



# TOROWHITE

ENGINEERED FUNCTIONAL ADDITIVES

## MATERIAL SAFETY DATA SHEET

# PHA 20

## PHARMA GRADE

### CALCIUM SULFATE DIHYDRATE

#### 1. SUBSTANCE / MIXTURE IDENTIFICATION AND COMPANY INFORMATION

##### 1.1 Product identification:

|                       |  |
|-----------------------|--|
| Trade name            | PHA 20                                 |
| Name of the substance | Calcium sulfate dihydrate              |
| Chemical name         | Calcium sulfate dihydrate              |
| Formula               | CaSO <sub>4</sub> (+2H <sub>2</sub> O) |
| Synonyms              | Ground natural gypsum                  |
| CAS-No                | 10101-41-4                             |
| EC-No                 | 231-900-3                              |
| REACH No              | Not applicable                         |

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

|                          |  |
|--------------------------|--|
| Use of the substance     | Pharma additive used as colouring agent, dough strengthener, firming agent, formulation aid, acidity regulator, stabilizer and thickener, etc. |
| Relevant identified uses | Industrial use, use by private consumers, research, commercial use, analytics, scientific education.   |
| Uses advised against     | Any different from advised uses.   |

##### 1.3 Details of the supplier providing the material safety data sheet:

|                 |  |
|-----------------|--|
| Company name    | Toro Gips S.L.   |
| Factory address | Polígono Industrial San Cristóbal, parcelas 3.1 y 3.2, 44540 Albalate del Arzobispo (Teruel) SPAIN |
| Email           | info@torowhite.com   |
| Homepage        | www.torowhite.com  |

**1.4 Emergency number:** Instituto Nacional de Toxicología y Ciencias Forenses (INTCF) +34 917689800

#### 2. POTENTIAL HAZARDOUS

##### 2.1 Classification of the substance or mixture:

Under Regulation (CE) No. 1272/2008: The substance has been classified as not hazardous. The product has not been classified according to CLP-regulation.



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### 2.2 Labelling elements:

|  |                |
|--|----------------|
| Labelling according to (CE) N° 1272/2008 | Not applicable |
| Hazard pictograms                        | None           |
| Signal word                              | None           |
| Safety information                       | None           |
| Hazards information                      | None           |

### 2.3 Other hazards:

PBT and vPvB measurements are not applicable. In any case, please note the information of the Safety Data Sheet.

## 3. COMPOSITION / INFORMATION ON INGREDIENTS

### 3.1 Substance:

|                   |   |
|-------------------|---|
| Chemical name     | Calcium Sulfate Dihydrate   |
| Formula           | CaSO <sub>4</sub> (+2H <sub>2</sub> O)                                  |
| Molecular weight: | 172,2 g/mol   |
| CAS No.           | 10101-41-4  |
| EINECS No.        | 231-900-3   |
| Stabilizers       | None  |
| Contaminations    | No contamination in relevant quantity for labelling and classification. |

**3.2 Mixtures:** Not applicable.

## 4. FIRST AIDS MEASURES

### 4.1 Description of first aids measures:

|  |   |
|--|---|
| General information                              | No adverse effects when the substance is used as specified.   |
| After inhalation                                 | Fresh air. Consult a physician in case of doubt or when complaints appear.  |
| After skin contact                               | Wash off skin with water and soap. Consult a physician in case of doubt or when complaints appear.                      |
| After eyes contact                               | Rinse eyes carefully with water during several minutes. Consult a physician in case of doubt or when complaints appear. |
| After ingestion                                  | Rinse out your mouth and drink plenty of water. Seek medical assistance.  |
| Personal protective information for first-aiders | Skin compatible neutral salt. Soluble dust. No allergic reactions known.  |

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

No specific symptoms or effects known.

### 4.3 Information of any immediate medical attention and special treatment needed:

No additional relevant information available.



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### 5. FIREFIGHTING MEASURES

#### 5.1 Extinguishing agents:

|                                 |  |
|---------------------------------|--|
| General information             | The product itself is non-combustible. In the event of surrounding fire, the following needs to be observed. |
| Suitable extinguishing agents   | Extinguishers: chemical powder, dry powder, foam and CO <sub>2</sub> .                                       |
| Unsuitable extinguishing agents | There is no limitation on types of extinguishers to be used.   |

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

Decomposition sets at temperatures above 1450°C and sulfur oxide (SO<sub>3</sub>) could appear.

#### 5.3 Advice for firefighters:

The substance is not combustible. Wear self-contained breathing apparatus and fight fire from a safe distance.

### 6. ACCIDENTAL RELEASE MEASURES

#### 6.1 Description of first aids measures:

|                             |   |
|-----------------------------|---|
| For non-emergency personnel | Avoid dust inhalation and ensure enough ventilation. The substances forms slippery surfaces when combined with water. |
| For emergency responders    | There are no additional requirements.   |

**6.2 Environmental precautions:** No special environmental protection measures needed.

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

Treat the recorded material in accordance with the disposal section.

**6.4 Reference to other sections:** Exposure control.

### 7. HANDLING AND STORAGE

#### 7.1 Precautions for safe handling:

|   |   |
|---|---|
| Precautions                                   | Avoid dust formation and contact with eyes.   |
| Fire protection measures                      | The product itself is non-combustible. No special measures needed.  |
| Measures to prevent emissions                 | If technically feasible, use equipment with local evacuation.   |
| Advice relating to general industrial hygiene | Do not eat, drink or smoke at the workplace. Wash hands before breaks and after work. Don't wear work clothing outside the workplace. |

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

|   |  |
|---|--|
| Technical requirements and storage conditions | Store in a dry place. No further specific requirements.                        |
| Incompatible materials to store with          | Store according to local regulations. The substance is excluded from the scope |
| Storage category                              | Non-flammable solid material (LGK 13) [storage category]                       |



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### 8. EXPOSURE CONTROL / PERSONAL PROTECTION

#### 8.1 Control parameters:

VLA – ED<sup>[1]</sup>: 10 mg/m<sup>3</sup> for particulate matter without asbestos and less than 1% in crystalline silica.

#### 8.2 Exposure controls:

|                                  |   |
|----------------------------------|---|
| Appropriate engineering controls | Ensure enough ventilation and no dust formation.  |
| Respiratory protection           | No protection is needed if appropriate engineering controls are executed. In case of dust formation use a filtered mask PPF type. |
| Hand protection                  | In case of prolonged or repeated use wear protective gloves (latex or nitrile).   |
| Body protection                  | Wear working clothes.   |
| Eye protection                   | Wear safety glasses.  |

[1] Occupational exposure limit value\_daily exposure. From Instituto Nacional de Seguridad y Salud en el Trabajo, 2018.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

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

|                                 |  |
|---------------------------------|--|
| Physical state                  | Solid powder   |
| Colour                          | White  |
| Odour                           | Natural  |
| Odour threshold                 | Not applicable   |
| pH in aqueous solutions (20°C)  | 7.0 - 8.0  |
| Melting point/freezing point    | 1450°C   |
| Boiling point                   | Not applicable   |
| Flash point                     | Not applicable   |
| Evaporation rate                | No information available   |
| Flammability                    | No information available   |
| Lower flammability limit        | Not applicable   |
| Upper flammability limit        | Not applicable   |
| Vapour density                  | Not applicable   |
| Relative density                | Approximately: 2 - 4 g/cm <sup>3</sup>                                   |
| Solubility (water)              | Approximately: 2,4 g/l at 20°C in CaSO <sub>4</sub> · 2 H <sub>2</sub> O |
| Partition coefficient n-octanol | Not applicable   |
| Auto-ignition temperature       | Not applicable   |
| Decomposition temperature       | Above 1450°C it decomposes into CaO and SO <sub>3</sub>                  |
| Viscosity                       | Not applicable   |
| Explosive properties            | Not explosive  |
| Oxidizing properties            | Not oxidizing  |

#### 9.2 Other information: None



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### 10. STABILITY AND REACTIVITY

**Reactivity:** No additional relevant information available.

**Chemical stability:** No thermal decomposition when handled and stored as specified.

**Possibility of hazardous reactions:** No hazardous reactions are known.

**Conditions to avoid:** Contamination with sulfur-reducing bacteria and water under anaerobic conditions should be avoided.

**Incompatible materials:** None known.

**Hazardous decomposition products:** At temperatures above 1450°C it decomposes into Calcium oxide and Sulfur trioxide.

### 11. TOXICOLOGICAL INFORMATION

#### 11.1 Information on toxicological effects:

Repeated or prolonged contact may cause removal of the natural fat from the skin resulting in nonallergic contact dermatitis and absorption through the skin. If spattered into the eyes may cause irritation and irreversible damage.

| 11.2 Relevant hazard class         | Effect dose   | Species             | Method               | Remark   |
|------------------------------------|---|---------------------|----------------------|--|
| Acute toxicity                     | Oral:<br>LD50 > 1581 mg/kg bw<br>Inhalation:<br>LC50 > 2,61 mg/L                                      | Rat                 | OECD 420<br>OECD 403 | Not classified<br>Maxim dose that can be administrated |
| Irritant/corrosive effects on skin | Not applicable  | N/A                 | OECD 404             | Not irritating to skin                                 |
| Acute damage/ irritation to eyes   | Not applicable  | Rabbit              | OECD 405             | Not irritating to eyes                                 |
| Germ cell mutagenicity             | Not applicable  | Bacteria            | Experimental study   | Mutation did not occur                                 |
| Carcinogenicity                    | No classification under CLP regulation based on evidence from genotoxicity studies and repeated doses |                     |                      |  |
| Reproduction toxicity              | NOAEL<br>298 / 208 mg/kg bw   | Rat (male / female) | OECD 422             | No signs for reproductive toxicity observed.           |

### 12. ENVIRONMENTAL INFORMATION

**Toxicity:** No relevant additional information available.

**Persistence and degradability:** No relevant additional information available.

**Bioaccumulation potential:** No relevant additional information available.

**Mobility in soil:** No relevant additional information available.

**Results of PBT and vPvB assessment:** No relevant additional information available.

**Other adverse effects:** No relevant additional information available.

### 13. DISPOSAL CONSIDERATIONS

#### Waste treatment methods. (See section 6)

Empty packaging has to be managed under local and national regulations. See Directive 2008/98/CE about waste framework.

|                                    |  |
|------------------------------------|--|
| European waste catalogue           | 17-08-02 Gypsum-based construction materials   |
| Uncleaned packaging recommendation | Contaminated packages are to be emptied as completely as possible. After appropriate cleaning, they may be used or recycled. |



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### 14. TRANSPORT INFORMATION

The substance has been classified as **not hazardous for transport**.

### 15. LEGISLATION

#### 15.1 Health, safety and environmental regulations/legislation specific for the substance or mixture:

The substance is not affected by:

- Regulation (EC) No. 1005/2009 of the European Parliament and of the Council of 16 september 2009 on substances that deplete the ozone layer.
- Directive 2012/18/UE (SEVESO III).
- Regulation (EC) No. 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.
- Regulation (EC) No. 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

#### 15.2 Chemical safety assessment:

Not applicable as the substance is not classified as dangerous under Regulation N° 1272/2008.

#### 15.3 REACH No:

A registration number is not available for this substance as the substance is 100% natural and therefore exempted from registration according REACH regulation Annex V, entry 6 + 7.

### 16. OTHER INFORMATION

The information provided in this Material Safety Data Sheet has been drawn up according to COMMISSION REGULATION (EU) No. 453/2010 of 20 May 2010 amending Regulation (EC) No. 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH). The information is based on actual knowledge and CE and national current legislation. The working conditions of users are outside of our knowledge and control. The substance cannot be used for other purpose not specified on this Material Safety Data Sheet without a written handling instruction. It is user's responsibility consider regulation requirements.

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**Toro Gips S.L.**

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