Dimethyladipate SIEF Agreement

This SIEF Agreement (hereinafter the “Agreement”) is entered into by and between:

Chemoxy International Ltd, All Saints Refinery, Cargo Fleet Road, Middlesbrough UK, TS3 6AF, as Lead Company of the DBE REACH Consortium, acting in its own name and in the name and on behalf of all Members of the DBE REACH Consortium in accordance to the Consortium Agreement dated 18 December 2009 (hereinafter referred to as "Lead Registrant")

And the SIEF Participant signatory of the present Agreement (hereinafter referred to as "Non-Lead Member")

Hereinafter referred to as “the Parties”.

Preamble

Whereas the Parties to this Agreement have pre-registered Reaction mass of dimethyl glutarate and dimethyl succinate and dimethyl adipate, have agreed on the identity and the sameness of the Substance, and thus are Participants of the same Substance Information Exchange Forum (“SIEF”) as potential registrants for that Substance under the meaning of Article 29 of the European Community Regulation EC 1907/2006 (“REACH”);

Whereas REACH imposes on manufacturers and importers as well as on Only Representatives the obligation to register the Substance within the prescribed deadlines;

Whereas REACH requires, subject to certain exceptions, multiple registrants of the same substance to share certain data and jointly submit through a Lead Registrant part of the information required for the registration relating to the Substance to the European Chemicals Agency (“Agency”);

Whereas the Lead Members defined in the Article 1 of this Agreement will have prepared the Joint Registration Dossier to be submitted to the Agency through the Lead Registrant;

Whereas the Members of the Consortium are aware that they have co-operation and data sharing obligations with other SIEF participants.

Whereas the Non-Lead Member has the intention to register the Substance and he is willing to appoint the Lead Registrant as lead registrant in order to have him to submit the Joint Registration Dossier.

Whereas the Agency represented in its REACH guidance that it is advisable for the SIEF participants to agree in writing certain SIEF operational rules concerning data sharing, rights on the developed information and sharing of costs.

Therefore, with a view to fulfilling their regulatory obligations under REACH in respect to the Substance, the Parties hereto have decided to pursue the following objectives (hereinafter the “Purpose”):

1. to agree on the operating rules governing the exchanges of information between the SIEF potential registrants (Title I);
2. to agree on the rules regarding the rights to participate in the joint submission of data, to use the (robust) study summaries and to refer to the relevant full study reports in the Joint Registration Dossier developed by the Lead Members (Title II);

under the terms and conditions set forth in this Agreement.

THE PARTIES HAVE AGREED UPON THE FOLLOWING:

Article I. Definitions

Terms written in capital letters are defined in the Preamble above, in this Article 1 or in other parts of this Agreement. To the extent not otherwise defined in this Agreement, any definition specified in REACH, in particular in Article 3, shall apply to this Agreement:

**Affiliate:** Any legal entity controlling, controlled by, or under common control with, either directly or indirectly, a Party or in case of an Only Representative, the affiliate of the non-EU manufacturer or in case of a third representative, the affiliate of the legal entity represented. For these purposes, “control” shall refer to: (i) the possession, directly or indirectly, of the power to direct the management or policies of a person, whether through the ownership of voting rights, by contract or otherwise; or (ii) the ownership, directly or indirectly, of 50 % or more of the voting rights or other ownership interest of a person.

**Data Owner:** Any entity holding rights to use Information on the Substance, either as SIEF participant or as non SIEF participant.

**Information:** studies, other scientific, statistical, or technical data, including but not limited to composition, characteristics, properties and processes and applications, and any information in any form made available by a Party or generated by the Parties jointly, pursuant to or in the course of this Agreement.

**Joint Registration Dossier:** The data that the Parties are required to submit jointly to the Agency in order to register the Substance, pursuant to Article 11 (1), paragraph 2 REACH.

**Only Representative:** any natural or legal person, as described in Article 8, REACH.

**Parties:** being the signing parties to this Agreement, having the quality of either:

- **Lead Member:** a SIEF participant who is subject to the registration requirements under REACH, who participates to the SIEF discussions in order to compile the Joint Registration Dossier and who is member of the DBE REACH Consortium.

- **Lead Registrant:** a SIEF participant who is subject to the registration requirements under REACH, which the Non-Lead Member agree hereto to appoint acting as Lead Registrant as defined under Article 11 (1) REACH. The Lead Registrant is a member of and duly represents and acts in the name and on behalf of the other members of the DBE REACH Consortium (‘Lead Members’).

- **Non-Lead Member:** a SIEF participant being neither a Lead Member nor a data holder (article 28 (7) REACH) and that agrees to rely on the Joint
Title I: SIEF OPERATING RULES

Article II. Confidentiality

1. The Parties shall:

   a) treat all Information as confidential and not disclose it to third parties, unless regulatory disclosure requirements apply. 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 of any request by competent authorities relating to the disclosure of that Information.

   Disclosure of Information as required for legal and/or regulatory purposes including the REACH Regulation, shall only take place by the Parties in a form (for example short summaries where possible) reflecting the minimum information required to be disclosed. This restriction does not apply to the Party who has provided the Information.

   b) use the Information only for the Purpose or otherwise as permitted under or in accordance with this Agreement.

   c) disclose the Information to their employees, Affiliates, external experts and/or consultants and if the Non-Lead Member is an Only Representative or a Third Party Representative, the non-EU manufacturer(s) or the legal entity(ies) represented by any of them, only on a need to know basis and only to the extent absolutely necessary for the Purpose or otherwise as permitted under or in accordance with this Agreement. Each Party shall have in place policies and procedures to ensure the confidentiality of Information, and require that its external experts and/or consultants also have such policies and procedures in place to ensure their compliance with these confidentiality obligations.

2. The obligations specified in Article II.1 above shall not apply to Information for which the receiving Party can reasonably demonstrate that such Information:

   a) was known to the receiving Party on a non-confidential basis prior to its disclosure pursuant to this Agreement;

   b) is publicly known at the time of disclosure or thereafter becomes publicly known without breach of the terms of this Agreement on the part of the receiving Party;

   c) becomes known to the receiving Party through disclosure by sources other than the disclosing Party, having a right to disclose such Information,
d) was independently developed by the receiving Party without access to the disclosing Party's Information, as evidenced by documentary records,

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 principles of operation, fall within any exception.

**Article III. Competition Law compliance**

1. The Parties acknowledge that any activities carried out under this Agreement have to be carried out in full compliance with EU competition law, in particular but not limited to Articles 101 and 102 EC Treaty as well as any applicable national laws. The Parties explicitly agree to observe Cefic REACH Competition Law compliance guidance attached in Annex 1 to this Agreement.

2. Should it become apparent at any time that this Agreement, any provision of this Agreement, or any activity or decision of the Parties, can have a potentially restrictive effect on open and fair competition, in breach of any statutory provision, each Party to this Agreement shall take immediate steps to remedy that situation.

**Article IV. Legal personality**

This Agreement or the cooperation contemplated herein shall not constitute or be deemed to constitute a legal entity or partnership between the Parties.

**Article V. Regular report of the preparation of the Joint Registration Dossier**

1. The Lead Registrant undertakes to inform the Non-Lead Member regularly on the development of the Joint Registration Dossier according to the general guidance in regard to SIEF management attached in Annex 1 to this Agreement.

2. The Non-Lead Member undertakes to make all best efforts to check proactively and regularly all up-dated Information that is made available by the Lead Registrant on the development of the Joint Registration Dossier.

3. The Parties agree that such communication may be channelled via the use of the Consortium Website and the consortium e-mail.

**TITLE II: DATA SHARING AND JOINT SUBMISSION OF THE DOSSIER**

**1. OBLIGATIONS OF THE LEAD REGISTRANT**

**Article VI. Participation in the joint submission of data by multiple registrants**

1. According to Article 11 (1) REACH, the Parties hereto agree to have the Joint Registration Dossier for the Substance submitted by the Lead Registrant on behalf of the Non-Lead
Member having fulfilled its obligations under Article IX to this Agreement, at least 3 months before end of the applicable registration deadline. Upon demand of the Agency, within the requested deadline and to the extent necessary, the Lead Registrant agrees to complete the Joint Registration Dossier.

2. Notwithstanding anything to the contrary under this Agreement, the Parties remain individually responsible to comply with REACH, in particular, but not limited to, in relation to the individual submission of the information required under Article 11(1) REACH.

3. The participation in the Joint Registration Dossier may deviate per requesting Non-Lead Member according to its tonnage band or possible opt-outs for certain endpoints.

4. If the Non-Lead Member requests the submission of the Joint Registration Dossier on behalf of itself and/or an Affiliate, the Non-Lead Member shall notify the Lead Registrant with the following information:
   (a) its name, address and other relevant data documenting such status of Affiliate; and
   (b) whether or not it acts for entity subject to restrictions pursuant to the United States Iranian Transactions Regulation (31 CFR Part 560) as from time to time amended, extended or re-enacted (hereinafter referred to as the ITR) within 2 months before the registration due date. Upon receipt of this information the Lead Registrant shall submit the Joint Registration Dossier also on behalf of such legal entity.

5. If the Non-Lead Member is a Third Party Representative and requests the submission of the Joint Registration Dossier on behalf of a legal entity represented by it in the SIEF, the Non-Lead Member shall notify the Lead Registrant under confidentiality obligations with the following information:
   (a) name, address and other relevant data of the represented legal entity; and
   (b) whether or not it acts for any entity subject to restrictions pursuant to the ITR within 2 months before the registration due date. Upon receipt of this information, the Lead Registrant shall submit the Joint Registration Dossier also on behalf of such legal entity.

6. If the Non-Lead Member is an Only Representative and requests the submission of the Joint Registration Dossier on behalf of more than one legal entity represented by it in the SIEF, the Non-Lead Member shall notify the Lead Registrant of the following information:
   (a) the number of legal entities he represents with the name, address and other relevant data of the represented legal entities; and
   (b) whether or not it acts for any entity subject to restrictions pursuant to the ITR not later than within 2 months before the registration due date. Upon receipt of this information, the Lead Registrant shall submit the Joint Registration Dossier also on behalf of such legal entity.

7. The Lead Registrant shall open a joint submission object in REACH-IT.

8. The Lead Registrant shall pay the fee (in accordance to Article 11 (4) REACH) as invoiced by the Agency for the submission of the Joint Registration Dossier without undue delay.

9. The Lead Registrant shall make available the data referred to in Article 11 (1) paragraph 2 REACH that have been submitted in the joint submission to the Non-Lead Member, and/or Non-Lead Member’s Affiliate notified under Article VI.4 of this Agreement, provided the Non-Lead Member has fulfilled its obligations under Article VI.4, VI.5 or VI.6 as applicable, and Article IX of this Agreement.
Article VII. Grant of right to use the (robust) studies summaries in the Joint Registration Dossier and to refer to the full study reports.

1. Subject to the payment of the Joint Registration Compensation as specified under Article IX of this Agreement, and provided the Non-Lead Member has fulfilled its obligations under Article VI.4, VI.5 or VI.6 as applicable, the Lead Registrant grants the Non-Lead Member the non-exclusive, non-transferable and non-terminable right which is restricted to the fulfillment of REACH requirements.

   (a) to use the (robust) studies summaries and other Information used in the Joint Registration Dossier within the applicable tonnage band and for which no opt-out has been claimed by the Non-Lead Member;

   (b) to refer to the full study reports on which basis the (robust) studies summaries have been developed; and

   (c) to grant the rights referred to under (a) and (b) hereabove to the Non-Lead Member and its Affiliates notified under Article VI.4 of this Agreement, with the right to sub-license such rights only to their Only Representatives.

   (d) Upon receipt of payment, the Lead Registrant will issue the Non-Lead Member with a Letter of Access, similar to the example given in Annex 2 of this Agreement. The Letter of Access will list the Information (including a study list) for which rights to refer are granted, based on the requested tonnage band of the Non-Lead Member.

   (e) In case the Lead Registrant has not received the right to sublicense the right to refer to studies to Non-Lead Members, the right to refer is to be granted by the study owner in a separate bilateral agreement only. The Lead Registrant shall inform the Non-Lead Member about the name of the respective study owner and respective Studies.

2. Notwithstanding the foregoing, if the Non-Lead Member is a Third Party Representative, he is granted only with the rights specified under (a) and (b) hereabove, and only for the purpose to pass them to the legal entities represented by him in the SIEF and notified to the Lead Registrant under Article VI.5.

3. The rights granted under this Article can be exercised only for the purpose of compliance with REACH. The Parties shall abstain from any other use, whether commercial or non-commercial. For the avoidance of doubt, any further use of the studies shall be subject to an additional written agreement.

4. The Lead Registrant represents that he has been granted or shall be granted by the Data Owners, being the owner(s) and/or the subjects authorized to grant the rights to use the (robust) studies summaries and to refer to the full study reports, the rights specified under Article VII paragraph 1.

Article VIII. Information on the submission of the Joint Registration Dossier

1. Provided the Non-Lead Member has fulfilled its obligations under Article VI.4, VI.5 or VI.6 as applicable, and the Non-Lead Member has fulfilled its obligations under Article IX, the Lead Registrant shall inform immediately the Non-Lead Member of the creation of the joint submission object in REACH-IT and shall provide the valid security token number and the name of the joint submission.
2. The Lead Registrant shall inform immediately the Non-Lead Member of the submission of the Joint Registration Dossier to the Agency and provide documentation of the same.

3. The Lead Registrant shall further communicate the confirmation that the joint registration has been successful and shall inform the Non-Lead Member of the reception of the relevant registration number that has been obtained from the Agency without undue delay.

2. OBLIGATIONS OF THE NON-LEAD MEMBER

Article IX. Financial compensation for the Joint Registration Dossier

1. Before execution by the Lead Registrant of its obligations pursuant to Title II.1 of this Agreement, the Non-Lead Member shall compensate in a fair, transparent and non-discriminatory way the Lead Registrant with a “Joint Registration Compensation” for the development and submission of the Joint Registration Dossier and the rights granted under Article VII of this Agreement.

2. The Joint Registration Compensation, in accordance with the principles set out in Annex 3, will comprise following elements:

   a) Administrative expenses reasonably incurred by the Lead Members and the Lead Registrant including but not limited to, secretarial services, management of confidential data, cost for the joint dossier preparation and costs of external experts.

   b) Expenses to acquire rights to use existing studies of an individual Lead Member and costs for studies jointly developed by the Lead Members according to Annexes VI to VIII of REACH.

   c) Costs for rights to use studies from Data Owners, if the Lead Registrant is authorized by Data Owners to transfer to Non-Lead Member the rights specified under Article VII. paragraph 1.

3. Expenses referred to above shall be allocated equally, in a transparent, fair and non-discriminatory way, to all SIEF participants with the intent to register the Substance, taking into account the following exceptions:

   a) Where a Non-Lead Member registers the Substance in a tonnage band lower than the one covered by the Joint Registration Dossier, it shall only be requested to compensate for those parts of the Registration Dossier that it is included in and for those studies it receives a right to refer for.

   b) Where the Non-Lead Member decides, based on Article 11 (3) REACH, to opt-out from the Joint Submission or some parts of the Joint Registration Dossier and submit the relevant information separately, it shall only be requested to compensate for those parts of the Joint Registration Dossier that are submitted jointly.

4. Based on the above, the Lead Registrant, directly or represented by the external service provider in charge of the management of the consortium, will send an invoice to the Non-Lead Members for their cost share after their request for joint submission (2010, 2013, 2018 and first time registrants). The Non-Lead Members will only receive the valid security token number after full payment of the invoice. Payment is due. in accordance with the schedule set out in paragraph 8 of Annex 3.
5. When cost and income estimations change, in particular in 2013 and 2018, additional payments or refunds respectively may be requested by the Lead Registrant and SIEF Members respectively. For refunds a threshold of 1.000 € per SIEF participant is applicable. Where a company wishes to re-coup costs less that 1000 €, they will bear the administrative and accounting costs of retrieving such refunds.

6. When new studies have to be purchased or performed after conclusion of this Agreement (e.g: when ECHA have reviewed and commented on the test plan for Annex IX and X studies), the resulting cost will be equally divided between all SIEF participants who are required to incorporate the results of these new studies into their registration dossier for their tonnage band, unless they claim to opt out in accordance with Article 11 (3) REACH. Upon receipt of payment, the Lead Registrant will issue the Non-Lead Member which has complied with its obligations under Article VI.4, VI.5 or VI.6 as applicable, with a revised Letter of Access listing the expanded study list and summaries, for which rights to refer are granted.

In the event that after conclusion of this Agreement, the Non-Lead Member company is required by REACH to update his registration to cover a higher tonnage band, the Non-Lead Member agrees to notify the Lead Registrant within 2 months of submitting the registration update. The Lead Registrant will review if the additional studies and summaries needed by the Non-Lead Member for the new tonnage band are already available in the joint dossier. If they are available the Non-Lead Member will be provided with an updated cost share and an invoice to share in the additional development costs of the relevant higher tier studies, unless they claim to opt out in accordance with Article 11 (3) REACH. The Lead Registrant will, within 30 days of receipt of payment, provide a revised Letter of Access listing the additional Information for which rights are granted. Payment is due with 1 month after receipt of an invoice by the Lead Registrant. If the information is not yet available (e.g. Annex IX or X studies where the test plan is pending ECHA review) the Non-Lead Member will be receive rights to refer to the testing plan in the joint submission and be contacted later if new studies are conducted subject to Paragraph 6 of this Article.

7. If it becomes apparent that before the submission of the Joint Registration Dossier the actual costs are higher than the payment set out under paragraph 4 above, the Lead Registrant has the right to adjust the payments by requiring additional payment from the Non-Lead Member.

8. If the SIEF comprises various Affiliates of the Non-Lead Member, only the Non-Lead Member within the SIEF shall be subject to the obligation to compensate the Joint Registration Dossier. Such single Joint Registration Compensation will be calculated on base of the highest tonnage band of all these Affiliates. Accordingly, the Affiliates of the compensating Non-Lead member, or the Affiliates of the non-EU established companies represented by an Only Representative being a Non-Lead Member, shall also have the right to refer to the Joint Registration Dossier under the same conditions without additional payment. In that case, the Non-Lead Member that has paid the compensation is responsible for compliance of its Affiliates or their Only Representative with the rights and obligations pursuant to this Agreement, including the confidentiality obligations under Title I, Article II of this Agreement.

9. If an Only Representative represents more than one non-EU entity within the SIEF, such Only Representative shall compensate the Lead Registrant on account of each non-EU entity it represents by the payment of a separate Joint Registration Compensation per Non-EU entity and its Affiliates.

10. If a Third Party Representative represents more than one entity within the SIEF, such Third Party Representative shall compensate the Lead Registrant on account of each entity it
represents by the payment of a separate Joint Registration Compensation per entity and its Affiliates.

11. 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 from 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 of withholding taxes.

12. 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.

3. OWNERSHIP OF INFORMATION

Article X. Ownership of Information

1. This Agreement does not grant any ownership rights or change existing ownership rights to any of the Information provided under this Agreement to the Non-Lead Member, on whatever form and whenever, by the Lead Registrant, including without limitation, the Joint Registration Dossier.

2. Such Information shall consist in any and all data and/or studies:

   a) Individually developed by one of the Lead Members;

   b) Collectively developed by the Lead Members for which they have acquired valid title or right to use; and

   c) Acquired from Data Owner(s) for which the Lead Members, or the Lead Registrant as the case may be, have been granted valid rights.

3. Neither this 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.

TITLE III: FINAL PROVISIONS

Article XI. Limitation of liability in the SIEF
1. The Parties shall undertake their Purpose related activities specified hereunder in good faith and according to all applicable laws and regulations, and they shall use all reasonable endeavours to ensure the best possible results based on the evidence, methods and techniques known at the time.

2. Each Party having submitted a study which has been used in the Joint Registration Dossier represents to the others (i) that it is the rightful owner of the study(ies) and free to grant rights therein, (ii) that, to the knowledge of this Party, these studies do not infringe on the rights, in particular, but without limitation, intellectual property rights, of any third party and (iii) that this Party has not received a claim or notice of any alleged infringement.

3. It is the individual responsibility of each Party to critically assess the Information that is generated or that is made available. Each Party assumes the full responsibility for its own use of the Information so developed or received. No warranty for acceptance by the Agency of the Joint Registration Dossier or any data it contains is given.

4. None of the Parties, including the Lead Registrant, shall be held liable for any direct, indirect or consequential loss or damage incurred by any Party in connection with the activities contemplated in this Agreement.

5. The preceding limitation of liability does not apply in case of the breach of an obligation, the fulfilment of which is of particular significance to the achievement of the contractual purpose (cardinal obligation); in case of damage caused by gross negligence or wilful misconduct, as well as in case of damage to the life, body or health.

6. If a cardinal obligation is violated through slight negligence, liability is restricted to such typical damage, which was reasonably foreseeable on conclusion of the Agreement.

**Article XII. Term and termination**

1. This Agreement shall be in force until 31 December 2022.

2. This Article and the provisions relating to the protection of confidentiality (Article II), ownership of Information (Article X), dispute resolution and applicable law (Article XV) and limitation of the liability (Article XI) shall survive the termination of this Agreement. With regard to the studies, the obligations specified in Article II of this Agreement shall survive for a period of twelve (12) years following the initial submission to the Agency. With regard to all other Information, the obligations specified in Article II shall survive for a period of 5 years after termination of the SIEF.

3. The Lead Registrant has the right to terminate its functions as lead registrant under the cumulative conditions that:
   - it has been validly replaced in its functions within the SIEF;
   - its assignee has accepted to be bound by the obligations of the Lead Registrant under this Agreement; and
   - the Non-Lead Member has been notified about such replacement.

4. The Non-Lead Member has the right to terminate the present Agreement subject a prior written notice to the Lead Registrant at the latest nine months before the relevant registration deadline. No reimbursement shall be due.
Article XIII. Legal entity change

The consent of the other Party shall not be required in case a Party assigns, transfers or delegates its rights and obligations under this Agreement to any of its Affiliates or to a legal successor in ownership by sale, division, merger or consolidation of all or substantially the whole of the business relevant to the Substance referred to in this Agreement, subject to acceptance by the assignee of the terms of this Agreement, to be notified to the other Party without undue delay.

Article XIV. Administration and reporting of costs

1. All financial settlements, billings, and reports rendered under this Agreement shall reflect properly the facts which may be relied upon as being complete and accurate in any further recording and reporting made by a Party for any purpose.

2. In accordance with generally accepted accounting procedures, documentation will be maintained and preserved including but not limited to written and electronic records, records on expenses, books of account, correspondence, memoranda and receipts.

Article XV. Dispute resolution and applicable law

1. This Agreement is subject to the laws of Germany.

2. All disputes shall be finally settled under the rules of arbitration of the DIS (Deutsche Institution für Schiedsgerichtsbarkeit e.V.). The award shall be binding on the parties. The arbitral tribunal consists of three arbitrators, of which one acts as chairperson; the chairperson shall have a university degree in law. The arbitral tribunal shall decide on the regulation of the cost of arbitration, including, but not limited to, arbitrators’ fees, lawyers’ fees and costs of arbitration, in accordance with the outcome of arbitration: these costs shall be paid by the losing Member in the arbitration. Arbitration shall take place in Düsseldorf, Germany. The language of the arbitration proceedings shall be English.

3. 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 remaining contractual provisions. The invalid provisions are to be replaced, backdated to the time of their becoming ineffective, by provisions which come closest to achieving their objective.

The Parties are validly bound by this Agreement when the Non-Lead Member has given its consent to this Agreement.
ANNEXES:

Annex 1

CEFIC guidance on competition compliance and SIEF management

SIEF Timechart.xlsx

Cefic REACH
guidance DO & DON'T
Annex 2
Letter of Access Template

Letter of Access to Data for REACH Registration by the Lead Registrant for Dimethyladipate (EC# 211-020-6).


Dear Sirs,

Subject to the terms set forth in the SIEF Agreement for Registration under REACH dated [...] between the Lead Registrant and the Non Lead Member, and in consideration of the payment of the relevant compensation of xxxx Euros, by this letter, the Lead Registrant grants the Non Lead Member and its Affiliates the license to refer to the below studies and grants the Non Lead Member the right to sub-license to its Affiliates the granted rights, solely for the purpose of preparing a REACH registration dossier on the below Substances for submission to the European Chemicals Agency:

GRANTEE:

SUBSTANCE(S): The substance(s) specified in Appendix 1

STUDIES: The data and summaries specified in Appendix 2.

Sincerely,

For: The Lead Registrant

Signature:

Name:

Title:

Date:

Appendix 1: Name of the substance

Appendix 2: [list relevant studies and insert description of the data, studies, summaries, waiving arguments, testing proposals and/or assessments, insofar as relevant]
Annex 3

Rules of calculation of the Joint registration compensation

1. Costs of the studies for the actual endpoints

Only studies with a quality assessed as category 1 or 2 in accordance with the Klimisch et al will be used in the Joint Registration Dossier, i.e., reports with the following classifications:
   a) reliable without restriction; and
   b) reliable with restrictions.

The actual historical cost for the key study for each end-point will be adopted to determine the financial value of a report.

The replacement cost for the key study for each endpoint has been adopted depending upon the Klimisch rating assigned to the study as last resort when the historical costs cannot be reasonably determined. That replacement cost will be adopted according to the Average Prices of the “Fleischer List” (Appendix 1; Journal of Business Chemistry, Vol. 4, Issue 3, September 2007, page 96 ff).

The final study value is assessed with reference to the Fleischer List plus administrative expenses assessed with reference to a Fixed Surcharge of 4.2 to 25% of the sum total of the study value defined in the table below (as set out in Annex 6, paragraph 3(b) of the DBE Consortium Agreement).

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<th>Correction factor administration %</th>
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<tr>
<td>&gt; 300,000</td>
<td>4.2%</td>
<td>&gt; 12,600</td>
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</tbody>
</table>

2. REACH Rebate

A rebate of 50% will be made to account for the access to the studies only being granted for use for REACH registration only (no transfer of the actual study report and study data). If studies are to be used for another purpose, a bilateral agreement shall be developed with the relevant data owner(s).

3. New Studies

In case of new studies launched by the Lead Company in order to fulfil the requirements of REACH annexes 7 and 8 the costs to be shared are equal to the real costs paid plus the
relevant Administrative Expenses. A rebate of 50% will then be applied to the cost of the new studies for the restricted use for REACH purposes only (no transfer of the actual study report and study data). If rights to use such new studies are to be granted to third parties to be used for another purpose, a bilateral agreement shall be developed with the Lead Company on behalf of all co-owners of the new studies, with any compensation obtained from a third party to be shared equally between the co-owners.

In the event that new studies must be commissioned at the request of the European Chemicals Agency (ECHA) for REACH annexes 9 and 10 the costs will be shared equally between all registrants (ie Consortium and SIEF members).

All calculated values must be documented.

4. Administrative dossier costs

Administrative expenses for Registration dossier preparation include:
- Experts costs for technical works by the Lead Company (consortium members: data gap analysis, studies valuation, preparation of IUCLID V dossier, CSR preparation;
- Administrative and Trustee costs: coordination, accounting, secretariat;
- Consortium establishment costs and operating costs (“Sweat equity”); and
- Other SIEF running costs, current and up to 2018.

5. Cost Sharing basis

Access to individual data: Any SIEF Member (including for read across purposes) can get a letter of access to be entitled for the usage agreed (by default this access is restricted to REACH Registration only) after fulfilling its cost compensation requirements agreed upon.

Access to a full dossier for a certain tonnage band: any potential Registrant can get a letter of access and electronic data to be entitled for the usage of the full Registration dossier for its Registration under REACH after fulfilling its cost compensation requirements agreed upon.

SIEF members should have access to the information submitted by the Lead Registrant on behalf of the Joint submission members (article 11.1 paragraph 2 REACH). This means that by paying the letter of access to the Lead Company in order to participate to the Joint Submission, the SIEF members should have access to the end-points results as well as a copy of the (robust) study summaries (unless flagged as confidential. In this case, only the result will be made available).

Every registrant only participates in the share of the costs related to the annexes, and the corresponding existing and new studies, required for that registrant’s volume band. As defined under article IX.8 herein, the costs will be shared by group of Legal entities in the SIEF (one share per company and its affiliates).

A deduction scheme will be applied for calculating a reduction in the expenses of the respective Lead Company for the preparation of the Core Data as provided in Article 5.1(1)(e) of the DBE Consortium Agreement, for a SIEF Member who registers the substance with either a lower tonnage band or as an intermediate. The deduction scheme referenced in Article 5.1 (5) of the DBE Consortium Agreement, and dealing with refundable expenses, shall apply.
6. Additional Costs

The basic dossier cost above does NOT include the possible cost of taking into account any further studies which may be communicated after fixing this cost, nor any modifications of the dossier which could result from such information, nor any administrative costs of updating the dossier if this becomes necessary in the future. Despite the fact that the cost of the testing proposal itself is included in the technical work of the dossier and is consequently included in the basic dossier cost, said basic dossier cost does not include the future study costs of any submitted Testing Proposal, nor of any other additional testing ECHA may require after examination of the dossier. All such additional costs must be shared between all registrants (where concerned according to tonnage bands), and will be additional to those indicated here.

Also not included are ECHA registration fees which remain the individual responsibility of the Non-Lead Member, and do not include the cost of preparing and submitting the Non-Lead Registrant's company specific information and registration.

The Access Rights are accorded for use for REACH Registration of the specified substance only, and for use for no other purposes and for no other substances.

7. Cost sharing detailed factors.

**Cost Elements**

- **Old studies** members
  - Fleischer list or actual price

- **Old studies** 3rd party
  - Actual price as agreed

- **New studies**
  - Consortium actual price

- **Consortium Manager**
  - SLA with consortium

- **Lead company**
  - Service SLA in consortium (IUCLID)

- **Experts Time**
  - of members pre-consort./ New Joiner Fee SWEAT EQUITY

**Valuation**

- All studies = 100% price (Fleischer list or actual) + admin. exp. (Annex 6 §3b)

- 50% REACH Rebate
  - Value of Studies (except for studies from 3rd parties)

- **Service Cost**
  - 10% Dossier Creation

- **Cost of dossier**
  - + 10% Consort. Oper. Cost divided by 2010 + 2013 registrants

- **LoA**

"new studies" in this diagram do not include future studies requested by the ECHA for Annexes 9 and 10

8. Finalisation of payment and registration

The Agreement will be available for SIEF participants on November 12th, 2012.

The SIEF participants are invited to sign the Agreement before December 30th 2012.

The Joint Registration Compensation will be calculated in early 2013.

There will be no review or update of the Joint Registration Compensation until the next registration phase, excepted application of article IX 6 of the Agreement.

After payment of the final invoice and a registration number has been received from ECHA, an up-to-date “Token” to confirm the LOA Applicant’s membership in the REACH IT Joint Submission will be provided. Then a Letter of Access will be sent to the LOA Applicant.
signed by the Consortium Secretariat on behalf of the Lead Registrant and the other Consortium Members. The above process may be modified as a function of ECHA formalities.