

[REDACTED]
11 March 2021

The Claimant

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

Copy to:

The Other Party

[REDACTED]
[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 11 May 2021.

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 (robust) study summaries, can be found in Annexes II and III. However, **the Claimant cannot make use**

¹ Regulation (EC) N° 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.

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.

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 VII 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.

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

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

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).
2. The obligation 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. 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. The parties must 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. The potential and existing registrants must 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 1 February 2021 and by the Other Party on 16 February 2021 regarding the negotiations between the parties up to the data sharing dispute submission.
5. On 11 July 2019, the Claimant contacted the Other Party to agree on engaging an independent third party to clarify whether the substance of each party can be registered with jointly submitted hazard information.⁵ Between 18 July 2019 and 5 September 2019 the parties exchanged several emails in which they finally concluded that an independent third party would carry out the task and discussed the relevant timelines.⁶
6. In the following exchanges, the parties agreed with the third party on a teleconference to take place on 12 September 2019.⁷ Following the teleconference, the third party sent to the Claimant and the Other Party on 19 and 20 September 2019 the 'three-way agreement' discussed at the teleconference for review.⁸
7. On 9 and 17 October 2019 the Claimant and the Other Party sent their comments on the 'three-way agreement' to the third party.⁹ In the following exchanges, the third party incorporated the comments provided by both parties to the agreement and invited them to

⁵ Claimant; 11/07/2019

⁶ Other Party; 18/07/2019, Claimant; 26/07/2019, Other Party; 13/08/2019, Claimant; 16/08/2019, Other Party; 21/08/2019, Claimant; 05/09/2019.

⁷ Other Party; 06/09/2019, Claimant; 11/09/2019

⁸ Third party; 19/09/2019, Claimant; 20/09/2019, Third party; 20/09/2019

⁹ Claimant; 09/10/2019, Other Party; 17/10/2019

sign it.¹⁰

8. On 22 October 2019, the Claimant indicated that it was unable to accept the agreement as revised by the Other Party.¹¹ One of the reasons indicated by the Claimant was that the conditions imposed by the Other Party went beyond the REACH requirements on substance identification. In this regard, the Claimant pointed out that *'the onus is on each party to provide analytical data that permit identification and characterisation of each party's UVCB substance, and that distinguish it from any solvents, diluents, or additives that may also be present'*.
9. On 5 November 2019, the Other Party responded that it found the Claimant's objections unacceptable.¹² In particular, the Other Party noted that *'it is well known that analytical, physicochemical and toxicological data on a substance should be obtained in such a manner that interference from solvents, additives or diluents is avoided. For the substance in question, the presence of diluents or solvents would interfere in properly identifying and quantifying the substance. [...] For an apple-to apple comparison, we would expect [the Claimant] to submit analytical data on the substance itself for the sameness determination.'*
10. The next communication was sent by the Claimant on 31 July 2020.¹³ The Claimant reiterated its objection rejecting *'the data quality stipulation proposed by [the Other Party], as this concern is already covered in [the third party's] proposal. The proposal states clearly that [the third party] may request additional information to perform its evaluation. It is important to both parties and to the European Chemicals Agency (ECHA) that [the third party] be a truly independent third party for the purposes of this sameness determination and, in that role, be the sole arbiter of what data are necessary and sufficient to form and support its scientific opinion.'*
11. Between 12 August and 16 September 2020, the Claimant sent several reminders requesting the Other Party to respond to the Claimant's communication dated 31 July 2020.¹⁴ On 24 August 2020 the Other Party indicated that the matter was under review.¹⁵
12. On 24 September 2020, the Other Party indicated that it found the Claimant's latest proposals unacceptable.¹⁶ The Other Party noted that *'[the Other Party] does not wish to stipulate on the quality of the analytical data that [the Claimant] should be providing. [...] To unequivocally demonstrate that [the parties'] substances have the same composition, the analytical data must be on samples that consist of the UVCB substance only, as [the Other Party's] data are. If [the Claimant] cannot provide such data, this whole exercise would be in vain. We must agree on this basic premise for this project to begin.'*
13. On 18 November 2020, the Claimant expressed its disagreement with the Other Party's demand that the parties agree beforehand on the substance data to be sent to the third party.¹⁷ In this regard, the Claimant noted that *'it is important to both [parties] that [the third party] be the sole arbiter -- a truly independent third party -- of data quality and sufficiency in this substance sameness evaluation. [...] It is [the Claimant's] view that allowing [the third party] to be a truly independent third party and to proceed with the evaluation is beneficial to [the Other Party] and places any potential burdens and risks on [the Claimant]. By adding*

¹⁰ Third party; 18/10/2019, Other Party; 18/10/2019, Third party; 21/10/2019

¹¹ Claimant; 22/10/2019.

¹² Other Party; 05/11/2019

¹³ Claimant; 31/07/2020

¹⁴ Claimant; 12/08/2020, 24/08/2020, 01/09/2020, 09/09/2020, 16/09/2020

¹⁵ Other Party; 24/08/2020

¹⁶ Other Party; 24/09/2020

¹⁷ Claimant; 18/11/2020

stipulations on data quality rather than allowing [the third party] to move forward with the evaluation of whatever data [the parties] choose to provide, [the Other Party] appears, by its course of conduct, to be interfering with the third party evaluation and preventing [the Claimant] from registering its substance, rather than working cooperatively toward resolution of the substance sameness matter.[..] ECHA, not [the parties, or the third party] has the final responsibility and authority to determine whether or not [the Claimant's] registration dossier is complete with respect to the analytical characterization data.'

14. On 1 December 2020, the Other Party reiterated its position that *'the analytical data submitted by [the Claimant] must be on the registered substance itself, without the presence of solvents, diluents or other additives. This would ensure unequivocal assessment of comparable data for the sameness determination.'*¹⁸
15. On 15 January 2021, the Claimant informed the Other Party that in view of the latter's refusal to permit the third party to be the sole assessor of whether the substance of each party can be registered with the same hazard information, the Claimant would proceed with informing ECHA on the failure to reach an agreement.¹⁹
16. The data sharing dispute was initiated on 19 January 2021 and supplemented on 1 February 2021.
17. It is noted that throughout the parties discussions, another point of contention related to the Claimant's proposal to include in the 'three-way agreement' a provision allowing the third party to submit information directly to ECHA upon request. However, towards the end of the negotiations,²⁰ the Claimant agreed to remove its proposal and thereby this issue was no longer a point of disagreement when the data sharing dispute was initiated. Consequently, the summary of the facts as well as ECHA's assessment focuses on the parties' disagreement that lasted until the end of the negotiations related to the clarification requested by the third party on whether the substance of each party can be registered with jointly submitted hazard information.

C. Assessment

18. In the beginning of the negotiations the parties engaged actively in discussions to agree on an independent third party to assess whether the substance of each party can be registered with jointly submitted hazard information. Both parties reacted promptly to each other requests and made alternative proposals which led to agreeing on a specific third party which would carry out that task in an independent fashion.
19. The Other Party required the inclusion of a clause in the contractual arrangement with the third party which aimed to make sure *'that interference from solvents, additives or diluents is avoided'*²¹ in the substance related information that the parties would have to send to the third party. The Other Party justified its demand by claiming that for an unequivocal demonstration that the parties' substances *'have the same composition, the analytical data must be on samples that consist of the UVCB substance only'*.²²
20. The Claimant disagreed on the inclusion of such clause claiming that the independent third party should be the sole arbiter in determining whether the substance of the respective parties can be registered with jointly submitted information, as agreed by the parties. The Claimant

¹⁸ Other Party; 01/12/2020

¹⁹ Claimant; 15/01/2021

²⁰ Claimant; 18/11/2020

²¹ See above at paragraph 9

²² See above at paragraph 12

claimed that in case the third party would need more information to perform its assessment, the draft contractual agreement already provided for the possibility that the third party would request additional information from the parties. The Claimant also pointed out that he bears the risk of the substance of the respective parties being found not to be registered with jointly submitted information. The Claimant also stressed that only ECHA is eventually responsible and competent to determine whether the substance of each registrant can have the same EC identifier and whether the hazard information jointly submitted is representative for the substance of both registrants.

21. As explained in Section A, the registrants must make sure that they reply to each other's arguments, concerns and questions and try to understand the other party's position and consider it in the negotiations. The evidence shows that the Other Party failed to respond to the Claimant's specific arguments raised against the inclusion in the contractual arrangement of the clause required by the Other Party.
22. The parties never reached a stage of negotiations where they could have discussed the terms of the sharing of the data and costs. As such, the parties' discussions stopped at this preliminary stage without there being any real negotiations regarding the information and data required, or the sharing of costs for such information.
23. Thus, by failing to respond to the Claimant's specific points raised against the inclusion of the relevant clause in the contractual arrangement, the Other Party prevented the negotiations from moving forward in a timely and constructive manner regarding the Claimant's request to share data.
24. In the light of the above, it can be concluded that the Claimant made every effort to find an agreement on the sharing of data with the Other Party, whereas the Other Party failed to do so.

D. Conclusion

25. The Claimant made every effort to reach an agreement on the sharing of information.
26. 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 11 May 2021. In case it is not submitted by the indicated date, the present permission to refer will be revoked.