

## REACH Consortium for Calcium Sulphate Procedure to join the consortium or to obtain a LOA 01 February 2017

### 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.

(conf Annex I of the Consortium Agreement)

### Letter of Access to SIDS initial Assessment report for SIAM 17 – OECD HPV dossier on Calcium Sulphate

#### **1. Letter of access to the above-mentioned assessment**

On 15 March 2010, The Calcium Sulphate Consortium obtained a letter of access to SIDS Initial assessment report for SIAM 17 –OECD HPV dossier on calcium sulphate carried out the Korean Ministry of the Environment in 2003 according to GLP.

The following tests are covered by the LOA:

- ✚ 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**
- ✚ 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**

**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 newsletter are also covered by the Korean letter of access if they join the consortium.

**If you are covered by the Korean LOA, the price structure to become a member of the consortium is as follows:**

*(Euro)*

	<b>2016</b> (Base Price)	<b>2017</b>
Administrative fee	1.664,62	1.708,66
Compensation fee	5.548,75	5.695,56
Variable costs (technical costs & tests)	3.329,25	3.417.33
<b>TOTAL (EURO)</b>	<b>10.542,62</b>	<b>10.821.55</b>

- **Revised each year on the basis of the Belgian official consumer price index.**

**Base: January 2016 : 124,35 – January 2017 : 127,64 (2.65%)**

New cost structure =  $\frac{\text{Consortium Base price} \times 127,64}{124,35}$

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

**The costs of the calcium Sulphate Consortium to grant a LOA to SIEF members covered by the Korean LOA are:**

*(Euro)*

	<b>2016</b> (Base Price)	<b>2017</b>
Administrative fee	1.664,62	1.708,66
Compensation fee	6.103,64	6.265,13
Variable costs (technical costs & tests)	3.329,25	3.417.33
<b>TOTAL (EURO)</b>	<b>11.097,51</b>	<b>11.391.12</b>

- **Revised each year on the basis of the Belgian official consumer price index.**

**Base: January 2016 : 124,35 – January 2017 : 127,64 (2.65%)**

New cost structure =  $\frac{\text{Consortium Base price} \times 127,64}{124.35}$

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

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).

## **2. What to do if you are a SIEF member not mentioned in Annex I and you wish to register the substance?**

### **a. First step**

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

#### **Contact details:**

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**National Institute of Environmental Research (NIER)**

**Environmental Research Complex, Hwangyeong-ro 42, Seo-gu,  
Incheon, Korea, 404-708**

**ENVIGO RESEARCH LIMITED is available to help you on this issue.**

*(New name of Harlan Laboratories Limited – Effective 21.09.2015)*

Contact person : **Ms Lesley CREIGHTON**

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### **b. Second step**

You contact the calcium sulfate coordinator giving the evidence that you have obtained the Korean LOA.

**c. Third step**

- i. You can choose to become a member of the consortium with the following price structure:

(Euro)

	<b>2016</b> (Base Price)	<b>2017</b>
Administrative fee	1.664,62	1.708,66
Compensation fee	5.548,75	5.695,56
Variable costs (technical costs & tests)	2.219,51	2.278,23
<b>TOTAL (EURO)</b>	<b>9.432,88</b>	<b>9.682,45</b>

- **Revised each year on the basis of the Belgian official consumer price index.**

**Base: January 2016 : 124,35 – January 2017 : 127,64 (2.65%)**

New cost structure =  $\frac{\text{Consortium Base price} \times 127,64}{124,35}$

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

- ii. You can choose the LOA option to the dossier with the following price structure:

(Euro)

	<b>2016</b> (Base Price)	<b>2017</b>
Administrative fee	1.664,62	1.708,66
Compensation fee	6.103,64	6.265,13
Variable costs (technical costs & tests)	2.219,51	2.278,23
<b>TOTAL (EURO)</b>	<b>9.987,77</b>	<b>10.252,02</b>

- **Revised each year on the basis of the Belgian official consumer price index.**

**Base: January 2016 : 124,35 – January 2017 : 127,64 (2.65%)**

New cost structure =  $\frac{\text{Consortium Base price} \times 127,64}{124,35}$

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

## **LOA to the three tests performed by the Consortium**

### **1. Background**

Tests realized by the Calcium Sulphate Consortium:

- Activated sludge, respiration inhibition test (OECD n°209,1984: method C 11 of Commission regulation (EC) n°440/2008; US EPA Draft ecological effects test guidelines OPPTS 850.6800);
- Acute Inhalation (Nose only) toxicity study in the rat (test method 770.20);
- L5178Y Mouse Lymphoma Assay (test method 724.13).

The total costs of the test amounts to 39.000 Euro.

### **2. Cost for the letter of access to the above-mentioned tests**

- **For one company applying for the letter of access:**
  - i. 5% of 39.000 Euro, i.e. 1.950,00 Euro
  - ii. Receive the three tests in Iuclid 5 format: 500 Euro
  - iii. No sub-licensing permitted
- **For a consortium applying for the letter of access:**
  - iv. 30% of 39.000,00 Euro, i.e; 11.700,00 Euro
  - v. Receive the three tests in Iuclid 5 format: 500 Euro
  - vi. Sub-licensing permitted to a list of SIEF member intending to register (no dormant SIEF members)

### **3. Procedure for application**

- The Applicant sends the attached application form duly filled in and signed (consortium or company) by email to the Coordinator email: [reach@eurogypsum.org](mailto:reach@eurogypsum.org);
- The applicant sends the original by courier to the address of the coordinator: Eurogypsum, attn Christine Marlet, rue de la Presse, 4 – 1000 Brussels;
- The Coordinator send the invoice by email to the applicant who has 15 working days to settle the invoice;
- Once the money is in the coordinator bank account, the coordinator has 10 working days to issue the letter of access which will be sent by email and by courier to the applicant;
- If asked for, the coordinator will send the Iuclid 5 tests with the LOA by email.

**Application form and approval for use are available on demand.**

## Consortium Status

1. As of 1<sup>st</sup> January 2011, the consortium consists in 261 legal entities;
2. As of 1<sup>st</sup> January 2011, 23 LOA to the dossier were granted;
3. The guidance document on how to register was delivered to the consortium members on 22 April 2010;
3. Joint registration was carried out on 10 May 2010;
4. The analysis methods for individual registration purposes are available at: [http://www.eurogypsum.org/publications\\_02.html](http://www.eurogypsum.org/publications_02.html)
5. The SD was carried out.

### **IMPORTANT NOTE**

The Calcium Sulphate ITP does not provide consultancy on the individual registration. We strongly recommend you to use an external body to help you comply with your individual registration. Harlan Laboratories can do it for you should you need a recommendation in this regard.

### **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 Giulini 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
Zakłady Chemiczne "Alwernia" SA