

[REDACTED]
19 April 2022

The Claimant

[REDACTED]
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Represented by

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

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.

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 20 June 2022.

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, 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 a 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 12 years ago in an earlier 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. ECHA will provide the Claimant with these (robust) study summaries in a separate communication. These can be used for REACH registration purposes without compensation. In case the Claimant wishes to use in their registration dossier these (robust) study summaries older than 12 years, the share of the cost the Claimant will pay to the Other Party will not have to cover these (robust) study summaries.

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 [REDACTED] 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 of them.

Instructions to the Claimant on how to submit a registration dossier making use of the permission to refer are provided in Annex IV.

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 the procedure pursuant to Article 27(5) of the REACH Regulation, ECHA performs an assessment to determine whether the parties made every effort to reach an agreement on the sharing of information and associated costs for the purposes of registration. In doing so, ECHA checks whether the parties' obligations related to the sharing of data and data costs have been complied with, including whether the parties complied with the requirements of fairness, transparency and non-discrimination (Article 5 of Implementing Regulation 2016/9). 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 make every effort to find an agreement that is transparent, fair and non-discriminatory is laid down in Article 27(2) and (3) of the REACH Regulation and further defined in Articles 2 and 4 of Implementing Regulation 2016/9. According to Article 27(2), the obligation to make every effort to achieve a data sharing agreement arises on the previous registrant of a substance upon the request by a potential registrant for the same substance, as referred to in Article 26(3) of the REACH Regulation.
3. Article 27(3) of the REACH Regulation and Article 2 of Implementing Regulation 2016/9 provide for the requirement of data and cost sharing to be transparent. Article 2(2) of Implementing Regulation 2016/9 requires a previous registrant of a substance for which a data sharing agreement has already been reached to provide a potential registrant, upon request, with (1) the itemisation of data, including *'the cost of each data item, a description indicating the information requirements in [the REACH Regulation] to which each cost corresponds and a justification of how the data to be shared satisfies the information requirement'*, and (2) *'the itemisation and justification of any cost of creating and managing the data-sharing agreement and the joint submission of information between registrants of the same substance'*.
4. Article 2(3) of Implementing Regulation 2016/9 also requires registrants of the same substance who submitted information jointly to *'document yearly any further costs incurred in relation to the operation of their data-sharing agreement'*. The annual documentation must *'include, for the purposes of the reimbursement mechanism, a record of any compensation received from new registrants'*.

B. Summary of facts

5. This summary of facts is based on the documentary evidence submitted by the Claimant on 28 February 2022 and by the Other Party on 25 March 2022.
6. During the negotiations relating to the present dispute, most e-mail messages were exchanged between the company [REDACTED], acting on behalf of the Claimant, on one side, and [REDACTED], acting on behalf of the Other Party, on the other side. For the sake of simplicity, no distinction is made below between the Claimant and the Claimant's representative, or between the Other Party and the Other Party's representative, and only the Claimant and the Other Party are referred to as taking part in the exchange.
7. On 8 October 2021, the Claimant informed the Other Party of the Claimant's intention to register the Substance in the [REDACTED] tonnage band and requested the *'Joint Submission Agreement'* and the price for the access to the data submitted by the Other Party.⁵

⁵ E-mail message of the Claimant of 8 October 2021.

8. On 29 October 2021, after a first reply from the Other Party,⁶ the Claimant requested a breakdown of the costs for the access to data.⁷
9. On 15 November 2021, the Other Party provided a table with a high-level overview of data and data sharing for (*inter alia*) the tonnage band of interest of the Claimant.⁸ The table listed costs for the studies in the Other Party's registration and included an overall figure relating to the 'Consortium Management until 2018' based on a '2010 budget calculation' as well as an individual data sharing cost '[b]ased on the assumption of the 2010 number of registrants'. The sum so calculated was then further converted into a lump sum.⁹ A one-page explanation of the factors considered and the costs included in the calculation was also provided.¹⁰
10. On 24 November 2021, the Claimant requested clarifications and raised objections on the calculation of costs, focusing (*inter alia*) on the application of a 'multiplying factor' in the calculation of the fee, on the reliance on an outdated number of co-registrants, and on the circumstance that costs would not be shared equally among all registrants. Consequently, the Claimant requested a new cost breakdown keeping into account the fairness, transparency and non-discrimination principles.¹¹
11. On 16 December 2021, the Other Party reacted to each point raised by the Claimant and stated that the breakdown would be made available on condition that the Claimant indicated if the substance of their interest was in a nanoform, in a 'bulk' form or 'surface-treated'.¹²
12. Between 4 January 2022 and 17 February 2022, a discussion took place between the parties on the identification of the substance of interest to the Claimant and the consequences on the Other Party's data sharing obligations.¹³
13. The Claimant stated that the substance in question was not in a nanoform.¹⁴ While announcing more analyses to clarify this aspect,¹⁵ they argued that it was the responsibility of the potential registrant to conclude on the substance sameness and that analytical data on the substance identity would not be shared.¹⁶
14. By contrast, the Other Party argued that the Substance 'in general is a nanostructured material'¹⁷ and that in any event, as the Other Party's dossier only covered nanoforms, the information included therein could not be relied upon for the registration of non-nanoforms.¹⁸ As to the sharing of data on the nanoform, the Other Party explained that a recalculation of the cost breakdown was currently under way and the most recent breakdown available (from

⁶ E-mail message of the Other Party of 11 October 2021.

⁷ E-mail message of the Claimant of 29 October 2021.

⁸ E-mail message of the Other Party of 15 November 2021, 14:37.

⁹ Document 'Calculation of a LoA Price for [REDACTED]'.

¹⁰ Document 'Explanation of the factors considered and the costs included in the price of the Letter of Access (LoA) for [REDACTED] for the tonnage band [REDACTED]'.

¹¹ E-mail message of the Claimant of 24 November 2021.

¹² E-mail message of the Other Party of 16 December 2021, 9:49.

¹³ E-mail messages of the Claimant of 4 January 2022, 18:16, 14 January 2022, 19 January 2022, 3 February 2022 and 8 February 2022. E-mail messages of the Other Party of 7 January 2022, 19 January 2022, 14:40 and 14:52, 8 February 2022 and 17 February 2022.

¹⁴ E-mail message of the Claimant of 14 January 2022.

¹⁵ E-mail messages of the Claimant of 3 and 8 February 2022.

¹⁶ E-mail message of the Claimant of 8 February 2022.

¹⁷ E-mail message of the Other Party of 7 January 2022.

¹⁸ E-mail message of the Other Party of 19 January 2022.

2010) had already been provided. In addition, the Other Party provided a list of studies in the existing registration and the associated costs.¹⁹

15. The Claimant reiterated their request for a cost breakdown on multiple occasions between 4 January and 8 February 2022.²⁰
16. On 7 March 2022, the Claimant submitted to ECHA the present data sharing dispute. This dispute refers to information requested to the Other Party by the Claimant for a registration in the [REDACTED] tonnage band.²¹

C. Assessment

17. As explained in section A, ECHA is called upon to determine whether the parties complied with their obligations related to the sharing of data and data costs in the negotiations outlined in section B.
18. The Agency's assessment starts from the first criterion laid down in Article 2 of Implementing Regulation 2016/9, namely whether the agreement was negotiated in accordance with the transparency requirement.²² It is apparent from the exchange between the parties that, at the time of the negotiations, a data sharing agreement had already been concluded by previous registrants of the Substance.²³ This case therefore falls within the scope of Article 2(2) of Implementing Regulation 2016/9.
19. In addition, when carrying out its assessment, the Agency has paid due regard to all individual actions and communications of the parties as well as the development of the negotiations over time.²⁴ Finally, the Agency's assessment centred upon the elements on which the parties could not agree during their negotiations, and which therefore led to the filing of the dispute.²⁵
20. On a preliminary point, it should be noted that the information submitted by the Other Party in their registration referred to the Substance in a nanoform,²⁶ whereas the Claimant first stated that the substance of interest to them was not in a nanoform.²⁷ Based on this circumstance, the Other Party took the view that, in essence, no data sharing obligations were applicable to them, unless the Claimant came to conclude, following further analysis, that their substance of interest was also in a nanoform.²⁸
21. As outlined in section A, obligations relating to the sharing of existing data arise on a previous registrant upon the request by a potential registrant of the same substance. A distinction between nanoforms and non-nanoforms of a substance does not prevent the consideration that all such forms still belong to the same substance. In any case, the data sharing obligation set out in Title III of the REACH Regulation applies among registrants of the same substance, irrespective of the form of the substance in which existing registrants and potential registrants may have an interest. The data sharing obligation set out in Article 27 was triggered by the

¹⁹ E-mail message of the Other Party of 17 February 2022.

²⁰ E-mail messages of the Claimant of 4 January 2022, 18:16, 19 January 2022, 3 February 2022 and 8 February 2022.

²¹ E-mail message of the Claimant of 8 October 2021.

²² See, to this effect, Decision of the Board of Appeal of 15 April 2019, Case A-010-2017, *REACH & Colours and REACH & Colours Italia*, paragraph 85.

²³ E-mail messages of the Other Party of 11 October 2021 and 16 December 2021, 9:49.

²⁴ See, to this effect, Decision of the Board of Appeal of 15 April 2019, Case A-010-2017, *REACH & Colours and REACH & Colours Italia*, paragraph 87.

²⁵ *Ibid.*, paragraph 88.

²⁶ E-mail messages of the Other Party of 7 January 2022, 19 January 2022, 14:40, and 17 February 2022.

²⁷ E-mail message of the Claimant of 14 January 2022.

²⁸ E-mail messages of the Other Party of 19 January 2022, 14:40, 8 February 2022 and 17 February 2022.

unequivocal request of the Claimant to share the data required for the registration of the substance already registered by the Other Party.

22. The Claimant asked for an itemisation of the data sharing costs from the Other Party on 29 October 2021²⁹ and reiterated this request throughout the negotiations.³⁰ The Other Party provided a high-level overview of the costs,³¹ an explanation of how costs were calculated³² and a list of the studies for the [REDACTED] tonnage band³³. The Claimant repeatedly argued that the information provided by the Other Party was insufficient and not in line with the transparency requirement for the following reasons.
23. Firstly, the Claimant argued that no itemisation of administrative costs was made available. ECHA observes that, while certain categories of costs (*'management fees, legal fees, sweat equity of the companies working on the dossiers, the fees of external experts and some others'*) were mentioned by the Other Party when addressing the Claimant's observations,³⁴ specific figures were provided neither for each underlying cost item nor for each category. This represents a failure of the Other Party to comply with Article 2(2) of Implementing Regulation 2016/9.
24. Secondly, the Claimant³⁵ challenged a *'multiplying factor'* that was applied to both study and administrative costs in order to determine the final data sharing fee, while no explanation was provided to justify this factor. The Other Party confirmed the application of this multiplying factor.³⁶ Yet, no detail was provided on how that factor was calculated, despite the explicit request of the Claimant in that sense³⁷. On the opposite, the Other Party stated in reply that *'[t]here is no single multiplication factor, but a three-dimensional matrix used to distribute the costs in a fair manner between the number of registrants and the tonnage bands'*. No additional description was made available, due to the alleged 'extreme complexity' of the underlying calculation.³⁸ This also represents a failure to comply with Article 2(2) of Implementing Regulation 2016/9 on the itemisation of both study costs and administrative costs.
25. Thirdly, the Claimant argued that price calculations were based on an estimated number of registrants dating back to 2009.³⁹ In response, the Other Party simply referred the Claimant to the 'News' section of the Other Party's website.⁴⁰ ECHA notes that no evidence has been provided on whether the requested information was actually available on that website at the time of the negotiations and whether it was satisfactory to the Claimant.
26. In this respect, the Other Party also argued that a recalculation of costs was under way, and the most recent information available was dating back to 2010.⁴¹ This argument is incompatible with Article 2(3) of Implementing Regulation 2016/9, which sets out the obligation for participants to a data sharing agreement to keep an annual update of costs,

²⁹ E-mail message of the Claimant of 29 October 2021.

³⁰ See footnote 20.

³¹ Document *'Calculation of a LoA Price for [REDACTED]'*.

³² Document *'Explanation of the factors considered and the costs included in the price of the Letter of Access (LoA) for [REDACTED] for the tonnage band [REDACTED]'*.

³³ E-mail message of the Other Party of 17 February 2022.

³⁴ E-mail message of the Other Party of 16 December 2021, 9:49.

³⁵ E-mail message of the Claimant of 24 November 2021, *sub* paragraph 1.

³⁶ E-mail message of the Other Party of 16 December 2021, 9:49.

³⁷ E-mail message of the Claimant of 24 November 2021, *sub* paragraph 1.

³⁸ E-mail message of the Other Party of 16 December 2021, 9:49.

³⁹ E-mail message of the Claimant of 24 November 2021, *sub* paragraph 7.

⁴⁰ E-mail message of the Other Party of 16 December 2021, 9:49.

⁴¹ E-mail messages of the Other Party of 16 December 2021, 9:49, and 17 February 2022.

including a record of compensations received from registrants joining at a later point. Therefore, the circumstance that a recalculation was under way could not be invoked as a justification.

27. In any case, updated information on the number of co-registrants is indispensable for a potential registrant to understand how costs are shared among participants to the agreement. The request of the Claimant was therefore legitimate and the failure to address it constitutes a breach of the Other Party's obligation to make every effort to reach an agreement in a transparent way, pursuant to Article 27(3) of the REACH Regulation.
28. Fourthly, the Claimant contested that groups of affiliated registrants were granted a single letter of access. The Claimant argued that the contribution of those affiliated companies to the data sharing costs as one legal entity resulted in a discrimination against registrants without affiliates.⁴² The Other Party objected that a compensation per corporate group was a standard practice in the industry.⁴³
29. However, ECHA's Board of Appeal has already taken position on this point. In its decision in Case A-014-2018, the Board of Appeal stated that '*a general and absolute exemption of all affiliates from the requirement to pay a share of the costs is not objectively justified*'.⁴⁴ The Other Party consequently failed to comply with the requirements for data and cost sharing to be non-discriminatory as regards the status of registrants' affiliates.

D. Conclusion

30. The Other Party failed to comply with their obligations with a view to achieve an agreement on the sharing of information and associated costs, as provided for by Article 27(3) of the REACH Regulation and Article 2(2) of Implementing Regulation 2016/9.
31. 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 20 June 2022. In case it is not submitted by the indicated date, the present permission to refer will be revoked.

⁴² E-mail message of the Claimant of 24 November 2021, *sub* paragraph 8.

⁴³ E-mail message of the Other Party of 16 December 2021, 9:49.

⁴⁴ Decision of the Board of Appeal of 23 July 2020, Joint Cases A-014-2018 to A-021-2018, *Tecnofluid*, paragraph 69.