with the aim of making a mark or design on his or her body.

making a mark or design on his or her body.
3. If a substance not listed in Appendix 13 falls within more than one of points (a) to (g) of paragraph 1, the strictest concentration limit laid down in the points in question shall apply to that substance. If a substance listed in Appendix 13 also falls within one or more of points (a) to (g) of paragraph 1, the concentration limit laid down in point (h) of paragraph 1 shall apply to that substance.
4. By way of derogation, paragraph 1 shall not apply to the following substances until 4 January 2023: (a) Pigment Blue 15:3 (CI 74160, EC No 205-685-1, CAS No 147-14-8);
(b) Pigment Green 7 (CI 74260, EC No 215-524-7, CAS No 1328-53-6).
5. If Part 3 of Annex VI to Regulation (EC) No 1272/2008 is amended after 4 January 2021 to classify or re-classify a substance such that the substance then becomes caugable by point (a) (b) (c) or (d) of paragraph 1 of this entry, or such

that it then falls within a different one of those points from the one within which it fell previously, and the date of ap-plication of that new or revised classification is after the date referred to in paragraph 1 or, as the case may be, para-graph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect on the date of application of that new or revised classification.

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



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<ul> <li>1272/2008.</li> <li>The information shall be clearly visible, easily legible and marked in a way that is indelible.</li> <li>The information shall be written in the official language(s) of the Member State(s) where the mixture is placed of market, unless the Member State(s) concerned provide(s) otherwise.</li> <li>Where necessary because of the size of the package, the information listed in the first subparagraph, except for (a), shall be included instead in the instructions for use.</li> <li>Before using a mixture for tattooing purposes, the person using the mixture shall provide the person undergoin procedure with the information marked on the package or included in the instructions for use pursuant to this p graph.</li> <li>8. Mixtures that do not contain the statement "Mixture for use in tattoos or permanent make-up" shall not be us tattooing purposes.</li> <li>9. This entry does not apply to substances that are gases at temperature of 20 °C and pressure of 101,3 kPa, or of ate a vapour pressure of more than 300 kPa at temperature of 50 °C, with the exception of formaldehyde (CAS N 00-0, EC No 200-001-8).</li> <li>10. This entry does not apply to the placing on the market of a mixture for use for tattooing purposes, or to the a mixture for tattooing purposes, when placed on the market exclusively as a medical device or an accessory to medical device, within the same meaning. Where the placing on the market or use may not be extended in the market or use may not be extended or the state or placed on the market exclusively as a medical device or an accessory to a medical device.</li> </ul>	6. If Annex II or Annex IV to Regulation (EC) No 1223/2009 is amended after 4 January 2021 to list or change the list
<ul> <li>amendment takes effect after the date referred to in paragraph 1, or, as the case may be, paragraph 4, of this en that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect from date falling 18 months after entry into force of the act by which that amendment was made.</li> <li>7. Suppliers placing a mixture on the market for use for tattooing purposes shall ensure that, after 4 January 202 mixture is marked with the following information: <ul> <li>(a) the statement "Mixture for use in tattoos or permanent make-up";</li> <li>(b) a reference number to uniquely identify the batch;</li> <li>(c) the list of ingredients in accordance with the nomenclature established in the glossary of common ingredient names pursuant to Article 33 of Regulation (EC) No 1223/2009, or in the absence of a common ingredient name, purposes pand to Article 33 of Regulation (EC) No 1223/2009, or in the absence of a common ingredient mame or IUPAC name, the CAS and EC number. Ingredient' me any substance added during the process of formulation and present in the mixture for use for tattooing purpose purities shall not be regarded as ingredients. If the name of a substance, used as ingredient within the meaning this entry, is already required to be stated on the label in accordance with Regulation (EC) No 1272/2008, that in ent does not need to be marked in accordance with this Regulation;</li> <li>(d) the additional statement "pH regulator" (or substances falling under point (d)(i) of paragraph 1;</li> <li>(e) the statement "Contains nickel. Can cause allergic reactions." if the mixture contains nickel below the concention limit specified in Appendix 13;</li> <li>(f) the statement "Contains chromium (VI). Can cause allergic reactions." if the mixture contains chromium (VI) be the information shall be clearly visible, easily legible and marked in a way that is indelible. The information shall be visite, oncerned provide(s) otherwise.</li> <li>Where necessary because of the size of th</li></ul></li></ul>	of a substance such that the substance then becomes caught by point (e), (f) or (g) of paragraph 1 of this entry, or
that amendment shall, for the purposes of applying this entry to that substance, be freated as taking effect from date falling 18 months after entry into force of the act by which that amendment was made. 7. Suppliers placing a mixture on the market for use for tattooing purposes shall ensure that, after 4 January 202 mixture is marked with the following information: (a) the statement "Mixture for use in tattoos or permanent make-up"; (b) a reference number to uniquely identify the batch; (c) the list of ingredients in accordance with the nomenclature established in the glossary of common ingredient names pursuant to Article 33 of Regulation (EC) No 1223/2009, or in the absence of a common ingredient name, IUPAC name. In the absence of a common ingredient name or IUPAC name, the CAS and EC number. Ingredient be listed in descending order by weight or volume of the ingredients at the time of formulation. "Ingredient" me any substance added during the process of formulation and present in the mixture for use for tattooing purposs purities shall not be regarded as ingredients. If the name of a substance, used as ingredient within the meaning this entry, is already required to be stated on the label in accordance with Regulation; (d) the additional statement "pH regulator" for substances falling under point (d)(i) of paragraph 1; (e) the statement "Contains chromium (VI). Can cause allergic reactions." if the mixture contains nickel below the concen tion limit specified in Appendix 13; (f) the statement "Contains chromium (VI). Can cause allergic reactions." if the mixture contains chromium (VI) b the concentration limit specified in Appendix 13; (g) safety instructions for use insofar as they are not already required to be stated on the label by Regulation (EC 1272/2008. The information shall be clearly visible, easily legible and marked in a way that is indelible. The information shall be written in the official language(s) of the Member State(s) where the mixture is placed on market, unless the Member State(s) c	such that it then fails within a different one of those points from the one within which it fell previously, and the
<ul> <li>date falling 18 months after entry into force of the act by which that amendment was made.</li> <li>7. Suppliers placing a mixture on the market for use for tattooing purposes shall ensure that, after 4 January 202 mixture is marked with the following information: <ul> <li>(a) the statement "Mixture for use in tattoos or permanent make-up";</li> <li>(b) a reference number to uniquely identify the batch;</li> <li>(c) the list of ingredients in accordance with the nomenclature established in the glossary of common ingredient names pursuant to Article 33 of Regulation (EC) No 1223/2009, or in the absence of a common ingredient name, pursuant to Article 33 of Regulation (EC) No 1223/2009, or in the absence of a common ingredient name, pursuant to Article 33 of Regulation (EC) No 1223/2009, or in the absence of a common ingredient mame pursuant to Article 33 of Regulation (EC) No 1223/2009, or in the absence of a common ingredient mame pursuant to Article 33 of Regulation (EC) No 1223/2009, or in the absence of a common ingredient mame, pursubstance added during the process of formulation and present in the mixture for use for tattooing purpose purities shall not be regarded as ingredients. If the name of a substance, used as ingredient within the meaning this entry, is already required to be stated on the label in accordance with Regulation (EC) No 1272/2008, that in ent does not need to be marked in accordance with this Regulation;</li> <li>(d) the additional statement "pH regulator" for substances falling under point (d)(i) of paragraph 1;</li> <li>(e) the statement "Contains nickel. Can cause allergic reactions." if the mixture contains nickel below the concentration limit specified in Appendix 13;</li> <li>(f) the statement "Contains chromium (VI). Can cause allergic treactions." if the mixture contains chromium (VI) be the formation shall be clearly visible, easily legible and marked in a way that is indelible.</li> <li>The information shall be clearly visible, easily legible and marked in a way that</li></ul></li></ul>	amenoment takes effect after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry
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<ul> <li>mixture is marked with the following information: <ul> <li>(a) the statement "Mixture for use in tattoos or permanent make-up";</li> <li>(b) a reference number to uniquely identify the batch;</li> <li>(c) the list of ingredients in accordance with the nomenclature established in the glossary of common ingredient name, pursuant to Article 33 of Regulation (EC) No 1223/2009, or in the absence of a common ingredient name, IUPAC name, In the absence of a common ingredient name or IUPAC name, the CAS and EC number. Ingredient be listed in descending order by weight or volume of the ingredients at the time of formulation. "Ingredient" me any substance added during the process of formulation and present in the mixture for use for tattooing purpose purities shall not be regarded as ingredients. If the name of a substance, used as ingredient within the meaning this actrady nequired to be stated on the label in accordance with Regulation;</li> <li>(d) the additional statement "pH regulator" for substances falling under point (d)(i) of paragraph 1;</li> <li>(e) the statement "Contains nickel. Can cause allergic reactions." if the mixture contains nickel below the concention limit specified in Appendix 13;</li> <li>(g) safety instructions for use insofar as they are not already required to be stated on the label by Regulation (EC) 1272/2008.</li> <li>The information shall be clearly visible, easily legible and marked in a way that is indelible.</li> <li>The information shall be written in the official language(s) of the Member State(s) where the mixture is placed for (a), shall be vince in the instructions for use pursoes, the package, the information listed in the first subparagraph, except for (a), shall be included in the instructions for use.</li> <li>8. Mixtures that do not contain the statement "Mixture for use in tattoos or permanent make-up" shall not be us tattooing purposes, the person using the mixture shall provide the person undergoir procedure with the information marked on the package or included in</li></ul></li></ul>	
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<ul> <li>(e) the statement "Contains nickel. Can cause allergic reactions." if the mixture contains nickel below the concention limit specified in Appendix 13;</li> <li>(f) the statement "Contains chromium (VI). Can cause allergic reactions." if the mixture contains chromium (VI) be the concentration limit specified in Appendix 13;</li> <li>(g) safety instructions for use insofar as they are not already required to be stated on the label by Regulation (EC 1272/2008.</li> <li>The information shall be clearly visible, easily legible and marked in a way that is indelible.</li> <li>The information shall be written in the official language(s) of the Member State(s) where the mixture is placed or market, unless the Member State(s) concerned provide(s) otherwise.</li> <li>Where necessary because of the size of the package, the information listed in the first subparagraph, except for (a), shall be included instead in the instructions for use.</li> <li>Before using a mixture for tattooing purposes, the person using the mixture shall provide the person undergoir procedure with the information marked on the package or included in the instructions for use pursuant to this p graph.</li> <li>8. Mixtures that do not contain the statement "Mixture for use in tattoos or permanent make-up" shall not be us tattooing purposes.</li> <li>9. This entry does not apply to substances that are gases at temperature of 20 °C and pressure of 101,3 kPa, or or ate a vapour pressure of more than 300 kPa at temperature of 50 °C, with the exception of formaldehyde (CAS N 00-0, EC No 200-001-8).</li> <li>10. This entry does not apply to the placing on the market of a mixture for use for tattooing purposes, or to the a mixture for tattooing purposes, when placed on the market exclusively as a medical device or an accessory to medical device, within the meaning of Regulation (EU) 2017/745, or when used exclusively as a medical device or an accessory to accessory to a medical device, within the same meaning. Where the placing on the market or use ma</li></ul>	(d) the additional statement "pH regulator" for substances falling under point (d)(i) of paragraph 1:
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Regulation shall apply cumulatively.	Regulation shall apply cumulatively.

#### LIST OF SUBSTANCES SUBJECT TO AUTHORISATION (REACH, ANNEX XIV)/SVHC - candidate list

Not listed.

#### **Seveso Directive**

2012/	012/18/EU (Seveso III)			
Νο	Dangerous substance/hazard categories	Qualifying quantity (tonnes) for the ap- plication of lower and upper-tier re- quirements	Notes	
	not assigned			

#### **Deco-Paint Directive**

VOC content	0 %
VOC content	0 g/l

#### **Industrial Emissions Directive (IED)**

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



#### Calciumchloride-dihydraat CELLPURE® ≥99 %, CELLPURE®

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VOC content	0 %
VOC content	0 <sup>g</sup> /l

# Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

not listed

# Regulation concerning the establishment of a European Pollutant Release and Transfer Register (PRTR)

not listed

#### Water Framework Directive (WFD)

List of pollutants (WFD)				
Name of substance	Name acc. to inventory	CAS No	Listed in	Remarks
Calciumchloride-dihydraat	Metals and their compounds		a)	

#### Legend

a) Indicative list of the main pollutants

#### Regulation on the marketing and use of explosives precursors

not listed

#### **Regulation on drug precursors**

not listed

#### Regulation on substances that deplete the ozone layer (ODS)

not listed

#### Regulation concerning the export and import of hazardous chemicals (PIC)

not listed

#### **Regulation on persistent organic pollutants (POP)**

not listed

#### **Other information**

Directive 94/33/EC on the protection of young people at work. Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.

#### **National inventories**

Country	Inventory	Status
AU	AIIC	substance is listed
CA	DSL	substance is listed
CN	IECSC	substance is listed
EU	ECSI	substance is listed
EU	REACH Reg.	substance is listed
JP	CSCL-ENCS	substance is listed
KR	KECI	substance is listed
MX	INSQ	substance is listed

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



#### Calciumchloride-dihydraat CELLPURE® ≥99 %, CELLPURE®

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Country	Inventory	Status
NZ	NZIoC	substance is listed
PH	PICCS	substance is listed
TR	CICR	substance is listed
TW	TCSI	substance is listed
US	TSCA	substance is listed (ACTIVE)
VN	NCI	substance is listed

#### Legend

Legenu	
AIIC	Australian Inventory of Industrial Chemicals
CICR	Chemical Inventory and Control Regulation
CSCL-ENCS	List of Existing and New Chemical Substances (CSCL-ENCS)
DSL	Domestic Substances List (DSL)
ECSI	EC Substance Inventory (EINECS, ELINCS, NLP)
IECSC	Inventory of Existing Chemical Substances Produced or Imported in China
INSQ	National Inventory of Chemical Substances
KECI	Korea Existing Chemicals Inventory
NCI	National Chemical Inventory
NZIoC	New Zealand Inventory of Chemicals
PICCS	Philippine Inventory of Chemicals and Chemical Substances (PICCS)
REACH Reg.	
TCSI	
TSCA	Toxic Substance Control Act
NCI NZIOC PICCS REACH Reg. TCSI	National Chemical Inventory New Zealand Inventory of Chemicals Philippine Inventory of Chemicals and Chemical Substances (PICCS) REACH registered substances Taiwan Chemical Substance Inventory

#### 15.2 Chemical safety assessment

According to REACH, Article 14 (1) a chemical safety assessment has been carried out for this substance or components of this mixture when the substance has been registered in quantities of 10 tonnes or more per year per registrant.

## **SECTION 16: Other information**

#### Indication of changes (revised safety data sheet)

Section	Former entry (text/value)	Actual entry (text/value)	Safety- relev- ant
1.1	Index No: 017-013-00-2		yes
1.1		EC number: 600-075-5	yes
1.1	EC number: 233-140-8	CAS number: 10035-04-8	yes
2.1		Classification according to Regulation (EC) No 1272/2008 (CLP): change in the listing (table)	yes
2.1	Remarks: For full text of Hazard- and EU Hazard-state- ments: see SECTION 16.		yes
2.2		Pictograms: change in the listing (table)	yes
2.3	Other hazards: There is no additional information.	Other hazards	yes
2.3		Results of PBT and vPvB assessment: According to the results of its assessment, this substance is not a PBT or a vPvB.	yes

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



## Calciumchloride-dihydraat CELLPURE® ≥99 %, CELLPURE®

#### article number: HN04

Section	Former entry (text/value)	Actual entry (text/value)	Safety- relev- ant
2.3		Endocrine disrupting properties: Does not contain an endocrine disruptor (ED) at a concentration of ≥ 0,1%.	yes
3.1	Index No: 017-013-00-2		yes
11.1		Acute toxicity: change in the listing (table)	yes
14.2	UN proper shipping name: not relevant	UN proper shipping name: not assigned	yes
14.3	Transport hazard class(es): not relevant	Transport hazard class(es): none	yes
14.3	Class: -		yes
14.4	Packing group: not relevant	Packing group: not assigned	yes
14.5	Environmental hazards: none (non-environmentally hazardous acc. to the dangerous goods regulations)	Environmental hazards: non-environmentally hazardous acc. to the dan- gerous goods regulations	yes
14.8	• Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN): Not subject to ADR, RID and ADN.		yes
15.1	• Regulation 649/2012/EU concerning the ex- port and import of hazardous chemicals (PIC): Not listed.		yes
15.1	• Regulation 1005/2009/EC on substances that deplete the ozone layer (ODS): Not listed.		yes
15.1	• Regulation 850/2004/EC on persistent organic pollutants (POP): Not listed.		yes
15.1	• Restrictions according to REACH, Annex XVII: not listed	Restrictions according to REACH, Annex XVII	yes
15.1		Dangerous substances with restrictions (REACH, Annex XVII): change in the listing (table)	yes
15.1		Seveso Directive	yes
15.1		2012/18/EU (Seveso III): change in the listing (table)	yes
15.1		Deco-Paint Directive	yes
15.1		VOC content: 0 %	yes
15.1		VOC content: 0 <sup>g</sup> / <sub>l</sub>	yes
15.1		Industrial Emissions Directive (IED)	yes
15.1		VOC content: 0 %	yes
15.1		VOC content: 0 <sup>g</sup> / <sub>l</sub>	yes

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



## Calciumchloride-dihydraat CELLPURE® ≥99 %, CELLPURE®

#### article number: **HN04**

Section	Former entry (text/value)	Actual entry (text/value)	Safety- relev- ant
15.1	Directive 2000/60/EC establishing a framework for Community action in the field of water policy (WFD): not listed	Water Framework Directive (WFD)	yes
15.1	National inventories: Substance is listed in the following national in- ventories: - EINECS/ELINCS/NLP (Europe) - REACH (Europe)		yes
15.1		List of pollutants (WFD): change in the listing (table)	yes
15.1		Regulation on the marketing and use of explos- ives precursors: not listed	yes
15.1		Regulation on drug precursors: not listed	yes
15.1		Regulation on substances that deplete the ozone layer (ODS): not listed	yes
15.1		Regulation concerning the export and import of hazardous chemicals (PIC): not listed	yes
15.1		Regulation on persistent organic pollutants (POP): not listed	yes
15.1		Other information: Directive 94/33/EC on the protection of young people at work. Observe employment restric- tions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.	yes
15.1		National inventories	yes
15.1		National inventories: change in the listing (table)	yes
15.2	Chemical Safety Assessment: No Chemical Safety Assessment has been car- ried out for this substance.	Chemical safety assessment: According to REACH, Article 14 (1) a chemical safety assessment has been carried out for this substance or components of this mixture when the substance has been registered in quantities of 10 tonnes or more per year per registrant.	yes

## Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concern- ing the International Carriage of Dangerous Goods by Road)
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DGR	Dangerous Goods Regulations (see IATA/DGR)
EC50	Effective Concentration 50 %. The EC50 corresponds to the concentration of a tested substance causing 50 % changes in response (e.g. on growth) during a specified time interval

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



#### Calciumchloride-dihydraat CELLPURE® ≥99 %, CELLPURE®

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Abbr.	Descriptions of used abbreviations
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identi- fier of substances commercially available within the EU (European Union)
ED	Endocrine disruptor
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
ErC50	≡ EC50: in this method, that concentration of test substance which results in a 50 % reduction in either growth (EbC50) or growth rate (ErC50) relative to the control
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Na- tions
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods Code
LC50	Lethal Concentration 50%: the LC50 corresponds to the concentration of a tested substance causing 50 % lethality during a specified time interval
LD50	Lethal Dose 50 %: the LD50 corresponds to the dose of a tested substance causing 50 % lethality during a specified time interval
NLP	No-Longer Polymer
РВТ	Persistent, Bioaccumulative and Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regula- tions concerning the International carriage of Dangerous goods by Rail)
SVHC	Substance of Very High Concern
VOC	Volatile Organic Compounds
vPvB	Very Persistent and very Bioaccumulative

#### Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU.

Agreement concerning the International Carriage of Dangerous Goods by Road (ADR). Regulations concerning the International Carriage of Dangerous Goods by Rail (RID). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

#### List of relevant phrases (code and full text as stated in section 2 and 3)

Code	Text
H319	Causes serious eye irritation.

#### Disclaimer

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.