

[REDACTED]  
Helsinki, 14 December 2018

*The Claimant*

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

*Represented by*

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

Copy to:  
*The Other Party*

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

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 ACCESS TO A JOINT SUBMISSION AND THE SHARING OF DATA**

**A. Decision**

**ECHA grants you permission to refer to the information you requested from the Existing Registrant of the Substance and access to the joint submission.**

This decision is adopted under Articles 30(3) and 11 of Regulation (EC) No 1907/2006 ('REACH Regulation')<sup>1</sup> and Article 5 of the Commission Implementing Regulation (EU) 2016/9 on joint submission of data and data-sharing in accordance with REACH

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<sup>1</sup> 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.

(‘Implementing Regulation 2016/9’)<sup>2</sup>.

The reasons for this decision are set out in Annex I. The list of studies that ECHA grants you permission to refer to, along with copies of the (robust) study summaries, can be found in Annexes II and III, respectively. Instructions on how to submit your registration dossier are provided in Annex IV.

This decision will be published in an anonymised version on ECHA’s website<sup>3</sup>.

## **B. Observations**

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

According to Article 30(3) of the REACH Regulation, the Existing Registrant shall have a claim on you for an equal share of the cost, which shall be enforceable in the national courts, provided that the full study report or reports (if applicable) are made available to you.

Furthermore, please note that with the present decision ECHA gives you a permission to refer to studies only involving tests on vertebrate animals. However, the obligation of a SIEF member to share data on request by another SIEF member also extends to data not related to vertebrate animals.

ECHA will inform the competent national enforcement authorities of the present decision. The national enforcement authorities may take enforcement actions according to Articles 30(6) and 126 of the REACH Regulation.

## **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. If an appeal is submitted, this decision will be suspended. Further details, including the appeal fee, are set out at <http://echa.europa.eu/web/guest/regulations/appeals>.

Yours sincerely,

Christel Schilliger-Musset<sup>4</sup>

Director of Registration

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<sup>2</sup> 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.

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

<sup>4</sup> As this is an electronic document, it is not physically signed. This decision has been approved according to the ECHA’s internal decision-approval process.

## **Annex I: REASONS FOR THE DECISION**

### **A. Applicable law**

1. When a dispute is submitted to ECHA pursuant to Article 30(3) of the REACH Regulation, ECHA performs an assessment of the parties' efforts to reach an agreement (Article 5 of the Implementing Regulation 2016/9). According to Article 30(3) of the REACH Regulation and Article 3(2) of the Implementing Regulation 2016/9, ECHA may grant permission to refer to the relevant vertebrate studies and access to the joint submission, if the claimant has made every effort to find an agreement on the sharing of the data and access to the joint submission and the other party has failed to do so.
2. The obligation to make every effort to find an agreement on the sharing of data that is fair, transparent and non-discriminatory is laid down in Article 30(1) of the REACH Regulation. It is further defined in Articles 2 and 4 of the Implementing Regulation 2016/9. Under Article 11 of the REACH Regulation, multiple registrants of the same substance must submit data jointly.
3. Making every effort means that the existing and potential 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 each other'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.
4. In particular, every effort means for existing registrants to timely provide all information that is necessary for potential registrants to enter the joint submission for the same substance.

## B. Summary of facts

5. This summary of facts is based on the documentary evidence submitted by the Claimant on 22 October 2018. The Other Party has not submitted any evidence by the deadline set.
6. On 24 October 2016 the Claimant requested the LoA cost for [REDACTED] and [REDACTED], the SIP and the SIEF agreement template related to this substance. On 3 December 2016 the Other Party's representative replied that the legal and financial framework for the management of the substance was undergoing an evaluation and asked the Claimant to 'wait for a proposal by the end of 1. qtr 2017, hopefully a bit earlier'.<sup>5</sup>
7. On 29 June 2017 the Claimant sent a reminder reiterating the requests made on 24 October 2016. On 28 July the Claimant sent another reminder to the Other Party's representative. On 1 August 2017 the Other Party's representative replied that the [REDACTED] responsible for this substance would deal with the Claimant's request after the summer holidays. The Other Party's representative noted that 'in case [the Claimant] are in a hurry may look for a provisional agreement/access [sic]'.<sup>6</sup>
8. On 27 September 2017 and on 9 October 2017 the Claimant sent new reminders reiterating the requests made on 24 October 2016. On 29 November 2017 the Other Party's representative sent to the Claimant a communication from the Lead Registrant for this substance, and on the same day the Claimant requested an [REDACTED] version of the communication. On 6 December 2017 the Claimant again requested the LoA cost and the SIP, and on 13 December 2017 they sent a reminder.
9. On 18 December 2017 the Other Party's representative sent to the Claimant a communication from the Lead Registrant. On 13 February 2018 the Claimant informed the Other Party that the substance they imported was in conformity with the indications provided in the Other Party's dossier. The Claimant pointed out that they would not provide 'information about the manufacturing process which is confidential. Other documents from [the Claimant's] supplier are also confidential and [the Claimant is] not allowed to share them'.<sup>7</sup> The Claimant requested the Other Party to provide them 'with the LOA cost and SIP as it become urgent for [the Claimant] [sic]'.<sup>8</sup> On the same day the Other Party replied that '[their] SIP and consequently all [REDACTED] study referred to [the Other Party's] [REDACTED] were been formulated for [REDACTED] the substance in question'.<sup>9</sup> The Other Party noted that '[the Claimant] need[s] [the Claimant's] [REDACTED] and consequently [REDACTED] to complete the registration'.<sup>10</sup> On the same day, 13 February 2018, the Claimant in turn communicated that they would check with their supplier whether the Claimant's source is [REDACTED] or [REDACTED]. In the same message the Claimant requested the Other Party to provide them, in the meantime, with 'the LoA cost for [REDACTED]'. On the following day the Other Party informed the Claimant that the LoA price was [REDACTED] Euro.
10. On 22 February 2018 the Claimant communicated that they did not know yet whether the process used to produce the substance was of [REDACTED] origins and they communicated that they will receive this information from their supplier soon. In the same message the Claimant requested the Other Party to provide the SIP, the SIEF agreement and the invoice for a [REDACTED] dossier [REDACTED], and indicated details for invoicing. On 28 February the Other Party asked the Claimant to send them 'a declaration and/or a product data sheet and/or a flowsheet to demonstrate the production of [REDACTED]. Then

<sup>5</sup> Other Party; 3 December 2016

<sup>6</sup> Other Party; 1 August 2018.

<sup>7</sup> Claimant; 13 February 2018.

<sup>8</sup> Claimant; 13 February 2018.

<sup>9</sup> Other Party; 13 February 2018.

<sup>10</sup> Other Party; 13 February 2018.

[the Other Party] provide to send [to the Claimant] all documents [the Claimant] request.'

11. On 27 July 2018 the Claimant indicated that their 'dossier was postponed; it is needed again.' They requested the SIP, SIEF agreement and invoice for [redacted] dossier [redacted].<sup>11</sup> The Claimant communicated that their substance was of [redacted] but pointed out that they merely imported it, 'so the fact that [the Claimant's] substance is [redacted] is not a problem. [redacted] So [the Claimant] see no reason [redacted] [redacted].'<sup>12</sup> Later on the Claimant sent four reminders asking for the SIP, SIEF agreement and invoice.<sup>13</sup> In their reminder of 8 October 2018 the Claimant noted that they now urgently needed the requested information.
12. On 9 October 2018 the Other Party observed that 'the existing registration was done for [redacted] and consequently [redacted] [as well]. [The Other Party] are working to create [redacted], ready probably for the end of current year.'<sup>14</sup> On the same day the Claimant contacted the Other Party to arrange a phone call to discuss the matter and repeated the arguments already put forward on 27 July 2018. Again on the same day, 9 October 2018, the Other Party replied that the Claimant, while being an importer, was responsible for the effects of the substance on downstream users. The Other Party asked the following: 'Do[es the Claimant] know the [redacted] and its chemical, physical, toxicological and ecotoxicological effects? If yes, please send [to the Other Party] all studies [the Claimant] have under the spirit of REACH. If no, as LR [the Other Party] are responsible to verify these aspects, probably it will be the same but now [the Other Party] are not able to tell it. By the way, sorry but this week [the Other Party] are not available for a phone call.'<sup>15</sup>
13. On 10 October 2018 the Claimant noted that they had first contacted the Other Party in October 2016 but had not received the SIP and SIEF agreement yet. The Claimant highlighted that the substance in question was a [redacted] [redacted] and additionally qualified as 'an [redacted] [redacted]'. The Claimant stated that the Lead Registrant's responsibility is 'to define the criteria of the sameness based on known potential critical impurities and to mention them in a SIP to be shared with potential co-registrants.' The Claimant requested that, if the Other Party had concerns about impurities triggered by the [redacted] process, the Other Party should name these concerns in the SIP and give thresholds for them based on scientific knowledge. In the Claimant's view, the Other Party 'cannot exclude co-registrants for a [redacted] because they use a different process to obtain the substance. From the historical exchanges [the Claimant] have the impression that [the Other Party] exclude[s] the [redacted] for reasons which are not to be considered under REACH. [The Other Party] also refuse[s] to have a call to clarify the situation so [the Claimant] will be forced to open a data sharing dispute if [the Claimant] do[es] not obtain the necessary clarification from [the Other Party's] side before 17.10.2018.'
14. On 19 October 2018 the Claimant informed the Other Party that they would initiate a data sharing dispute during the following week. The Claimant explained that although they had provided the Other Party with all necessary information and accepted the LoA cost, the Other Party refused to sell them the LoA due to the [redacted] of the substance without indicating any threshold for potential impurities of concern.<sup>16</sup>

<sup>11</sup> Claimant; 27 July 2018.

<sup>12</sup> Claimant; 27 July 2018.

<sup>13</sup> Claimant 21 September 2018. Claimant; 2 October 2018. Claimant; 8 October 2018. Claimant; 9 October 2018.

<sup>14</sup> Other Party; 9 October 2018.

<sup>15</sup> Other Party; 9 October 2018 (second email sent by the Other Party on this day).


<sup>16</sup> Claimant; 19 October 2018.


15. On 22 October 2018 the Claimant submitted a claim under Article 30 of the REACH Regulation concerning the failure to reach an agreement on access to the joint submission and the sharing of information with the Other Party.




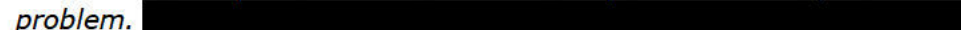
### **C. Assessment**

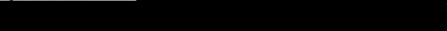
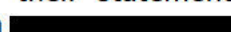

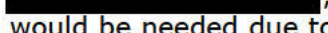
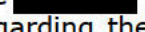
16. As explained in section A., ECHA assesses the efforts made by the parties in the negotiations that were outlined in section B.

17. The Claimant first requested the LoA cost, the SIP and a SIEF agreement template on 24 October 2016. All such items are necessary for a potential registrant to be able to assess the demands of existing registrants and eventually, if they agree on the terms proposed, enter the joint submission and thereby comply with regulatory obligations.

18. Despite the fact that these items were requested by the Claimant on 24 October 2016, the Other Party only provided the LoA cost and even that more than one year after the initial request, and by simply indicating the figure of  Euro.<sup>17</sup> Further, the SIP and SIEF agreement template were never provided despite various reminders.<sup>18</sup> The Claimant demonstrated its willingness to progress negotiations and reach an agreement by making timely and legitimate requests and sending reminders.<sup>19</sup> On the other hand, the Other Party did not reply in a timely manner and did not provide the requested information even after several reminders from the Claimant. Making every effort in the negotiations entails that an existing registrant needs to take into account the urgency for the potential registrant to register, and not delay sending vital information, such as the LOA cost, SIEF agreement and the SIP. By not providing to the Claimant SIEF agreement and the SIP, and providing the LoA cost more than a year after the first request the Other Party showed a failure to make efforts to find an agreement.

19. Further to this, the Other Party requested a *'declaration and/or product data sheet and/or flowsheet to demonstrate the production of *<sup>20</sup> as a prerequisite to provide the SIP, SIEF agreement and the invoice. In an earlier e-mail, the Claimant already explained the confidential nature of the manufacturing process and that they were not allowed to share confidential information.<sup>21</sup>

20. During the negotiations, the Other Party indicated that  in case the Claimant produced the substance through a  process.<sup>22</sup> First, the Claimant explained that *'the fact that [the Claimant's] substance is  is not a problem.* 

<sup>23</sup> When the Other Party repeated their statement, the Claimant made further effort by explaining that the substance being a   , there was no reason to assume that special work on the substance would be needed due to the  process.<sup>24</sup> The Claimant pointed out that, if the Other Party had any concerns regarding the sameness of the substance, the Other Party should clarify these and set thresholds for known critical impurities in the SIP.<sup>25</sup> However, the Other Party did not address this demand and never provided the SIP to the Claimant.

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<sup>17</sup> Other Party; 14 February 2018.

<sup>18</sup> Claimant; 29 June 2017. Claimant; 27 September 2017. Claimant; 9 October 2017. Claimant; 6 December 2017; Claimant; 13 December 2017; Claimant; 22 February 2018. Claimant; 2 October 2018. Claimant; 8 October 2018. Claimant; 9 October 2018. Claimant; 10 October 2018.

<sup>19</sup> Claimant; 22 February 2018.

<sup>20</sup> Other Part; 28 February 2018.

<sup>21</sup> Claimant; 13 February 2018.

<sup>22</sup> Other Party; 13 February 2018; Other Party; 9 October 2018 (referring to both emails sent by the Other Party on this day).

<sup>23</sup> Claimant; 27 July 2018.

<sup>24</sup> Claimant; 9 October 2018 (second email sent by the Claimant on this day). Claimant; 10 October 2018.

<sup>25</sup> Claimant; 10 October 2018. Claimant; 19 October 2018.

21. As a further effort, on 9 October 2018 the Claimant proposed a phone call to discuss these concerns,<sup>26</sup> but the Other Party was not available for the call during that week and did not propose any call in turn.<sup>27</sup> To show their intention to reach an agreement the Other Party could have suggested other dates for the phone call or replied to the Claimant's explanation in an email. However, instead of pursuing a constructive approach to progress the negotiations, the Other Party did not reply to the Claimant's last two emails.
22. In light of the above, the Claimant could consider that the negotiations with the Other Party would not progress further and they filed the dispute to ECHA as a measure of last resort.

#### **D. Conclusion**

23. Throughout the negotiations the Claimant made legitimate and timely requests concerning items that were necessary to their registration. They sent several reminders and responded to the Other Party's request for confidential information and substance sameness concerns by providing plausible arguments. The Claimant encouraged the Other Party to clarify the issue of substance sameness and offered the opportunity of a phone call to the Other Party. Under the circumstances, the Claimant made every effort to facilitate the progress of negotiations and reach an agreement with the Other Party.
24. Conversely, the Other Party provided the LoA cost only more than a year later than it was first requested and failed to provide the SIEF agreement and the SIP. In certain cases, the Other Party did not reply in a timely manner and requested confidential information as a precondition for data sharing.
25. Consequently, ECHA concludes that the Claimant made every effort to reach an agreement on access to the joint submission and the sharing of information, while the Other Party did not make every effort.
26. Therefore, ECHA grants the Claimant access to the joint submission and permission to refer to the studies specified in Annex II.

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<sup>26</sup> Claimant; 9 October 2018 (second email sent by the Claimant on this day).

<sup>27</sup> Other Party; 9 October 2018 (second email sent by the Other Party on this day).

"ECHA reminds you that following Article 16 of Regulation (EC) No 1049/2001, the documents attached are subject to copyright protection."