

## REACH Consortium for Calcium Sulphate Procedure to join the consortium or to obtain a LOA 1<sup>st</sup> January 2019

### Substance Covered by the Consortium

Chemical name	EINECS	CAS	Formula	Typical content % (w/w)	Lower Content % (w/w)	Upper Content % (w/w)
Calcium Sulphate	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.

### Procedure to become a member of the Calcium Sulphate Consortium or to buy a Letter of Access to the Calcium Sulphate Registration Dossier

The contact for the calcium sulphate coordination is:

**Antoinette Mirco**  
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## 1. LOA (first & second second steps)

The applicant must obtain the letter of access to SIDS initial assessment report for SIAM 17-OECD HPV dossier on calcium sulphate.

**The following test are covered by the letter of access to the Korean studies are:**

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

You need to obtain the letter of access from the Korean Ministry of environment.

### Contact details:

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**ENVIGO RESEARCH LIMITED is available to help make contact with the NIER in Korea**  
(New name of Harlan Laboratories Limited – Effective 21.09.2015)

Contact person : **Ms Lesley CREIGHTON**, Regulatory Services Manager

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**Who does not need the letter of access to the Korean test to apply for a letter of access to the calcium sulphate registration dossier or for becoming a member of the calcium sulphate consortium?**

- The legal entities having joined the consortium **before 30 January 2010** are covered by the Korean letter of access.
- The legal entities –SIEF members- **mentioned in Annex I of this procedure are** also covered by the Korean letter of access if they join the consortium.

The coordinator will send the approval for use document and the VAT fiche.

After the return of the LoA received by the Korean Ministry, the approval for use document and the VAT fiche, the coordinator will send the invoice according the fees 2018. When the payment is arrived the application for use document will be sent.

## 2. [CONSORTIUM \(first and second steps\)](#)

If you choose to become a member of the consortium, the coordinator will send (first step):

- To obtain the Korean LoA (please see details above)
- the consortium agreement for your signature;
- VAT fiche.

After the return of the consortium agreement duly signed and the VAT fiche, the coordinator will send you (second step):

- the invoice (second step),
- the general assembly minutes of 2009 and 2010;
- the contract signed between the consortium and Envigo (former Harlan laboratories).

### Nota bene

The affiliated of the consortium members are covered by the letter of access to the Korean studies but as a legal entity, they shall pay the fee to register and receive the token. The Consortium member has to send a letter to the Consortium coordinator asking for adding a legal entity to his consortium. . The Coordinator will send the VAT fiche to obtain the financial information of the legal entity and then proceed to the invoice.

## 3. [AFTER INVOICE PAYMENT OF LOA OR CONSORTIUM MEMBERSHIP FEES \(Third step\)](#)

**Upon receipt of payment for LOA or consortium membership, the coordinator will send the token with**

- Chemical safety report;
- Iuclid dossier;
- MSDS;
- exposure assessment for calcium sulphate;
- analysis methods for FGD gypsum;
- verification completeness check;
- guidance on dossier update;
- Dossier update June 2016;

## 4. [MEMBERSHIP FEES](#)

### a. Consortium membership fees

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

	<b>2018</b>	<b>2019</b>
Administrative fee	1.713,61	1.747,75
Compensation fee	5.712,07	5.825,86
Variable costs (technical costs & tests)	3.427,24	3.495,51
<b>TOTAL (EURO)</b>	<b>10.852,92</b>	<b>11.069,12</b>

(Euro)

The price is revised each year on the basis of the Belgian official consumer price index.  
**Base: January 2018 : 128,01 – January 2019 : 130,56 (+1,99%)**

New cost structure =  $\frac{\text{Consortium Base price} \times 130,56}{128,01}$

The administrative fee is transferred to the coordinator and the compensation fee is refunded according to tonnage to the members **having joined the consortium before the AG of 9 June 2009.**

b. The price structure to buy a letter of access

(Euro)

**Consortium calculation 2019 :**

	<b>2018</b>	<b>2019</b>
Administrative fee	1.713,61	1.747,75
Compensation fee	6.283,29	6.408,46
Variable costs (technical costs & tests)	3.427,24	3.495,51
<b>TOTAL (EURO)</b>	<b>11.424,14</b>	<b>11.651,72</b>

– Revised each year on the basis of the Belgian official consumer price index.  
**Base: January 2018: 128,01 – January 2019: 130,56 (+1,99%)**

– New cost structure =  $\frac{\text{Consortium Base price} \times 130,56}{128,01}$

A discount could be applied for the purpose of registering calcium sulphate between 1 and 10 tons and 1 and 100 tons. The coordinator has to send a letter to be signed by the registrant.

NOTA BENE

**The Letter of Access option** does not involve ownership of any data or studies produced or obtained by the consortia, and it does not allow the company access to view or to use these data/studies. The Letter of Access grants the company the right to refer to the Registration Dossier as a co-Registrant.

**The Consortium Steering Group considers that all the costs incurred by the Consortia 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: SIEF MEMBERS COVERED BY THE KOREAN LOA**

Agraria Fertilizante SL
Agroterm
Alustockach GmbH
Alpha Hawk Chemicals Industries Limited
AS Silmet
Baikowski SAS
B-Lands Consulting
<i>BJ Services</i>
BK Giuliani GmbH
Buckman Laboratories
Carmeuse France
CIRS
Colacem SPA
CS Additive GmbH
C.S.B. GmbH
Donau Chemie AG
Duslo a.s.
Ets Legre Mante
Francis Flower
FOSFAN S.A.
Getzner Werkstoffe GmbH
GYMCOL S.A.
Hauert HBG Dünger AG
Holcim Süddeutschland GmbH
Huntman Performance Products
MEGA Brands America Inc.
MEGA Brands Europe NV
Nyrstar Budel BV, Nyrstar France SAS
Orchidée France S.A.S.
Panreac Quimica SAU
Phosphoric Acid Fertilizers Industry
PPHU Pro-Lab sp. z o.o.
SAS Lob Green
SEC Gummimischungen GmbH
Sigma-Aldrich Logistik GmbH
Spolek pro chemickou a hutní výrobu A.S.
TSG Europe
TSGE acting on behalf of client 14-9
TÜV SÜD Industrie Service GmbH
VWR Lab Products Private Limited
WeylChem Frankfurt GmbH

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Zakłady Chemiczne "Alwernia" SA