

JONES DAY

AVOCATS - ADVOCATEN

MICHÈLE GRÉGOIRE⁽⁶⁾
Avocat à la Cour de cassation
Advocaat bij het Hof van Cassatie
Member of the Belgian Supreme Court Bar

4, RUE DE LA RÉGENCE • REGENTSCHAPSSTRAAT 4
1000 BRUSSELS, BELGIUM
TELEPHONE: 32.(0)2.645.14.11 • FACSIMILE: 32.(0)2.645.14.45

PHILIPPE LACONTE
HOWARD M. LIEBMAN⁽⁴⁾
DAVID ROGER

Members of the Brussels Bar
⁽¹⁾Member of the Rome Bar
⁽²⁾Member of the Paris Bar
⁽³⁾Member of the New York Bar
⁽⁴⁾Member of the District of
Columbia Bar
⁽⁵⁾Member of the Düsseldorf Bar
⁽⁶⁾Admitted to the Paris Bar
⁽⁷⁾Member of the Naples Bar
⁽⁸⁾Member of the Berlin Bar
⁽⁹⁾Member of the
Frankfurt am Main Bar
⁽¹⁰⁾Member of the Swedish Bar

BERNARD AMORY
RENATO ANTONINI⁽¹⁾
CHANTAL BIERNAUX
CHARLOTTE BREUVART⁽²⁾
FERDINAND BRUGHMANS
SÉBASTIEN CHAMPAGNE
SERGE CLERCKX
THOMAS DE MUYNCK⁽³⁾
LAURENT DE MUYTER
CHARLES de NAVACELLE⁽²⁾⁽³⁾
YVAN DESMEDT
MATTHIEU DUPLAT
KAARLI H. EICHHORN⁽¹⁰⁾
VANESSA FONCKE
JÖRG HLADJK⁽⁶⁾
URSULA SCHLISSNER⁽⁵⁾
CRISTIANA SPONTONI⁽¹⁾
MARIO TODINO⁽⁷⁾
ALEXANDRE VERHEYDEN⁽³⁾
PHILIPP WERNER⁽⁸⁾

DIRECT NUMBER: +32 (0)2 645 14 60
USCHLISSNER@JONESDAY.COM

February 22, 2019

TO WHOM IT MAY CONCERN

VIA E-MAIL

Dear SIEF Member,


Re: REACH SIEF Communication C.I. Pigment Blue 1 (CAS 1325-87-7)¹

We are writing to you on behalf of Ferro Performance Pigments Belgium N.V, appointed as Lead Registrant for the REACH joint registration of the substance C.I. Pigment Blue 1, to notify you that the joint registration dossier has been accepted and the registration process is complete for this substance. The Joint Submission Agreement, including a Letter of Access (“LoA”) price calculation, as well as a list of the data used, is attached.

If you wish to participate in the joint submission and purchase an LoA, we kindly ask you to fill in, sign and send back to us (amccabe@jonesday.com) a scanned copy of the attached ‘LoA Application Form’. Once your LoA application has been duly accepted and payment has been made, you shall receive the joint submission token to join the registration and file the individual parts of your registration dossier, as well as a copy of the CSR for individual filing. The only use supported in the CSR is for ink applications. The Lead Registrant shall also provide you with Guidance on Safe Use to be submitted individually.

Thank you for your attention.

Kind regards,



Ursula Schliessner
Partner
www.JonesDayReach.com

*Annexes: Letter of Access (‘LoA’) Application Form – C.I. Pigment Blue 1
Joint Registration Agreement – C.I. Pigment Blue 1*

cc: Airi McCabe: amccabe@jonesday.com

¹ Ethanaminium, N-[4-[[4-(diethylamino)phenyl][4-(ethylamino)-1-naphthalenyl]methylene]-2,5-cyclohexadien-1-ylidene]-N-ethyl-, molybdatetungstatephosphate, CAS: 1325-87-7; EC: 215-410-7.



Letter of Access ('LoA') Application Form

C.I. Pigment Blue 1

(To be filled in and emailed back to Ms. McCabe (amccabe@jonesday.com))

NOTE:

*** By completing and sending the LoA application form to Jones Day, you shall be considered as having accepted the terms of the respective Joint Registration Agreement.**

*** Only once formal invoices will have been issued and settled, the LoA will be considered as issued and effective.**

*** The CSR was prepared by the Lead Registrant and *submitted jointly*. The Guidance on Safe Use will be provided by the Lead Registrant, but must be *submitted individually*.**

Substance
Ethanaminium, N-[4-[[4-(diethylamino)phenyl][4-(ethylamino)-1-naphthalenyl]methylene]-2,5-cyclohexadien-1-ylidene]-N-ethyl-, molybdatetungstatephosphate, C.I. Pigment Blue 1; EC 215- 410- 71; CAS 1325-87-7

Current Prices LoA	
<input type="checkbox"/> Up to 10 tons	EUR 42,548 (excl. VAT)*
<input type="checkbox"/> 10 - 100 tons <u>with</u> CSR:	EUR 124,808 (excl. VAT)*
<input type="checkbox"/> 10 - 100 tons without CSR:	EUR 123,682 (excl. VAT)*
<i>* Based on two co-registrants, incl. Lead Registrant</i>	

Please fill in applicable joint submission category. Any change in category (higher tonnage) will require notification to Jones Day to adapt price.

Restrictions (optional):	
a.	<input type="checkbox"/> 'Opt-out' pursuant to Article 11 (3) for the following mandatory joint parts. <input type="checkbox"/> Article 10 (a) <input type="checkbox"/> Article 10 (a) (iv) <input type="checkbox"/> Article 10 (a) (vi) <input type="checkbox"/> Article 10 (a) (vii)

Identification		
Company:		
.....		
REACH-IT UUID Number:		
Company reference name or number (optional):		
VAT number:		
<i>If you do not fill out a VAT number, you will be charged 21%.</i>		
Address:		
.....		
Postal Code:	City:	Country:
<i>Please give full details of person authorized to make the application:</i>		
Mr <input type="checkbox"/> Ms <input type="checkbox"/> Dr <input type="checkbox"/>		
Last Name:		First Name:
Phone Number:		Fax Number:
E-mail address:		

Registration

In his registration, the Applicant acts:

- a. for **himself**
- b. as **Only Representative** pursuant to Article 8 REACH for the following non-EU manufacturer;
Please give full contact details of **non-EU legal entity** represented by Only Representative
If you act on behalf of several non-EU legal entities that are not related to each other, please fill a new application form in for each of your principals.

Company:
.....

Address:
.....

Postal Code: City: Country:

Mr Ms Dr

Last Name: First Name:

Phone Number: Fax Number:

E-mail address:

- c. as **Third Party Representative** pursuant to Article 4 REACH.

Do you want to disclose the name of the party you represent?

- a. Yes
- b. No

Company Name:
.....

REACH-IT UUID Number:

Address:
.....

Postal Code: City: Country:

Mr Ms Dr

Last Name: First Name:

Phone Number: Fax Number:

E-mail address:

Applicable Joint Submission:		
<p>Is the company to be invoiced the same as the legal entity registering under REACH?</p> <p>a. <input type="checkbox"/> Yes</p> <p>b. <input type="checkbox"/> No</p> <p style="text-align: center;"><i>If no, please give full company details of legal entity to be invoiced:</i></p> <p>Company:</p> <p>VAT number:</p> <p style="text-align: center;"><i>If you do not fill in a VAT number, you will be charged 21%.</i></p> <p>Address:</p> <p>.....</p> <p>Postal Code: City: Country:</p>		

General Terms and Conditions:

1. The right of referral only gives access to the Joint Registration Dossier of the substance for the registration as specified above.
2. The right of referral is solely granted in favor of the Applicant (and, only where applicable, the Affiliates listed herein), and is not transferable to any other entity or person.
3. Unless otherwise specified below at 5., the Applicant is not authorized to receive any copies of the Joint Registration Dossier nor is the Applicant authorized to inspect or view the Joint Registration Dossier or any related specific document in whole or in part, outside the conditions set out in the Joint Registration Agreement.
4. This Letter of Access shall in no event be construed as granting the Applicant any property rights whatsoever in the Joint Registration Dossier.
5. In as far as the Joint Registration Dossier may contain a Chemical Safety Report ("CSR") and Guidance on Safe Use, and the Applicant is participating in joint submission for those parts of the dossier, or has otherwise acquired rights to them, those will be made available to the Applicant as needed and may be used by it in as far as needed for purposes of safe handling and elaboration of eSDS and must be filed by it individually if set out in the Joint Registration Agreement.
6. If the Applicant has chosen to prepare itself the CSR, exposure scenarios and guidance on safe use, but does otherwise fully participate in the Joint Registration Dossier, it shall receive an electronic copy of parts Article 10 (a) (iv), (vi), (vii) REACH of the Joint Registration Dossier and shall have the rights to use for this purpose only the (robust) study summaries and other information contained therein as well as to refer to the full study reports on which basis the (robust) study summaries have been developed.
7. In any event and regardless of the rights and restrictions set forth above, the Applicant shall always receive a list of uses which are covered by the CSR, the proposed classification and labeling as well as the PNECs and DNELs where available.

This Letter of Access does not create any rights for third parties or any liability towards third parties in relation to the data for which access is granted.

Applicant's certifications and undertakings:

- The Applicant hereby declares that it is aware of, agrees and complies with the provisions of the Joint Registration Agreement issued by the Lead Registrant, which shall apply in its entirety in addition to the provisions set out hereunder.
- The Applicant declares that it has wired the Letter of Access Pre-payment fee to the following bank account within 30 calendar days of signature of this Letter of Access. The joint token will be issued after receipt of the pre-payment. The invoice for the Letter of Access / Joint Submission will be issued after pre-payment has been received.
- If Applicant chooses not to disclose the Third Party represented, Jones Day reserves the right to appoint a neutral party that is entitled to audit the accuracy of the Third Party Representative's submission whilst guaranteeing the confidentiality of the Third Party. The Third Party Representative hereby agrees to such third party audit.

I have read and I agree with the legal Terms of the Agreement.

Signature of LoA applicant:

Name:

Date:

* * *

Joint Registration Agreement

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

Ferro Performance Pigments Belgium N.V., Kortrijkstraat 153, B-8930 Menen, Belgium, as lead registrant of the substance:

Ethanaminium, N-[4-[[4-(diethylamino)phenyl][4-(ethylamino)-1-naphthalenyl]methylene]-2,5-cyclohexadien-1-ylidene]-N-ethyl-, molybdatetungstatephosphate, C.I. Pigment Blue 1 (hereinafter referred to as "**Lead Registrant**")

and

The SIEF Participant signatory to the present Agreement (hereinafter referred to as "**Co-Registrant**")

Hereinafter referred to as "**the Parties**"

Preamble

Whereas the Parties to this Agreement have pre-registered Ethanaminium, N-[4-[[4-(diethylamino)phenyl][4-(ethylamino)-1-naphthalenyl]methylene]-2,5-cyclohexadien-1-ylidene]-N-ethyl-, molybdatetungstatephosphate, C.I. Pigment Blue 1 [CAS number 1325- 87- 7; EC number 215-410-7] (as further defined herein to as "**Substance**"), 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 Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (hereinafter referred to as "**REACH**").

Whereas REACH imposes on manufacturers and importers as well as on only representatives the obligation to register the Substance under the meaning of Article 5;

Whereas REACH 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 Parties will prepare the Joint Registration Dossier for the tonnage band of 10-100 t/a to be submitted to the Agency through the Lead Registrant;

Whereas the Parties are aware that they have co-operation and data sharing obligations with other participants of the joint registration for the Substance;

Whereas the Co-registrant has the intention to register the Substance and he is willing to appoint the Lead Registrant as lead registrant in order to have him submit the Joint Registration Dossier;

Whereas REACH requires existing registrants and/or potential registrants to make every effort to reach an agreement on sharing the data and to ensure that the cost of sharing the Information required for registration are determined in a fair, transparent and non-discriminatory way.

Therefore, with a view to fulfilling their regulatory obligations under REACH 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 (potential) registrants of the Substance (Title I);
2. To agree on the rules regarding the rights to participate in the joint registration of data, to use the (robust) study summaries and to refer to the relevant full study reports in the Joint Registration Dossier (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 I or in other parts of this Agreement. To the extent not otherwise defined in this Agreement, any definition specified in REACH, 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 party 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 property rights over information on the Substance, either as existing or potential participant or as non-participant of the joint registration.

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 or lawfully acquired from third parties, pursuant to or in the course of this Agreement.

Joint Registration Dossier: The Information 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 of REACH.

Parties: being the parties to this Agreement, having the quality of either:

- **Lead Registrant:** a legal entity that has been appointed by the Co-Registrant(s) to submit the joint information for the Substance under the meaning of Article 11 of REACH to the Agency. For the Joint Registration Dossier under this Agreement, the appointed Lead Registrant is Ferro Performance Pigments Belgium N.V.

- **Co-Registrant:** a legal entity that is subject to the registration requirements for this Substance under REACH, and who wishes to join 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, and/or an Only Representative.

Substance: Ethanaminium, N-[4-[[4-(diethylamino)phenyl][4-(ethylamino)-1-naphthalenyl]methylene]-2,5-cyclohexadien-1-ylidene]-N-ethyl-, molybdatetungstatephosphate, C.I. Pigment Blue 1 [CAS number 1325-87-7; EC number 215-410-7] the Substance Identity Profile and classification and labelling agreed to attached as Annex 3.

Title I: JOINT REGISTRATION 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 REACH, 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 Co-Registrant 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. 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 101 and 102 TFEU as well as any applicable national laws. The Parties explicitly agree to observe Section 7 (Information sharing under competition rules) of the ECHA Guidance on data-sharing (Version 3.1, January 2017), as may be adapted from time to time, as Annex 1 to this Agreement.

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.

2. Each Party shall, with respect to such Party's activities in relation to this Agreement, comply with all relevant export, import, and sanctions laws, regulations, orders, and authorizations to include without limitation, the Export Administration Regulations (EAR), International Traffic in Arms Regulations (ITAR), and regulations and orders administered by the Treasury Department's Office of Foreign Assets Control. Such performance shall apply to the export, re-export and import of controlled technology, data, software, services, and/or hardware.

Accordingly, Party or Parties shall not transfer Information without the appropriate government export authorization. Each Party shall be individually responsible for its compliance with any applicable export or import laws and regulations. No Party shall be required to indemnify another Party with regard to export control compliance, and in particular with regard to the sharing, transmission, acceptance or receipt of export or import controlled technical data and Information.

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. Report on the development of the Joint Registration Dossier

1. Without prejudice to the other information duties set out hereunder, the Lead Registrant undertakes to inform all Co-registrants on the further development of the Joint Registration Dossier, in particular with regard to cost sharing, annually.
2. If there are no relevant changes within the reporting period the Lead Registrant may adjourn such reporting.
3. The Lead Registrant undertakes to make reasonable efforts to update the Co-Registrants on regulatory developments concerning the Joint Registration Dossier.
4. The Parties agree that such communication may be channelled via the use of email.

TITLE II: DATA SHARING AND JOINT REGISTRATION OF THE DOSSIER

1. OBLIGATIONS OF THE LEAD REGISTRANT

Article VI. Participation in the joint registration 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 in 10-100 t/a submitted by the Lead Registrant on behalf of the Co-registrant having fulfilled its obligations under Article IX to this Agreement. Upon demand of the Agency, within the requested deadline and to the extent necessary, the Lead Registrant agrees to complete the Joint Registration Dossier. This work shall be performed by a reputable consultancy ("Consultancy") at the choice of the Lead Registrant.
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) of REACH.
3. The participation in the Joint Registration Dossier may deviate per requesting Co-Registrant according to its tonnage band or possible opt-outs for certain endpoints. The Lead Registrant shall not be obliged to upgrade the Joint Registration Dossier to higher tonnage categories. A Co-registrant(s) wishing to make such an upgrade, shall organize it and bear the relevant cost.

4. If the Co-Registrant requests the submission of the Joint Registration Dossier on behalf of an Affiliate, the Co-Registrant shall notify the Lead Registrant with its name, address and other relevant data documenting such status of Affiliate within two weeks before the registration due date. Upon receipt of such information, the Lead Registrant shall be allowed to enable the participation to the joint submission also to such Affiliate.

5. If the Co-Registrant is a third party representative and/or an Only Representative and requests the submission of the Joint Registration Dossier on behalf of a legal entity represented by him, the Co-Registrant shall notify the Lead Registrant under confidentiality obligations with the name, address and other relevant data of the represented legal entity within two weeks before the registration due date. Upon receipt of such information, the Lead Registrant shall be allowed to enable the participation to the joint registration also to such legal entity.

6. In accordance with Article 12(2) of REACH, the Lead Registrant shall submit the registration dossier for the Substance in 10-100 t/a at the latest by May 24, 2018. This deadline shall be prolonged by any days in which the Lead Registrant experiences technical issues with REACH-IT.

7. Due to delays of testing programme, the Lead Registrant acknowledges that certain studies will not be available by May 31, 2018, and as such the Joint Registration Dossier will be incomplete at that date. To the extent that Information shall not be available by May 31, 2018, the Lead Registrant shall request by May 31, 2018 from the Agency an extension of the deadline to complete the dossier on the basis of the Directors' Contact Group ("DCG") exceptional circumstances tools (DCG issue 10.3, "*Completeness of registration dossiers – Data required in Annexes VII and VIII of REACH not yet available by the registration deadline*").

8. At any time the Lead Registrant shall make available the Joint Registration Dossier in the up-to-date IUCLID format (i.e. data referred to in Article 11(1) paragraph 2 of REACH that have been submitted in the joint registration) to the Co-Registrant, and/or Co-Registrant's Affiliate notified under Article VI. 4 of this Agreement, by request and provided the Co-Registrant has fulfilled its obligations under Article IX of this Agreement.

9. The Lead Registrant shall settle any inquiry or regulatory scrutiny of the Agency or other competent authorities (including but not limited to draft compliance check decisions, substance evaluation, Annex XV REACH dossiers, Risk Management Options Analyses etc.) connected to the Substance in compliance with REACH and Regulation 1272/2008 and in a way to minimize related expenses. This shall also apply to inquiries of other third parties (including but not limited to other potential joint registrants). In the event that such inquiries or regulatory scrutiny could lead to additional costs to be shared by the Co-Registrants or if there could be a critical impact to its use of the Substance (e.g. classification, risk management issues, etc.) the Lead Registrant shall inform the Co-Registrants promptly of any inquiry or regulatory scrutiny of the Agency or other competent authorities or other third parties. The Parties shall cooperate closely and consent on any formal responses to such inquiry or scrutiny without undue delay. Should the Co-Registrants fail to react or unduly delay its comments or unreasonably withhold its consent to the Lead Registrant's responses to such inquiry or regulatory scrutiny, the Lead Registrant may respond on its own. Any related Cost and Expenses shall be charged to the Co-Registrants as Joint Registration Compensation in accordance with the provisions of Article IX.

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 Co-Registrant 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 Co-Registrant;

(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 Co-Registrants' 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 Co-Registrant 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 joint registration 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. In case the Joint Registration Dossier includes data owned by Data Owners (other than the Lead Registrant), the respective parts of the Joint Registration Dossier can only be submitted on behalf of other joint registrants if either

a) the Lead Registrant is entitled to pass on usage rights to the respective data; or

b) the respective Co-Registrant has acquired usage rights directly from the Data Owners.

The relevant studies are listed in Annex 4.

Article VIII. Information on the submission of the Joint Registration Dossier

Provided the Co-Registrant has fulfilled its obligations under Article IX, the Lead Registrant shall provide him without undue delay the valid security token number and the joint submission name of the Joint Registration Dossier.

2. OBLIGATIONS OF THE CO-REGISTRANT 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 and in accordance with the Commission Implementation Regulation (EU) 2016/9 the Co-Registrant shall compensate in a fair, transparent and non-discriminatory way the Lead Registrant with a “**Joint Registration Compensation**” for the development, submission and follow-up on 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 2, will comprise the following elements:

a) Administrative expenses reasonably incurred by the Lead Registrant including but not limited to, secretarial services, management of confidential data, costs for the individual and Joint Registration Dossier preparation and costs of external experts, including legal experts;

b) Expenses to acquire rights to use existing studies and costs for studies developed by the Lead Registrant according to Annex VII, VIII and IX of REACH;

c) Costs for rights to use studies from Data Owners, if the Lead Registrant is authorized by Data Owners to transfer to Co-Registrants the rights specified under Article VII. paragraph 1.

d) Costs for the preparation of the Chemical Safety Report which may be made available by the Lead Registrant to the Co-Registrants, if applicable.

3. Expenses referred to above shall be allocated equally, in a transparent, fair and non-discriminatory way, to all Co-Registrants, taking into account the following exceptions:

a) Where a Co-Registrant 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 Joint Registration Dossier that it is included in and for those studies it receives a right to refer for.

b) Where the Co-Registrant decides, based on Article 11 (3) or REACH, to opt-out from some or all parts of the Joint Registration Dossier and submit the relevant information separately and provides the required justification to the Agency pursuant to Article 11 (3) last paragraph of REACH, it shall only be requested to compensate for those parts of the Joint Registration Dossier that are submitted jointly. In this case the Joint Registrant shall inform the Lead Registrant of the parts he intends to opt-out from.

4. Based on the above, the Lead Registrant shall send an invoice to the Co-Registrant for its cost share after their request for joint registration. The Co-Registrant will only receive the valid security token number without undue delay after payment of the invoice. Payment is due within 1 (one) month after receipt of an invoice issued by the Lead Registrant.

5. When cost and income estimations related to the Joint Registration Dossier change additional payments or refunds respectively may be requested by the Lead Registrant and Co-Registrants respectively. For refunds a threshold of 1,000 € per participant of the joint registration is applicable. Where a Party wishes to re-coup costs less than 1,000 €, that Party shall bear the administrative and accounting costs of retrieving such refunds.

6. In case new studies have to be purchased or performed or other dossier preparation, administrative or other cost have to be engaged after conclusion of this Agreement due to regulatory scrutiny or inquiries of the Agency or other competent authorities or due to requirements pursuant to Article 22 (1)(e), (f) and (g) of REACH, the resulting costs will be equally divided between all Co-Registrants who are required to incorporate the new information into the Joint Registration Dossier pursuant to their individual registration requirements, unless they claim to opt-out in accordance with Article 11 (3) of REACH.

7. If the joint registration comprises various Affiliates of the Co-Registrant, only one of these Affiliates within the joint submission shall be subject to the obligation to compensate the Joint Registration Dossier. Such single Joint Registration Compensation will be calculated on the basis of the highest tonnage band of all these Affiliates. Accordingly, the Affiliates of the compensating Joint Registrant, or the Affiliates of the non-EU established companies represented by an only representative being a Co-Registrant, shall also have the right to refer to the Joint Registration Dossier under the same conditions without additional payment. In that case, the Co-Registrant 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.

8. If an only representative represents more than one non-EU entity, 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.

9. If a third party representative represents more than one entity, 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.

10. 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.

11. 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. The Lead Registrant grants use rights pursuant to Article VII to the Co-Registrant for the Information provided under this Agreement, including the Joint Registration Dossier.
2. Such Information shall consist in any and all data and/or studies:
 - a) Individually developed by the Lead Registrant;
 - b) Acquired from Data Owner(s) for which the Lead Registrant and the Co-Registrants, 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 within the joint submission

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 or subject authorised to grant the right to use 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 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 for an indefinite period of time.
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 this Agreement.
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 joint registration;
 - its assignee has accepted to be bound by the obligations of the Lead Registrant under this Agreement; and
 - the Co-Registrants have been notified about such replacement.
4. Without prejudice to point 3 above (in other words regardless of the appointment of a new lead registrant), in case the Lead Registrant and/or the Co-Registrants cease to have REACH registration obligations in relation to the Substance, they shall each have the right to terminate the present Agreement with prior written notice to the other Parties of six months to the end of a calendar year, for the first time by December 31, 2018. No re-imburement of previously paid Joint Registration Compensation shall be due in this case.

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 or electronic records, records on expenses, books of account, correspondence, memoranda and receipts for 12 years from the conclusion of this Agreement.
3. The Lead Registrant may be required upon request of the Co-Registrant to have the relevant data validated by an external auditor annually at the cost of the requesting party. The Lead Registrant shall provide documentation thereof.

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 International Chamber of Commerce ICC shall be applicable. The place of any hearing shall be Brussels and the language of the arbitration shall be English.

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 by their duly authorized representatives, sign this Agreement

For: The Lead Registrant

Name of legal entity:

Street:

ZIP-Code:

City:

Country:

Contact Name:

Contact Email:

Place:

Date:

Signed by:

For: The Co-Registrant

Name of legal entity:

Street:

ZIP-Code :

City:

Country:

Contact Name:

Contact Email:

Place:

Date:

Signed by :

7. INFORMATION SHARING UNDER COMPETITION RULES

7.1. Competition law applying to REACH activities

As it is expressly stated in the REACH Regulation *“this Regulation should be without prejudice to the full application of the Community competition rules.”* (Recital 48), rules of competition law adopted at EU level (hereinafter “Competition rules”), may apply to REACH and all related activities, including data-sharing.

This section on the Competition rules is intended to help the REACH actors to assess the compatibility of their activities for sharing data and information in the context of REACH.

Additionally, Competition rules can apply to other aspects of REACH related activities.

Data-sharing and information exchange may occur at different steps of the REACH process. This section is only limited to the most common types of questions related thereto. Furthermore, this section may apply to any form of cooperation that actors may decide to adopt in order to fulfil their obligations under REACH (see section 8).

NB: REACH actors should always ensure that their activities comply with Competition rules irrespective of the form of cooperation they choose.

7.2. EU competition law and Articles 101 and 102 of the Treaty on the Functioning of the European Union (TFEU) in brief

EU Competition law is not intended to inhibit legitimate activities of companies. Its objective is to protect competition in the market as a means of enhancing consumer welfare. Therefore, agreements between companies or decisions by associations or concerted practice or abusing behaviours which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the common market are prohibited (Articles 101 and 102 TFEU).

Any agreement that infringes Article 101 is void and unenforceable. In addition, in case of an investigation by the European Commission or by a national competition authority, companies that have implemented a conduct in breach of Articles 101 or 102 may face significant fines. Such an investigation may be initiated either by the authority itself; following a complaint by a third party; or following a leniency application to the competent competition authority of a party to the unlawful agreement that would like to cease its unlawful activity. The most flagrant example of illegal conduct infringing Article 101 TFEU would be the creation of a cartel between competitors (which may involve price-fixing and/or market sharing).

Article 102 TFEU prohibits undertakings holding a dominant position in a market from abusing that position. In the specific context of registration activities under REACH, these TFEU provision could cover a variety of conduct and practices that would either ultimately lead to explicit price coordination between competitors or allow the lead or any other co-registrants to obtain some kind of competitive advantage over the other co-registrants/competitors. An example of a situation of

concern would be where a lead registrant or data holder who also has a dominant position within the internal market imposes an excessive cost burden on competitors⁵⁸.

For more information on EU competition issues and related FAQs in context of REACH registration please refer to the Commission Directorate-General for Competition, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs and Directorate-General Environment document at:
http://ec.europa.eu/growth/sectors/chemicals/reach/about/index_en.htm.

7.3. Exchange of information under REACH and EU competition law

The REACH Regulation requires the sharing of information between companies *"in order to increase the efficiency of the registration system, to reduce costs and to reduce testing on vertebrate animals"* (Recital 33); it also mentions that SIEFs are aimed to *"help exchange of information on the substances that have been registered"* (Recital 54).

REACH provides for significant flows of information between actors, at various stages throughout its implementation process. Examples are:

- for phase-in substances in the pre-registration and the pre-SIEF stage;
- within SIEF (including for classification and labelling);
- during the inquiry for non-phase-in and phase-in substances, which have not been pre-registered, in order to evaluate if a substance has already been registered;
- in the context of information to be shared between downstream users and their suppliers;
- in the context of joint registration.

NB: Actors have to make sure that their exchanges do not go beyond what is required under REACH in a manner that would be contrary to EU Competition law, as explained below.

Firstly, actors must avoid any illegal activity (e.g. creating cartels) when complying with REACH.

Secondly, actors should restrict the scope of their activity to what is strictly required by REACH to avoid creating unnecessary risks of infringing EU Competition law.

Thirdly, if actors have to exchange information which is sensitive under EU Competition law, then it is advisable that they use precautionary measures to prevent infringement.

7.3.1. Avoiding misuse of exchange of information under REACH to conduct cartels

A cartel is an illegal practice (whether or not reflected in a formal or informal agreement) between competitors who collaborate to fix prices or restrict supply or their

⁵⁸ The fact that the potential registrant considers the price charged to be high does not demonstrate that it is excessive within the meaning of the EU case law on Article 102 TFEU.

production capacities or divide up markets or consumers and that shield the member of the cartel from competition.

Examples of activities to be avoided between competitors:

- Fixing the prices of products or conditions of sale;
- Limiting production, fixing production quotas or limiting the supply of products to the markets;
- Dividing up the market or sources of supply, either geographically or by class of customers;
- Limiting or controlling investments or technical developments.

NB: Any exchange of information under REACH must not be used by actors to organise or cover the operation of a cartel.

7.3.2. The scope of the activities should be limited to what is necessary under REACH

It is important to ensure that the exchange of information under REACH is limited to what is required. Article 25(2) of the REACH Regulation gives examples of information which must not be exchanged: "Registrants shall refrain from exchanging information concerning their market behaviour, in particular as regards production capacities, production or sales volumes, import volumes or market share."

Examples of non-public information which must not be exchanged under REACH:

- Individual company prices, price changes, terms of sales, industry pricing policies, price levels, price differentials, price marks-ups, discounts, allowances, credit terms etc.;
- Costs of production or distribution etc.;
- Individual company figures on sources of supply costs, production, inventories, sales etc.;
- Information as to future plans of individual companies concerning technology, investments, design, production, distribution or marketing of particular products including proposed territories or customers;
- Matters relating to individual suppliers or customers, particularly in respect of any action that might have the effect of excluding them from the market.

Actors should also refrain from exchanging technical information if this exchange is not necessary under REACH and especially if this exchange of information may provide competitors with the ability to identify individual company information and to align their market behaviour.

NB: Actors should restrict the scope of their exchange of information strictly to what is required for REACH activities.

7.3.3. Type of information to be exchanged with caution

Even if most of the information to be exchanged under REACH is unlikely to be problematic under EU Competition law rules (because this information is to the greatest extent purely scientific or technical and it may not enable competitors to align their market behaviour) there are instances where actors need to be very careful.

In particular, actors may be induced to exchange information on individual production, import or sales volumes. For example, in the context of a joint CSA/CSR actors may want to know the aggregate volumes of produced and imported substances by exchanging information on individual volumes, in order to estimate the overall impact on the environment. Actors may also want to share REACH-related costs based on their individual production or sales volumes. In addition, if an only representative, who has to keep certain information like quantities imported up-to-date, represents several non-EU manufacturers of a substance, such manufacturers may be induced to exchange individual volume information between them through their only representative.

Some tips are provided below on how to avoid the risk that the exchange of such volume information, to the extent that it is relevant under REACH, constitutes an infringement of Article 101 TFEU.

7.3.3.1. Reference to bands rather than individual figures when feasible

The REACH Regulation mentions that “Requirements for generation of information on substances should be tiered according to the volumes of manufacture or importation of a substance, because these provide an indication of the potential for exposure of man and the environment to the substance, and should be described in detail” (Recital 34), thus indicating the use of tonnage bands.

NB: Actors should refer to their respective tonnage band as defined under REACH and refrain from exchanging individual or more detailed volume figures.

7.3.3.2. Use of precautionary measures if individual sensitive information would still need to be exchanged

If under particular circumstances, actors need to either use individual or aggregate figures (for example at the occasion of carrying out of CSA/CSR) or individual figures may be otherwise identifiable it is recommended to use an independent third party (“Trustee”).

Who could be a Trustee? A legal or natural person not directly or indirectly linked to a manufacturer/importer or their representatives. This Trustee may be for example a consultant, a law firm, a laboratory, a European/international organisation, etc. The Trustee will not represent any actor, as he should be independent, and can be hired by the members of the joint submission, for example to help for certain activities. It is advisable that the Trustee signs a confidentiality agreement that will ensure that the Trustee undertakes not to misuse sensitive information he receives (i.e. disclose it to the participating companies or anyone else).

The following activities can be facilitated by a Trustee for competition law purposes:

Produce aggregated anonymous figures: When REACH actors need to refer to the aggregate of sensitive individual figures, the Trustee will request the actors to provide their individual input. The input will be collated, checked and aggregated into a composite return that does not give the possibility of deducing individual figures (e.g., by ensuring that there will be a minimum of three real inputs). In addition, no joint discussion must take place between this Trustee and several actors on the anonymous or aggregated figures. Questions should be addressed on an individual basis between each actor and the Trustee, who shall not reveal any other data during such discussion.

Calculation of cost allocation based on individual figures for cost sharing: Where actors decide that all or part of their cost sharing should be based on their individual figures (e.g. sales or production volumes) or where individual figures may be identifiable, the Trustee will request from each actor to provide the relevant confidential individual information. He will then send to each actor an invoice corresponding to their particular amount. Only the receiving company would see their particular share of the total amount to be paid.

Companies need to send sensitive individual information to the authorities, without circulating it to the other actors: The Trustee would produce a non-confidential version of the same document for the actors or the public that shall not contain sensitive information.

7.4. Excessive pricing

Depending on the circumstances (e.g. high market share, characteristics of the market), co-registrants with a more prominent role (e.g. lead registrant, consortium members) may be considered to be in a dominant position, e.g. with regards to the provision of the LoA concerning a particular substance. This is not in itself unlawful, but applying Article 102 TFEU, a firm that holds a position has a special responsibility not to allow its conduct to impair competition in the Internal Market. The concept of abuse is an objective one and there is no need to prove fault or subjective intent on the part of the dominant firm to abuse its position.

If a dominant firm charges excessive prices for essential inputs such as the LoA, this could be considered abusive within the meaning of Article 102 TFEU. In order for prices to be considered excessive, (i) the difference between the costs actually incurred by the Lead Registrant and the price actually charged for the LoA must be excessive; and (ii) the price must be either unfair in itself, or unfair when compared to the prices charged for comparable LoAs (the United Brands test⁵⁹). The fact that the potential registrants consider the price charged to be high does not demonstrate that it is excessive within the meaning of the EU case law on Article 102 TFEU. Excessive prices for LoAs might eventually lead to the exclusion of smaller competitors (foreclosure) or might discourage new entrants on the relevant product market.

⁵⁹ Case 27/76 United Brands, paragraph 252.

7.5. Recommended tips for REACH actors when working together

Competition compliance	<p>Before entering into an exchange of information under REACH ensure you have read and understood this guidance and that you will apply it.</p> <p>In case of doubt, or questions, please seek advice (e.g. from a legal advisor).</p>
Record keeping	<p>Prepare agendas and minutes for conference calls or meetings which accurately reflect the matters and discussions held between actors.</p>
Vigilance	<p>Limit your discussion or meeting activities to the circulated agenda.</p> <p>Protest against any inappropriate activity or discussion (whether it occurs during meetings, conference calls, social events, or when working via electronic means – for example using a dedicated intranet). Ask for these to be stopped. Disassociate yourself and have your position clearly expressed in writing, including in the minutes.</p>

NB: This section does not intend to substitute the applicable competition law provisions, as these have been interpreted by the European Courts, and applied by the European Commission and the national competition authorities. This guidance is only designed to allow REACH actors to make a preliminary assessment of their conduct under EU Competition law.

This Guidance is designed in a generic way and thus does not and cannot cover all the different scenarios that may arise from data-sharing obligations provided by REACH. In case of uncertainty, ECHA would recommend to seek legal advice from a lawyer specialised in competition law.

7.6. Remedies to report anticompetitive practices

As far as competition enforcement is concerned, national law and EU law operate in parallel. If the practices in question have an effect on intra-EU trade, EU competition rules will be applicable⁶⁰.

The European Commission, National Competition Authorities and national courts are all empowered to apply EU competition rules. The main rules on procedure, including

⁶⁰ For further information, please consult the Commission Guidelines on the effect on trade concept contained in Articles 81 and 82 of the Treaty, OJ C 101 of 27.04.2004.

those on case allocation between the Commission and National Competition Authorities, are set out in Council Regulation 1/2003⁶¹.

If, having regard to these procedural rules, it appears that the European Commission is well placed to act, a complaint can be filed. An explanation can be found at the following address: http://ec.europa.eu/competition/contacts/antitrust_mail.html

It should be noted that unlike national courts, the European Commission does not have the power to award damages to firms that are victims of a breach of the competition rules.

For more details on the prohibition of antitrust behaviours, please consult the relevant webpage of the European Commission - Directorate General Competition, at the following link: http://ec.europa.eu/competition/index_en.html.

⁶¹ Council Regulation (EC) 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty OJ L 1, 04.01.2003, p.1-25.

ANNEX 2

Rules for calculation of the Joint Registration Compensation

Ethanaminium, N-[4-[[4-(diethylamino)phenyl][4-(ethylamino)-1-naphthalenyl]methylene]-2,5-cyclohexadien-1-ylidene]-N-ethyl-, molybdatetungstatephosphate, C.I. Pigment Blue 1 [CAS number 1325-87-7; EC number 215-410-7]

1. Expenses and costs pursuant to Article IX. 2 are allocated pursuant to the provisions in Article IX.
2. Already available privately-owned studies at the time of conclusion of this Agreement are valued based on the principles set out in Annex 4. The resulting value is shared equally between the concerned registrants. The relevant studies including the agreed Joint Registration Compensation at this present time are listed in Annex 4.
3. Cost set out in Annex 4 (see the Excel spreadsheet below) are considered adjusted for the date on which the Joint Registration Dossier shall be submitted in accordance with Article VI.6. For Co-Registrants joining after 2018 an adjustment according to the inflation rate in the Euro zone as published by Eurostat shall be applicable.
4. Recalculations of the shares, pursuant to point 1 above, will take place annually but may be adjourned if there are no relevant changes within the reporting period. Reimbursements will be granted accordingly if the resulting difference is at least 1,000 € per Co-Registrant. Such reimbursements shall be executed every six years.

ANNEX 3**Substance Identification Profile****Ethanaminium, N-[4-[[4-(diethylamino)phenyl][4-(ethylamino)-1-naphthalenyl]methylene]-2,5-cyclohexadien-1-ylidene]-N-ethyl-, molybdatetungstatephosphate, C.I. Pigment Blue 1**

Colour Index	Pigment Blue 1
CAS number	1325-87-7
EC number	215-410-7
EC name	Ethanaminium, N-[4-[[4-(diethylamino)phenyl][4-(ethylamino)-1-naphthalenyl]methylene]-2,5-cyclohexadien-1-ylidene]-N-ethyl-, molybdatetungstatephosphate
IUPAC name	Reaction product of [4-bis[4-(diethylamino)phenyl]methylidene]naphthalen-1-ylidene]-ethylazanium chloride with phosphotungstomolybdic acid
Chemical Structure	<p>Phosphotungstomolybdic acid salt of</p>
Classification & Labelling according to CLP Regulation (EC) No 1272/2008	<p>H315: Causes skin irritation H411: Toxic to aquatic life with long lasting effects H319: Causes serious eye irritation H252: Self-heating in large quantities; may catch fire.</p>

No impurities affecting classification & labelling of the substance and/or affecting tox and/or eco-tox properties should be present. SVHC substances should be below the legal threshold of 1000 ppm. Any other impurity should be below the applicable regulatory thresholds.

Each company is fully responsible for its own production of analytical data, consequent identification and individual submission of this part to the Agency.

ANNEX 4

List of studies and related cost calculation

Literature List

List of underlying data used in the EU REACH
registration dossier for

Ethanaminium, N-[4-[[4-(diethylamino)phenyl][4-(ethylamino)-1-naphthalenyl]methylene]-2,5-cyclohexadien-1-ylidene]-N-ethyl-,
molybdatetungstatephosphate
C. I. Pigment Blue 1 (PB1)

EC number 215-410-7, CAS number 1325-87-7

Refer to Article VII of the SIEF Agreement for details of the rights that will be granted on payment of the Joint Registration Compensation, Article IX of the SIEF Agreement.

IUCLID Number	Annex	Description	Reference type, number	Laboratory/Author	Year	Title	Klimisch score	Price charged (€)	Tonnage Band
4.2	VII	Melting/freezing point	No study number	CAPPELLE PIGMENTS Kortrijkstraat 153 B-8930, Menen, Belgium	2015	Determination of melting point of C.I. Pigment Blue 1 (CAS 1325-87-7)	1	94	1-10 10-100
4.4	VII	Relative density	No study number	CAPPELLE PIGMENTS Kortrijkstraat 153 B-8930, Menen, Belgium	2015	Determination of powder density of C.I. Pigment Blue 1 (CAS 1325-87-7)	1	125	1-10 10-100
4.8	VII	Water solubility	No study number	CAPPELLE PIGMENTS Kortrijkstraat 153 B-8930, Menen, Belgium	2017	Determination of water solubility of sparingly soluble mineral pigments at pH1 Determination of water solubility of sparingly soluble mineral pigments at pH 5.5 and pH 8.5 Determination of water solubility of sparingly soluble mineral pigments at pH7	1	797	1-10 10-100
4.7	VII	Partition coefficient n-octanol/water	No study numbers	CAPPELLE PIGMENTS Kortrijkstraat 153 B-8930, Menen, Belgium	2017	Determination of 1-octanol solubility of C.I. Pigment Blue 1 down to <0.1mg/L Determination of water solubility of C.I. Pigment Blue 1 down to <0.1mg/L	1	438	1-10 10-100
4.13	VII	Flammability	No study number	CAPPELLE PIGMENTS Kortrijkstraat 153 B-8930, Menen, Belgium	2017	Determination of Flammability of C.I. Pigment Blue 1 (CAS 1325-87-7)	1	125	1-10 10-100
4.12	VII	Self-ignition temperature	NOTOX project code: 254947	NOTOX B.V. Hambakenwetering 3, 5231 DD 's-Hertogenbosch, The Netherlands	1999	Determination of the Ability for Self-Heating of C.I. Pigment Blue 1 - C.I. 42595:2	1	1125	1-10 10-100
4.15	VII	Oxidising properties	BJ47KR	Envigo Research Limited,	2018	This report is scheduled to be available in July 2018	1	595	1-10 10-100
4.5	VII	Granulometry	No study number	Ferro Performance Pigments Belgium N.V, Kortrijkstraat 153, B-8930 Menen, Belgium	2016	PB 01 Particle size analysis	1	94	1-10 10-100

IUCLID Number	Annex	Description	Reference type, number	Laboratory/Author	Year	Title	Klimisch score	Price charged (€)	Tonnage Band
7.3.1 7.10.1 7.10.2 7.10.3 7.10.5	VII	Skin irritation or skin corrosion	Study number: 456582	Sun Chemical, A/S Regulatory Affairs and Product Stewardship, P.O. Box 283, DK-4600 KØGE, Denmark	2006	Primary Skin Irritation Corrosion Study with Test product P.V.3 in the Rabbit (4-Hour Semi-occlusive Application) Read across substance	1	1,250	1-10 10-100
7.3.2 7.10.1 7.10.2 7.10.3 7.10.5	VIII	Eye irritation	Study number: 546/15 546/16	Safepharm Laboratories Limited, P.O. Box No. 45, Derby, DE1 2BT UK	1993 1993	0151N/ 901035: Acute Eye Irritation Test in the Rabbit 0155N/ 881715: Acute Eye Irritation Test in the Rabbit Read across substances	1	1,010	10-100
7.4.1 7.10.4	VII	Skin sensitisation	Study number: BS84BL	Envigo Research Limited, Shardlow Business Park, Shardlow, Derbyshire, DE72 2GD, UK	2018	Lumière Blue Cufe 6255F: Local Lymph Node Assay in the Mouse - Pooled Method Read across substance	1	2,726	1-10 10-100
7.6.1	VII	<i>In vitro</i> gene mutation study in bacteria	Study number: SN60GX	Envigo Research Limited. Shardlow Business Park, Shardlow, Derbyshire, DE72 2GD, UK	2017	Lumière Blue PTM 0154N: Reverse Mutation Assay 'Ames Test' using Salmonella typhimurium and Escherichia coli	1	2,726	1-10 10-100
7.6.1	VIII	<i>In vitro</i> cytogenicity study in mammalian cells or <i>in vitro</i> micronucleus study	Study number: LG88DR	Envigo Research Limited, Shardlow Business Park, Shardlow, Derbyshire, DE72 2GD, UK	2017	Lumière Blue PTM 0154N: Micronucleus Test in Human Lymphocytes <i>in vitro</i>	1	12,938	10-100
7.6.1	VIII	<i>In vitro</i> gene mutation study in mammalian cells	Study number: PN29MN	Envigo Research Limited., Shardlow Business Park, Shardlow, Derbyshire, DE72 2GD, UK	2018	Lumière Blue PTM 0154N: V79 HPRT Gene Mutation Assay	1	12,861	10-100
7.2.1	VII	Acute toxicity by oral route	Report number: 546/24	Safepharm Laboratories Limited, P.O. Box No.45, Derby, DE1 2BT, UK	1993	0151 N/90 1035: Acute Oral Toxicity (Limit Test) in in the Rat	1	922	1-10 10-100

IUCLID Number	Annex	Description	Reference type, number	Laboratory/Author	Year	Title	Klimisch score	Price charged (€)	Tonnage Band
7.8.1	VIII	Screening for reproductive/developmental toxicity	Study number: HJ88HL	Envigo CRS, S.A.U. Centro Industrial Santiga, c/Argenters, 6 08130-Santa Perpètua de Mogoda Barcelona / Spain	2017	Lumière Blue PTM 0154N: 14-day Oral (Gavage) Dose-Range Toxicity Study for OECD 422	1	8,033	10-100
7.8.1	VIII	Screening for reproductive/developmental toxicity	Study number: FV50NT	Envigo CRS, S.A.U. Centro Industrial Santiga, c/Argenters, 6 08130-Santa Perpètua de Mogoda Barcelona / Spain	2018	Lumière Blue PTM 0154N: Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Study in the Wistar Rat by Oral Gavage Administration	1	112,639	10-100

IUCLID Number	Annex	Description	Reference type, number	Laboratory/Author	Year	Title	Klimisch score	Price charged (€)	Tonnage Band
6.1.3	VII	Short-term toxicity testing on invertebrates	Study number: 412291-B 412291-A 354353	NOTOX B.V. Hambakenwetering 7, 5231 DD 's-Hertogenbosch, The Netherlands	2004 2004 2002	Acute Toxicity Studies in Daphnia Magna with Water Soluble Fractions of Paste of PB1 – 310304 Acute Toxicity Studies in Daphnia Magna with Water Soluble Fractions of Paste of PB1 – 310304 using Acetone as a Pre-solvent Acute Toxicity Study in Daphnia Magna with 0151N (Non-GLP Study)	2	1,872	1-10 10-100
6.1.5 6.1.6	VII	Growth inhibition study aquatic plants	LJ48GW MX85MG	Envigo Research Limited, Shardlow Business Park, Shardlow, Derbyshire, DE72 2GD, UK	2018	This report is scheduled to be available in August 2018 Read across substance	1	11,665	1-10 10-100
6.1.1	VIII	Short-term toxicity testing on fish	Study number: 546/037	Safepharm Laboratories Limited, P.O. Box No. 45, Derby, DE1 2BT UK	1999	Lumière Blue 0151N (CI Pigment Blue 1): Acute Toxicity to Rainbow Trout (Oncorhynchus mykiss)	1	2,516	10-100
6.1.4	VII	Long-term toxicity testing on invertebrates	FV50NT	Envigo Research Limited, Shardlow Business Park, Shardlow, Derbyshire, DE72 2GD, UK	2018	This report is scheduled to be available in August 2018 Read across substance	1	16,388	1-10 10-100

Prices are calculated according to the details provided in the SIEF Agreement for the substance.
Where an endpoint for the appropriate REACH Annex is not listed it has been covered by a waiver.

Letter of Access calculation and fees

Ethanaminium, N-[4-[[4-(diethylamino)phenyl][4-(ethylamino)-1-naphthalenyl]methylene]-
2,5-cyclohexadien-1-ylidene]-N-ethyl-, molybdatetungstatephosphate
C. I. Pigment Blue 1 (PB1)

EC number 215-410-7, CAS number 1325-87-7

LoA price

Tonnage band		Total registration cost	LoA price (based on 2 registrants)
1-10 Tonnes		82,097 €	41,048 €
Total for 10-100 Tonnes		246,617 €	123,308 €
Higher tonnages		Not supported	
	<1000 tpa TII registration		
	>1000 tpa TII registration		

Notes The LoA price is based upon one other registrant joining in 2018 (or beyond)

Each LoA will incur a non-refundable administrative charge from the Financial Subcontractor of €1,500 (not in above)

Number of registrants (including Lead Registrant)

Tonnage band	2018	2019	2020	2021	2022			Total
1-10 Tonnes	0	0	0	0	0	0	0	0
10-100 Tonnes	1	0	0	0	0	0	0	1
Higher tonnages	Not supported							
<1000 tpa TII registration	0	0	0	0	0	0	0	
>1000 tpa TII registration	0	0	0	0	0	0	0	

Incremental costs

Tonnage band	Data	Dossier prep., SIEF management ¹	Other costs ²	Total incremental cost	Total registration cost
1-10 Tonnes	41,952 €	21,609 €	18,536 €	82,097 €	82,097 €
Additional for 10-100 Tonnes	148,987 €	14,406 €	1,127 €	164,520 €	246,617 €
Higher tonnages	Not supported				
<1000 tpa TII registration					
>1000 tpa TII registration					

¹ Item indentified with * in the table below

² Items identified with ** in the table below

Breakdown of dossier preparation, SIEF management and other costs

CSR preparation **	1,127 €	Assigned only to 10-100 Tonnes
Dossier preparation cost, including SIEF management *	36,015 €	Assigned in ratio 60/100 for 1-10, 10-100 Tonnes, respectively
Estimated post-registration (maintenance) costs from 2019 to 2022 (excluding costs on compliance checks and other regulatory scrutiny) **	2,932 €	Assigned equally to both bands. However future work performed will be assigned to the appropriate tonnage band when calculating reimbursements
LoA subcontractor **	4,000 €	
Miscellaneous costs 1 – 10 (Legal costs and cost of work performed by the Lead Registrant) **	11,604 €	
Miscellaneous costs 10 - 100 **	0 €	

As additional registrants join the registration , the effective LoA price will reduce.
When sufficient funds are available, reimbursement(s) will be made to co-registrants.