

[REDACTED]
29 January 2021

The Claimant

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Copy to:

The Other Party

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Sent via REACH-IT

Decision number: [REDACTED]

Dispute reference number: [REDACTED]

Name of the substance (the 'Substance'): [REDACTED]

EC number of the Substance: [REDACTED]

DECISION ON A DISPUTE RELATED TO THE SHARING OF DATA

A. Decision

Based on Article 27(6) of Regulation (EC) No 1907/2006 ('REACH Regulation')¹ and Article 5 of the Commission Implementing Regulation (EU) 2016/9 on joint submission of data and data-sharing in accordance with REACH ('Implementing Regulation 2016/9')²,

ECHA grants the Claimant permission to refer to information requested from the Other Party for the purpose of a registration under the REACH Regulation. However, this decision is subject to the receipt by ECHA of the proof that the Claimant has paid the Other Party a share of the costs incurred pursuant to Article 27(6) of the REACH Regulation ('proof of payment'), within two months from the notification of the present decision, i.e. by 29 March 2021.

¹ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ L 396, 30.12.2006, p.1, as last amended.

² Commission Implementing Regulation (EU) 2016/9 of 5 January 2016 on joint submission of data and data sharing in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), OJ L 3, 6.1.2016, p.41.

The reasons for this decision are set out in Annex I.

The list of studies covered by the present decision, along with copies of the corresponding (robust) study summaries, can be found in Annexes II and III, respectively. However, **the Claimant cannot make use of this permission to refer** to submit a registration dossier for the Substance **before submitting to ECHA a proof of payment and before receiving from ECHA an acknowledgment of receipt.**

Provided that the Other Party makes the full study report available to the Claimant, the Other Party has a claim on the Claimant for an equal share of the cost it has incurred, which is enforceable in the national courts.

If the Claimant does not provide ECHA with proof of payment within two months from the notification of the present decision, ECHA will issue a decision revoking the present decision. In such case, the Claimant may continue negotiating to reach an agreement with the Other Party. Should these subsequent negotiations fail, the Claimant can submit a new dispute to ECHA.

(Robust) study summaries submitted at least twelve years previously are not subject to cost sharing. It is useful to note that (robust) study summaries for some of the studies listed in Annex II have been submitted to ECHA more than twelve years ago in another registration dossier. Article 25(3) of the REACH Regulation allows registrants to use any (robust) study summary submitted in the framework of a registration at least twelve years previously for the purposes of registration. In a separate communication from the present decision, ECHA will provide the Claimant the (robust) study summaries submitted to ECHA in this other registration dossier, which can be used for REACH registration purposes without compensation. The Claimant may decide to use in their registration dossier the (robust) study summaries submitted in this other dossier, rather than the ones included in Annex III of the present decision. In this case, the share of the cost the Claimant will pay to the Other Party will not have to cover the (robust) study summaries the Claimant will use from the other registration dossier.

This decision will be published in an anonymised version on ECHA's website³.

B. Observations

The present decision may not cover all the Claimant's information needs under Annex VIII of the REACH Regulation.

Despite the present decision, both parties are still free to reach a voluntary agreement. ECHA strongly encourages the parties to negotiate further in order to reach an agreement that will be satisfactory for both parties.

Instructions to the Claimant on how to submit a registration dossier making use of the permission to refer are provided in Annex IV. For more detailed technical instructions covering your specific situation, any party may contact ECHA's Helpdesk, with a reference to the present dispute submission number:
[https://comments.echa.europa.eu/comments cms/Contact_REACH.aspx](https://comments.echa.europa.eu/comments/cms/Contact_REACH.aspx).

³ Available at <https://echa.europa.eu/regulations/reach/registration/data-sharing/data-sharing-disputes/echa-decisions-on-data-sharing-disputes-under-reach>.

C. Appeal

Either party may appeal this decision to the Board of Appeal of ECHA within three months of its notification. The appeal must set out the grounds for appeal. Further details, including the appeal fee, are set out at <http://echa.europa.eu/web/guest/regulations/appeals>.

Authorised⁴ by

Minna Heikkilä
Head of Legal Affairs

⁴ As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

Annex I: REASONS FOR THE DECISION

A. Applicable law

1. In a dispute pursuant to Article 27(5) of the REACH Regulation, ECHA performs an assessment of the efforts of the parties to reach an agreement (Article 5 of Implementing Regulation 2016/9). According to Article 27(6) of the REACH Regulation and Article 3(2) of Implementing Regulation 2016/9, ECHA may grant permission to refer to the requested studies, if the claimant has made every effort to find an agreement on the sharing of the data and the other party has failed to do so. The permission to refer is subject to the proof that the potential registrant has paid a share of the costs incurred by the previous registrant(s) ('proof of payment').
2. The obligation to make every effort to find an agreement that is transparent, fair and non-discriminatory is laid down in Articles 27(2) and 27(3) of the REACH Regulation. It is further defined in Articles 2 and 4 of Implementing Regulation 2016/9.
3. Making every effort means that the registrants must negotiate as constructively as possible and in good faith. They must make sure that the negotiations move forward in a timely manner, express their arguments and concerns, ask questions and reply to each other's arguments, concerns and questions. They must try to understand the other party's position and consider it in the negotiations. Making every effort also means that the parties need to be consistent in their negotiating strategy. They should raise their concerns in a timely manner and behave in a consistent and predictable manner as reliable negotiators. When they face dissent on an aspect, the parties have to explore alternative routes and make suitable attempts to unblock the negotiations. As the potential and existing registrants themselves bear the obligation to make every effort to find an agreement, they need to exhaust all possible efforts before submitting a dispute to ECHA with the claim that negotiations have failed.

B. Summary of facts

4. This summary of facts is based on the documentary evidence submitted by the Claimant on 03 December 2020 and by the Other Party on 31 December 2020.
5. At the time of the submission of the dispute, both parties were existing registrants of the substance. The Claimant requested the Other Party to share data for the purpose of submitting information required under Annex VIII of the REACH Regulation following an increase of the quantity of the substance they manufactured or imported.
6. On 08 April 2020, the Claimant informed the Other Party it had submitted an inquiry to ECHA regarding the tonnage upgrade of the Substance. They informed the Other Party that ECHA provided them with a list of studies submitted less than 12 years previously. The Claimant asked for the sharing of the studies included in the list and for the cost of a letter of access.⁵
7. On the same day, the Other Party replied that they are acting as only representative and that they will bring the request to the attention of the non-EU manufacturer and discuss it with them.⁶
8. On 30 April and 11 May 2020, the Claimant sent reminders to the Other Party.⁷ On 11 May 2020, the Other Party reverted to the Claimant to invoke the pandemic situation in order to

⁵ Claimant; 08/04/2020.

⁶ Other Party; 08/04/2020.

⁷ Claimant; 30/04/2020 and 11/05/2020

justify the difficulty and the delay in replying to the data sharing request.⁸ On 18 May 2020, the Claimant acknowledged the difficulty resulting from the pandemic situation and gave a deadline for receiving a reply to their request at the end of May 2020.⁹

9. On 29 May 2020, the Other Party referred to a prior ECHA data sharing decision to invoke that *"Intellectual property rights, patent, substance identity profile, and substance sameness, has not changed a bit. Because the Claimant is not trying to dissolve all issues raised at the decision"*. In addition, the Other Party also claimed ECHA *"permitted [their] application to tonnage-up as multi-constituent substance in February 2017"*. On this ground, the Other Party stated that they cannot *"accept the substance sameness of [Claimant's substance] and [Other Party's substance]"* and therefore cannot share the data on their substance. The Other Party also asked the Claimant to inform them on *"any agreement in the meantime with patent owner that means you are not infringement of the exclusive patent."*¹⁰
10. On 05 June 2020, the Claimant provided to the Other Party the quotation of a reply of an inquiry to ECHA referring to the identity of the Substance: *"Based on the composition reported in your registration dossier and in the registration dossier submitted by [the Other Party], ECHA is of the opinion that the substance manufactured by you and the one from [the Other Party] should be registered jointly because they have in common one main constituent that is present at concentrations above 80%. Accordingly, a joint registration would be appropriate and data sharing negotiations should take place"*. On this ground, the Claimant challenged the Other Party's statement that their substance was a multi-constituent substance. The Claimant therefore requested the Other Party to confirm ECHA's conclusion on mono-constituent status of their substance and to confirm whether their respective substances are the same.¹¹
11. On 15 June 2020, the Claimant sent a reminder¹², to which the Other Party replied by a waiting reply indicating that they had consulted ECHA.¹³ On 10 September 2020, the Claimant sent a reminder.¹⁴ On the same day, the Other Party sent a waiting reply.¹⁵
12. On 23 September 2020, the Claimant sent another reminder and informed the Other Party it would submit a data sharing dispute before ECHA in case of absence of reply before the end of month.¹⁶
13. On 25 September 2020, the Other Party indicated that the non-EU manufacturer was *"still reviewing ECHA's information and update"*. They requested the Claimant to share with them in the meantime the information on the composition of their substance that they submitted under section 1.2 of their registration dossier.¹⁷
14. On 30 September 2020, the Claimant argued that the Other Party had no legitimacy to request them to share details contained in their registration dossier and informed them that a data sharing dispute will be lodged to ECHA.¹⁸

⁸ Other Party; 11/05/2020.

⁹ Claimant; 18/05/2020.

¹⁰ Other Party; 29/05/2020.

¹¹ Claimant; 05/06/2020.

¹² Claimant; 15/06/2020.

¹³ Other Party; 19/06/2020.

¹⁴ Claimant; 10/09/2020.

¹⁵ Other Party; 10/09/2020.

¹⁶ Claimant; 23/09/2020.

¹⁷ Other Party; 25/09/2020.

¹⁸ Claimant; 30/09/2020.

15. On 09 November 2020, the Claimant reminded the Other Party that ECHA had confirmed that both substances had the same component in a concentration above 80% and that, on this basis, they had an obligation to share data. They also informed the Other Party that a data sharing dispute will be submitted on 15/11/2020 in case the requested studies would not be shared.¹⁹
16. The Claimant submitted the data sharing dispute on 03 December 2020.

C. Assessment

17. On 29 May 2020, after several reminders from the Claimant, the Other Party provided arguments as to why they would refuse sharing the data requested. These arguments related to a concern of violation of a pending patent held by another operator and the fact that the substances registered by the Claimant and the Other Party would in fact not be the same. More specifically, the Other Party claimed that their substance was a multi-constituent while the substance of the Claimant was a mono-constituent substance.²⁰
18. The Claimant replied to the Other Party on 05 June 2020. As from that reply, the negotiations focused exclusively on the identity of the substance registered respectively by the Claimant and the Other Party. More specifically, the Claimant pointed out that, in the context of an inquiry under Article 26 of the REACH Regulation, ECHA confirmed that both substances of the Claimant and the Other Party contain more than 80% of the same constituent. Accordingly, they are both a mono-constituent substance with the same identifier and their registrants are therefore subject to data sharing obligations. In that same message the Claimant requested the Other Party to confirm the mono-constituent nature of their substance and to recognise that their substance is the same as the Claimant's substance.²¹
19. The Claimant repeated their request on numerous occasions until the submission of the data sharing dispute.²²
20. Within the six months between the request of the Claimant and the submission of the data sharing dispute, the Other Party never justified why they would disagree with ECHA's finding that the substances of the respective parties had the same constituent in concentration above 80% and had thus to be considered the same substance. While the identity of the substance was initially raised by the Other Party to refuse the sharing of data, their failure to reply to the Claimant's argument precluded indisputably the negotiations from moving forward.

D. Conclusion

21. By responding to the Other Party's argument to refuse the sharing of data, the Claimant made every effort to reach an agreement on the sharing of information. However, the Other Party did not make every effort to reach an agreement on the sharing of information.
22. Therefore, ECHA grants the Claimant permission to refer to the studies specified in the Annex II, subject to the receipt by ECHA of the proof that the Claimant has paid the Other Party a share of the costs incurred. This proof of payment must be submitted to ECHA by 29 March 2021. In case it is not submitted by the indicated date, the present permission to refer will be revoked.

¹⁹ Claimant; 09/11/2020.

²⁰ See paragraph 9 above.

²¹ See paragraph 10 above.

²² See paragraphs 11, 12, 14 and 15 above.