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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>EINECS</th>
<th>CAS</th>
<th>Formula</th>
<th>Typical content % (w/w)</th>
<th>Lower Content % (w/w)</th>
<th>Upper Content % (w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium sulfate</td>
<td>231-900-3</td>
<td>7778-18-9</td>
<td>CaSO₄</td>
<td>87%</td>
<td>70%</td>
<td>100%</td>
</tr>
</tbody>
</table>

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

Please note: Companies intending to register CaSO₄ 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”.

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Consortium’s coordination

The EU REACH Consortium for Calcium Sulfate (EU-CaSO₄) is coordinated by EUROGYPSUM. Enquiries about the Consortium should be addressed to:

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Procedure

The following sections explain the different steps in the procedure to join the EU REACH Consortium for Calcium Sulfate (EU-CaSO₄) 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.

1st 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 intervene¹.

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

- Skin sensitisation study Biotoxtech (2002) B02113
- Micronucleus test KOSHA Report n° ICRC/2002/006
- Bacterial reverse mutation test KRICT test n° G01100

¹ 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 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
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-CaSO₄ registration dossier or becoming a member of the EU-CaSO₄ Consortium:

- Legal entities registering calcium sulfate with a tonnage band between 1 – 10 t/year².

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.

² 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.

2nd Step: Requesting a Letter of Access from the EU-CaSO4 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

3rd 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:

<table>
<thead>
<tr>
<th>Fees (EUR)</th>
<th>2021</th>
<th>2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administrative fee</td>
<td>1,780.15</td>
<td>1,890.88</td>
</tr>
<tr>
<td>Compensation fee</td>
<td>5,933.85</td>
<td>6,302.94</td>
</tr>
<tr>
<td>Variable costs (technical costs &amp; tests)</td>
<td>3,560.30</td>
<td>3,781.75</td>
</tr>
<tr>
<td><strong>TOTAL (EUR)</strong></td>
<td><strong>11,274.30</strong></td>
<td><strong>11,975.57</strong></td>
</tr>
</tbody>
</table>

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 = Consortium Base price x 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:

<table>
<thead>
<tr>
<th>Fees (EUR)</th>
<th>2021</th>
<th>2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administrative fee</td>
<td>1,780.15</td>
<td>1,890.88</td>
</tr>
<tr>
<td>Compensation fee</td>
<td>6,557.24</td>
<td>6,933.23</td>
</tr>
<tr>
<td>Variable costs (technical costs &amp; tests)</td>
<td>3,560.30</td>
<td>3,781.75</td>
</tr>
<tr>
<td><strong>TOTAL (EUR)</strong></td>
<td><strong>11,867.69</strong></td>
<td><strong>12,605.86</strong></td>
</tr>
</tbody>
</table>
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 = \( \text{Consortium Base price} \times \frac{117.21}{110.35} \)

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**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

Procedure to obtain a Letter of Access

Obtain a Korean Letter of Access (if tonnage above 10 tpa)

Consortium membership

- Consortium agreement and VAT fiche for signature
- Minutes & contract sent by Coordinator + Invoice for payment
- Token & documents sent by the Coordinator

Simple Letter of Access

- Application for use document & VAT fiche for signature
- Approval for use document sent by Coordinator + Invoice for payment
- Token & documents sent by the Coordinator