

Trisodium Citrate Cas#68-04-2 **SIEF Agreement**

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

Jungbunzlauer Austria AG	Plant Pernhofen	2064	Wulzeshofen	AT
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as Lead Company of the Citrics REACH Consortium, acting in its own name and in the name and on behalf of all Members of the Citrics REACH Consortium in accordance to the Consortium Agreement dated 8 December 2008 (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 *Trisodium Citrate Cas#68-04-2*, 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 the REACH Regulation imposes on manufacturers and importers as well as on only representatives the obligation to register the Substance within the prescribed deadlines;

Whereas the REACH Regulation 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] prepare[d] 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 the REACH Regulation 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 and 4 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 Citrics 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 Citrics 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 Registration Dossier prepared and/or made available by the Lead Registrant, on his own behalf, for its Affiliates, and/or on behalf of the represented potential registrants in case he is a third party representative.

Substance: *Trisodium Citrate Cas#68-04-2*

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 81 and 82 EC Treaty as well as any applicable national laws. The Parties explicitly agree to observe Cefic REACH Competition Law compliance guidance attached as 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 as Annex 2 to this Agreement.

2. In particular, in case the chemical safety report is included in the Joint Registration Dossier, the Lead Registrant undertakes to inform the Non-Lead Member on the list of uses to be covered in that chemical safety report without undue delay.

3. 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.

4. The Parties agree that such communication may be channelled via the use of the SIEFReach IT-platform.

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 2 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 an Affiliate, the Non-Lead Member shall notify the Lead Registrant with its name, address and other relevant data documenting such status of Affiliate within 3 months before the registration due date.
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 him in the SIEF, the Non-Lead Member shall notify the Lead Registrant under confidentiality obligations with the name, address and other relevant data of the represented legal entity within 3 months before the registration due date.
6. The Lead Registrant shall open a joint submission object in REACH-IT.
7. 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.
8. The Lead Registrant shall make available the data referred to in Article 11 (1) paragraph 2 and paragraph 4 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 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, the Lead Registrant grants the Non-Lead Member the non-exclusive, non-transferable and non-terminable right:
 - (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) here above to the Non-Lead Member's Affiliates notified under Article VI.4, with the right to sub-license such rights only to their only representatives.
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) here above, 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 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.

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 including costs for the preparation of the Chemical Safety Report 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, represented by ReachCentrum, 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 payment of the invoice within 21 days. Payment is due within 1 (one) month after receipt of an invoice issued by the Lead Registrant representative.

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 than 1000 €, they will bear the administrative and accounting costs of retrieving such refunds.

6. In case new studies have to be purchased or performed after conclusion of this Agreement, 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, unless they claim to opt out in accordance with Article 11 (3) REACH.

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 one of these Affiliates 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, unless caused by gross negligence or wilful misconduct. In particular, the Lead Members, including the Lead Registrant, shall not be held responsible and liable for delays in the completion and submission of the Joint Registration Dossier, unless caused by gross negligence or wilful misconduct.

Article XII. Term and termination

1. This Agreement shall be in force until 1 June 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.

3. The Lead Registrant may be required to have the relevant data validated by an external auditor annually and to provide documentation thereof upon request of the Non-Lead Member.

Article XV. Dispute resolution and applicable law

1. The Parties shall first attempt to settle amicably any dispute arising out of this Agreement. Any dispute shall be resolved by arbitration, ousting jurisdiction by ordinary courts, by a panel of three arbitrators. Each party to the dispute will nominate one arbitrator. These two arbitrators will then designate a third arbitrator who will also act as chairman. The arbitration decision shall be binding on the parties. The arbitration rules of the CEPANI shall be applicable. The place of any hearing shall be Brussels and the language of the arbitration shall be English.

Each Party may at any time request from any competent judicial authority any interim or conservatory measure.

2. This Agreement shall be governed by the laws of Belgium.

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



Cefic REACH
guidance DO & DON'T

Annex 2

General guidance in regard to SIEF management



List-of-Tasks-in-SIEF
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Annex 3:

**Rules of calculation of the Joint registration compensation for REACH dossier for P-
I182**



P-I182 Annex 3
Trisodium Citrate SIEF