JONES DAY

AVOCATS – ADVOCATEN

4, RUE DE LA RÉGENCE • REGENTSCHAPSSTRAAT 4

1000 BRUSSELS, BELGIUM

TELEPHONE: 32.(0)2.645.14.11 • FACSIMILE: 32.(0)2.645.14.45

February 11, 2025

TO WHOM IT MAY CONCERN

Dear Applicant,

Re: Gluconic Acid and its Derivatives ('Gluconic') REACH Consortium

This document contains the relevant information for purchasing a letter of access 'LoA' for joining the joint REACH registration for the substances:

- **GLUCONO-DELTA-LACTONE: EC 202-016-5; CAS 90-80-2;**
- **GLUCONIC ACID: EC 208-401-4; CAS 526-95-4**
- **POTASSIUM GLUCONATE: EC 206-074-2; CAS 299-27-4**

prepared by the **GLUCONIC REACH CONSORTIUM**. In addition, this PDF provides the relevant earlier SIEF communications issued by the Lead Registrant / Consortium.

If you wish to purchase a LoA, please fill in the next pages **'LOA APPLICATION FORM' and pdf them to the attention of ReachTeam@jonesday.com**. You will then receive a pre-payment notice by email for payment of the LoA price. As soon as we have received your payment in full, we will confirm that payment has been received and you will receive the joint submission token and any other necessary documentation (Chemical Safety Report, Guidance on Safe Use as the case may be) that you may need to join the Joint Submission via the ECHA REACH-IT portal (please see the ECHA Guidance on joining the Joint Submission). Potential registrants have to submit their individual parts (Article 10 (a) (i), (ii), (iii) and (x)) of the IUCLID 5 registration dossiers separately to ECHA by the relevant deadline.

Invoices for paid LoA fees will be issued by the Consortium on a periodic basis as soon as a sufficient number of LoAs have been processed and pre-paid.

If you have any questions, please do not hesitate to contact:

Preslava Dilkova at p.dilkova@jonesday.com / Telephone +32-2-645-1433

Letter of Access ('LoA') Application Form

Gluconic Acid and its Derivates REACH Consortium

LoA will be issued per group of companies. Please fill in the application form only ***once*** for all affiliated group companies.
(*To be filled in and emailed back to reachteam@jonesday.com*)

NOTE:
**** By completing and sending the LoA application form to Jones Day, you shall be considered as having accepted the terms of the respective SIEF Agreement overleaf.***
**** Only once formal invoices will have been issued and settled, the LoA will be considered as issued and effective.***
** LoA applicants will be informed by separate email or via SIEF communication if the CSR and guidance on safe use will be prepared jointly and also **submitted jointly**, or rather whether they will be prepared jointly but will have to be **submitted individually**. In the latter case, LoA applicants will receive the CSR and guidance on safe use via a Iuclid so-called "export file" and must then insert it themselves into their individual REACH registration.*

Substances:

☐ **Glucono-delta-lactone: EC 202-016-5; CAS 90-80-2;**
☐ **Gluconic acid: EC 208-401-4; CAS 526-95-4;**
☐ **Potassium gluconate: EC 206-074-2; CAS 299-27-4**

Current Prices LoA:

For the total annual tonnage of all three substances combined:

☐ 1 - 10 tons: EUR 50.767,- (excl. VAT)

☐ 10 - 100 tons: EUR 71.682,- (excl. VAT)

☐ 100 - 1000 tons: EUR 94.107,- (excl. VAT)

☐ Above 1000 tons: EUR 145.766,- (excl. VAT)

Please fill in applicable joint submission category. Any change in category (higher tonnage or change from intermediate to full substance registration) will require notification to Jones Day to adapt price.

Restrictions (optional):

a. ☐ 'Opt-out' pursuant to Article 11 (3) for the following mandatory joint parts.
☐ Article 10 (a)
☐ Article 10 (a) (iv),
☐ Article 10 (a) (vi),
☐ Article 10 (a) (vii),
☐ Article 10 (a) (ix)

EUI-1219486131v1
Date Edited: 02/12/25

Identification

Company: .....

.....

REACH-IT UUID Number: .....

Company reference name or number (optional): .....

VAT number: .....

If you do not fill out a VAT number, you will be charged 21%.

Address: .....

.....

Postal Code: ..... City: ..... Country: .....

Please give full details of person authorized to make the application:

Mr ☐ Ms ☐ Dr ☐

Last Name: ..... First Name: .....

Phone Number: ..... Fax Number: .....

E-mail address: .....

Please give full company details for all affiliates to be covered by this Letter of Access:
Example: The Miracle Chemicals Co. Ltd; 95130 Rome, 25 Nano Boulevard, Belgium

Affiliates: .....

.....

.....

.....

.....

.....

.....

.....

Registration

In his registration, the Applicant acts:

a. ☐ for **himself**

b. ☐ as **Only Representative** pursuant to Article 8 REACH for the following non-EU manufacturer;
Please give full contact details of **non-EU legal entity** represented by Only Representative
If you act on behalf of several non-EU legal entities that are not related to each other, please fill in new application form for each of your principals.

Company: .....

.....

Address: .....

.....

Postal Code: ..... City: ..... Country: .....

Mr ☐ Ms ☐ Dr ☐

Last Name: ..... First Name: .....

Phone Number: ..... Fax Number: .....

E-mail address: .....

c. ☐ as **Third Party Representative** pursuant to Article 4 REACH.

Do you want to disclose the name of the party you represent?
a. ☐ Yes
b. ☐ No

Company Name: .....

.....

REACH-IT UUID Number: .....

Address: .....

.....

Postal Code: ..... City: ..... Country: .....

Mr ☐ Ms ☐ Dr ☐

Last Name: ..... First Name: .....

Phone Number: ..... Fax Number: .....

E-mail address: .....

Applicable Joint Submission:

Is the **company to be invoiced** the same as the legal entity registering under REACH?

a. ☐ Yes

b. ☐ No

If no, please give full company details of legal entity to be invoiced:

Company: .....

VAT number: .....

If you do not fill in a VAT number, you will be charged 21%.

Address: .....

.....

Postal Code: ..... City: ..... Country: .....

General Terms and Conditions:

1. The right of referral only gives access to the Joint Registration Dossier of the substance for the registration as specified above.
2. The right of referral is solely granted in favor of the Applicant (and, only where applicable, the Affiliates listed herein), and is not transferable to any other entity or person.
3. Unless otherwise specified below at 6., the Applicant is not authorized to receive any copies of the Joint Registration Dossier nor is the Applicant authorized to inspect or view the Joint Registration Dossier or any related specific document in whole or in part, outside the general inspection period granted by the Consortium and outside the conditions set out in the SIEF Agreement.
4. This Letter of Access shall in no event be construed as granting the Applicant any property rights whatsoever in the Joint Registration Dossier.
5. Nothing in this letter shall require the Consortium members to file any additional data.
6. In as far as the Joint Registration Dossier may contain a chemical safety report ("CSR") and guidance on safe use, and the Applicant is participating in joint submission for those parts of the dossier, or has otherwise acquired rights to them, those will be made available to the Applicant as needed and may be used by it in as far as needed for purposes of safe handling and elaboration of eSDS and must be filed by it individually if set out in the SIEF Agreement.
7. If the Applicant has chosen to prepare itself the CSR, exposure scenarios and guidance on safe use, but does otherwise fully participate in the Joint Registration Dossier, it shall receive an electronic copy of parts Article 10 (a) (iv), (vi), (vii) and (ix) REACH of the Joint Registration Dossier and shall have the rights to use for this purpose only the (robust) study summaries and other information contained therein as well as to refer to the full study reports on which basis the (robust) study summaries have been developed.
8. In any event and regardless of the rights and restrictions set forth above, the Applicant shall always receive a list of uses which are covered by the CSR, the proposed classification and labeling as well as the PNECs and DNELs where available.

This Letter of Access does not create any rights for third parties or any liability towards third parties in relation to the data for which access is granted.

This letter of access is issued by the above Lead Registrant or Consortium Members and they have prepared the respective registration dossier(s). No attorney-client relationship with Jones Day is created by signing this LoA application / change form / the SIEF / Cooperation / Joint Submission Agreement or payment of the LoA (proforma) invoice.

Applicant's certifications and undertakings:

1. The Applicant hereby declares that it is aware of, agrees and complies with the provisions of the SIEF Agreement issued by the Lead Registrant, which shall apply in its entirety in addition to the provisions set out hereunder.
2. In case the Applicant has applied for an intermediate LoA only, the Applicant hereby declares that it is aware that registration as an intermediate pursuant to Articles 17 and 18 REACH is conditional upon fulfillment of the conditions set out there under.
3. The Applicant declares that it has wired the Letter of Access Pre-payment fee to the following bank account within 30 calendar days of signature of this Letter of Access. Following receipt of the payment in full, the applicant will receive the security token. The invoice for the Letter of Access / Joint Submission will be issued at latest at the end of the applicable year of registration (end 2010, end 2013, end of 2018, as the case may be).
4. If Applicant chooses not to disclose the Third Party represented, Jones Day reserves the right to appoint a neutral party that is entitled to audit the accuracy of the Third Party Representative's submission whilst guaranteeing the confidentiality of the Third Party. The Third Party Representative hereby agrees to such third party audit.

I have read and I agree with the legal Terms of the Agreement.

Signature of LoA applicant: ……..

Name: ……..

Date: ……..

* * *

REACH:

- 10th SIEF Communication Gluconic Acid – 17 February 2025

- **Glucono-delta-lactone; CAS 90-80-2; EINECS 202-016-5**
- **Gluconic acid; CAS 526-95-4; EINECS 208-401-4**

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MICHÈLE GRÉGOIRE(4)
Avocat à la Cour de cassation
Advocaat bij het Hof van Cassatie
Member of the Belgian Supreme Court Bar

CHANTAL BIERNAUX
CHARLOTTE BREUVART(2)
FERDINAND BRUGHMANS
SÉBASTIEN CHAMPAGNE
SERGE CLERCKX
THOMAS DE MUYNCK(3)
LAURENT DE MUYTER
YVAN DESMEDT
PRESLAVA DILKOVA(10)
MATTHIEU DUPLAT
KAARLI H. EICHHORN(8)
VANESSA FONCKE
JÖRG HLADJK(7)
PIERRE-OLIVIER MAHIEU
NADIYA NYCHAY(9)
CRISTIANA SPONTONI(1)
MARIO TODINO(5)
JONAS VAN DEN BOSSCHE
GEOFFROY VAN DE WALLE
ALEXANDRE VERHEYDEN(3)
PHILIPP WERNER(6)

DIDIER DE VLIEGHER
PHILIPPE LACONTE
PAUL VAN HOOGHTEN
SARA VANDERSTRAETEN
LAURENT VERCAUTEREN

Members of the Brussels Bar
(1)Member of the Rome Bar
(2)Member of the Paris Bar
(3)Member of the New York Bar
(4)Admitted to the Paris Bar
(5)Member of the Naples Bar
(6)Member of the Berlin Bar
(7)Member of the Frankfurt am Main Bar
(8)Member of the Swedish Bar
(9)Member of the Ukrainian Bar
(10)Member of the Pleven Bar

E-MAIL: REACHTEAM@JONESDAY.COM

By Electronic Mail

331413-600001

February 17, 2025

TO WHOM IT MAY CONCERN

Dear Joint Registrants,

Re: REACH: 10th SIEF Communication - Dossier updates for Gluconic Acid (EC 208-401-4; CAS 526-95-4) and Glucono-Delta-Lactone (EC 202-016-5; CAS 90-80-2)

On behalf of Jungbunzlauer SA (Lead Registrant) and the Gluconic Acid and its Derivatives REACH Consortium, we hereby wish to inform you that the REACH registration dossiers of Glucono-Delta-Lactone and Gluconic Acid were updated and passed the ECHA completeness check.

The dossier updates concern the inclusion of QSAR data aimed to substitute the carrying of long-term toxicity testing on fish and long-term daphnia testing. It remains to be seen whether ECHA will accept this approach. If you wish to receive the updated CSRs and/or IUCLIDs, please contact us at ReachTeam@jonesday.com.

Thank you for your attention. For any information on purchasing a Letter of Access, please visit our website https://jonesdayreach.com/substances/.

Kind regards,

Preslava Dilkova

REACH:

- 9th SIEF Communication Gluconic Acid – 24 July 2024 (incl. LoA price calculations (pre- and post-August 2022)

- **Glucono-delta-lactone; CAS 90-80-2; EINECS 202-016-5**
- **Gluconic acid; CAS 526-95-4; EINECS 208-401-4**
- **Potassium gluconate; CAS 299-27-4; EINECS 206-074-2**

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E-MAIL: REACHTEAM@JONESDAY.COM

June 24, 2024

By Electronic Mail

331413-600001

TO WHOM IT MAY CONCERN

Dear Joint Registrants,

Re: REACH: 9th SIEF Communication

On behalf of Jungbunzlauer SA (Lead Registrant) and the Gluconic Acid and its Derivatives REACH Consortium of the following three substances,

- Glucono-Delta-Lactone: EC 202-016-5; CAS 90-80-2;
- Gluconic Acid: EC 208-401-4; CAS 526-95-4; and
- Potassium Gluconate: EC 206-074-2; CAS 299-27-4,

we hereby wish to inform you that the Consortium has recently successfully completed a dossier update converting to the most recent IUCLID version and improving the three registration dossiers in general. In that context, it was also inevitable to make a testing proposal for long term fish toxicity. Accordingly, LoA prices have been updated as well, see attached.

If you wish to receive the updated CSRs and/or IUCLIDs, we invite you to first pay up the difference – if any – between the previous LoA price and the current LoA price. We will then send you the joint documents.

For any inquiries, please contact us at ReachTeam@jonesday.com.

Thank you for your attention. For any information on purchasing a Letter of Access, please visit our website https://jonesdayreach.com/substances/.

Kind regards,

Ursula Schliessner

Attachment (1)

Gluconic Acid REACH Consortium : LoA price calculation for 3 substances combined						
6 SIEF members (2 members above 1000 tons, 2 co-reg at 100-1000 tons, 2 co-regs at 1-10 tons) (updated June 2024)						
Consortium Management (*)	**Tonnage band**	**Budget**	**Above 1000 tons**	**100 -1000 tons**	**10 - 100 tons**	**1 - 10 tons**
2009 budget - Consortium Management	All	€ 58.500	€ 14.625	€ 7.313	€ 7.313	€ 7.313
2010 budget - Consortium Management	All	€ 54.900	€ 13.725	€ 6.863	€ 6.863	€ 6.863
2013 budget - Consortium Management	All	€ 14.000	€ 3.500	€ 1.750	€ 1.750	€ 1.750
2014 budget - Consortium Management	All	€ 8.000	€ 2.000	€ 1.000	€ 1.000	€ 1.000
2015 budget - Consortium Management	All	€ 22.000	€ 5.500	€ 2.750	€ 2.750	€ 2.750
2016 budget - Consortium Management	All	€ 8.000	€ 2.000	€ 1.000	€ 1.000	€ 1.000
2017 budget - Consortium Management	All	€ 8.000	€ 2.000	€ 1.000	€ 1.000	€ 1.000
2018 budget - Consortium Management	All	€ 8.000	€ 2.000	€ 1.000	€ 1.000	€ 1.000
2019 budget - Consortium Management	All	€ 11.000	€ 2.750	€ 1.375	€ 1.375	€ 1.375
2020 budget - Consortium Management	All	€ 11.000	€ 2.750	€ 1.375	€ 1.375	€ 1.375
2021 budget - Consortium Management	All	€ 11.000	€ 2.750	€ 1.375	€ 1.375	€ 1.375
2022 budget - Consortium Management	All	€ 20.000	€ 5.000	€ 2.500	€ 2.500	€ 2.500
2023 budget - Consortium Management	All	€ 12.000	€ 3.000	€ 1.500	€ 1.500	€ 1.500
2024 budget - Consortium Management	All	€ 12.000	€ 3.000	€ 1.500	€ 1.500	€ 1.500
2025 budget - Consortium Management	All	€ 15.000	€ 3.750	€ 1.875	€ 1.875	€ 1.875
TOTAL - Consortium Management		**€ 273.400**	**€ 68.350**	**€ 34.175**	**€ 34.175**	**€ 34.175**

Gluconic Acid REACH Consortium : LoA price calculation for 3 substances combined						
6 SIEF members (2 members above 1000 tons, 2 co-reg at 100-1000 tons, 2 co-regs at 1-10 tons) (updated June 2024)						
Dossier Preparation	**Tonnage band**	**Budget**	**Above 1000 tons**	**100 -1000 tons**	**10 - 100 tons**	**1 - 10 tons**
2009 - Data collection and read-across	All	€ 8.100	€ 2.025	€ 1.013	€ 1.013	€ 1.013
2009 - Robust study summaries in IUCLID 5	All	€ 14.900	€ 3.725	€ 1.863	€ 1.863	€ 1.863
2009 - Klimisch rating	All	€ 600	€ 150	€ 75	€ 75	€ 75
2009 - Toxicological studies : Local Lymph Node Assay (LLNA) in mice OECD 429 & Flash point EU A9	All	€ 3.417	€ 570	€ 570	€ 570	€ 570
2009 - Toxicological studies : Acute skin irritation study in the rabbit OECD 404 & Acute eye irritation study in the rabbit OECD 405 & Acute dermal toxicity study in the rat OECD 402	All	€ 3.075	€ 513	€ 513	€ 513	€ 513
TOTAL - 2009		**€ 30.092**	**€ 6.982**	**€ 4.032**	**€ 4.032**	**€ 4.032**
Dossier Preparation	**Tonnage band**	**Budget**	**Above 1000 tons**	**100 -1000 tons**	**10 - 100 tons**	**1 - 10 tons**
2010 - Endpoint summary records in IUCLID 5/hazard assessment	All	€ 12.100	€ 3.025	€ 1.513	€ 1.513	€ 1.513
2010 - CSR incl. PBT assessment/testing proposal	10 t <	€ 8.400	€ 2.800	€ 1.400	€ 1.400	-
2010 - Testing (autoflammability)	All	€ 2.525	€ 421	€ 421	€ 421	€ 421
2010 - Testing (oxygen inhibition by activated sludge)	10 t <	€ 1.743	€ 436	€ 436	€ 436	-
2010 - Translation of Düsseldorf University (toxicokinetics)	10 t <	€ 1.500	€ 375	€ 375	€ 375	-
2010 - Licensing of studies (acute oral toxicity in rats)	10 t <	€ 500	€ 125	€ 125	€ 125	-
2010 - Licensing of studies (6 months oral toxicity in rats)	10 t <	€ 44.500	€ 11.125	€ 11.125	€ 11.125	-
2010 - Internal existing data (see Appendix 3 - Data sheet)	All	€ 32.550	€ 8.138	€ 4.069	€ 4.069	€ 4.069
2010 - Internal existing data (see Appendix 3 - Data sheet: IUCLID 6.1.1)	All	€ 6.700	€ 1.675	€ 838	€ 838	€ 838
2010 - Expenses	All	€ 500	€ 125	€ 63	€ 63	€ 63

Gluconic Acid REACH Consortium : LoA price calculation for 3 substances combined						
6 SIEF members (2 members above 1000 tons, 2 co-reg at 100-1000 tons, 2 co-regs at 1-10 tons) (updated June 2024)						
TOTAL - 2010		**€ 111.018**	**€ 28.244**	**€ 20.363**	**€ 20.363**	**€ 6.902**
2013 - Permission to refer to studies "The effect of ether anesthesia on cerebral glucose metabolism"	10 t <	€ 325	€ 81	€ 81	€ 81	-
2013 - Compliance check decision : update of dossier	10 t <	€ 4.500	€ 1.125	€ 1.125	€ 1.125	-
2013 - Transfer of dossier in IUCLID 5.4	All	€ 2.500	€ 625	€ 313	€ 313	€ 313
2013 - Budget increase (Consultancy for compliance check)	10 t <	€ 1.000	€ 250	€ 250	€ 250	-
2013 - Budget increase (Consultancy for compliance check)	10 t <	€ 1.850	€ 463	€ 463	€ 463	-
TOTAL - 2013		**€ 10.175**	**€ 2.544**	**€ 2.231**	**€ 2.231**	**€ 313**
Dossier Preparation	**Tonnage band**	**Budget**	**Above 1000 tons**	**100 -1000 tons**	**10 - 100 tons**	**1 - 10 tons**
2015 - Toxicological studies: Mutagenicity studies (Ames, MLA/TK and metaphase analysis) - Incl. additional budget of EUR 1.250 adopted in October 2015.	10 t <	€ 26.340	€ 4.610	€ 4.610	€ 4.610	-
2015 - Toxicological studies: Mutagenicity test on bacteria (OCDE 471)	All	€ 5.040	€ 588	€ 588	€ 588	€ 588
2015 - Toxicological studies: Chromosomes aberrations in vitro human lymphocyte metaphase analysis (OCDE 473)	10 t <	€ 31.960	€ 5.593	€ 5.593	€ 5.593	-
2015 - Toxicological studies: Mutation assay at TK locus in L5178Y mouse lymphoma cells (OCDE 476)	10 t <	€ 21.180	€ 3.707	€ 3.707	€ 3.707	-
2015 - Toxicological studies: Scientific data entry on IUCLID for 3 studies (adopted in Dec 2015)	10 t <	€ 720	€ 126	€ 126	€ 126	-
2015 - Dossier update: include new studies into 3 registration dossiers, update dossiers for submission (adopted in Dec 2015)	10 t <	€ 5.000	€ 1.667	€ 833	€ 833	-
TOTAL - 2015		**€ 90.240**	**€ 16.290**	**€ 15.456**	**€ 15.456**	**€ 588**
Dossier Preparation	**Tonnage band**	**Budget**	**Above 1000 tons**	**100 -1000 tons**	**10 - 100 tons**	**1 - 10 tons**

Gluconic Acid REACH Consortium : LoA price calculation for 3 substances combined						
6 SIEF members (2 members above 1000 tons, 2 co-reg at 100-1000 tons, 2 co-regs at 1-10 tons) (updated June 2024)						
2020 - Dossier update (vote March 2019)	All	€ 10.000	€ 2.500	€ 1.250	€ 1.250	€ 1.250
TOTAL - 2020		**€ 10.000**	**€ 2.500**	**€ 1.250**	**€ 1.250**	**€ 1.250**
Dossier Preparation	**Tonnage band**	**Budget**	**Above 1000 tons**	**100 -1000 tons**	**10 - 100 tons**	**1 - 10 tons**
2023 - Dossier update (vote June 2023)	All	€ 20.000	€ 5.000	€ 2.500	€ 2.500	€ 2.500
TOTAL - 2023		**€ 20.000**	**€ 5.000**	**€ 2.500**	**€ 2.500**	**€ 2.500**
Dossier Preparation	**Tonnage band**	**Budget**	**Above 1000 tons**	**100 -1000 tons**	**10 - 100 tons**	**1 - 10 tons**
2025 - Toxicological studies: testing on fish (OECD 2010 and 2011, limit test) (adopted in March 2024)	100 t <	€ 90.000	€ 15.750	€ 15.750	-	-
2025 - Dossier update: Administrative costs; testing proposal and dossier update for two substances and study monitoring (EUR 15,000)	100 t <	€ 15.000	€ 3.750	€ 3.750	-	-

Gluconic Acid REACH Consortium : LoA price calculation for 3 substances combined						
6 SIEF members (2 members above 1000 tons, 2 co-reg at 100-1000 tons, 2 co-regs at 1-10 tons) (updated June 2024)						
TOTAL - 2025		**€ 105.000**	**€ 19.500**	**€ 19.500**	**€ -**	**€ -**
TOTAL - CONSORTIUM MANAGEMENT AND DOSSIER PREPARATION		**€ 649.925**	**€ 149.410**	**€ 99.507**	**€ 80.007**	**€ 49.760**
ADMIN COST (15%)			€ 22.411	€ 14.926	€ 12.001	€ 7.464
TOTAL WITH ADMIN COST			€ 171.821	€ 114.434	€ 92.009	€ 57.224
Handling Fee			€ 1.000	€ 1.000	€ 1.000	€ 1.000
TOTAL LOA PRICE			**€ 172.821**	**€ 115.434**	**€ 93.009**	**€ 58.224**
(*) Administrative cost is divided proportionally, i.e. joint registrants that are above 1000t for all substances combined pay 2 administrative cost shares, the others 1 each. Administration costs are all costs, except study costs or administrative costs related to specific end point missing data. Price of new studies is 70% to LoA applicants						

Gluconic Acid REACH Consortium : LoA price calculation for 3 substances combined - As of 1st August 2022						
6 SIEF members (updated June 2024)						
Consortium Management (*)	**Tonnage band**	**Budget**	**Above 1000 tons**	**100 -1000 tons**	**10 - 100 tons**	**1 - 10 tons**
2009 budget - Consortium Management	All	€ 58.500	€ 14.625	€ 7.313	€ 7.313	€ 7.313
2010 budget - Consortium Management	All	€ 54.900	€ 13.725	€ 6.863	€ 6.863	€ 6.863
2013 budget - Consortium Management	All	€ 14.000	€ 3.500	€ 1.750	€ 1.750	€ 1.750
2014 budget - Consortium Management	All	€ 8.000	€ 2.000	€ 1.000	€ 1.000	€ 1.000
2015 budget - Consortium Management	All	€ 22.000	€ 5.500	€ 2.750	€ 2.750	€ 2.750
2016 budget - Consortium Management	All	€ 8.000	€ 2.000	€ 1.000	€ 1.000	€ 1.000
2017 budget - Consortium Management	All	€ 8.000	€ 2.000	€ 1.000	€ 1.000	€ 1.000
2018 budget - Consortium Management	All	€ 8.000	€ 2.000	€ 1.000	€ 1.000	€ 1.000
2019 budget - Consortium Management	All	€ 11.000	€ 2.750	€ 1.375	€ 1.375	€ 1.375
2020 budget - Consortium Management	All	€ 11.000	€ 2.750	€ 1.375	€ 1.375	€ 1.375
2021 budget - Consortium Management	All	€ 11.000	€ 2.750	€ 1.375	€ 1.375	€ 1.375
2022 budget - Consortium Management	All	€ 20.000	€ 5.000	€ 2.500	€ 2.500	€ 2.500
2023 budget - Consortium Management	All	€ 12.000	€ 3.000	€ 1.500	€ 1.500	€ 1.500
2024 budget - Consortium Management	All	€ 12.000	€ 3.000	€ 1.500	€ 1.500	€ 1.500
2025 budget - Consortium Management	All	€ 15.000	€ 3.750	€ 1.875	€ 1.875	€ 1.875
TOTAL - Consortium Management		**€ 273.400**	**€ 68.350**	**€ 34.175**	**€ 34.175**	**€ 34.175**

Gluconic Acid REACH Consortium : LoA price calculation for 3 substances combined - As of 1st August 2022						
6 SIEF members (updated June 2024)						
Dossier Preparation	**Tonnage band**	**Budget**	**Above 1000 tons**	**100 -1000 tons**	**10 - 100 tons**	**1 - 10 tons**
2009 - Data collection and read-across	All	€ 8.100	€ 2.025	€ 1.013	€ 1.013	€ 1.013
2009 - Robust study summaries in IUCLID 5	All	€ 14.900	€ 3.725	€ 1.863	€ 1.863	€ 1.863
2009 - Klimisch rating	*All (**)*	€ -	€ -	€ -	€ -	€ -
2009 - Toxicological studies : Local Lymph Node Assay (LLNA) in mice OECD 429 & Flash point EU A9	*All (**)*	€ -	€ -	€ -	€ -	€ -
2009 - Toxicological studies : Acute skin irritation study in the rabbit OECD 404 & Acute eye irritation study in the rabbit OECD 405 & Acute dermal toxicity study in the rat OECD 402	*All (**)*	€ -	€ -	€ -	€ -	€ -
TOTAL - 2009		**€ 23.000**	**€ 5.750**	**€ 2.875**	**€ 2.875**	**€ 2.875**
Dossier Preparation	**Tonnage band**	**Budget**	**Above 1000 tons**	**100 -1000 tons**	**10 - 100 tons**	**1 - 10 tons**
2010 - Endpoint summary records in IUCLID 5/hazard assessment	All	€ 12.100	€ 3.025	€ 1.513	€ 1.513	€ 1.513
2010 - CSR incl. PBT assessment/testing proposal	10 t <	€ 8.400	€ 2.800	€ 1.400	€ 1.400	-
2010 - Testing (autoflammability)	*All (**)*	€ -	€ -	€ -	€ -	€ -
2010 - Testing (oxygen inhibition by activated sludge)	*10 t <(**)*	€ -	€ -	€ -	€ -	€ -
2010 - Translation of Düsseldorf University (toxicokinetics)	*10 <*	€ -	€ -	€ -	€ -	€ -
2010 - Licensing of studies (acute oral toxicity in rats)	*10 t <(**)*	€ -	€ -	€ -	€ -	€ -
2010 - Licensing of studies (6 months oral toxicity in rats)	*10 t <(**)*	€ -	€ -	€ -	€ -	€ -
2010 - Internal existing data (see Appendix 3 - Data sheet)	*All (**)*	€ -	€ -	€ -	€ -	€ -
2010 - Internal existing data (see Appendix 3 - Data sheet: IUCLID 6.1.1)	*All (**)*	€ -	€ -	€ -	€ -	€ -

Gluconic Acid REACH Consortium : LoA price calculation for 3 substances combined - As of 1st August 2022						
6 SIEF members (updated June 2024)						
2010 - Expenses	All	€ 500	€ 125	€ 63	€ 63	€ 63
TOTAL - 2010		**€ 21.000**	**€ 5.950**	**€ 2.975**	**€ 2.975**	**€ 1.575**
2013 - Permission to refer to studies "The effect of ether anesthesia on cerebral glucose metabolism"	10 t <	€ 325	€ 81	€ 81	€ 81	-
2013 - Compliance check decision : update of dossier	10 t <	€ 4.500	€ 1.125	€ 1.125	€ 1.125	-
2013 - Transfer of dossier in IUCLID 5.4	All	€ 2.500	€ 625	€ 313	€ 313	€ 313
2013 - Budget increase (Consultancy for compliance check)	10 t <	€ 1.000	€ 250	€ 250	€ 250	-
2013 - Budget increase (Consultancy for compliance check)	10 t <	€ 1.850	€ 463	€ 463	€ 463	-
TOTAL - 2013		**€ 10.175**	**€ 2.544**	**€ 2.231**	**€ 2.231**	**€ 313**
Dossier Preparation	**Tonnage band**	**Budget**	**Above 1000 tons**	**100 -1000 tons**	**10 - 100 tons**	**1 - 10 tons**
2015 - Toxicological studies: Mutagenicity studies (Ames, MLA/TK and metaphase analysis) - Incl. additional budget of EUR 1.250 adopted in October 2015.	10 t <	€ 26.340	€ 4.610	€ 4.610	€ 4.610	-
2015 - Toxicological studies: Mutagenicity test on bacteria (OCDE 471)	All	€ 5.040	€ 588	€ 588	€ 588	€ 588
2015 - Toxicological studies: Chromosomes aberrations in vitro human lymphocyte metaphase analysis (OCDE 473)	10 t <	€ 31.960	€ 5.593	€ 5.593	€ 5.593	-
2015 - Toxicological studies: Mutation assay at TK locus in L5178Y mouse lymphoma cells (OCDE 476)	10 t <	€ 21.180	€ 3.707	€ 3.707	€ 3.707	-
2015 - Toxicological studies: Scientific data entry on IUCLID for 3 studies (adopted in Dec 2015)	10 t <	€ 720	€ 126	€ 126	€ 126	-
2015 - Dossier update: include new studies into 3 registration dossiers, update dossiers for submission (adopted in Dec 2015)	10 t <	€ 5.000	€ 1.667	€ 833	€ 833	-
TOTAL - 2015		**€ 90.240**	**€ 16.290**	**€ 15.456**	**€ 15.456**	**€ 588**

Gluconic Acid REACH Consortium : LoA price calculation for 3 substances combined - As of 1st August 2022						
6 SIEF members (updated June 2024)						
Dossier Preparation	**Tonnage band**	**Budget**	**Above 1000 tons**	**100 -1000 tons**	**10 - 100 tons**	**1 - 10 tons**
2020 - Dossier update (vote March 2019)	All	€ 10.000	€ 2.500	€ 1.250	€ 1.250	€ 1.250
TOTAL - 2020		**€ 10.000**	**€ 2.500**	**€ 1.250**	**€ 1.250**	**€ 1.250**
Dossier Preparation	**Tonnage band**	**Budget**	**Above 1000 tons**	**100 -1000 tons**	**10 - 100 tons**	**1 - 10 tons**
2023 - Dossier update (vote June 2023)	All	€ 20.000	€ 5.000	€ 2.500	€ 2.500	€ 2.500
TOTAL - 2023		**€ 20.000**	**€ 5.000**	**€ 2.500**	**€ 2.500**	**€ 2.500**
Dossier Preparation	**Tonnage band**	**Budget**	**Above 1000 tons**	**100 -1000 tons**	**10 - 100 tons**	**1 - 10 tons**
2025 - Toxicological studies: testing on fish (OECD 2010 and 2011, limit test) (adopted in March 2024)	**100 t <**	**€ 90.000**	€ 15.750	**€ 15.750**	**€ -**	**€ -**
2025 - Dossier update: Administrative costs; testing proposal and dossier update for two substances and study monitoring (EUR 15,000)	**100 t <**	**€ 15.000**	**€ 3.750**	**€ 3.750**	**€ -**	**€ -**

Gluconic Acid REACH Consortium : LoA price calculation for 3 substances combined - As of 1st August 2022						
6 SIEF members (updated June 2024)						
TOTAL - 2025		**€ 105.000**	**€ 19.500**	**€ 19.500**	**€ -**	**€ -**
TOTAL - CONSORTIUM MANAGEMENT AND DOSSIER PREPARATION		**€ 552.815**	**€ 125.883**	**€ 80.963**	**€ 61.463**	**€ 43.276**
ADMIN COST (15%)			€ 18.883	€ 12.144	€ 9.219	€ 6.491
TOTAL WITH ADMIN COST			€ 144.766	€ 93.107	€ 70.682	€ 49.767
Handling Fee			€ 1.000	€ 1.000	€ 1.000	€ 1.000
TOTAL LOA PRICE			**€ 145.766**	**€ 94.107**	**€ 71.682**	**€ 50.767**
(*) Administrative cost is divided proportionally, i.e. joint registrants that are above 1000t for all substances combined pay 2 administrative cost shares, the others 1 each. Administration costs are all costs, except study costs or administrative costs related to specific end point missing data. Price of new studies is 70% to LoA applicants.						
(**) As of 1st August 2022.						

REACH:

- 8th SIEF Communication Gluconic Acid – 20 June 2023 (incl. LoA price calculations)

- **Glucono-delta-lactone; CAS 90-80-2; EINECS 202-016-5**
- **Gluconic acid; CAS 526-95-4; EINECS 208-401-4**
- **Potassium gluconate; CAS 299-27-4; EINECS 206-074-2**

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June 20, 2023 By Electronic Mail

331413-600001

TO WHOM IT MAY CONCERN

Dear SIEF Members and Joint Registrants,

Re: REACH: 8th SIEF Communication

On behalf of Jungbunzlauer SA (Lead Registrant) and the Gluconic Acid and its Derivatives REACH Consortium of the following three substances,

- Glucono-Delta-Lactone: EC 202-016-5; CAS 90-80-2;
- Gluconic Acid: EC 208-401-4; CAS 526-95-4; and
- Potassium Gluconate: EC 206-074-2; CAS 299-27-4,

we hereby attach new LoA price calculations, applicable as of August 1, 2022 (at the end of 12 years data protection period).

Thank you for your attention. For any information on purchasing a Letter of Access, please visit out website https://jonesdayreach.com/substances/ or contact us at ReachTeam@jonesday.com.

Kind regards,

Ursula Schliessner

Attachment (1)

Gluconic Acid REACH Consortium : LoA price calculation for 3 substances combined - As of 1st August 2022

Assumption: 6 SIEF members

Consortium Management (*)	Tonnage band	Budget	Above 1000 tons	100 -1000 tons	10 - 100 tons	1 - 10 tons
2009 budget - Consortium Management	All	€ 58.500	€ 14.625	€ 7.313	€ 7.313	€ 7.313
2010 budget - Consortium Management	All	€ 54.900	€ 13.725	€ 6.863	€ 6.863	€ 6.863
2013 budget - Consortium Management	All	€ 14.000	€ 3.500	€ 1.750	€ 1.750	€ 1.750
2014 budget - Consortium Management	All	€ 8.000	€ 2.000	€ 1.000	€ 1.000	€ 1.000
2015 budget - Consortium Management	All	€ 22.000	€ 5.500	€ 2.750	€ 2.750	€ 2.750
2016 budget - Consortium Management	All	€ 8.000	€ 2.000	€ 1.000	€ 1.000	€ 1.000
2017 budget - Consortium Management	All	€ 8.000	€ 2.000	€ 1.000	€ 1.000	€ 1.000
2018 budget - Consortium Management	All	€ 8.000	€ 2.000	€ 1.000	€ 1.000	€ 1.000
2019 budget - Consortium Management	All	€ 11.000	€ 2.750	€ 1.375	€ 1.375	€ 1.375
2020 budget - Consortium Management	All	€ 11.000	€ 2.750	€ 1.375	€ 1.375	€ 1.375
2021 budget - Consortium Management	All	€ 11.000	€ 2.750	€ 1.375	€ 1.375	€ 1.375
2022 budget - Consortium Management	All	€ 20.000	€ 5.000	€ 2.500	€ 2.500	€ 2.500
2023 budget - Consortium Management	All	€ 12.000	€ 3.000	€ 1.500	€ 1.500	€ 1.500
2024 budget - Consortium Management	All	€ 12.000	€ 3.000	€ 1.500	€ 1.500	€ 1.500
2025 budget - Consortium Management	All	€ 15.000	€ 3.750	€ 1.875	€ 1.875	€ 1.875
TOTAL - Consortium Management		**€ 273.400**	**€ 68.350**	**€ 34.175**	**€ 34.175**	**€ 34.175**
Dossier Preparation	**Tonnage band**	**Budget**	**Above 1000 tons**	**100 -1000 tons**	**10 - 100 tons**	**1 - 10 tons**
2009 - Data collection and read-across	All	€ 8.100	€ 1.350	€ 1.350	€ 1.350	€ 1.350
2009 - Robust study summaries in IUCLID 5	All	€ 14.900	€ 2.483	€ 2.483	€ 2.483	€ 2.483
2009 - Klimisch rating	*All (**)*	€ -	€ -	€ -	€ -	€ -
2009 - Toxicological studies : Local Lymph Node Assay (LLNA) in mice OECD 429 & Flash point EU A9	*All (**)*	€ -	€ -	€ -	€ -	€ -
2009 - Toxicological studies : Acute skin irritation study in the rabbit OECD 404 & Acute eye irritation study in the rabbit OECD 405 & Acute dermal toxicity study in the rat OECD 402	*All (**)*	€ -	€ -	€ -	€ -	€ -
TOTAL - 2009		**€ 23.000**	**€ 3.833**	**€ 3.833**	**€ 3.833**	**€ 3.833**

Gluconic Acid REACH Consortium : LoA price calculation for 3 substances combined - As of 1st August 2022

Assumption: 6 SIEF members

Dossier Preparation	Tonnage band	Budget	Above 1000 tons	100 -1000 tons	10 - 100 tons	1 - 10 tons
2010 - Endpoint summary records in IUCLID 5/hazard assessment	All	€ 12.100	€ 2.017	€ 2.017	€ 2.017	€ 2.017
2010 - CSR incl. PBT assessment/testing proposal	10 t	€ 8.400	€ 2.100	€ 2.100	€ 2.100	-
2010 - Testing (autoflammability)	*All (**)*	€ -	€ -	€ -	€ -	€ -
2010 - Testing (oxygen inhibition by activated sludge)	*10 t <(**)*	€ -	€ -	€ -	€ -	€ -
2010 - Translation of Düsseldorf University (toxicokinetics)	10 t <	€ 1.500	€ 375	€ 375	€ 375	-
2010 - Licensing of studies (acute oral toxicity in rats)	*10 t <(**)*	€ -	€ -	€ -	€ -	€ -
2010 - Licensing of studies (6 months oral toxicity in rats)	*10 t <(**)*	€ -	€ -	€ -	€ -	€ -
2010 - Internal existing data (see Appendix 3 - Data sheet)	*All (**)*	€ -	€ -	€ -	€ -	€ -
2010 - Internal existing data (see Appendix 3 - Data sheet: IUCLID 6.1.1)	*10 t <(**)*	€ -	€ -	€ -	€ -	€ -
2010 - Expenses	All	€ 500	€ 83	€ 83	€ 83	€ 83
TOTAL - 2010		**€ 22.500**	**€ 4.575**	**€ 4.575**	**€ 4.575**	**€ 2.100**
2013 - Permission to refer to studies "The effect of ether anesthesia on cerebral glucose metabolism"	10 t <	€ 325	€ 81	€ 81	€ 81	-
2013 - Compliance decision check : update of dossier	10 t <	€ 4.500	€ 1.125	€ 1.125	€ 1.125	-
2013 - Transfer of dossier in IUCLID 5.4	All	€ 2.500	€ 417	€ 417	€ 417	€ 417
2013 - Budget increase (Consultancy for compliance check)	10 t <	€ 1.000	€ 250	€ 250	€ 250	-
2013 - Budget increase (Consultancy for compliance check)	10 t <	€ 1.850	€ 463	€ 463	€ 463	-
TOTAL - 2013		**€ 10.175**	**€ 2.335**	**€ 2.335**	**€ 2.335**	**€ 417**
Dossier Preparation	**Tonnage band**	**Budget**	**Above 1000 tons**	**100 -1000 tons**	**10 - 100 tons**	**1 - 10 tons**
2015 - Toxicological studies: Mutagenicity studies (Ames, MLA/TK and metaphase analysis) - Incl. additional budget of EUR 1.250 adopted in October 2015.	10 t <	€ 26.340	€ 6.585	€ 6.585	€ 6.585	-
2015 - Toxicological studies: Mutagenicity test on bacteria (OCDE 471)	All	€ 5.040	€ 840	€ 840	€ 840	€ 840
2015 - Toxicological studies: Chromosomes aberrations in vitro human lymphocyte metaphase analysis (OCDE 473)	10 t <	€ 31.960	€ 7.990	€ 7.990	€ 7.990	-
2015 - Toxicological studies: Mutation assay at TK locus in L5178Y mouse lymphoma cells (OCDE 476)	10 t <	€ 21.180	€ 5.295	€ 5.295	€ 5.295	-

Gluconic Acid REACH Consortium : LoA price calculation for 3 substances combined - As of 1st August 2022						
Assumption: 6 SIEF members						
2015 - Toxicological studies: Scientific data entry on IUCID for 3 studies (adopted in Dec 2015)	All	€ 720	€ 120	€ 120	€ 120	€ 120
2015 - Dossier update: include new studies into 3 registration dossiers, update dossiers for submission (adopted in Dec 2015)	All	€ 5.000	€ 833	€ 833	€ 833	€ 833
TOTAL - 2015		**€ 90.240**	**€ 21.663**	**€ 21.663**	**€ 21.663**	**€ 1.793**
Dossier Preparation	**Tonnage band**	**Budget**	**Above 1000 tons**	**100 -1000 tons**	**10 - 100 tons**	**1 - 10 tons**
2020 - Dossier update (vote March 2019)	All	€ 10.000	€ 1.667	€ 1.667	€ 1.667	€ 1.667
TOTAL - 2020		**€ 10.000**	**€ 1.667**	**€ 1.667**	**€ 1.667**	**€ 1.667**
Dossier Preparation	**Tonnage band**	**Budget**	**Above 1000 tons**	**100 -1000 tons**	**10 - 100 tons**	**1 - 10 tons**
2023 - Dossier update (vote June 2023)	All	€ 20.000	€ 3.333	€ 3.333	€ 3.333	€ 3.333
TOTAL - 2023		**€ 20.000**	**€ 3.333**	**€ 3.333**	**€ 3.333**	**€ 3.333**
TOTAL - CONSORTIUM MANAGEMENT AND DOSSIER PREPARATION		**€ 449.315**	**€ 105.757**	**€ 71.582**	**€ 71.582**	**€ 47.318**
ADMIN COST (15%)			€ 15.864	€ 10.737	€ 10.737	€ 7.098
TOTAL WITH ADMIN COST			€ 121.621	€ 82.319	€ 82.319	€ 54.416
Handling Fee			€ 1.000	€ 1.000	€ 1.000	€ 1.000
TOTAL LOA PRICE			**€ 122.621**	**€ 83.319**	**€ 83.319**	**€ 55.416**

(*) Administrative cost is divided proportionally, i.e. joint registrants that are above 1000t for all substances combined pay 2 administrative cost shares, the others 1 each.
(**) As of 1st August 2022.

REACH:

- 7th SIEF Communication Gluconic Acid – 29 May 2018 - Extension of SIEF Agreement

- **Glucono-delta-lactone; CAS 90-80-2; EINECS 202-016-5**
- **Gluconic acid; CAS 526-95-4; EINECS 208-401-4**
- **Potassium gluconate; CAS 299-27-4; EINECS 206-074-2**

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May 29, 2018

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TO WHOM IT MAY CONCERN

BY E-MAIL

Dear SIEF Members and Joint Registrants,

Re: REACH: 7th SIEF Communication – Gluconic Acid and its Derivatives REACH Consortium – Extension of SIEF Agreement

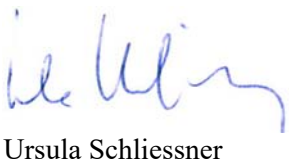
On behalf of the Lead Registrant Jungbunzlauer SA of the following three substances,

- Glucono-Delta-Lactone: EC 202-016-5; CAS 90-80-2;
- Gluconic Acid: EC 208-401-4; CAS 526-95-4; and
- Potassium Gluconate: EC 206-074-2; CAS 299-27-4,

we hereby wish to notify you that Jungbunzlauer S.A. has decided to extend the validity of the SIEF Agreement (available on www.jonesdayreach.com) for an indefinite period of time. It shall continue to apply to any, including future, activities in relation to the joint registration of the three substances. It would otherwise expire on June 1, 2018.

We trust that you agree with this approach unless we receive your reasoned objections by June 15, 2018.

Kind regards,



Ursula Schliessner

REACH:

- 6th SIEF Communication Gluconic Acid – 8 June 2016 (incl. revised Appendix 3: LoA Calculation)

- **Glucono-delta-lactone; CAS 90-80-2; EINECS 202-016-5**
- **Gluconic acid; CAS 526-95-4; EINECS 208-401-4**
- **Potassium gluconate; CAS 299-27-4; EINECS 206-074-2**

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June 8, 2016

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TO WHOM IT MAY CONCERN

BY E-MAIL

Dear SIEF Members,

Re: REACH: 6th SIEF Communication

We have proceeded to a re-calculation of the LoA prices to take into account work conducted since 2010, please see attached.

Sincerely,

Ursula Schliessner

Enclosure (1)
- Appendix 3 (revised)

Gluconic Acid REACH Consortium : LoA price calculation for 3 substances combined							APPENDIX 3
Assumption : 3 SIEF members (2 members above 1000 tons plus 1 below 1000 tons)							
Consortium Management	**Tonnage band**	**Budget**	**Above 1000 tons**	**100 -1000 tons**	**10 - 100 tons**	**1 - 10 tons**	
2009 budget - Consortium Management	All	€ 58,500	€ 23,400	€ 11,700	€ 11,700	€ 11,700	
2010 budget - Consortium Management	All	€ 54,900	€ 21,960	€ 10,980	€ 10,980	€ 10,980	
2013 budget - Consortium Management	All	€ 14,000	€ 5,600	€ 2,800	€ 2,800	€ 2,800	
2014 budget - Consortium Management	All	€ 8,000	€ 3,200	€ 1,600	€ 1,600	€ 1,600	
2015 budget - Consortium Management	All	€ 22,000	€ 8,800	€ 4,400	€ 4,400	€ 4,400	
2016 budget - Consortium Management	All	€ 8,000	€ 3,200	€ 1,600	€ 1,600	€ 1,600	
2017 budget - Consortium Management	All	€ 8,000	€ 3,200	€ 1,600	€ 1,600	€ 1,600	
2018 budget - Consortium Management	All	€ 8,000	€ 3,200	€ 1,600	€ 1,600	€ 1,600	
TOTAL - Consortium Management		**€ 181,400**	**€ 72,560**	**€ 36,280**	**€ 36,280**	**€ 36,280**	
Dossier Preparation	**Tonnage band**	**Budget**	**Above 1000 tons**	**100 -1000 tons**	**10 - 100 tons**	**1 - 10 tons**	
2009 - Data collection and read-across	All	€ 8,100	€ 2,700	€ 2,700	€ 2,700	€ 2,700	
2009 - Robust study summaries in IUCLID 5	All	€ 14,900	€ 4,967	€ 4,967	€ 4,967	€ 4,967	
2009 - Klimisch rating	All	€ 600	€ 200	€ 200	€ 200	€ 200	
2009 - Toxicological studies : Local Lymph Node Assay (LLNA) in mice OECD 429 & Flash point EU A9	All	€ 3,417	€ 1,139	€ 1,139	€ 1,139	€ 1,139	
2009 - Toxicological studies : Acute skin irritation study in the rabbit OECD 404 & Acute eye irritation study in the rabbit OECD 405 & Acute dermal toxicity study in the rat OECD 402	All	€ 3,075	€ 1,025	€ 1,025	€ 1,025	€ 1,025	
TOTAL - 2009		**€ 30,092**	**€ 10,031**	**€ 10,031**	**€ 10,031**	**€ 10,031**	

Dossier Preparation	Tonnage band	Budget	Above 1000 tons	100 -1000 tons	10 - 100 tons	1 - 10 tons
2010 - Endpoint summary records in IUCLID 5/hazard assessment	All	€ 12,100	€ 4,033	€ 4,033	€ 4,033	€ 4,033
2010 - CSR incl. PBT assessment/testing proposal	10 t <	€ 8,400	€ 2,800	€ 2,800	€ 2,800	-
2010 - Testing (autoflammability)	All	€ 2,525	€ 842	€ 842	€ 842	€ 842
2010 - Testing (oxygen inhibition by activated sludge)	10 t <	€ 1,743	€ 581	€ 581	€ 581	-
2010 - Translation of Düsseldorf University (toxicokinetics)	10 t <	€ 1,500	€ 500	€ 500	€ 500	-
2010 - Licensing of studies (acute oral toxicity in rats)	10 t <	€ 500	€ 167	€ 167	€ 167	-
2010 - Licensing of studies (6 months oral toxicity in rats)	10 t <	€ 44,500	€ 14,833	€ 14,833	€ 14,833	-
2010 - Internal existing data (see Appendix 3 - Data sheet)	All	€ 32,550	€ 10,850	€ 10,850	€ 10,850	€ 10,850
2010 - Internal existing data (see Appendix 3 - Data sheet: IUCLID 6.1.1)	10 t <	€ 6,700	€ 2,233	€ 2,233	€ 2,233	-
2010 - Expenses	All	€ 500	€ 167	€ 167	€ 167	€ 167
TOTAL - 2010		**€ 111,018**	**€ 37,006**	**€ 37,006**	**€ 37,006**	**€ 15,892**
2013 - Permission to refer to studies "The effect of ether anesthesia on cerebral glucose metabolism"	10 t <	€ 325	€ 108	€ 108	€ 108	-
2013 - Compliance decision check : update of dossier	10 t <	€ 4,500	€ 1,500	€ 1,500	€ 1,500	-
2013 - Transfer of dossier in IUCLID 5.4	All	€ 2,500	€ 833	€ 833	€ 833	€ 833
2013 - Budget increase (Consultancy for compliance check)	10 t <	€ 1,000	€ 333	€ 333	€ 333	-
2013 - Budget increase (Consultancy for compliance check)	10 t <	€ 1,850	€ 617	€ 617	€ 617	-
TOTAL - 2013		**€ 10,175**	**€ 3,392**	**€ 3,392**	**€ 3,392**	**€ 833**

Dossier Preparation	Tonnage band	Budget	Above 1000 tons	100 -1000 tons	10 - 100 tons	1 - 10 tons
2015 - Toxicological studies: Mutagenicity studies (Ames, MLA/TK and metaphase analysis) - Incl. additional budget of EUR 1.250 adopted in October 2015.	10 t <	€ 26,340	€ 8,780	€ 8,780	€ 8,780	-
2015 - Toxicological studies: Mutagenicity test on bacteria (OCDE 471)	All	€ 5,040	€ 1,680	€ 1,680	€ 1,680	€ 1,680
2015 - Toxicological studies: Chromosomes aberrations in vitro human lymphocyte metaphase analysis (OCDE 473)	10 t <	€ 31,960	€ 10,653	€ 10,653	€ 10,653	-
2015 - Toxicological studies: Mutation assay at TK locus in L5178Y mouse lymphoma cells (OCDE 476)	10 t <	€ 21,180	€ 7,060	€ 7,060	€ 7,060	-
2015 - Toxicological studies: Scientific data entry on IUCID for 3 studies (adopted in Dec 2015)	All	€ 720	€ 240	€ 240	€ 240	€ 240
2015 - Dossier update: include new studies into 3 registration dossiers, update dossiers for submission (adopted in Dec 2015)	All	€ 5,000	€ 1,667	€ 1,667	€ 1,667	€ 1,667
TOTAL - 2015		**€ 90,240**	**€ 30,080**	**€ 30,080**	**€ 30,080**	**€ 3,587**
TOTAL - CONSORTIUM MANAGEMENT AND DOSSIER PREPARATION		**€ 422,925**	**€ 153,068**	**€ 116,788**	**€ 116,788**	**€ 66,622**
ADMIN COST (15%)			€ 22,960	€ 17,518	€ 17,518	€ 9,993
TOTAL WITH ADMIN COST			€ 176,029	€ 134,307	€ 134,307	€ 76,616
Handling Fee			€ 1,000	€ 1,000	€ 1,000	€ 1,000
TOTAL LOA PRICE			**€ 177,029**	**€ 135,307**	**€ 135,307**	**€ 77,616**

GLUCONIC ACID AND ITS DERIVATIVES REACH CONSORTIUM – Appendix 3 to 6th SIEF Communication

2. Internal Existing Data (Revised valuation sheet: Corrected August 26, 2013 & May 30, 2016)

IUCLID	Endpoint	Owner	Year	Study Endpoint	Cantox Rating	File name	study status	Substance	Letter of Access	Comments, Source of cost study	Study cost (Euro)
4.1	Physical State	JUNGBUNZLAUER S.A. (also available from ROQUETTE Frères)	2009	Physical State	2	MSDS GA.pdf	key study	Gluconic acid	Not required	common proposal by IES	**50 €**
4.1	Physical State	JUNGBUNZLAUER S.A. (also available from ROQUETTE Frères)	2009	Physical State	2	^End-p7.14 Annex 3^eml 091112	key study	GDL	Not required	common proposal by IES	**50 €**
4.1	Physical State	JUNGBUNZLAUER S.A. (also available from ROQUETTE Frères)	2003	Physical State	2	MSDS GdL.pdf	supportive	GDL	Not required	common proposal by IES	**50 €**
4.1	Physical State	JUNGBUNZLAUER S.A. (also available from ROQUETTE Frères)	2004	Physical State	2	MSDS PG.pdf	key study	PG	Not required	common proposal by IES	**50 €**
4.12	Auto flammability	JUNGBUNZLAUER S.A.	1998	Self-Ignition Temperature	2	Caractérisation de l'inflammabilité et de l'explosibilité de poussières de Gluco Delta Lactone.pdf	supportive	GDL	Not required	VCI	**1,300 €**
4.12	Auto flammability	ROQUETTE Frères~~JUNGBUNZLAUER S.A.~~	2005	Self-Ignition Temperature	2	INERIS.pdf	key study	GDL	Not required	VCI	**1,300 €**
4.14	Explosiveness	JUNGBUNZLAUER S.A.	1998	Explosion	2	Caractérisation de l'inflammabilité et de l'explosibilité de poussières de Gluco Delta Lactone.pdf	supportive	GDL	Not required	VCI	**2,800 €**
4.14	Explosiveness	ROQUETTE Frères~~JUNGBUNZLAUER S.A.~~	2005	Explosion	2	INERIS.pdf	supportive	GDL	Not required	VCI	**2,800 €**
4.19	Thermal stability	ROQUETTE Frères	2005	Thermal stability	2	INERIS.pdf	key study	GDL	Not required	common proposal by	**250 €**

IUCLID	Endpoint	Owner	Year	Study Endpoint	Cantox Rating	File name	study status	Substance	Letter of Access	Comments, Source of cost study	Study cost (Euro)
										IES	
4.19	Thermal stability	JUNGBUNZLAUER S.A.	1998	Thermal stability	2	Caractérisation de l'inflammabilité et de l'explosibilité de poussières de Gluco Delta Lactone.pdf	supportive	GDL	Not required	common proposal by IES	**250 €**
4.19	Thermal stability	JUNGBUNZLAUER GmbH	2008	Thermal stability	2	DSC_Jungbunzlauer.pdf	supportive	GDL	Not required	common proposal by IES	**250 €**
5.2.1	Biodegradation in water	~~JUNGBUNZLAUER S.A.~~ HPV Consortium = JB 12 (JUNGBUNZLAUER S.A.)	2001	Aerobic biodegradation	1	ECOTOX_04	key study	Sodium Gluconate	Not required	VCI	**3,600 €**
5.2.1	Biodegradation in water	~~JUNGBUNZLAUER S.A.~~ HPV Consortium = JB 13 (JUNGBUNZLAUER S.A.)	2001	Anaerobic biodegradation	1	ECOTOX_06	supportive	Sodium Gluconate	Not required	VCI	**3,500 €**
5.2.1	Biodegradation in water	Public : Z. Wasser Abwasser Forsch	1981		2		supportive	Metal-gluconates	Not required	public domain	**0 €**
6.1.1	Short-term toxicity to fish (*)	JUNGBUNZLAUER GmbH	1992	Acute toxicity to fish	3	ECOTOX_14	key study	Sodium Gluconate	Not required	VCI	**3,200 €**
6.1.1	Short-term toxicity to fish (*)	HPV Consortium = F 13 (Fujisawa Pharmaceutical Co., Ltd/Roquette)	2002	Acute toxicity to fish	1	ECOTOX_13	key study	Sodium Gluconate	Not required	VCI	**3,500 €**
6.1.3	Short-term toxicity to aquatic invertebrates (**)	JUNGBUNZLAUER GmbH	1997	Acute toxicity to Invertebrates	3	ECOTOX_15	unsuitable	GDL	Not required	VCI	**2,800 €**
6.1.3	Short-term toxicity to aquatic invertebrates	~~JUNGBUNZLAUER S.A.~~ HPV Consortium = JB 11 (JUNGBUNZLAUER S.A.)	2001	Acute toxicity to Invertebrates	2	ECOTOX_11	key study	Sodium Gluconate	Not required	VCI	**2,800 €**
6.1.5	Toxicity to aquatic algae and	JUNGBUNZLAUER GmbH	1997	Acute toxicity to plants	3	ECOTOX_15	supportive	GDL	Not required	VCI	**4,500 €**

IUCLID	Endpoint	Owner	Year	Study Endpoint	Cantox Rating	File name	study status	Substance	Letter of Access	Comments, Source of cost study	Study cost (Euro)
	cyanobacteria										
6.1.5	Toxicity to aquatic algae and cyanobacteria	~~JUNGBUNZLAUER S.A.~~ HPV Consortium = JB 10 (JUNGBUNZLAUER S.A.)	2001	Acute toxicity to plants	2	ECOTOX_09	key study	Sodium Gluconate	Not required	VCI	**4,500 €**
6.1.7	Toxicity to microorganisms	JUNGBUNZLAUER GmbH	1992	Acute toxicity to micro-organisms	3	ECOTOX_14	supportive	GDL	Not required	VCI	**1,700 €**
7.6.1.	Genetic toxicity in vitro	U.S. Food and Drug Administration	1974	Genetic toxicity in vitro	3	IN_VITRO_TOX_02	unsuitable	GDL	Not required	public domain	**0 €**
7.6.1.	Genetic toxicity in vitro	U.S. Food and Drug Administration	1974	Genetic toxicity in vitro	3	IN_VITRO_TOX_02	unsuitable	GDL	Not required	public domain	**0 €**
7.8.2	Developmental toxicity/teratogenicity	Food & Drug Research Laboratories	1973	Developmental toxicity/Teratogenicity (mice)	2	TERATO_STUDIES_02	key study	GDL	Not required	public domain	**0 €**
7.8.2	Developmental toxicity/teratogenicity	Food & Drug Research Laboratories	1973	Developmental toxicity/Teratogenicity (rat)	2	TERATO_STUDIES_02	key study	GDL	Not required	public domain	**0 €**
7.8.2	Developmental toxicity/teratogenicity	Food & Drug Research Laboratories	1973	Developmental toxicity/Teratogenicity (hamster)	2	TERATO_STUDIES_02	supportive	GDL	Not required	public domain	**0 €**
7.8.2	Developmental toxicity/teratogenicity	Food & Drug Research Laboratories	1973	Developmental toxicity/Teratogenicity (rabbit)	2	TERATO_STUDIES_02	supportive	GDL	Not required	public domain	**0 €**
7.10.3	Direct observations	Public	1962	Other (exposure experience)	2	OTHER_03	Not a required endpoint	PG	Not required	public domain	**0 €**
7.12	Additional toxicological information	Public : The Journal of Laboratory and Clinical Medicine Vol 26	1941	Repeated dose toxicity (cats)	2	OTHER_07	Not a required endpoint	GDL	Not required	public domain	**0 €**

IUCLID	Endpoint	Owner	Year	Study Endpoint	Cantox Rating	File name	study status	Substance	Letter of Access	Comments, Source of cost study	Study cost (Euro)
7.12	Additional toxicological information	Public: Journal of Nutrition. 1943. Volume 26: 309-317	1943		2	OTHER_04	Not a required endpoint	GDL	Not required	public domain	**0 €**
7.12	Additional toxicological information	Public: Journal of the American Medical Association. 1967. 199(3): 215-217	1967	Intestinal toxicity (dog)	2	OTHER_02	Not a required endpoint	PG	Not required	public domain	**0 €**
											39,250 €

(*) The studies apply across all tonnage bands, except 6.1.1. which applies only above 10 tons.

(**) Used as supporting for GDL only

REACH:

- 5th SIEF Communication Gluconic Acid - 12 October 2010 (incl. revised valuation sheet August 2013)

- **Glucono-delta-lactone; CAS 90-80-2; EINECS 202-016-5**
- **Gluconic acid; CAS 526-95-4; EINECS 208-401-4**
- **Potassium gluconate; CAS 299-27-4; EINECS 206-074-2**

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URSULA SCHLIESSNER
(32-2) 278-1224

EMAIL ADDRESS
uschliessner@mckennalong.com

October 12, 2010

BY ELECTRONIC MAIL

TO WHOM IT MAY CONCERN

Re: REACH: 5th SIEF Communication

- **Glucono-delta-lactone CAS 90-80-2 EINECS 202-016-5**
- **Gluconic acid CAS 526-95-4 EINECS 208-401-4**
- **Potassium gluconate CAS 299-27-4 EINECS 206-074-2**

Dear SIEF Member:

McKenna Long & Aldridge LLP act as Manager of the Gluconic Acid and its Derivatives REACH Consortium (the 'Consortium'). We refer to the earlier SIEF communications issued by the Lead Registrant Jungbunzlauer, in particular the last SIEF communication of June 10, 2010 (a copy of which is herewith attached again as **Appendix 1**) and are pleased to inform you that the joint registration dossier including CSR has been successfully filed and accepted by ECHA.

Set out below is critical information about the next steps to be taken by SIEF members.

1) Joint Registration Dossier - Inspection Period

The final joint registration dossier will be made available for inspection at the offices of McKenna Long & Aldridge LLP during office hours **between 13 October to 27 October 2010, upon appointment taken at least 48 hours in advance.**

IUCLID Chapters 4-7 will be made available in html format to co-registrants upon request after 4) below has been completed.

2) CSR

The CSR was prepared jointly and was submitted jointly (see ECHA Data Submission Manual.[1]) A copy of the CSR will be provided to interested SIEF members simultaneously with the joint submission name and token upon their request. Guidance on safe use has not been prepared by the Lead Registrant for joint submission.

[1] http://echa.europa.eu/doc/reachit/dsm_19_how_joint_csr_en.pdf

3) SIEF Agreement

We ask that those SIEF members that wish to participate in joint registration sign and return to us by e-mail the signature page of the SIEF Agreement that was posted by Jungbunzlauer to the SIEF in October 2009, a copy of which is again attached hereto (**Appendix 2**).

4) Participation in Joint Submission - Letters of Access

We would further kindly ask those SIEF members who wish to participate in joint submission to fill in a letter of access (LoA) application at www.mlalaw.eu. An on-line tool will guide you through the procedure and payment requirements. For your information, the price for an LoA for all three substances together (1,000 tons) will be €145,618 (excl. VAT where applicable) (**Appendix 3**). The LoA price has been calculated on the basis of 2 SIEF members requiring 2010 registration, as no other SIEF member other than the two Consortium members have indicated their interest for 2010 registration. Reimbursements if any will be made for the first time after the 2013 registration deadline has passed. **Companies (including their Affiliates) that have a combined annual tonnage (all three substances together) of less than 1000t will receive a 50% rebate of the line item "Consortium Management". Only those companies that have combined less than 1000t should tick one of the "less than 1000t" boxes in their on-line LoA application form.** Once your LoA application has been duly accepted and payment has been made, you shall automatically receive the joint submission token to file the individual parts of your registration dossiers. **Participation in joint submission is conditional upon completing the procedure and obtaining the LoA at** www.mlalaw.eu.

Thank you very much for your attention.

Kind regards,

Ursula Schliessner
Partner
McKenna Long & Aldridge LLP

3 Appendices

Appendix 1 : SIEF Communication of June 10, 2010

MEMO **Jungbunzlauer**

TO:	GLUCONIC SIEF MEMBERS
CC:	
FROM:	LEAD REGISTRANT
DATE:	10/06/2010
SUBJECT:	SIEF COMMUNICATION REGISTRATION

Re: Fourth SIEF Communication

- **Glucono-delta-lactone CAS 90-80-2 EINECS 202-016-5**
- **Gluconic acid CAS 526-95-4 EINECS 208-401-4**
- **Potassium gluconate CAS 299-27-4 EINECS 206-074-2**

Dear SIEF Members,

Further to our first SIEF communication of February 11, 2009, we are pleased to report that the REACH joint registration dossiers for the three substances above are nearing finalization and that Jungbunzlauer SA as Lead Registrant is currently intending to file them with ECHA during week 24 of 2010 (week of June 14, 2010).

Please note the following items of information:

1) SIEF Agreement

The SIEF Agreement was posted in the three SIEFs on October 1, 2009 and we have not received any objections. It is thus valid. The SIEFs were informed December 7, 2009 that the SIEF agreement has been endorsed.

2) Classification & Labelling

According to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (REACH):

- Based on the available data and the current CLP criteria, Gluconic Acid is not classified as hazardous.
- Based on the available data and the current CLP criteria, D-glucono-1,5-lactone is not classified as hazardous.
- Based on the available data and the current CLP criteria, Potassium Gluconate is not classified as hazardous.

The same applies as regards Directive 67/548 classification & labelling, not “dangerous”.

3) **DNELs and PNECs**

a) ***Gluconic Acid***

- Final DNELs
  Worker – Inhalation = 59 mg/m3
  Worker – Dermal = 11.9 mg/kg/d

- Final DNELs
  General Population – Inhalation = 14.6 mg/m3
  General Population – Oral&Dermal = 5.9 mg/kg/d

- PNEC Summary:

PNEC aqua (freshwater) in mg/L	0.1
PNEC aqua (marine waters) in mg/L	0.01
PNEC aqua (intermittent releases) in mg/L	1
PNEC STP in mg/L	6.498
PNEC sediment in mg/kg sediment dw	0.36
PNEC marine-sediment in mg/kg sediment dw	0.36
PNEC soil in mg/kg sediment dw	0.0135
PNEC oral in mg/kg food	N/A

b) ***D-glucono 1,5 Lactone***

- Final DNELs
  Worker – Inhalation = 59 mg/m3
  Worker – Dermal = 11.9 mg/kg/d

- Final DNELs
  General Population – Inhalation = 14.6 mg/m3
  General Population – Oral& Dermal = 5.9 mg/kg/d

- PNEC Summary:

PNEC aqua (freshwater) in mg/L	0.1
PNEC aqua (marine waters) in mg/L	0.01
PNEC aqua (intermittent releases) in mg/L	1
PNEC STP in mg/L	6.498
PNEC sediment in mg/kg sediment dw	0.36
PNEC marine-sediment in mg/kg sediment dw	0.36
PNEC soil in mg/kg sediment dw	0.014
PNEC oral in mg/kg food	N/A

c) *Potassium Gluconate*

- Final DNELs
  Worker – Inhalation = 59 mg/m3
  Worker – Dermal = 11.9 mg/kg/d

- Final DNELs
  General Population – Inhalation = 14.6 mg/m3
  General Population – Oral& Dermal = 5.9 mg/kg/d

- PNEC Summary:

PNEC aqua (freshwater) in mg/L	0.1
PNEC aqua (marine waters) in mg/L	0.01
PNEC aqua (intermittent releases) in mg/L	1
PNEC STP in mg/L	6.498
PNEC sediment in mg/kg sediment dw	0.36
PNEC marine-sediment in mg/kg sediment dw	0.36
PNEC soil in mg/kg sediment dw	0.013
PNEC oral in mg/kg food	N/A

4) Price for Participation in Joint Submission (Letter of Access - LoA)

We refer to Section 4. (a), (b) and (c) of the SIEF Agreement: The cost for non-Consortium Members is the same as for Consortium Members plus an additional 15% administrative fee. The number of Consortium Members has not changed from the original two Members. Based on the expectation that only two SIEF members (including the existing Consortium Members) would require 2010 registration, the LoA cost is thus expected to be (pending confirmation) as follows:

(Production total of all 3 substances combined above 1000 t)

Management	€ 112,400
Dossier preparation	€ 54,100
New studies (plus translation) (Annex 2)	€ 11,875
Licensing cost exist. studies third parties	approx. € 60,000 (negotiations still ongoing)
Licensing cost exist. studies Consortium members (Annex 1)	€40,428
Subtotal	**€ 278,803**
Divided by 2 (=LoA price per SIEF member who would not be (co)owner of either new or existing studies)	**€ 139,401.50**
Administrative Fee 15%	€20,910
LoA issuance fee	€ 1,000
Total LoA value	**€ 161,312 (per LoA, 2 SIEF members)**

If a total of three SIEF members (including Consortium Members) will participate in joint registration, the division factor should be "3", and thus price for the LoA per individual registrant will be reduced.

For LoAs for below 1000 t for all three substances combined, the management cost factor will be calculated at 50%, all other cost factors remain the same.

In order to come to an exact estimate of number of SIEF members interested in registration and thus an exact LoA price, may we ask you again to respond back to us by June 22, 2010 on your registration intentions. Please let us know whether you require 2010 registration of one or all of the above substances.

Unless we hear from you, we shall assume that no 2010 registration will be needed and shall use the above division factor of 2 to calculate the LoA price.

We will communicate again at the beginning of July on the successful filing of the Lead Registrant dossier; the mechanics for applying for LoAs (issuance of joint submission token and payment) and the dossier inspection period and contact information.

Yours Sincerely,

Jungbunzlauer SA

Eric BULOT

Appendix 2: SIEF Agreement

SIEF AGREEMENT

Gluconic Acid and its Derivatives

1. Definitions

(a) *Affiliate* Any legal or natural person, which directly or indirectly through one or more intermediaries owns, controls, is controlled by, or is under common control with another legal person. For the purpose of this definition, a legal person shall be deemed to 'control' another legal person if it has the direct or indirect power to direct or cause the direction of the general management and policies of another legal person whether through the ownership of securities or capital stock, voting stock, by contract or otherwise. A legal person shall presumptively be deemed to control another legal person if it owns, directly or indirectly through one or more intermediaries and whether legally or beneficially fifty per cent (50%) or more of the outstanding voting securities or capital stock or other comparable equity or ownership interest of such legal person. Only Affiliates subject to REACH registration of the Substances and that are members of the respective SIEFs have the rights of Affiliates for purposes of this SIEF Agreement.

(b) *Consortium* shall mean the Gluconic Acid and its Derivatives Consortium, to which Jungbunzlauer SA is a member.

(c) *Information* means all studies, other scientific, statistical, or technical information or data, including but not limited to composition, characteristics, properties, processes and applications, and any other information in whatever form made available by a Party or generated by the Parties jointly, pursuant to or within the remit of this SIEF Agreement.

(d) *LoA* shall mean a letter of access to the Registration dossier(s) granted by the Consortium to individual Parties as applicable to them and as attached as Annex 1 to this SIEF Agreement. The LoA entitles the respective Party (and its Affiliates) on a non-exclusive basis to refer to the information submitted to ECHA by the Lead Registrant for purposes of REACH registration, but it does not grant any additional rights. In particular, it cannot be used or transferred or relied upon either for REACH or for any other purpose by or to other legal entities, including Affiliates of the Parties, unless those other legal entities would qualify for a free update of the original registration(s) pursuant to Article 5 (1) (c) of Commission Regulation (EC) No 340/2008 or are named in this SIEF Agreement.

(e) *Parties* shall mean the parties to this SIEF Agreement who have either signed this SIEF Agreement, or have not communicated to Jungbunzlauer SA their objection to it pursuant to 5.(k) and are not listed as 'dormant' pre-registrants in the REACH-IT system.

(f) *REACH* shall mean Regulation EC (No) 1907/2006 and all subsequent Regulations, Decisions, and other measures adopted in connection thereto.

(g) *Registration dossier(s)* means the joint mandatory (Article 10 (a) (i), (ii), (iii), (iv), (vi), (vii) (ix) REACH) and joint voluntary (Article 10 (a) (v), (vi), (b) REACH) parts of the REACH registration dossier(s) for the Substance(s).

(h) *Substance(s)* means the substances listed in 2.(a) of this SIEF Agreement.

(i) All other terms used herein shall have the same meaning as under REACH.

2. Scope

(a) This SIEF Agreement covers the substances

- Glucono-delta-lactone CAS 90-80-2; EINECS 202-016-5 (D-glucono-1,5-lactone) Molecular formula C6H1006
- Gluconic acid CAS 526-95-4; EINECS 208-401-4 (D-gluconic acid) Molecular formula C6H1207
- Potassium gluconate CAS 299-27-4 EINECS 206-074-2 Molecular formula C6H1207.K

as further identified below.

Component	**Concentration Range**	**Typical Concentration**
CAS 90-80-2	80-100%	99%-100,5%
CAS 526-95-4	80%-100% (on DS basis)	80%-100%
CAS 299-27-4	80%-100%	99%-101%

unless a Party expressly indicates that it shall be covered only with regard to specific Substance(s) in the signature line below, in which case this SIEF Agreement shall be considered applicable to that Party and its Affiliates only with regard to the specific Substances indicated.

The Parties have agreed in previous communications on the identity and sameness of the respective substance and are thus members of the same SIEF(s).

(b) This SIEF Agreement is applicable to all communications, actions and submissions made by the Parties individually or jointly within the scope of REACH in as far as these fall within the remit of SIEFs pursuant to Article 29 REACH.

(c) This SIEF Agreement is applicable to all members of the respective SIEFs (including the members of the Consortium) in as far as they are members of the respective SIEFs of the Substance(s). Consortium members are represented for purposes of this SIEF Agreement by the Lead Registrant.

3. General Rules of Cooperation

(a) The Parties agree that Jungbunzlauer SA or its legal successor or another SIEF member assigned by it pursuant to 5. (f) below will act as Lead Registrant for the Substances and will prepare, within the framework of the Consortium, the Registration dossier(s) of the REACH registration dossiers for the Substances as and in as far as required, and make requests pursuant to Article 19 (a) (xi) REACH as deemed necessary. Upon demand of ECHA, within the requested deadline and to the extent necessary, the Lead Registrant also agrees to complete the Registration dossier(s). Parties that are not members of the Consortium will participate in the joint registration efforts via LoA.

(b) The Registration dossiers will be prepared in time so that all Parties can meet the November 30, 2010 registration deadline, except for Potassium Gluconate, for which the Lead Registrant will submit in time for the May 31, 2013 registration deadline. However, the Potassium Gluconate Registration dossier shall also already be finalized as far as possible in 2010.

(c) In view of the tight work schedule, the Parties agree that the Lead Registrant will use its best efforts to develop the Registration dossiers within the Consortium, and they acknowledge that he has engaged a reputable technical consultant to assist him in its efforts. Parties will therefore not object or call into question the Registration dossiers so prepared in as far as applicable to them, and Parties hereby agree to the Registration dossier(s) as developed by the Lead Registrant within the Consortium.

(d) The Lead Registrant undertakes in turn to regularly update the Parties in writing on the progress made on the Registration dossier(s) as applicable to the Parties. He may ask for cooperation and comments as he sees fit.

(e) The Registration dossiers shall cover a list of common non-confidential uses as appropriate should the Substances meet the criteria for classification as dangerous , to be agreed by the Parties in as far as applicable to them by December 31, 2009. To this extent and where necessary, the Lead Registrant shall communicate a preliminary list of non-confidential uses to the Parties by November 30, 2009. If no comments or additions are received by the Lead Registrant or his appointed Trustee (McKenna Long & Aldridge LLP) by December 31, 2009, this list shall be considered as final. Parties joining the SIEFs after December 31, 2009 but before June 30, 2010 (respectively December 31, 2012 for Potassium Gluconate) have the right to make their uses known to the Lead Registrant within five days of joining the SIEFs. The Lead Registrant shall integrate these new uses into the Registration dossier(s) provided the new-joining SIEF member carries separately the cost related thereto as determined by the Lead Registrant, unless at least one other Party is also interested in this new use, in which case the additional cost is shared among all Parties.

(f) Based on previous SIEF communications initiated by the Lead Registrant, it appears that no data is available within the SIEF except the data identified and gathered by the Consortium. In order to confirm this situation, the Lead Registrant shall be communicating to the Parties a list of data well in advance of the November 30, 2010 registration deadline. Parties may comment on this list or further supplement it within a month of such communication. If no comments or additions are received within that deadline, the data list shall be considered as final.

(g) Any opt-out chosen by a Party pursuant to Article 11 (3) REACH must be communicated to the Lead Registrant by June 30, 2010, unless a Party joins the SIEF(s) after that date, at which point it must be communicated within five working days after joining.

(h) The Lead Registrant shall pay the registration fee pursuant to Article 11 (4) REACH as invoiced by ECHA for the submission of the joint registration dossier(s) without undue delay.

(i) The Lead Registrant shall make the completed Registration dossier(s) available for inspection by the Parties during business hours at the offices of its Consortium Manager McKenna Long & Aldridge LLP from July 31,, 2010 to August 15, 2010. Any Party joining the SIEF(s) after the inspection period is entitled to inspect the Registration dossier(s) at the aforementioned premises after having taken an appointment.

(j) Provided the Party has fulfilled its payment obligations hereunder, the Lead Registrant shall immediately inform the Party of the creation of a 'joint submission object' in REACH-IT and shall provide the valid security token number and the name of the joint submission. The Lead Registrant shall also inform immediately the Parties of the submission of the Registration

dossier to ECHA and provide evidence of the same. The Lead Registrant shall further communicate the confirmation that the Registration dossier has been accepted as 'complete' and the registration number assigned pursuant to Article 20 (3) REACH.

4. Cost Sharing

(a) According to the Consortium Agreement, interested companies may join the Consortium at any time. Parties that are or will become members of the Consortium prior to the first registration deadline(s) individually applicable to them for registration of their Substance(s), shall participate in cost sharing as per the provisions of the Consortium Agreement. All other Parties shall participate in cost sharing as set out at (b) below and 3.(e) last sentence above.

(b) The price for the LoA(s) granted pursuant to 3. (a) above is the same as the cost for the Consortium members plus 15% processing cost. The Consortium currently estimates the **administration cost** for development of the three registration dossiers covered by the Consortium at a total of approximately € 150,000, excluding the costs (in particular legal and administrative costs) that may be necessary to obtain licenses for third party studies or any additional unexpected cost. The Consortium Agreement provides that all administration costs are shared equally regardless of tonnage band and number of substances to be registered except that Consortium members (including their Affiliates) that achieve the 1000t band or more of annual production of all three Substances combined pay a double share. This rule has been developed and is considered fair because the Substances are related, not all Substances are suggested to require exposure scenarios, and the Consortium is making every effort to using economies of scale, read-across etc. for the three Registration dossier(s).

Data cost is shared based on whether data is needed for a specific Substance or whether a Party claims opt-out per Article 11 (3) REACH. Hence, there may potentially be variations in cost per LoA depending on the data needed. The Consortium is in the process of obtaining licenses for the use of data and is therefore not yet in a position to fully estimate the data cost. Data cost will be communicated as soon as this is possible. Currently, the total data cost is estimated roughly at € 500,000 for the totality of the data.

Based on the above estimate and in view of the fact that the Consortium currently has two members, the price of an LoA would be estimated at a maximum of €50,000 plus 15% **(excluding data cost)** if only one other SIEF member (including potential Affiliates) (above 1000t combined) was to join the Registration dossiers for the three Substances. If a total of 10 SIEF members (for all three SIEFs) were to join the Registration dossiers, the LoAs to the Registration Dossiers for all three Substances would cost approx. €15,000 plus 15% (again excluding data cost).

(c) The Lead Registrant will calculate the price of the LoA by July 31, 2010 based on the expected number of Parties that will participate in the Registration dossiers and will instruct the members of the Consortium to issue an invoice on the calculated amount to be paid within 30 days of issuance. Should the number of registrants be lower or higher than expected, or should new studies have to be purchased or performed as deemed necessary by the Consortium or pursuant to ECHA's request, the Lead Registrant will cause the members of the Consortium to either issue additional invoices to be paid under the same terms or to issue credit notes for overpaid amounts as the case may be. No interest shall be applicable in either case on both sides. However, a Party that does not pay an invoice within the 30 days of issuance shall at no times be entitled to receive an LoA or its LoA shall be considered as revoked. Due to the administrative burden upon the Consortium and the unlikelihood of new market entrants, no reimbursements shall be made after May 31, 2013 regardless of the

number of additional registrants after that date unless the reimbursement per Party would be more than €2.000.

(d) The Lead Registrant will instruct the members of the Consortium to issue LoAs after receipt of a Party's payment and after Party has had the option to inspect the Registration dossier(s) as far as it is concerned by it pursuant to 3. (i).

(e) The Lead Registrant shall at all times account for the cost of the Registration dossier(s) and shall keep records thereof for the duration of this SIEF Agreement. Any Party shall have the right to have the accounts audited at its own cost upon prior notice of at least five working days.

5. Miscellaneous Provisions

(a) *Assignment* This SIEF Agreement is linked to the joint registration obligations of REACH and can therefore not be assigned or transferred by the Parties without prior approval of the Lead Registrant unless the assignee is an Affiliate or successor in law subject to REACH registration of the Substance(s), or is an Only Representative or Third Party Representative replacing a previous Only Representative or Third Party Representative of the same principal.

(b) *Communications* All communications within the framework of this SIEF Agreement shall be done by electronic mail and shall be considered valid upon receipt of an automatic confirmation of receipt received by the sender. The Lead Registrant shall install an email address or other electronic platform for communication within the SIEFs. Parties agree to regularly and proactively communicate within this platform provided, and to answer any information and communication requests of the Lead Registrant within five working days at the latest unless the Lead Registrant expressly provides a longer response time. Unless other contact details are indicated below, the contact details available in REACH-IT shall be used at all times. Parties shall at all times keep their REACH-IT contact details updated and functional. In case the REACH-IT contact details of a Party are not functional and no other valid and functional contact information has been provided below, the Lead Registrant shall be considered as released from any obligations under this SIEF Agreement.

(c) *Compliance* The Parties shall at all times comply with the applicable laws, including EC competition law.

(d) *Confidentiality and Non-Use* The Parties agree to (i) treat all Information as confidential and not disclose it to third parties, unless regulatory disclosure requirements are applicable. Each Party shall advise immediately the other Parties in writing of any disclosure or misuse by any Party or a third party of Information, as well as any request by competent authorities relating to disclosure of Information; Disclosure of Information as required for legal and/or regulatory purposes including for purposes of REACH shall only take place in a form reflecting the minimum information required to be disclosed. The Parties agree to (ii) use the Information only for purposes and as permitted hereunder; (iii) not to analyze, test or reverse engineer or have analyzed, tested or reverse engineered any samples, formulas, combination of formulas or any technical or scientific methodology, chemistry or know-how provided by any of the Parties for their components, formulations or processes; (iv) not to file any patent, utility model or design application based upon Information or samples; (v) to disclose Information to their employees, Affiliates, external experts and/or other consultants; and if the Party is an Only Representative or Third Party representative to the non-EU manufacturer or legal entity represented by the Third Party Representative, on a strictly need-to-know basis to the extent permitted and absolutely necessary hereunder. Each Party shall have in place policies and procedures to ensure compliance herewith and shall ensure that the aforementioned entities and persons also have such policies and procedures in place.

The confidentiality and non-disclosure obligations above shall not apply to Information for which the receiving Party can reasonably demonstrate that such Information (i) was known to

the receiving Party on a non-confidential basis prior to its disclosure pursuant to this SIEF Agreement; (ii) is publicly known at the time of disclosure or thereafter becomes publicly known without breach of the terms of this SIEF Agreement on the part of the receiving Party; (iii) becomes known to the receiving Party through disclosure by sources other than the disclosing Party, having a right to disclose such Information; (iv) was independently developed by the receiving Party without access to the disclosing Party's information, as evidenced by documentary records; (v) becomes subject to disclosure to governmental authorities with lawful authority to seek such Information.

Specific items of Information shall not fall within any exception merely because they are combined with more general Information falling within any exception. Likewise, any combination of specific items of Information shall not fall within any exception merely because the specific items fall within any exception, but only if the combination itself, and its principle of operation, fall within any exception.

The obligations on confidentiality and non-use shall remain in effect and shall survive the duration of this SIEF Agreement. In the event of non-compliance with the duties here above, Parties are entitled to exclude the breaching Party from any further cooperation hereunder by decision of an independent law firm appointed by the Lead Registrant upon recommendation of the Brussels Bar. The obligation to render compensation for damages in accordance with the applicable legal provisions shall remain unaffected.

(e) *Dispute resolution and applicable law* Any dispute hereunder that cannot be settled amicably shall be resolved by arbitration with a single arbitrator to be appointed by the Brussels Bar. The arbitration rules of the ICC shall be applicable. The arbitration decision shall be binding on the parties. The place of any hearing shall be Brussels and the language of the arbitration shall be English. Belgian law shall govern this SIEF Agreement. If at any time any provision of this Agreement is or becomes invalid or illegal in any respect, this shall have no effect on the validity of the remainder of this SIEF Agreement. The invalid provisions are to be replaced retroactively by provisions which come closest to achieving the objectives.

(f) *Duration and Termination* This SIEF Agreement shall be in force until June 1, 2018, except for its provisions under 5. (d), (e) and (h), which shall survive its term indefinitely. The confidentiality obligations related to studies survive for 12 years after their first submission to ECHA; all other confidentiality obligations shall survive until June 1, 2023.

The Lead Registrant has to the right to terminate its functions as Lead Registrant provided another SIEF member has validly agreed to replace him within the SIEF, has agreed to the terms of this SIEF Agreement, and has taken up its functions accordingly. The other Parties must be informed about this replacement without undue delay.

Parties have the right to terminate this SIEF Agreement at the latest by May 31, 2010. Any costs caused individually, i.e. for individual uses, must be paid by them. The provisions under 5. (d), (e) and (h) shall survive termination as specified above.

(g) *Individual Responsibility* Notwithstanding the cooperation within this SIEF Agreement, the Parties and their Affiliates remain individually responsible for compliance with REACH, in particular, but not limited to, their individual submission of information required under Article 11 (1) REACH.

(h) *Liability* The Lead Registrant shall only be liable to the other Parties in connection with the activities contemplated in this SIEF Agreement, including delays in the completion and submission of the Registration dossier, in case of gross negligence and wilful misconduct. He shall not be liable for consequential damage and lost profits. This limitation of liability does not apply in case of claims for death, personal injury or wilful misconduct. No warranty for acceptance of the Registration dossier or Information it contains, or acceptance of a study by ECHA at dossier evaluation (according to Title XI REACH) is given.

(i) *Payments* All payments due hereunder shall be net payments, i.e. free of any bank or transfer charges or similar charges and without deduction of any taxes, levies or other dues payable. If payer is required to withhold any tax or to make any other deduction from any such payments, then the said payments shall be increased to the extent necessary to ensure that, after making of the required deduction or withholding, payee receives and retains (free from any liability in respect of any such deduction or withholding) a net sum equal to the sum which it would have received and so retained had no such deduction or withholding been made or required to be made (gross-up amount). If upon application of the beneficiary any withholding tax can be reduced, or refunded, or an exemption form withholding tax is granted, payer shall file on behalf of payee for such reduction, refund or exemption. Payee shall render any assistance to payer to obtain such withholding tax reduction, refund or exemption. Payer shall be entitled to any refund or withholding taxes. Indirect taxes, including but not limited to Value Added Tax (VAT), Goods and Service Tax (GST), service tax, business tax, as applicable pursuant to the relevant tax law, shall be borne by payer. However, payer is entitled to withhold any payment of indirect taxes unless payee has provided payer with a sufficient invoice for purposes of indirect taxation.

(j) *Rights* This SIEF Agreement does not grant any ownership rights or change existing ownership rights to any of the Information provided under this SIEF Agreement to the Parties. Neither this SIEF Agreement nor any disclosure of Information shall vest any present or future rights in any patents, trade secrets, or property rights, and no license is granted. No legal entity or partnership for legal or tax purposes is created under this SIEF Agreement. The Parties are themselves responsible for any fiscal payments and declarations related to the working of this SIEF Agreement.

(k) ***Validity / Entry into Effect*** **This SIEF Agreement enters into effect between the Lead Registrant and the respective Party either by the Party filling in the required information below and returning a signed copy of this SIEF Agreement within 20 work days of submission to the Party, or alternatively by non-objection to it within 20 work days of submission to the Party. In case more than half of the SIEF members of one or more of the SIEFs of the Substances object within this deadline, it shall be considered as not adopted for the respective SIEF.**

COMPANY:

_____

(Print company name and address)

AFFILIATES:

_____

(Print names and addresses of Affiliates that are SIEF members and that shall be covered by this SIEF Agreement)

(NON-EU/EEA) COMPANIES REPRESENTED :

_____

(In case the Party is an Only Representative; indicate here the names of all the affiliated companies of one group represented by the OR to which this SIEF Agreement should be applicable; In case the OR has pre-registered for several groups of companies, he must sign separate SIEF Agreements for each of the groups; Likewise, if a TPR represents several independent companies for the Substances, he must sign separate SIEF agreements for each of the independent companies represented)

AUTHORIZED REPRESENTATIVE:

_____

(Print name of Representative authorized to sign this SIEF Agreement)

SIGNATURE:

_____

(Signature of Authorized Representative)

SUBSTANCES ELECTED NOT TO BE COVERED:

Substance	**Affiliate Name** (fill in name of Affiliate(s) that should not be covered by this SIEF Agreement for each of the Substances below)	**Not covered** (tick box if no coverage under this SIEF Agreement desired)
Glucono-delta-lactone CAS 90-80-2; EINECS 202-016-5 (D-glucono-1,5-lactone) Molecular formula C6H1006		
Gluconic acid CAS 526-95-4; EINECS 208-401-4 (D-gluconic acid) Molecular formula C6H1207		
Potassium gluconate CAS 299-27-4 EINECS 206-074-2 Molecular formula C6H1207.K		

CONTACT INFORMATION:

_____

(Print Contact details for person responsible for SIEF communication)

Annex 1

MODEL LETTER OF ACCESS

[address of regulatory authority]

Letter of Access for the registration of the substance ……..*[insert name of the substance to be registered]* under *REACH*

Dear Sirs,

The Consortium for the registration of the substance …….. *[insert name of the substance to be registered]* under *REACH* (here thereafter referred to as "the Consortium") agrees that the data, studies, summaries, waiving argumentations, reasoning of testing proposals and/or assessments specified in detail below owned or subject to a use right by the members of the Consortium and submitted by the Consortium in support of the registration under *REACH [insert name of law]* of

Substance ……..…… *[insert the exact name of the substance to be registered]*

(hereinafter collectively referred to as the "Dossier"), may be referred

by Applicant: *Company XYZ / List of Affiliates*

in order to support Applicant's registration of the above mentioned substance under REACH.

The Dossier covers documents as follows: *[if reference is restricted to certain parts of the Dossier insert exact name of the data, studies, summaries, waiving arguments, testing proposals and/or assessments]*

The right to refer to the Dossier is subject to the following restrictions:

1. The right of referral only gives access to the Dossier of the substance for the registration as specified above.

2. The right of referral is solely granted in favor of *Company XYZ* and is not transferable to any other entity or person.

3. *Company XYZ* is not authorized to receive any copies of the Dossier nor is *Company XYZ* authorized to inspect or view the Dossier at ECHA or any related specific document in whole or in part.

4. This Letter of Access shall in no event be construed as granting *Company XYZ* any property rights whatsoever in the Dossier.

5. Nothing in this letter shall require *The Consortium* to file any additional data.

6. In as far as the Dossier may contain chemical safety reports, use and exposure scenarios and guidance on safe use, those will be made available to Company XYZ and may be used by it in as far as needed for purposes of safe handling and elaboration of eSDS.

This Letter of Access does not create any rights for third parties or any liability towards third parties in relation to the data for which access is granted.

Signature: Authorized Representative of the Consortium

Appendix 3: LoA price calculation

1. Consortium Budget

CONSORTIUM MANAGEMENT		2009 Budget Events	Cost (Euro)
Drafting of Consortium Agreement based on MLA model (compatible with VCI and CEFIC model). Negotiating and follow-up work to finalize Consortium Agreement (estimate of three days for changes to agreement and negotiation).	MLA	1	€ 10,000
Steering Committee - organization, preparation of agenda, attendance, drafting of minutes (2 hours meeting time) (senior lawyer/partner)	MLA	2	€ 7,000
Technical Committee - review of minutes for compliance with competition law and REACH, excluding attendance (junior lawyer)	MLA	3	€ 2,700
Accounting	MLA		€ 3,000
General Management of the Consortium	MLA		€ 3,000
Third Party Communication & Legal Advice	MLA		€ 10,000
Data Management & Secretariat for Technical Committee	Ciba		€ 13,300
Meetings of Technical Committee including administration support and preparation	Ciba	3	€ 8,000
Additional TC meeting	Ciba		€ 1,500
TOTAL : CONSORTIUM MANAGEMENT			**€ 58,500**
DOSSIER PREPARATION		**2009 Budget**	Cost (Euro)
Data collection and read-across	Ciba		€ 8,100
Robust study summaries in IUCLID 5	Ciba		€ 14,900
Klimisch rating	Ciba		€ 600
Toxicological studies : Local Lymph Node Assay (LLNA) in mice OECD 429 & Flash point EU A9	Harlan		€ 3,417
Toxicological studies : Acute skin irritation study in the rabbit OECD 404 & Acute eye irritation study in the rabbit OECD 405 & Acute dermal toxicity study in the rat OECD 402	CERB		€ 3,075
TOTAL DOSSIER PREPARATION			**€ 30,092**
TOTAL CONSORTIUM MANAGEMENT & DOSSIER PREPARATION			**€ 88,592**

CONSORTIUM MANAGEMENT		2010 Budget	
		Events	Cost (Euro)
Steering Committee - organization, preparation of agenda, attendance, drafting of minutes (2 hours meeting time) (senior lawyer/partner)	MLA	2	€ 7,000
Technical Committee - review of minutes for compliance with competition law and REACH, excluding attendance (junior lawyer)	MLA	3	€ 2,700
Accounting	MLA		€ 3,000
General Management of the Consortium	MLA		€ 3,000
Legal advice	MLA		€ 10,000
LoA Management : IT-tool	MLA		€ 1,500
LoA Management : €1,000 per LoA - estimate - 3	MLA		€ 3,000
Data Management & Secretariat for Technical Committee	Ciba		€ 15,200
Meetings of Technical Committee including administration support and preparation	Ciba	3	€ 9,500
TOTAL CONSORTIUM MANAGEMENT			**€ 54,900**
DOSSIER PREPARATION		**2010 Budget**	
			Cost (Euro)
Endpoint summary records in IUCLID 5/hazard assessment	Ciba		€ 12,100
CSR incl. PBT assessment/testing proposal	Ciba		€ 8,400
Testing	Ciba		€ 2,525
Testing	SGS		€ 1,743
Translation of Düsseldorf University	Ciba contact		€ 1,500
Licensing of studies	Purac		€ 500
Licensing of studies	Fuso		€ 44,500
TOTAL DOSSIER PREPARATION			**€ 71,268**
TOTAL CONSORTIUM MANAGEMENT & DOSSIER PREPARATION			**€ 126,168**

APPENDIX 3

2. Internal Existing Data (Revised Valuation Sheet: corrected August 26, 2013)

IUCLID	Endpoint	Owner	Year	Study Endpoint	Cantox Rating	File name	study status	Substance	Letter of Access	Comments, Source of cost study	Study cost (Euro)
4.1	Physical State	JUNGBUNZLAUER S.A. (also available from ROQUETTE Frères)	2009	Physical State	2	MSDS GA.pdf	key study	Gluconic acid	Not required	common proposal by IES	**50 €**
4.1	Physical State	JUNGBUNZLAUER S.A. (also available from ROQUETTE Frères)	2009	Physical State	2	^End-p7.14 Annex 3^eml 091112	key study	GDL	Not required	common proposal by IES	**50 €**
4.1	Physical State	JUNGBUNZLAUER S.A. (also available from ROQUETTE Frères)	2003	Physical State	2	MSDS GdL.pdf	supportive	GDL	Not required	common proposal by IES	**50 €**
4.1	Physical State	JUNGBUNZLAUER S.A. (also available from ROQUETTE Frères)	2004	Physical State	2	MSDS PG.pdf	key study	PG	Not required	common proposal by IES	**50 €**
4.12	Auto flammability	JUNGBUNZLAUER S.A.	1998	Self-Ignition Temperature	2	Caractérisation de l'inflammabilité et de l'explosibilité de poussières de Gluco Delta Lactone.pdf	supportive	GDL	Not required	VCI	**1,300 €**
4.12	Auto flammability	ROQUETTE Frères~~JUNGBUNZLAUER S.A.~~	2005	Self-Ignition Temperature	2	INERIS.pdf	key study	GDL	Not required	VCI	**1,300 €**
4.14	Explosiveness	JUNGBUNZLAUER S.A.	1998	Explosion	2	Caractérisation de l'inflammabilité et de l'explosibilité de poussières de Gluco Delta Lactone.pdf	supportive	GDL	Not required	VCI	**2,800 €**
4.14	Explosiveness	ROQUETTE Frères~~JUNGBUNZLAUER S.A.~~	2005	Explosion	2	INERIS.pdf	supportive	GDL	Not required	VCI	**2,800 €**

APPENDIX 3

4.19	Thermal stability	ROQUETTE Frères	2005	Thermal stability	2	INERIS.pdf	key study	GDL	Not required	common proposal by IES	**250 €**
4.19	Thermal stability	JUNGBUNZLAUER S.A.	1998	Thermal stability	2	Caractérisation de l'inflammabilité et de l'explosibilité de poussières de Gluco Delta Lactone.pdf	supportive	GDL	Not required	common proposal by IES	**250 €**
4.19	Thermal stability	JUNGBUNZLAUER GmbH	2008	Thermal stability	2	DSC_Jungbunzlauer.pdf	supportive	GDL	Not required	common proposal by IES	**250 €**
5.2.1	Biodegradation in water	~~JUNGBUNZLAUER S.A.~~ HPV Consortium = JB 12 (JUNGBUNZLAUER S.A.)	2001	Aerobic biodegradation	1	ECOTOX_04	key study	Sodium Gluconate	Not required	VCI	**3,600 €**
5.2.1	Biodegradation in water	~~JUNGBUNZLAUER S.A.~~ HPV Consortium = JB 13 (JUNGBUNZLAUER S.A.)	2001	Anaerobic biodegradation	1	ECOTOX_06	supportive	Sodium Gluconate	Not required	VCI	**3,500 €**
5.2.1	Biodegradation in water	Public : Z. Wasser Abwasser Forsch	1981		2		supportive	Metal-gluconates	Not required	public domain	**0 €**
6.1.1	Short-term toxicity to fish	JUNGBUNZLAUER GmbH	1992	Acute toxicity to fish	3	ECOTOX_14	key study	Sodium Gluconate	Not required	VCI	**3,200 €**
6.1.1	Short-term toxicity to fish	HPV Consortium = F 13 (Fujisawa Pharmaceutical Co., Ltd/Roquette)	2002	Acute toxicity to fish	1	ECOTOX_13	key study	Sodium Gluconate	Not required	VCI	**3,500 €**
6.1.3	Short-term toxicity to aquatic invertebrates (*)	JUNGBUNZLAUER GmbH	1997	Acute toxicity to Invertebrates	3	ECOTOX_15	unsuitable	GDL	Not required	VCI	**2,800 €**
6.1.3	Short-term toxicity to aquatic invertebrates	~~JUNGBUNZLAUER S.A.~~ HPV Consortium = JB 11 (JUNGBUNZLAUER S.A.)	2001	Acute toxicity to Invertebrates	2	ECOTOX_11	key study	Sodium Gluconate	Not required	VCI	**2,800 €**
6.1.5	Toxicity to aquatic algae and	JUNGBUNZLAUER GmbH	1997	Acute toxicity to plants	3	ECOTOX_15	supportive	GDL	Not required	VCI	**4,500 €**

APPENDIX 3

	cyanobacteria										
6.1.5	Toxicity to aquatic algae and cyanobacteria	~~JUNGBUNZLAUER S.A.~~ HPV Consortium = JB 10 (JUNGBUNZLAUER S.A.)	2001	Acute toxicity to plants	2	ECOTOX_09	key study	Sodium Gluconate	Not required	VCI	**4,500 €**
6.1.7	Toxicity to microorganisms	JUNGBUNZLAUER GmbH	1992	Acute toxicity to micro-organisms	3	ECOTOX_14	supportive	GDL	Not required	VCI	**1,700 €**
7.6.1.	Genetic toxicity in vitro	U.S. Food and Drug Administration	1974	Genetic toxicity in vitro	3	IN_VITRO_TOX_02	unsuitable	GDL	Not required	public domain	**0 €**
7.6.1.	Genetic toxicity in vitro	U.S. Food and Drug Administration	1974	Genetic toxicity in vitro	3	IN_VITRO_TOX_02	unsuitable	GDL	Not required	public domain	**0 €**
7.8.2	Developmental toxicity/teratogenicity	Food & Drug Research Laboratories	1973	Developmental toxicity/Teratogenicity (mice)	2	TERATO_STUDIES_02	key study	GDL	Not required	public domain	**0 €**
7.8.2	Developmental toxicity/teratogenicity	Food & Drug Research Laboratories	1973	Developmental toxicity/Teratogenicity (rat)	2	TERATO_STUDIES_02	key study	GDL	Not required	public domain	**0 €**
7.8.2	Developmental toxicity/teratogenicity	Food & Drug Research Laboratories	1973	Developmental toxicity/Teratogenicity (hamster)	2	TERATO_STUDIES_02	supportive	GDL	Not required	public domain	**0 €**
7.8.2	Developmental toxicity/teratogenicity	Food & Drug Research Laboratories	1973	Developmental toxicity/Teratogenicity (rabbit)	2	TERATO_STUDIES_02	supportive	GDL	Not required	public domain	**0 €**
7.10.3	Direct observations	Public	1962	Other (exposure experience)	2	OTHER_03	Not a required endpoint	PG	Not required	public domain	**0 €**
7.12	Additional toxicological information	Public : The Journal of Laboratory and Clinical Medicine Vol 26	1941	Repeated dose toxicity (cats)	2	OTHER_07	Not a required endpoint	GDL	Not required	public domain	**0 €**
7.12	Additional toxicological information	Public: Journal of Nutrition. 1943. Volume 26: 309-317	1943		2	OTHER_04	Not a required endpoint	GDL	Not required	public domain	**0 €**

7.12	Additional toxicological information	Public: Journal of the American Medical Association. 1967. 199(3): 215-217	1967	Intestinal toxicity (dog)	2	OTHER_02	Not a required endpoint	PG	Not required	public domain	**0 €**
											39,250 €

(*) used as supporting for GDL only

3. LoA Price Calculation (for 3 substances combined)

	Assumption : 2 SIEF members		
-	TOTAL	Above 1000 tons	Less than 1000 tons
2009 budget - Consortium Management	€ 58,500	€ 29,250	€ 14,625
2009 budget - Dossier Preparation	€ 30,092	€ 15,046	€ 15,046
2010 Budget - Consortium Management (less LOA)	€ 51,900	€ 25,950	€ 12,975
2010 Budget - Dossier Preparation (incl. new data)	€ 26,268	€ 13,134	€ 13,134
Fuso & Purac licence fee	€ 45,000	€ 22,500	€ 22,500
Internal existing data	€ 39,250	€ 19,625	€ 19,625
Expenses	€ 500	€ 250	€ 250
TOTAL	**€ 251,510**	**€ 125,755**	**€ 98,155**
Admin cost (15%)		€ 18,863	€ 14,723
TOTAL WITH ADMIN COST		**€ 144,618**	**€ 112,878**
Handling Fee		€ 1,000	€ 1,000
TOTAL LOA PRICE	-	**€ 145,618**	**€ 113,878**