

## Calcium Sulfate Registration under EU REACH

Procedure to join the EU REACH Consortium  
or the EU SIEF (via Letter of Access)

01 January 2022

### Substance identity profile

| Chemical name   | EINECS    | CAS       | Formula           | Typical content % (w/w) | Lower Content % (w/w) | Upper Content % (w/w) |
|-----------------|-----------|-----------|-------------------|-------------------------|-----------------------|-----------------------|
| Calcium sulfate | 231-900-3 | 7778-18-9 | CaSO <sub>4</sub> | 87%                     | 70%                   | 100%                  |

#### Impurities

|                   |            |
|-------------------|------------|
| Clays             | 0 % - 30 % |
| Calcite, dolomite | 0 % - 30 % |
| Silica            | 0 % - 10 % |
| Celestine         | 0 % - 4 %  |
| pH                | 5-9        |

**Please note: Companies intending to register CaSO<sub>4</sub> containing impurities not identified in this specification, even if present in quantities <0.1 %, that have an effect on the hazard classification of this substance are responsible for declaring these impurities and addressing any subsequent additional data or information requirements in their own registration dossier. This can be done using the PNECs and DNELS of the relevant substances when available.**

As hydrates of calcium sulfate (calcium sulfate dihydrate and/or calcium sulfate hemihydrate) have to be registered under the water-free form in EU-REACH, the Consortium/SIEF also includes the registration of those substances as "calcium sulfate".

#### EU-CaSO<sub>4</sub> – European REACH Consortium for Calcium Sulfate

Coordinator: EUROGYPSUM

Rue de la Presse 4  
B-1000 Brussels  
Belgium

Tel.: +32 2 227 11 30

Fax: +32 2 218 31 41

[reach@eurogypsum.org](mailto:reach@eurogypsum.org)

[www.eurogypsum.org/reach](http://www.eurogypsum.org/reach)

AISBL

VAT:  
BE 0883 992 474

## Consortium's coordination

The EU REACH Consortium for Calcium Sulfate (EU-CaSO<sub>4</sub>) is coordinated by EUROGYPSUM. Enquiries about the Consortium should be addressed to:

Tristan Suffys  
EUROGYPSUM  
Rue de la Presse 4  
B-1000 Brussels, Belgium  
Tel.: +32 2 227 11 30  
Email: [reach@eurogypsum.org](mailto:reach@eurogypsum.org)

## Procedure

The following sections explain the different steps in the procedure to join the EU REACH Consortium for Calcium Sulfate (EU-CaSO<sub>4</sub>) or obtain a Letter of Access. A graphic overview of the procedure is included in [Annex II](#).

NB: In the case of Only Representatives acting for different customers, a **distinct application** would need to be filed for **each represented customer**.

### *1<sup>st</sup> Step: Obtaining a Korean Letter of Access (LoA)*

Except in a few cases mentioned in the box on "[Exemptions](#)" below this subsection, **all applicants must first obtain** from the Korean Ministry of Environment a Letter of Access (LoA) to the SIDS initial assessment report for the SIAM 17-OECD HPV dossier on calcium sulfate. **Please note that a fee will be applied to purchase this LoA**, in which we do not intervene<sup>1</sup>.

The following tests are covered by the Letter of Access to the Korean studies:

- Acute oral toxicity. **KOSHA (2002) Report G02082 study**
- Skin sensitisation study **Biotoxtech (2002) B02113**
- Micronucleus test **KOSHA Report n° ICRC/2002/006**
- Bacterial reverse mutation test **KRICT test n° G01100**

---

<sup>1</sup> For information only, to our knowledge, the cost of the Korean LoA in 2021 was in the range of USD 28-30,000 (for single letter or groups of up to five parties).

- The Acute Toxicity of Calcium sulphate dihydrate to Fish **KRICT (2003) n°EG02087**
- The Acute Toxicity of Calcium sulphate dihydrate to Daphnia magna **KRICT (2003) Report n° EG02088**
- Growth Inhibition Test of Calcium sulphate dihydrate to algae **KRICT (2003) n° EG02079**
- Combined Repeated Dose Toxicity with the Reproduction/Developmental Toxicity Screening Test Study **LG Science/toxicology centre (2002) Report S506**

The relevant contacts to request this Korean LoA are as follows:

Hyein Chang (TEL. + 82-32-590-4772)  
or Seonjin Hong (TEL. + 82-32-590-4780)  
e-mail: [glpdata@keco.or.kr](mailto:glpdata@keco.or.kr)  
Korea Environment Corporation (KECO):  
<http://www.keco.or.kr/en/main/index.do>

Chemicals Assessment Support Division,  
Dept. of Chemicals Assessment,  
Korea Environment Corporation

*NB: Please note that the direct purchase of the Korean LoA from the Korean authorities may involve specific requirements regarding **payment through a legal entity registered in the Republic of Korea**. Should you require assistance on this matter, please contact us and we can refer you to a local intermediary company.*

**Exemptions:**

The legal entities having joined the Consortium **before 30 January 2010** are covered by the Korean LoA.

For new applications, only the following entities **do not need an LoA to the Korean studies** before applying for an LoA to the EU-CaSO<sub>4</sub> registration dossier or becoming a member of the EU-CaSO<sub>4</sub> Consortium:

- Legal entities registering calcium sulfate with a tonnage band between **1 – 10 t/year<sup>2</sup>**.

NB: As indicated above, Only Representatives acting for different legal entities need to file a distinct application for each represented legal entity. Therefore, if the Only Representative falls under the scope of exemptions from the Korean LoA, as an entity having joined the Consortium before 30 January 2010 or within the tonnage band 1-10 t/year, the exemption from the Korean LoA only applies if the request concerns the legal entity for which the member initially joined the registration.

<sup>2</sup> More details available [later in the document](#).

Entities which may fall into one of these categories are asked to [contact the Consortium's Coordinator](#) for any further details.

## *2<sup>nd</sup> Step: Requesting a Letter of Access from the EU-CaSO<sub>4</sub> Consortium (with or without Consortium membership)*

### **1) Consortium membership**

#### *First step*

If you choose to become a member of the Consortium, once you have obtained the Korean LoA and shared it with the Coordinator (see [subsection 1 of this document](#)), the Coordinator will first send you:

- The consortium agreement for your signature
- A VAT fiche

#### *Second step*

After return of the consortium agreement duly signed and the VAT fiche, the coordinator will then send you:

- The invoice
- The minutes of the General Assembly meetings of 2009 and 2010, as well as annual letters of the Consortium's President for the following years
- The contract signed between the Consortium and the trustee, Arcadis

### **2) Simple Letter of Access without Consortium membership**

#### *First step*

If you choose to purchase the reference rights to the joint dossier only, without being member of the Consortium, once you have obtained the Korean LoA and shared it with the Coordinator (see [subsection 1 of this document](#)), the Coordinator will send the following documents:

- The "application for use" document
- The VAT fiche

### *Second step*

After return of the “application for use” document duly signed and the VAT fiche, the Coordinator will send you:

- The invoice
- The “approval for use” document

## *3<sup>rd</sup> Step: Payment and sharing of documents*

### **1) Payment**

The applicant will have to pay the amount indicated in the invoice, which is calculated according to the formulae in [Annex I](#).

- For Consortium membership, the fee will be calculated according to [part A](#) of Annex I.
- For a simple LoA without Consortium membership, the fee will be calculated according to [part B](#) of Annex I.

### **2) Sharing of documents**

Upon receipt of payment for an LoA or Consortium membership, the Coordinator will send the **token** with the following documents:

- Chemical safety assessment
- Joint part of the registration dossier (parts 4-10) in PDF format

### *NB: Important information*

The Letter of Access option **does not involve ownership** of any data or studies produced or obtained by the consortium. The LoA grants the company the **right to refer** to the Registration Dossier as a co-Registrant.

The Consortium’s Steering Committee considers that **all the costs incurred by the Consortium in preparing the Registration Dossier should be considered** in calculating the costs of the Letter of Access. For example, this should include administrative and coordinator costs, all technical costs relating to the data/studies, exposure assessments, and dossier preparation as well as the management costs relating to the preparation of data-sharing agreements and managing the communications (e.g. discussions in the SIEFs).

## Annex I: Fees for Consortium Membership and Letter of Access

### Part A – Consortium membership

The price structure to become a **member of the Consortium** is as follows:

| <b>Fees (EUR)</b>                           | <b>2021</b>      | <b>2022</b>      |
|---|------------------|------------------|
| Administrative fee                          | 1,780.15         | 1,890.88         |
| Compensation fee                            | 5,933.85         | 6,302.94         |
| Variable costs<br>(technical costs & tests) | 3,560.30         | 3,781.75         |
| <b>TOTAL (EUR)</b>                          | <b>11,274.30</b> | <b>11,975.57</b> |

The price is revised each year on the basis of the Belgian official consumer price index ("health index") (basis 2013).

**Basis January 2021: 110.35 – Basis January 2022: 117.21 (+6.22%)**

New cost structure =  $\frac{\text{Consortium Base price} \times 117.21}{110.35}$

### Part B – Simple Letter of Access without Consortium membership

The price structure for purchasing a Letter of Access **without being a member** of the Consortium is as follows:

| <b>Fees (EUR)</b>                           | <b>2021</b>      | <b>2022</b>      |
|---|------------------|------------------|
| Administrative fee                          | 1,780.15         | 1,890.88         |
| Compensation fee                            | 6,527.24         | 6,933.23         |
| Variable costs<br>(technical costs & tests) | 3,560.30         | 3,781.75         |
| <b>TOTAL (EUR)</b>                          | <b>11,867.69</b> | <b>12,605.86</b> |

The price is revised each year on the basis of the Belgian official consumer price index ("health index") (basis 2013).

**Basis January 2021: 110.35 – Basis January 2022: 117.21  
(+6.22%)**

New cost structure =  $\frac{\text{Consortium Base price} \times 117.21}{110.35}$

**Exemptions for companies with tonnage band 1-10 or 1-100 t/a**

Companies registering calcium sulfate **between 1 and 100 tonnes per calendar year** are granted **a reduced fee of EUR 5,000**. The Korean Letter of Access is not needed if the imported or produced volume is **1-10 tonnes per calendar year**. Please contact the Coordinator if you fall within that range of tonnage, to obtain the request letter.

NB1: If the imported or produced volume at a later stage **exceeds 100 tonnes per calendar year**, the remaining part of the fee for the Letter of Access **must be paid**.

NB2: If the imported or produced volume at a later stage **exceeds 10 tonnes per calendar year**, it is the obligation of the company to purchase the Korean LoA and to present it to the Consortium Coordinator.

## Annex II: Overview of the Procedural Steps

