

REACH Consortium for Calcium Sulphate Procedure to join the consortium or to obtain and LOA 1st January 2020

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 ₄	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 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.

The contact for the calcium sulphate coordination is:

Antoinette Mirco

Rue de la presse 4

1000 Brussels

Tel 32 2 227 1145

Email : reach@eurogypsum.org

This document explains the different steps in the procedure to join the REACH Consortium for Calcium Sulphate or obtain a Letter of Access. A graphic overview of the procedure is included in Annex III.

1. First step: Obtaining a Korean Letter of Access (LoA)

The applicant 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 sulphate. **Please note that a fee will be applied to purchase this LoA**, in which we do not intervene.

The following tests are covered by the LoA 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**
- + 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**

Contact details:

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

While we do not intervene in the process of purchasing the Korean LoA and have no influence on the level of the fee applied by the Korean authorities, **COVANCE CRS Research Limited** (new name of Envigo Research Limited) is available to help make contact with the National Institute of Environmental Research (NIER) in Korea.

Contact person : **Ms Lesley CREIGHTON**, Regulatory Services Manager
COVANCE CRS Research Limited
Shardlow Business Park
London Road, Shardlow
Derbyshire
DE72 2GD - UNITED KINGDOM
Tel. T +44 (0) 1332 794652
Fax +44 (0)1332 799 018
Lesley.Creighton@covance.com
www.covance.com

Exemptions:

Only the following entities do not need an LoA to the Korean studies before applying for an LoA to the calcium sulphate registration dossier or becoming a member of the calcium sulphate consortium:

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- The legal entities having joined the consortium **before 30 January 2010** are covered by the Korean LoA.
- The legal entities –SIEF members- **mentioned in Annex I of this document are** also covered by the Korean LoA if they join the consortium.
- Legal entities registering calcium sulphate with a tonnage band between 1 – 10 t/year.

2. Second step: Letter of Access with or without Consortium membership

A. 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 part 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
- The contract signed between the Consortium and COVANCE CRS Research Limited (formerly Harlan laboratories and Envigo)

B. Simple Letter of Access without Consortium membership

First step

If you choose to buy the dossier without being member of the Consortium, once you have obtained the Korean LoA and shared it with the coordinator (see part 1 of this document),, the coordinator will send the following documents:

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

Second step

After return of the "approval for use" document duly signed and the VAT fiche, the coordinator will send you:

- The invoice
- The "application for use" document

3. Third step: Payment and sharing of documents

A. Payment

The applicant will have to pay the amount indicated in the invoice, which is calculated according to the formulae in Annex II.

For Consortium membership, the fee will be calculated according to part A of Annex II.

For a simple LoA without Consortium membership, the fee will be calculated according to part B of Annex II.

B. 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 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. Important information

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 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 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 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

ANNEX II: FEES FOR CONSORTIUM MEMBERSHIP AND LETTER OF ACCESS**A. Consortium membership**

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

Fees (Euro)	2019	2020
Administrative fee	1,747.75	1,768.77
Compensation fee	5,825.86	5,895.92
Variable costs (technical costs & tests)	3,495.51	3,537.54
TOTAL (EURO)	11,069.12	11,202.23

The price is revised each year on the basis of the Belgian official consumer price index.
Base: January 2019: 130.56 – January 2020: 132.13 (+1.20%)

New cost structure = $\frac{\text{Consortium Base price} \times 132.13}{130.56}$

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 GA of 9 June 2009.**

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:

Fees (Euro)	2019	2020
Administrative fee	1,747.75	1,768.77
Compensation fee	6,408.46	6,485.52
Variable costs (technical costs & tests)	3,495.51	3,537.54
TOTAL (EURO)	11,651.72	11,791.83

The fees are revised each year on the basis of the Belgian official consumer price index.
Base: January 2019: 130.56 – January 2020: 132.13 (+1.20%)

New cost structure = $\frac{\text{Consortium Base price} \times 132.13}{130.56}$

NB: A discount could be applied for the purpose of registering calcium sulphate **between 1 and 10 tons and 1 and 100 tons**. If you are falling within that range of tonnage, please contact the coordinator, who will send you a special form for signature.

ANNEX III: OVERVIEW OF THE PROCEDURAL STEPS

