

# JONES DAY

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(3) Member of the New York Bar

(4) Member of the Düsseldorf Bar

(5) Member of the District of Columbia Bar

(6) Member of the Turin Bar

April 18, 2014

TO WHOM IT MAY CONCERN

Dear Applicant,

**Re: Iron Oxides REACH Consortium ('IORC')**

This document contains the relevant information for purchasing a letter of access 'LoA' for joining the joint REACH registration for the substances:

- **IRON HYDROXIDE OXIDE YELLOW EC 257-098-5 (SYNONYMS 243-746-4; 215-176-6);**
- **TRIIRON TETRAOXIDE EC 215-277-5 (SYNONYMS 235-442-5; 215-169-8);**
- **DIIRON TRIOXIDE EC 215-168-2 (SYNONYMS 215-570-8; 215-275-4);**
- **IRON MANGANESE (TRI)OXIDE EC 235-049-9;**
- **MANGANESE FERRITE EC 269-056-3;**
- **ZINC FERRITE EC 269-103-8**

prepared by the **IORC**. In addition, this PDF provides the relevant earlier SIEF communications issued by the Lead Registrant / Consortium. Please note that the Consortium management was transferred from McKenna Long & Aldridge LLP to **JONES DAY** in 2014, with still the same person (Ursula Schliessner) in charge after the transfer. The pre-2014 documents are therefore under the McKenna Long & Aldridge LLP name.

If you wish to purchase a LoA, please fill in the next pages '**LOA APPLICATION FORM**' and **pdf them to the attention of the Reach Team: reachteam@jonesday.com**. You will then receive a pre-payment notice by email for payment of the LoA price. As soon as we have received your payment in full, we will confirm that payment has been received and you will receive the joint submission token and any other necessary documentation (Chemical Safety Report, Guidance on Safe Use as the case may be) that you may need to join the Joint Submission via the ECHA REACH-IT portal (please see the ECHA Guidance on joining the Joint Submission). Potential registrants have to submit their individual parts (Article 10 (a) (i), (ii), (iii) and (x)) of the IUCLID 5 registration dossiers separately to ECHA by the relevant deadline.

Invoices for paid LoA fees will be issued by the Consortium on a periodic basis as soon as a sufficient number of LoAs have been processed and pre-paid.

If you have any questions, please do not hesitate to contact us:

Ursula Schliessner at [uschliessner@jonesday.com](mailto:uschliessner@jonesday.com) / Telephone +32-2-645 1460

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## Letter of Access ('LoA') Application Form

### Iron Oxides REACH Consortium ('IORC')

LoA will be issued per group of companies. Please fill in the application form only **once** for all affiliated group companies.  
(To be filled in and emailed back to [reachteam@jonesday.com](mailto:reachteam@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 SIEF Agreement overleaf.**

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

**\* LoA applicants will be informed by separate email or via SIEF communication if the CSR and guidance on safe use will be prepared jointly and also **submitted jointly**, or rather whether they will be prepared jointly but will have to be **submitted individually**. In the latter case, LoA applicants will receive the CSR and guidance on safe use via a lucid so-called "export file" and must then insert it themselves into their individual REACH registration.**

#### Substances:

- Iron hydroxide oxide yellow EC 257-098-5 (synonyms 243-746-4; 215-176-6);
- Triiron tetraoxide EC 215-277-5 (synonyms 235-442-5; 215-169-8);
- Diiron trioxide EC 215-168-2 (synonyms 215-570-8; 215-275-4);
- Iron manganese (tri)oxide EC 235-049-9;
- Manganese ferrite EC 269-056-3;
- Zinc ferrite EC 269-103-8

#### Current Prices LoA:

For all six substances combined:

- 1-10 tons: EUR 3,426 (excl. VAT)
- 10-100 tons: EUR 9,601 (excl. VAT)
- 100 - 1000 tons: EUR 15,948 (excl. VAT)
- Above 1000 tons: EUR 18,174 (excl. VAT)

**Please fill in applicable joint submission category. Any change in category (higher tonnage or change from intermediate to full substance registration) will require notification to Jones Day to adapt price.**

#### Restrictions (optional):

- a.  'Opt-out' pursuant to Article 11 (3) for the following mandatory joint parts.
- Article 10 (a)
  - Article 10 (a) (iv),
  - Article 10 (a) (vi),
  - Article 10 (a) (vii),
  - Article 10 (a) (ix)

## Identification

Company: .....

.....

REACH-IT UUID Number: .....

Company reference name or number (optional): .....

VAT number: .....

***If you do not fill out a VAT number, you will be charged 21%.***

Address: .....

.....

Postal Code: ..... City: ..... Country: .....

***Please give full details of person authorized to make the application:***

Mr  Ms  Dr

Last Name: ..... First Name: .....

Phone Number: ..... Fax Number: .....

E-mail address: .....

***Please give full company details for all affiliates to be covered by this Letter of Access:***

*Example: The Miracle Chemicals Co. Ltd; 95130 Rome, 25 Nano Boulevard, Belgium*

***Affiliates:*** .....

.....

.....

.....

.....

.....

.....

.....

## 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 in new application form 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:

Is the **company to be invoiced** the same as the legal entity registering under REACH?

- a.  Yes
- b.  No

***If no, please give full company details of legal entity to be invoiced:***

Company: .....

VAT number: .....

***If you do not fill in a VAT number, you will be charged 21%.***

Address: .....

.....

Postal Code: ..... City: ..... Country: .....

### 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 6., 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 general inspection period granted by the Consortium and outside the conditions set out in the SIEF 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. Nothing in this letter shall require the Consortium members to file any additional data.
6. 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 SIEF Agreement.
7. 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) and (ix) 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.
8. 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 SIEF Agreement issued by the Lead Registrant, which shall apply in its entirety in addition to the provisions set out hereunder.
- In case the Applicant has applied for an intermediate LoA only, the Applicant hereby declares that it is aware that registration as an intermediate pursuant to Articles 17 and 18 REACH is conditional upon fulfillment of the conditions set out there under.
- 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, but at the latest at the end of the applicable year of registration (end 2010, end 2013, end of 2018, as the case may be).
- 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:* .....

\* \* \*

**REACH: SIEF Communications Iron Oxides and Related Substances  
EC 257-098-5 (synonyms 243-746-4; 215-176-6); EC 215-277-5 (synonyms  
235-442-5; 215-169-8); EC 215-168-2 (synonyms 215-570-8; 215-275-4);  
EC 235-049-9; EC 269-056-3; EC 269-103-8**

- Updated July 26, 2024 -

11 SIEF Communications:

**\*Current (September 2013) updated LoA prices are highlighted in blue and yellow.**

- 1) SIEF Communication dated September 29, 2010 (23 pages)
- 2) SIEF Communication dated March 4, 2011: Recalculation of LoA price for 1000t category and calculation of LoA price for 100-1000t category (4 pages)
- 3) SIEF Communication dated March 5, 2013: EC numbers with no Lead Registrant: LoAs to be purchased under other EC numbers (1 page)
- 4) **\*SIEF Communication dated September 16, 2013: Recalculation of all LoA Prices for all Tonnage Categories (5 pages)**
- 5) SIEF Communication dated January 12, 2016: Dossier Update 2015 (13 pages)
- 6) SIEF Communication dated March 23, 2020: Implementation of Amendment REACH; Regulation 2018/1881 (Diiron trioxide (red) and iron hydroxide oxide yellow) (20 pages)
- 7) SIEF Communication dated July 28, 2020: Nano boundary composition Yellow and Red Iron Oxide (Iron Hydroxide Oxide Yellow EC 257-098-5, CAS 51274-00-1; Diiron Trioxide (Red Iron Oxide) EC 215-168-2, CAS 1309-37-1) – Dossier update to be filed by Lead Registrant LANXESS Deutschland GmbH on July 28/29, 2020 (73 pages)
- 8) SIEF Communication dated September 14, 2020: Nano boundary composition Yellow and Red Iron Oxide (Iron Hydroxide Oxide Yellow EC 257-098-5, CAS 51274-00-1; Diiron Trioxide (Red Iron Oxide) EC 215-168-2, CAS 1309-37-1) – Dossier update filed by Lead Registrant LANXESS Deutschland GmbH on July 28/29, 2020 (1 page)
- 9) SIEF Communication dated February 9, 2022: Iron Oxides – Dossier update for all six substances was submitted to ECHA in December 2021. (1 page)
- 10) SIEF Communication dated January 17, 2023: Iron Oxides – Another registration Dossier update for all six substances was filed by Lead Registrant LANXESS Deutschland GmbH in October 2022. (4 pages)
- 11) REACH SIEF Communication dated July 25, 2024: Iron Oxides – Recalculation of all Letter of Access Prices for all Tonnage Categories (*preliminary*); new SIEF Cooperation Agreement (33 pages).

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<sup>2</sup> Member of the Düsseldorf Bar  
<sup>3</sup> Member of the Georgia Bar  
<sup>4</sup> Advocaat-Avocat - Member of the Brussels Bar

URSULA SCHLIESSNER  
(32-2) 278-1224

EMAIL ADDRESS  
uschliessner@mckennalong.com

September 29, 2010

BY ELECTRONIC MAIL

**TO WHOM IT MAY CONCERN**

- SIEF Communication on behalf of Iron Oxides REACH Consortium  
and Lead Registrant Lanxess Deutschland GmbH -

**Re: REACH: SIEF Communication Iron Oxides and Related Substances EC 257-098-5  
(synonyms 243-746-4; 215-176-6); EC 215-277-5 (synonyms 235-442-5; 215-169-8); EC  
215-168-2 (synonyms 215-570-8; 215-275-4); EC 235-049-9; EC 269-056-3; EC 269-103-8**

Dear SIEF Member:

Pursuant to our earlier SIEF communications to you in December 2009 and January/February 2010 respectively, we are pleased to report that the Members of the Iron Oxides Consortium have finalized the registration dossiers for the six substances. Lead Registrant Lanxess has filed them with ECHA and the technical completeness check has been passed.

**Set out below and overleaf is critical information for your perusal as well as about the next steps to be taken by SIEF members.**

1) Data

No new data was communicated to the Consortium pursuant to our SIEF requests. The Consortium has therefore used and chosen from the data previously collected. We shall assume that you agree with the Consortium's selection of data for use in the joint registration dossiers per Article 11 (1) and 29 (3) REACH.

2) Joint Registration Dossier - Inspection Period

The final joint registration dossiers will be made available for inspection at the offices of McKenna Long & Aldridge LLP during office hours between **October 4 and October 18, 2010, upon appointment taken at least 48 hours in advance.**

3) Classification & Labeling

Based on the data available and reviewed, the substances have not been classified in the registration dossiers under either Directive 67/548 or the CLP Regulation. However, individual SIEF members are responsible for their individual substances and it is the Consortium's understanding that depending on the manufacturing process used as well as storage and transport conditions, some companies may wish to consider classification of tri-iron tetra oxide as self-heating (category 1 or 2)

under the CLP Regulation. The Consortium agreed to have the different classifications in the IO black LEAD dossier so that the members of the JS can refer to it without using the opt-out possibility.

4) DNEL & PNECs

Based on the data available and reviewed, it was decided not to derive a PNEC. As regards DNEL, as there is no evidence of systemic toxicity, genotoxicity or carcinogenicity, it was decided to treat the group of substances as dust without specific toxicity and to apply the general dust limits. Overall, based on the substance-specific data on the mode of action of iron oxide after inhalation, the available 90 day inhalation toxicity study and ECHA guidance on how to select the critical DNEL in case of inert dusts, the current national Occupational Exposure Limits in Germany for dust of 10 mg/m<sup>3</sup> for inhalable and 3 mg/m<sup>3</sup> for respirable dust (TRGS900) are used as DNEL for long term exposure to iron oxides.

5) Chemical Safety Report

The CSR was prepared jointly by the Consortium members and has been submitted jointly in the Lead Registrant's dossiers (see for submission options ECHA Data Submission Manual [http://echa.europa.eu/doc/reachit/dsm\\_19\\_how\\_joint\\_csr\\_en.pdf](http://echa.europa.eu/doc/reachit/dsm_19_how_joint_csr_en.pdf)). A copy of the CSR will be provided to interested SIEF members upon request simultaneously with the joint submission name and token.

6) Uses and Guidance on safe use

The uses identified and covered in the CSR are set out in **Appendix 1**. Guidance on safe use has been prepared and submitted jointly. Copies are available to LoA applicants upon request once they have completed 9) below.

7) Substance ID

Substance sameness was agreed earlier in the SIEFs. The substance identity used is attached as **Appendix 2**. Additional information for registrants (screenshots) on how to fill in substance identity information in the individual dossier are available under the 'About Substances' section of [www.mlalaw.eu](http://www.mlalaw.eu).

8) SIEF Agreement

We ask that those SIEF members who wish to participate in joint registration sign and return to us by e-mail the signature page of the Lanxess SIEF Agreement attached hereto (**Appendix 3**).

9) Participation in Joint Submission - Letters of Access

We would further kindly ask those SIEF members who wish to participate in joint submission to fill in a letter of access (LoA) application at [www.mlalaw.eu](http://www.mlalaw.eu). An on-line tool will guide you through the procedure and payment requirements. For your information, the price for an LoA (1,000 tons) for the package of six substances all together will be €32,007 (excl. VAT where applicable). This price includes affiliated legal entities of the LoA applicant. It also includes the CSR. There will be no reductions for LoA applicants interested in single substance LoAs only (see SIEF Agreement) or without CSR in 2010. Once your LoA application has been duly accepted and payment has been

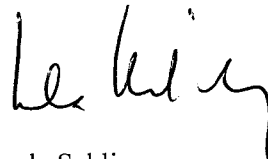
TO WHOM IT MAY CONCERN  
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made, you shall automatically receive the joint submission token to file the individual parts of your registration dossiers.

**Participation in joint submission is conditional upon completing the procedure and obtaining an LoA at [www.mlalaw.eu](http://www.mlalaw.eu).**

Thank you very much for your attention.

Kind regards,

A handwritten signature in black ink, appearing to read 'U. Schliessner', written in a cursive style.

Ursula Schliessner  
Partner  
McKenna Long & Aldridge LLP

### Appendix 1 - Uses

The “Synthetic Iron Oxides for non-metallurgical applications” are used by industry, mostly by professionals,

a) as pigments mainly but not exclusively in paints and varnishes, plastics, printing inks, construction materials, cosmetics, ceramics and toners.

b) There are also a multitude of technical applications where other properties of the substances are used, for example when applied as a raw material for chemical synthesis, as catalysts and others, e.g.:

glazes, frits, ceramic bricks and tiles,  
drilling fluids, casting fluxes,  
exothermic risers (foundries),  
carbon electrodes, graphite electrodes,  
casting powders,  
catalysts,  
ferrites, magnets and magnetic materials,  
matches,  
iron and steel applications as well as metallurgical processes,  
anti-vibrations materials for the automotive industry,  
intermediates for the production of substances,  
waste water treatment, and biogas installations  
animal feed, fertilizer additives.

#### **Uses by workers in industrial settings**

Identified use name:

mainly as colorants and some other technical applications

Market sector by type of chemical product:

PC 1: Adhesives, sealants

PC 2: Adsorbents

PC 3: Air care products

PC 7: Base metals and alloys

PC 8: Biocidal products (e.g. disinfectants, pest control)

PC 9a: Coatings and paints, thinners, paint removes

PC 9b: Fillers, putties, plasters, modelling clay

PC 9c: Finger paints

PC 11: Explosives

PC 12: Fertilisers

PC 14: Metal surface treatment products, including galvanic and electroplating products

PC 15: Non-metal-surface treatment products

PC 16: Heat transfer fluids

PC 17: Hydraulic fluids SU 1: Agriculture, forestry and fishing

PC 18: Ink and toners

PC 19: Intermediate

PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents

PC 21: Laboratory chemicals

PC 23: Leather tanning, dye, finishing, impregnation and care products

PC 24: Lubricants, greases, release products

PC 25: Metal working fluids

PC 26: Paper and board dye, finishing and impregnation products: including bleaches and other processing aids

PC 27: Plant protection products

PC 28: Perfumes, fragrances

PC 29: Pharmaceuticals

PC 30: Photo-chemicals

PC 31: Polishes and wax blends

PC 32: Polymer preparations and compounds  
PC 33: Semiconductors  
PC 34: Textile dyes, finishing and impregnating products; including bleaches and other processing aids  
PC 35: Washing and cleaning products (including solvent based products)  
PC 36: Water softeners  
PC 37: Water treatment chemicals  
PC 38: Welding and soldering products (with flux coatings or flux cores.), flux products  
PC 39: Cosmetics, personal care products  
PC 0: Other:PC5 Artists supply and Hobby preparations PC6: Automotive Care Products PC10 Buildings and construction preparations, UCN code 62 – electromechanical components, UCN code 26 – Food / Feedstuff flavourings and nutrients  
Sector of use:  
SU 2a: Mining (without offshore industries)  
SU 2b: Offshore industries  
SU 4: Manufacture of food products  
SU 5: Manufacture of textiles, leather, fur  
SU 6a: Manufacture of wood and wood products  
SU 6b: Manufacture of pulp, paper and paper products  
SU 7: Printing and reproduction of recorded media  
SU 8: Manufacture of bulk, large scale chemicals (including petroleum products)  
SU 9: Manufacture of fine chemicals  
SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys)  
SU 11: Manufacture of rubber products  
SU 12: Manufacture of plastics products, including compounding and conversion  
SU 13: Manufacture of other non-metallic mineral products, e.g. plasters, cement  
SU 14: Manufacture of basic metals, including alloys  
SU 15: Manufacture of fabricated metal products, except machinery and equipment  
SU 16: Manufacture of computer, electronic and optical products, electrical equipment  
SU 17: General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment  
SU 18: Manufacture of furniture  
SU 19: Building and construction work  
SU 20: Health services  
SU 23: Electricity, steam, gas water supply and sewage treatment  
SU 24: Scientific research and development  
SU 0: Other:SU3 Industrial use

### Uses by professional workers

Identified use name:

mainly as colorants and some other technical applications

Market sector by type of chemical product:

PC 1: Adhesives, sealants  
PC 2: Adsorbents  
PC 3: Air care products  
PC 7: Base metals and alloys  
PC 8: Biocidal products (e.g. disinfectants, pest control)  
PC 9a: Coatings and paints, thinners, paint removers  
PC 9b: Fillers, putties, plasters, modelling clay  
PC 9c: Finger paints  
PC 11: Explosives  
PC 12: Fertilisers  
PC 14: Metal surface treatment products, including galvanic and electroplating products  
PC 15: Non-metal-surface treatment products  
PC 16: Heat transfer fluids  
PC 17: Hydraulic fluids SU 1: Agriculture, forestry and fishing  
PC 18: Ink and toners  
PC 19: Intermediate  
PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents  
PC 21: Laboratory chemicals



PC 23: Leather tanning, dye, finishing, impregnation and care products  
 PC 24: Lubricants, greases, release products  
 PC 25: Metal working fluids  
 PC 26: Paper and board dye, finishing and impregnation products: including bleaches and other processing aids  
 PC 27: Plant protection products  
 PC 28: Perfumes, fragrances  
 PC 29: Pharmaceuticals  
 PC 30: Photo-chemicals  
 PC 32: Polymer preparations and compounds  
 PC 34: Textile dyes, finishing and impregnating products; including bleaches and other processing aids  
 PC 35: Washing and cleaning products (including solvent based products)  
 PC 36: Water softeners  
 PC 37: Water treatment chemicals  
 PC 38: Welding and soldering products (with flux coatings or flux cores.), flux products  
 PC 39: Cosmetics, personal care products  
 PC 31: Polishes and wax blends  
 PC 0: Other:PC5 Artists supply and Hobby preparations PC6: Automotive Care Products PC10 Buildings and construction preparations, UCN code 62 – electromechanical components, UCN code 26 – Food / Feedstuff flavourings and nutrients  
 Sector of use:  
 SU 2a: Mining (without offshore industries)  
 SU 2b: Offshore industries  
 SU 4: Manufacture of food products  
 SU 5: Manufacture of textiles, leather, fur  
 SU 6a: Manufacture of wood and wood products  
 SU 6b: Manufacture of pulp, paper and paper products  
 SU 7: Printing and reproduction of recorded media  
 SU 8: Manufacture of bulk, large scale chemicals (including petroleum products)  
 SU 9: Manufacture of fine chemicals  
 SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys)  
 SU 11: Manufacture of rubber products  
 SU 12: Manufacture of plastics products, including compounding and conversion  
 SU 13: Manufacture of other non-metallic mineral products, e.g. plasters, cement  
 SU 14: Manufacture of basic metals, including alloys  
 SU 15: Manufacture of fabricated metal products, except machinery and equipment  
 SU 16: Manufacture of computer, electronic and optical products, electrical equipment  
 SU 17: General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment  
 SU 18: Manufacture of furniture  
 SU 19: Building and construction work  
 SU 20: Health services  
 SU 23: Electricity, steam, gas water supply and sewage treatment  
 SU 24: Scientific research and development  
 SU 0: Other:SU3 Industrial use

### Uses by consumers

Identified use name:

mainly as colorants and some other technical applications

Chemical product category:

PC 1: Adhesives, sealants  
 PC 2: Adsorbents  
 PC 3: Air care products  
 PC 4: Anti-freeze and de-icing products  
 PC 7: Base metals and alloys  
 PC 8: Biocidal products (e.g. disinfectants, pest control)  
 PC 9a: Coatings and paints, thinners, paint removers  
 PC 9b: Fillers, putties, plasters, modelling clay  
 PC 9c: Finger paints  
 PC 12: Fertilisers

PC 14: Metal surface treatment products, including galvanic and electroplating products  
PC 15: Non-metal-surface treatment products  
PC 18: Ink and toners  
PC 19: Intermediate  
PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents  
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PC 24: Lubricants, greases, release products  
PC 25: Metal working fluids  
PC 26: Paper and board dye, finishing and impregnation products: including bleaches and other processing aids  
PC 27: Plant protection products  
PC 28: Perfumes, fragrances  
PC 29: Pharmaceuticals  
PC 30: Photo-chemicals  
PC 31: Polishes and wax blends  
PC 32: Polymer preparations and compounds  
PC 34: Textile dyes, finishing and impregnating products; including bleaches and other processing aids  
PC 35: Washing and cleaning products (including solvent based products)  
PC 36: Water softeners  
PC 37: Water treatment chemicals  
PC 38: Welding and soldering products (with flux coatings or flux cores.), flux products  
PC 39: Cosmetics, personal care products  
PC 0: Other:PC5 Artists supply and Hobby preparations PC6: Automotive Care Products PC10 Buildings and construction preparations, UCN code 62 – electromechanical components, UCN code 26 – Food / Feedstuff flavourings and nutrients

### **2.3. Uses advised against**

No uses advised against are identified

**Appendix 2 - Identity**

Chemical name <sup>1</sup>	Diiron trioxide	Triiron tetroxide	Iron hydroxide oxide	Iron manganese trioxide	Manganese ferrite black spinel	Zinc ferrite
IUPAC name	Iron(III)oxide	Iron oxide			Manganese ferrite black spinel	Zinc ferrite brown spinel
Other names (usual name, trade name, abbreviation)	C.I. Pigment Red 101 C.I. 77491 Bayferrox 130 Diiron trioxide Iron(III)oxide Ferric oxide Red iron oxide Iron oxide red Copperas red	C.I. Pigment Black 11 C.I. 77499 Bayferrox 306 Triiron tetroxide Iron(II,III)oxide Ferric ferrous oxide Black iron oxide Iron oxide black	C.I. Pigment Yellow 42 C.I. 77492 Bayferrox 920 Z Ferrous oxide hydroxide Iron(III)oxide hydroxide Yellow iron oxide Iron oxide yellow	C.I. Pigment Brown 43 C.I. 77536 Bayferrox 645 T <sup>3</sup> Iron manganese oxide	C.I. Pigment Black 33 C.I. 77537 C.I.: 77494 Bayferrox 303 T <sup>3</sup> Colortherm Black 303 T Spinel black Manganese ferrite Spinels, iron manganese black	Colortherm 3950 C.I. 77496
EINECS No.	215-168-2	215-277-5	257-098-5	235-049-9	269-056-3	269-103-8
CAS name and CAS No.	Iron oxide (Fe <sub>2</sub> O <sub>3</sub> ) 1309-37-1	Iron oxide (Fe <sub>3</sub> O <sub>4</sub> ) 1317-61-9	Iron hydroxide oxide yellow (Fe(OH)O) 51274-00-1	Iron manganese oxide (FeMnO <sub>3</sub> ) 12062-81-6	C.I. Pigment Black 26 68186-94-7	C.I. Pigment Yellow 119 68187-51-9
Other identity code <sup>1</sup> : Related CAS/EC No.	Hematite (Fe <sub>2</sub> O <sub>3</sub> ) 1317-60-8 Iron oxide 1332-37-2 Maghemite (Fe <sub>2</sub> O <sub>3</sub> ) 12134-66-6 Iron oxide (Fe <sub>2</sub> O <sub>3</sub> ), dihydrate (9CI) 50811-63-7 (EC 215-166-1)	Magnetite (Fe <sub>3</sub> O <sub>4</sub> ) 1309-38-2 12227-89-3	Goethite (Fe(OH)O) 1310-14-1 Iron hydroxide oxide 20344-49-4 (EC 243-746-4) Lepidocrocite (Fe(OH)O) (9CI) 12022-37-6.	Iron manganese oxide 12789-36-5 (deleted CAS No.) Iron manganese oxide 11115-91-6	C.I. Pigment Black 33 188735-18-4 Iron manganese oxide ((Fe,Mn) <sub>2</sub> O <sub>3</sub> ) 75864-23-2	
Molecular formula	Fe <sub>2</sub> O <sub>3</sub>	Fe <sub>3</sub> O <sub>4</sub>	FeOOH	(Fe,Mn) <sub>2</sub> O <sub>3</sub> FeMnO <sub>3</sub>	(Fe,Mn) <sub>3</sub> O <sub>4</sub>	ZnFe <sub>2</sub> O <sub>4</sub>
Structural information (Crystal lattice <sup>2</sup> )	corundum (α, trigonal; cubic, spheric, spicular) spinel (γ)	inverse spinel (cubic)	diaspore (α) (spicular) boehmite (γ)	corundum	spinel	spinel
Minerals of identical or similar composition	Hematite (α) Haematite (α) Maghemite (γ)	Magnetite	Goethite (α) Lepidocrocite (γ)	Bixbyite	Franklinite ((Fe,Mn,Zn) <sub>3</sub> O <sub>4</sub> ); Jacobsite (MnFe <sub>2</sub> O <sub>4</sub> )	Franklinite ((Fe,Mn,Zn) <sub>3</sub> O <sub>4</sub> )
MW (g/mole)	159.69	231.53	88.85	158.79	174.8	241.06

<sup>1</sup> EINECS name. Greek letters refer to crystal modifications.

<sup>2</sup> Roempp, 2007.

<sup>3</sup> See text.

The chemical and physical properties of the CIC pigments depend on the manufacturing conditions, e.g. the composition the raw materials mixture and the calcining process itself. For the iron oxides which consist of metal and oxygen only 2 crystal lattices are important:

▫ Corundum ( $Al_2O_3$ ) structure with a basic formula of  $M_2O_3$  and an oxygen/metal ratio of 1.5.  $Fe_2O_3$  and  $(Fe,Mn)_2O_3$  belong in this group. Since hematite ( $Fe_2O_3$ ) is a well-known representative of this group, this structure is occasionally referred to as hematite structure.

▫ Spinel ( $MgAl_2O_4$ ) structure with a basic formula of  $M_3O_4$  and an oxygen/metal ratio of 1.33.  $Fe_3O_4$ ,  $(Fe,Mn)_3O_4$ , and  $ZnFe_2O_4$  are members of this group. The crystals of this group are very stable and can even be formed when the stoichiometry is not completely fulfilled e.g. alpha-modification of  $Fe_2O_3$ .

Due to their structural similarity, their similar physico-chemical, ecological and toxicological properties and their major application iron oxides with manganese and zinc in the crystal matrix have been included in the "Synthetic Iron Oxides for metallurgical and non- metallurgical applications" category (Table 1 and Category Justifications).

Since all members of the category are inorganic, UV- IR- NMR- and MS-spectroscopy are of minor importance for analysis. HPLC and GC are not applicable because these substances form heavy crystals which are almost insoluble in water and organics and have an extremely low vapour pressure. The substances can be characterized by X-ray diffractometry and also by semi quantitative determination of elements by X-ray fluorescence analysis.

Iron oxides containing impurities which would lead to a Classification and Labelling other than stated in chapter 3 of the CSR are not members of the category.

**Appendix 3 - SIEF Agreement**

**SIEF and Joint Submission AGREEMENT**

**September 29, 2010**

**Iron Oxides**

**1. Definitions**

- (a) *Advantage Compensation* shall mean a fee that covers general costs incurred by the Parties to the Consortium Agreement in relation to their initiative, commitment and any other preliminary performance within the Consortium and for the purposes of preparing the Joint Registration Dossier, such as substantiated and reasonable travel costs, manpower allocated to the work in the Consortium, etc.
- (b) *Affiliate(s)* shall mean a corporation, which controls, is controlled by or is under common control with a Party, with control meaning at least 50% of the voting rights directly or indirectly owned. Unless provided otherwise, when referring to Affiliates in the context of this Agreement it is understood that this also comprises any Only Representative acting on behalf of a non-EU Affiliate of a Party. The corporations named in this Agreement are to be considered as Affiliates of Parties who have obligations to register the Substance(s).
- (c) *Consortium* shall mean the members of the Iron Oxides REACH Consortium (established by the *Consortium Agreement* of 2009), of which Lanxess Deutschland GmbH is a member.
- (d) *Information* shall mean all studies, other scientific, statistical, or technical information or data, including but not limited to composition, characteristics, properties, processes and applications, and any other information in whatever form made available by a Party or generated by the Parties jointly, or licensed by or made available to the Consortium by third parties pursuant to or within the remit of this SIEF Agreement.
- (e) *LoA(s)* shall mean a letter of access to the Joint Registration Dossier granted by the Consortium to individual Parties and as attached as Annex 1 to this SIEF Agreement. The LoA entitles the Party (and its Affiliates) on a non-exclusive basis to refer to the information submitted to ECHA by the Lead Registrant for purposes of REACH registration, but it does not grant any additional rights except those specifically stated therein. In particular, it cannot be used, or transferred or relied upon, either for REACH or for any other purpose, by other legal entities, including affiliates of the Parties other than those named in the SIEF Agreement, unless those other legal entities would qualify for a free update of the original registration(s) pursuant to Article 5 (1) (c) of Commission Regulation (EC) No 340/2008.
- (f) *Party* or *Parties* shall mean the parties to this SIEF Agreement who have *either* (i) signed this SIEF Agreement, and/or have paid for the LoA as laid down in 4, *or* (ii) following notification of this Agreement, have not communicated to the Lead Registrant their objection to become a member of the SIEF Agreement pursuant to 5.(k) and are not listed as 'inactivated' pre-registrants in REACH-IT.
- (g) *Joint Registration Dossier(s)* shall cover the joint mandatory (Article 10 (a) (iv), (vi), (vii) and (ix) REACH) and joint voluntary (Article 10 (a) (v), and (b) REACH) parts of the REACH Registration Dossier for the Substance(s). The Joint Registration Dossier(s) covers IUCLID core data for the data requirements for more than 1000 tonnes and the hazard

assessment for the Chemical Safety Report(s) for the uses previously identified by the Consortium, as well as guidance on safe use.

- (h) *Project Manager* shall mean an external consultancy responsible for the daily management of the Consortium (e.g. financial issues) engaged by the Consortium members. The current project manager is McKenna Long & Aldridge LLP.
- (i) *REACH* shall mean Regulation (EC) No 1907/2006 and all subsequent Regulations, Decisions, and other measures adopted in connection thereto.
- (j) *Substance(s)* shall mean the substance(s) listed in 2.(a) of this SIEF Agreement.
- (k) All other terms used herein shall have the same meaning as under REACH.

## 2. Scope

- (a) This SIEF Agreement covers the following substances, either by themselves, as part of multi-constituent substances, or as intermediates:

1) **Iron hydroxide oxide – Yellow**

- EC 257-098-5
- CAS 51274-00-1

2) **Triiron tetraoxide**

- EC 215-277-5
- CAS 1317-61-9

3) **Diiron trioxide**

- EC 215-168-2
- CAS 1309-37-1

4) **Iron manganese (tri)oxide**

- EC 235-049-9
- CAS 12062-81-6

5) **Manganese ferrite (black spinel)**

- EC 269-056-3
- CAS 68186-94-7

6) **Zinc ferrite (brown spinel)**

- EC 269-103-8
- CAS 68187-51-9

The Parties have agreed in previous communications on the identity and sameness of the Substances and are thus members of the same SIEF.

- (b) This SIEF Agreement is applicable to all communications, actions and submissions made by the Parties individually or jointly within the scope of REACH in as far as these fall within the remit of SIEFs pursuant to Article 29 REACH.

- (c) This SIEF Agreement is applicable to all members of the SIEF (including the members of the Consortium) of the Substances. Consortium members are represented for purposes of this SIEF Agreement by the Lead Registrant.

### **3. General Rules of Cooperation**

- (a) The Parties agree that Lanxess Deutschland GmbH or its legal successor or another SIEF member assigned by it pursuant to 5. (f) below will act as the Lead Registrant for the Substances and will prepare, within the framework of the Consortium, the Joint Registration Dossiers for REACH registration of the Substances as and in as far as required, and make requests pursuant to Article 10 (a) (xi) REACH as deemed necessary. Upon demand of ECHA, within the requested deadline and to the extent necessary, the Lead Registrant also agrees to complete the Joint Registration Dossiers. Parties that are not members of the Consortium will participate in the joint registration efforts via (g) below in conjunction with a LoA to be granted according to this SIEF Agreement.
- (b) The Joint Registration Dossier will be prepared in time using all reasonable efforts so that Parties can meet the November 30, 2010 registration deadline.
- (c) In view of the tight work schedule, the Parties agree that the Lead Registrant will use its reasonable efforts to develop the Joint Registration Dossiers within the Consortium, and they acknowledge that the Lead Registrant has engaged reputable support to assist it in its efforts. The Parties will therefore not object or call into question the Joint Registration Dossiers so prepared in as far as applicable to them, and the Parties hereby agree to the Joint Registration Dossiers as developed by the Lead Registrant within the Consortium.
- (d) The Lead Registrant undertakes in turn to regularly update the Parties in writing on the progress made on the Joint Registration Dossiers as applicable to the Parties. The Lead Registrant may ask for cooperation and comments as it sees fit.
- (e) The Lead Registrant shall pay the registration fee pursuant to Article 11 (4) REACH as invoiced by ECHA for the submission of the Joint Registration Dossier without undue delay.
- (f) The Lead Registrant shall make the Joint Registration Dossiers available for inspection by the Parties at the premises of its Project Manager McKenna Long & Aldridge LLP, Avenue de Tervueren 2, 1040 Brussels, Belgium, for a two weeks period, probably October 4 – October 18, 2010 during office hours. Any Party joining the SIEF after the inspection period is entitled to inspect the Joint Registration Dossier after having taken an appointment with the Project Manager.
- (g) Provided the Party has fulfilled its payment obligations hereunder, the Lead Registrant shall inform the Party of the creation of a ‘joint submission object’ in REACH-IT and shall provide the valid security token number and the name of the joint submission. The Lead Registrant shall also inform the Parties of the submission of the Joint Registration Dossier to ECHA. The Lead Registrant shall further communicate the confirmation that the Joint Registration Dossier has been accepted as ‘complete’ and the registration number assigned pursuant to Article 20 (3) REACH.

#### 4. Cost Sharing

The price for the LoA is calculated by taking into account management and administration expenses, costs for existing and new data, costs for the preparation of IUCLID by the Lead Registrant, costs for preparing the Chemical Safety Report and guidance on safe use, and handling fees, *as follows*:

##### (a) Joint Registration Dossier Preparation

###### (i) Expenses

The expenses incurred to manage the Consortium and to prepare the Joint Registration Dossier are set out in Annex 2, as may be amended from time to time by the Project Manager..

###### (ii) Existing and new data

The total value of the data is set out in Annex 2 hereto, whereby for the so-called Pauluhn study, the price is separately fixed per LoA at € 10.375 through a License Agreement with another consortium (the so-called HPV consortium) the members of which co-own the Pauluhn study. This license agreement provides that should more than 100 companies request this study, the price will be proportionally reduced.

###### (iii) Chemical Safety Report ("CSR") and guidance on safe use

The cost for the preparation of the CSR (including the hazard assessment and summaries) and the guidance on safe use part of the Joint Registration Dossier will be shared equally by all Parties..

##### (b) LoA Price Determination

The total amount of (a) above will initially be divided by 30 (number of Consortium members at the time of issuance of this SIEF Agreement, i.e. minimum number of expected registrants of the Substances) to determine the LoA price per Party requesting an LoA. The price so determined will constitute the net 2010 LoA price. If more than 30 registrants register by November 30, 2010, any over-payment collected will be reimbursed to all 2010 1000t registrants thereafter. 1000t and above registrants that register after the 2010 registration deadline will pay the same as those registrants in the same tonnage category that register by November 30, 2010 and will be reimbursed their over-payment, if any, after the 2013 registration deadline has passed.

The price for registrants in the 100-999t category will be calculated mid 2011 based on the declared firm license LoA intentions received by the Project Manager by mid-2011. Any payments collected from those registrants will be reimbursed to the 1000t registrants that have previously registered, after the 2013 registration deadline has passed.

The price for registrants below 100t will be set by the Consortium later based on whether new studies will be conducted after 2010 and how many registrants will register in the higher tonnage categories.



(c) Advantage Compensation

In addition, there is a fee for Advantage Compensation which is 15% of the net LoA price calculated under (b) above but excluding the Pauluhn study.

(d) Handling fee

The fee for handling the LoA request and the joint submission is expected to be € 1,200 per LoA.

(e) Update of the Joint Registration Dossier after submission of the Joint Registration Dossier in 2010

Any cost for Studies requested by ECHA after the Joint Registration Dossier has been submitted shall be allocated in equal parts to those Members who need the Studies, *i.e.* if ECHA requests a Study only for one Substance, only those Members that have registered **or will register** that Substance and that require the Study within their tonnage band equally share that new Study's cost. Any future expenses to manage the Consortium during the registration and LoA issuing procedures and other additional unexpected costs that might arise through further requirements from ECHA after registration can be charged to all Parties in equal shares later, unless the expenses relate to specific Substances, in which case the special rule above will apply.

(f) Other Rules

The Lead Registrant or the Project Manager will calculate the price of the LoA by September 30, 2010 and will issue a proforma invoice or payment notice accordingly to be paid within 30 days of issuance by each Party; following payment, the joint submission tokens will be issued. Formal invoices will be issued after the respective registration deadlines, and for the first time after November 30, 2010. In case the amounts received from the proforma invoices and payment notices are not sufficient to cover the cost, tokens will only be issued after receipt of the amounts from the final invoices. Should new studies have to be purchased or performed as deemed necessary by the Consortium or pursuant to ECHA's request, or technical responses to ECHA be necessary after registration, the Lead Registrant or the Project Manager will issue instructions to issue additional invoices to be paid under the same terms if the cost cannot be covered by the fees already collected. No interest shall be applicable in either case on both sides. However, a Party that does not pay an invoice or payment notice within the 30 days of issuance shall at no time be entitled to participate in the joint submission and receive an LoA, or its LoA and permission to participate in the joint submission shall be considered as revoked. The final settlement shall be handled by an independent auditor appointed by the Lead Registrant on June 1, 2022.

The Lead Registrant or the Project Manager will issue LoAs after receipt of a Party's payment and after the Party has had the option to inspect the Joint Registration Dossier as far as it is concerned by it pursuant to 3. (f).

The Lead Registrant or the Project Manager shall at all times account for the cost of the Joint Registration Dossier and shall keep records thereof for the duration of this SIEF Agreement. Any Party shall have the right to have the accounts audited at its own cost upon prior notice of at least five working days.

**5. Miscellaneous Provisions**

- (a) *Assignment.* This SIEF Agreement is linked to the joint registration obligations of REACH and can therefore not be assigned or transferred by the Parties without prior approval of the Lead Registrant unless the assignee is an Affiliate or successor in law subject to REACH registration of the Substance(s), or is an Only Representative or Third Party Representative replacing a previous Only Representative or Third Party Representative of the same principal and the assignment/transfer has been communicated to the Lead Registrant or its Trustee.
- (b) *Communications.* All communications within the framework of this SIEF Agreement shall be done by electronic mail and shall be considered valid upon receipt of an automatic confirmation of receipt received by the sender. The Lead Registrant or the Project Manager shall install an email address or other electronic platform for communication within the SIEF. The parties agree to regularly and proactively communicate within this platform provided, and to answer any information and communication requests of the Lead Registrant within five working days at the latest unless the Lead Registrant expressly provides a longer response time. Unless other contact details are indicated below, the contact details available in REACH-IT shall be used at all times. The Parties shall at all times keep their REACH-IT contact details updated and functional. In case the REACH-IT contact details of a Party are not functional and no other valid and functional contact information has been provided below, the Lead Registrant shall be considered as released from any obligations under this SIEF Agreement.
- (c) *Compliance.* The Parties shall at all times comply with the applicable laws, including EU competition law. The Lead Registrant has used its best efforts to acquire use/referral rights for all key and supporting studies used in the Joint Registration Dossier including for all members of the joint submission. Independent from this Agreement, Parties assert to observe copyrights and access rights of the public domain literature used for the Joint Registration Dossier required for their respective registration purposes under REACH in sufficient time before the submission of their respective individual dossier to ECHA. The Lead Registrant will provide Parties with a list of key and supporting studies and the respective ownership. After this Agreement has been signed and the payment obligation has been fulfilled, the access right to the key and supporting studies owned by the Consortium members individually or jointly is considered as granted. Parties will fully indemnify Lead Registrant in the event Parties have no sufficient access or copyrights to refer to all required key and supporting studies.
- (d) *Confidentiality and Non-Use.* Each Party agrees to: (i) treat all Information as confidential and not disclose it to third parties, unless regulatory disclosure requirements are applicable; (ii) immediately advise the other Parties in writing of any disclosure or misuse by any Party or a third party of Information, as well as any request by competent authorities relating to disclosure of Information; (iii) disclose Information as required for legal and/or regulatory purposes including for purposes of REACH only in a form reflecting the minimum information required to be disclosed; (iv) use the Information only for purposes and as permitted hereunder; (v) not to analyze, test or reverse engineer or have analyzed, tested or reverse engineered any samples, formulas, combination of formulas or any technical or scientific methodology, chemistry or know-how provided by any of the Parties for their components, formulations or processes; (vi) not to file any patent, utility model or design application based upon Information or samples; *and* (vii) not to disclose Information to their employees, Affiliates, external experts and/or other consultants; unless the Party is an Only Representative or Third Party representative to the non-EU manufacturer or legal entity

represented by the Third Party Representative, in which case it should only disclose Information on a strictly need-to-know basis to the extent permitted and absolutely necessary hereunder. Each Party shall have in place policies and procedures to ensure compliance herewith and shall ensure that the aforementioned entities and persons also have such policies and procedures in place.

The confidentiality and non-disclosure obligations above shall not apply to Information for which the receiving Party can reasonably demonstrate that such Information (i) was known to the receiving Party on a non-confidential basis prior to its disclosure pursuant to this SIEF Agreement; (ii) is publicly known at the time of disclosure or thereafter becomes publicly known without breach of the terms of this SIEF Agreement on the part of the receiving Party; (iii) becomes known to the receiving Party through disclosure by sources other than the disclosing Party, having a right to disclose such Information; (iv) was independently developed by the receiving Party without access to the disclosing Party's information, as evidenced by documentary records; *or* (v) becomes subject to disclosure to governmental authorities with lawful authority to seek such Information.

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.

The obligations on confidentiality and non-use shall remain in effect and shall survive the duration of this SIEF Agreement. In the event of non-compliance with the duties here above, Parties are entitled to exclude the breaching Party from any further cooperation hereunder by decision of the Consortium. The obligation to render compensation for damages in accordance with the applicable legal provisions shall remain unaffected.

- (e) *Dispute resolution and applicable law.* Any dispute hereunder that cannot be settled amicably shall be resolved by arbitration with a single arbitrator to be appointed by the Brussels Bar. The arbitration rules of the International Court of Arbitration ("ICC") shall be applicable. The arbitration decision, including on the payment of the cost of arbitration, shall be binding on the Parties. The place of any hearing shall be Brussels and the language of the arbitration shall be English. Belgian law shall govern this SIEF Agreement. If at any time any provision of this SIEF Agreement is or becomes invalid or illegal in any respect, this shall have no effect on the validity of the remainder of this SIEF Agreement. The invalid provisions are to be replaced retroactively by provisions which come closest to achieving the objectives.
- (f) *Duration and Termination.* This SIEF Agreement shall be in force until December 31, 2022, although its provisions under 5. (d), (e) and (h) shall survive its term indefinitely. Furthermore, the confidentiality obligations related to studies shall survive for 12 years after their first submission to ECHA, and all other confidentiality obligations shall survive until June 1, 2023.

The Lead Registrant has the right to terminate its functions as Lead Registrant provided another SIEF member has validly agreed to replace it within the SIEF, has agreed to the terms of this SIEF Agreement, and has taken up its functions accordingly. The other Parties must be informed about this replacement without undue delay.

Parties have the right to terminate this SIEF Agreement at the latest by October 15, 2010. The provisions under 5. (d), (e) and (h) shall survive termination as specified above.

- (g) *Individual Responsibility.* Notwithstanding the cooperation within this SIEF Agreement, the Parties and their Affiliates remain individually responsible for compliance with REACH, in particular, but not limited to, their individual submission of information required under Article 11 (1) REACH.
- (h) *Liability.* The Lead Registrant shall only be liable to the other Parties in connection with the activities contemplated in this SIEF Agreement, including delays in the completion and submission of the Joint Registration Dossier, in case of gross negligence or wilful misconduct. He shall not be liable for consequential damage and lost profits. This limitation of liability does not apply in case of claims for death, personal injury or wilful misconduct. No warranty for acceptance of the Joint Registration Dossier or Information it contains, or acceptance of a study by ECHA at dossier evaluation (according to Title VI REACH) is given.
- (i) *Payments.* 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. 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.
- (j) *Rights.* This SIEF Agreement does not grant any ownership rights or change existing ownership rights to any of the Information provided under this SIEF Agreement to the Parties. Neither this SIEF 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. No legal entity or partnership for legal or tax purposes is created under this SIEF Agreement. The Parties are themselves responsible for any fiscal payments and declarations related to the working of this SIEF Agreement.
- (k) *Validity / Entry into Effect.* This SIEF Agreement enters into effect between the Lead Registrant and the respective Party by (i) the Party filling in the required information below and returning a signed PDF copy of this SIEF Agreement; *and/or* (ii) payment by the Party for the LoA, *or* (iii) the non-objection by the SIEF member to become a Party to this SIEF Agreement, *provided that* not more than half of the SIEF members have communicated their objection to this Agreement by October 15, 2010.

**COMPANY - SIEF Member:**

\_\_\_\_\_

(Print company name and address)

**(NON-EU/EEA) COMPANIES REPRESENTED:**

\_\_\_\_\_

(In case the Party is an Only Representative (“OR”); indicate here the names of all the affiliated companies of one group represented by the OR to which this SIEF Agreement should be applicable; In case the OR has pre-registered for several groups of companies, he must sign separate SIEF Agreements for each of the groups; Likewise, if a Third Party Representative (“TPR”)<sup>1</sup> represents several independent companies for the Substance(s), he must sign separate SIEF agreements for each of the independent companies represented)

**AUTHORIZED REPRESENTATIVE:**

\_\_\_\_\_

(Print name of Representative authorized to sign this SIEF Agreement)

**SIGNATURE:**

\_\_\_\_\_

(Signature of Authorized Representative)

**Registration scope by group, i.e. affiliated companies together (take highest applicable tonnage band in the group total):**

- A: Tonnage band < 100 t
- B: Tonnage band 100 – 1,000 t
- C: Tonnage band > 1,000 t

**CONTACT INFORMATION:**

\_\_\_\_\_

(Print contact details for person responsible for SIEF communication)

<sup>1</sup> Unless the TPR voluntarily discloses the identity of the registrants represented, the Lead Registrant reserves the right and the TPR hereby agrees to have the identity of the registrants represented audited by an independent neutral auditor with appropriate confidentiality obligations.

**Annex 1 - Model Letter of Access<sup>2</sup>**

*[address of regulatory authority]*

**Letter of Access for the registration of the following substances**

- 1) **Iron hydroxide oxide – Yellow**
  - EC 257-098-5
  - CAS 51274-00-1
- 2) **Triiron tetraoxide**
  - EC 215-277-5
  - CAS 1317-61-9
- 3) **Diiron trioxide**
  - EC 215-168-2
  - CAS 1309-37-1
- 4) **Iron manganese (tri)oxide**
  - EC 235-049-9
  - CAS 12062-81-6
- 5) **Manganese ferrite (black spinel)**
  - EC 269-056-3
  - CAS 68186-94-7
- 6) **Zinc ferrite (brown spinel)**
  - EC 269-103-8
  - CAS 68187-51-9

**Note: LoA will be issued for all Substances together, not *per* single Substance.**

Dear Sirs,

The Iron Oxides REACH Consortium (here thereafter referred to as the “Consortium”) agrees that the data, studies, summaries, waiving argumentations, reasoning of testing proposals and/or assessments owned or subject to a use right by the members of the Consortium and submitted by the Consortium in support of the registration under *REACH* of the following Substances:

Iron hydroxide oxide – Yellow

Triiron tetraoxide

Diiron trioxide

<sup>2</sup> For information purposes only. The official Letter of Access will only be issued once payment has been made in accordance with Section 4 of the SIEF Agreement.

Iron manganese (tri)oxide

Manganese ferrite (black spinel)

Zinc ferrite (brown spinel)

(hereinafter collectively referred to as the “Joint Registration Dossier”), may be referred to

[*Company XYZ / List of Affiliates*] (hereafter the “Applicant”)

in order to support the Applicant’s registration of the above-mentioned substance(s) under REACH.

**In his registration, the Applicant acts: (*please tick appropriate box*)**

- for itself
- as an Only Representative pursuant to Article 8 REACH for the following non-EU manufacturer:  
\_\_\_\_\_
- as a Third Party Representative<sup>3</sup> pursuant to Article 4 REACH.

**In the Joint Registration Dossier, the Applicant would like to be covered concerning the following parts/documents: (*please tick appropriate box(es)*)**

- Mandatory joint parts of the Joint Registration Dossier (Article 10 (a) (iv), (vi), (vii) and (ix) REACH)
- Voluntary joint parts of the Joint Registration Dossier (Article 10 (a) (v) and (b) REACH) in as far as applicable (namely CSR and guidance on safe use)
- ‘Opt-out’ pursuant to Article 11 (3) for the following mandatory joint parts:

Article 10 (a)

- (iv)
- (vi)
- (vii)
- (ix)

<sup>3</sup> Unless the TPR voluntarily discloses the identity of the registrants represented, the Lead Registrant reserves the right and the TPR hereby agrees to have the identity of the registrants represented audited by an independent neutral auditor with appropriate confidentiality

On request, the Applicant may receive a summary of the *Information* submitted by the Consortium in support of the registration under *REACH*.

The right to refer to the Joint Registration Dossier is subject to the following restrictions:

1. The right of referral only gives access to the Joint Registration Dossier of the substances for the registration as specified above.
2. The right of referral is solely granted in favor of the Applicant and the Affiliates listed herein and is not transferable to any other entity or person.
3. Unless otherwise specified below at 6., 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 at ECHA or any related specific document in whole or in part, outside the general inspection period granted by the Consortium and outside the conditions set out in the SIEF 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. Nothing in this Letter of Access shall require *the Consortium members* to file any additional data.
6. In as far as the Joint Registration Dossier may contain CSR, use and exposure scenarios 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.

If the Applicant has chosen to himself prepare the CSR, use and exposure scenarios and guidance on safe use but does otherwise fully participate in the Joint Registration Dossier, he shall receive an electronic copy of parts Article 10 (a) (iv), (vi), (vii) and (ix) 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 and, as well as to refer to the full study reports on which basis the (robust) study summaries have been developed.

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.

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.

Signature: Authorized Representative of the Consortium.

The Applicant hereby declares that he is aware of, agrees and complies with the provisions of the SIEF Agreement issued by the Lead Registrant Lanxess Deutschland GmbH, which shall apply in its entirety in addition to the provisions set out hereunder.



**Annex 2 - Consortium Budget and LoA Calculation**

<b>IRON OXIDES REACH CONSORTIUM BUDGET</b>			
<b>APPROVED BUDGET : CONSORTIUM MANAGEMENT</b>	<b><u>2009</u></b>	<b><u>2010</u></b>	<b><u>TOTAL</u></b>
Steering Committee meetings - attend & chair, establish agenda and action plan, prepare minutes and maintain a clear record of decisions and votes (1 meeting in 2009 & 3 meetings 2010)	€ 9,600.00	€ 30,600.00	€ 40,200.00
Accounting fee	€ 7,000.00	€ 25,000.00	€ 32,000.00
General Management of the Consortium	€ 8,000.00	€ 27,000.00	€ 35,000.00
Third Party Communication (excluding SIEF)	€ 10,000.00	€ 10,000.00	€ 20,000.00
SIEF Communication (estimate)	-	€ 60,000.00	€ 60,000.00
LoA Management - On Line IT tool	-	€ 1,500.00	€ 1,500.00
Ad-hoc Legal Advice not related to Steering Committee meetings (e.g. cooperation agreements with other consortia, SIEF agreements, license fee agreements etc.) (estimate)	€ 15,000.00	€ 15,000.00	€ 30,000.00
Iron Platform - SIEF survey assistance	-	€ 5,000.00	€ 5,000.00
<b>TOTAL CONSORTIUM MANAGEMENT (excl. LoA)</b>	<b>€ 49,600.00</b>	<b>€ 174,100.00</b>	<b>€ 223,700.00</b>
<b>APPROVED BUDGET : DOSSIER PREPARATION</b>	<b><u>2009</u></b>	<b><u>2010</u></b>	<b><u>2010</u></b>
IUCLID 5 file/CSR Hazard Assessment/Pre-consortium costs Lead Company	€ 420,000.00	-	€ 420,000.00
Finalization of dossier	-	€ 40,000.00	€ 40,000.00
Licensing of studies (Lanxess) (net value)	-	€ 160,989.00	€ 160,989.00
Licensing of data from Iron Platform	-	€ 39,410.00	€ 39,410.00
Update of IUCLID dossier - Iron Platform	-	€ 60,754.00	€ 60,754.00
Update of IUCLID dossier - Lanxess	-	€ 20,000.00	€ 20,000.00
<b>TOTAL DOSSIER PREPARATION COSTS</b>	<b>€ 420,000.00</b>	<b>€ 321,153.00</b>	<b>€ 741,153.00</b>
<b>TOTAL CONSORTIUM MANAGEMENT &amp; DOSSIER PREPARATION COSTS</b>	<b>€ 469,600.00</b>	<b>€ 495,253.00</b>	<b>€ 964,853.00</b>

**Iron Oxides REACH Consortium :  
LoA price calculation for 6 substances combined**

	Assumption : 30 SIEF members	
	Consortium Budgets	LOA Calculation
2009 budget - Consortium Management	€ 49,600	€ 1,653
2009 budget - Dossier Preparation	€ 420,000	€ 14,000
2010 Budget less LOA - Consortium Management	€ 174,100	€ 5,803
2010 Budget less LoA - Dossier Preparation	€ 321,153	€ 10,705
Expenses	€ 2,800	€ 93
<b>TOTAL</b>	<b>€ 967,653</b>	<b>€ 32,255</b>
Income Cooperation with Iron Platform	€ (434,655)	€ (14,489)
<b>TOTAL</b>	<b>€ 532,998</b>	<b>€ 17,767</b>
Admin cost (15%)		€ 2,665
<b>TOTAL WITH ADMIN COST</b>		<b>€ 20,432</b>
Handling Fee		€ 1,200
<b>LOA PRICE</b>	-	<b>€ 21,632</b>
Pauluhn study license fee (to be forwarded to HPV Consortium)		€ 10,375
<b>TOTAL LOA PRICE</b>		<b>€ 32,007</b>

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March 4, 2011

## TO WHOM IT MAY CONCERN

- SIEF Communication on behalf of Iron Oxides REACH Consortium  
and Lead Registrant Lanxess Deutschland GmbH -

**Re: REACH: SIEF Communication Iron Oxides and Related Substances EC 257-098-5  
(synonyms 243-746-4; 215-176-6); EC 215-277-5 (synonyms 235-442-5; 215-169-8); EC  
215-168-2 (synonyms 215-570-8; 215-275-4); EC 235-049-9; EC 269-056-3; EC 269-103-8**

**Recalculation of LoA price for 1000t category and calculation of LoA price for  
100-1000t category**

Dear SIEF Member:

Pursuant to our last SIEF communication of September 29, 2010, we hereby inform you that:

(1) the LoA price for the 1000t category has been recalculated:

According to Section 4 (b) of the SIEF Agreement, the price needed to be recalculated, dividing the cost by 50 registrants in the above 1000t category, rather than by the original 30 (Consortium Members). The new LoA price for the 1000t category for the package of six substances all together is now **€28,570** (excl. VAT where applicable) (*see Annex 1*). This price includes affiliated legal entities of the LoA applicant. Both Consortium Members as well as previous LoA 1000t applicants will thus be partially reimbursed in the course of 2011.

(2) the LoA price for the 100-1000t category has been calculated:

8 LoAs were issued for the 100-1000t category in 2010. These early 2013 LoA applicants were asked to provisionally pay the full price pending the new calculation, and will thus be reimbursed in the course of 2011. The LoA price for the 100-1000t category for the package of six substances all together is **€25,171** (excl. VAT where applicable) (*see Annex 2*). This price includes affiliated legal entities of the LoA applicant. The following considerations have gone into this calculation mechanism: all work and data used for the 1000t dossier is also necessary for the 100t dossier. However, in view of the fact that for the 100t companies the cost per ton is proportionally more expensive, a fair reduction of 20% is applied.

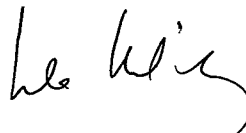
Finally, please note that a second batch of reimbursements to both the 1000t as well as the 100t registrants shall be effected after May 31, 2013, based on total LoAs sold by then (additional 1000t

Page 2

plus 100t LoAs). Please also note that the recalculated prices take into account new budget items for the period 2011-2018.

Thank you very much for your attention.

Kind regards,

A handwritten signature in black ink, appearing to read 'Ursula Schliessner', with a stylized flourish at the end.

Ursula Schliessner  
Partner  
McKenna Long & Aldridge LLP

**Annex 1: New LoA price for 1000t category****Iron Oxides REACH Consortium : New LoA price calculation 1000 t category (all six substances combined annually per LoA applicant and its Affiliates) - December 2010**

	50 SIEF members (*)	
	Consortium Budgets	LOA Calculation
2009 budget - Consortium Management	€ 49,600	€ 992
2009 budget - Dossier Preparation	€ 420,000	€ 8,400
2010 Budget less LOA - Consortium Management	€ 174,100	€ 3,482
2010 Budget less LoA - Dossier Preparation	€ 321,153	€ 6,423
2011 Budget	€ 152,000	€ 3,040
2012 Budget	€ 46,000	€ 920
2013 - 2018 Budget	€ 50,000	€ 1,000
Expenses	€ 4,000	€ 80
<b>TOTAL</b>	<b>€ 1,216,853</b>	<b>€ 24,337</b>
Income Cooperation with Iron Platform	€ (434,655)	€ (8,693)
Income (Umicore & Stora license agts.)	€ (43,264)	€ (865)
<b>TOTAL</b>	<b>€ 738,934</b>	<b>€ 14,779</b>
Admin cost (15%)		€ 2,217
<b>TOTAL WITH ADMIN COST</b>		<b>€ 16,995</b>
Handling Fee		€ 1,200
<b>LOA PRICE</b>		<b>€ 18,195</b>
Pauluhn study license fee (to be forwarded to HPV Consortium)		€ 10,375
<b>TOTAL LOA PRICE</b>		<b>€ 28,570</b>

(\*) i.e. 30 Consortium Members + 20 "above 1000t category" paid LoA applicants

**Annex 2: LoA price for 100-1000t category**
**Iron Oxides REACH Consortium : LoA price calculation 100 - 1000 t category (all six substances combined below 1000t annually per LoA applicant and its Affiliates) - December 2010**

	Consortium Budgets	LOA Calculation
2009 budget - Consortium Management	€ 49,600	€ 992
2009 budget - Dossier Preparation	€ 420,000	€ 8,400
2010 Budget less LOA - Consortium Management	€ 174,100	€ 3,482
2010 Budget less LoA - Dossier Preparation	€ 321,153	€ 6,423
2011 Budget	€ 152,000	€ 3,040
2012 Budget	€ 46,000	€ 920
2013 - 2018 Budget	€ 50,000	€ 1,000
Expenses	€ 4,000	€ 80
<b>TOTAL</b>	<b>€ 1,216,853</b>	<b>€ 24,337</b>
Income Cooperation with Iron Platform	€ (434,655)	€ (8,693)
Income (Umicore & Stora license agts.)	€ (43,264)	€ (865)
<b>TOTAL</b>	<b>€ 738,934</b>	<b>€ 14,779</b>
Admin cost (15%)		€ 2,217
<b>TOTAL WITH ADMIN COST</b>		<b>€ 16,995</b>
<b>incl. 20% reduction for lower tonnage band</b>		<b>€ 13,596</b>
Handling Fee		€ 1,200
<b>LOA PRICE</b>		<b>€ 14,796</b>
Pauluhn study license fee (to be forwarded to HPV Consortium)		€ 10,375
<b>TOTAL LOA PRICE</b>		<b>€ 25,171</b>

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March 5, 2013

**TO WHOM IT MAY CONCERN**

- SIEF Communication on behalf of Iron Oxides REACH Consortium  
and Lead Registrant Lanxess Deutschland GmbH -

**Re: REACH: SIEF Communication Iron Oxides and Related Substances EC 257-098-5 (synonyms 243-746-4; 215-176-6); EC 215-277-5 (synonyms 235-442-5; 215-169-8); EC 215-168-2 (synonyms 215-570-8; 215-275-4); EC 235-049-9; EC 269-056-3; EC 269-103-8; EC numbers with no Lead Registrant: LoAs to be purchased under other EC numbers**

Dear SIEF Members,

In anticipation of the upcoming May 31, 2013 registration deadline for 100t +, please note that for certain iron oxides, more than one EC number was used in the past. It is therefore possible that for certain of these EC numbers no Lead Registrant has been agreed / identified to ECHA. Please note that for five of these EC numbers in lack of a Lead Registrant in ECHA's recent list of substances for which no LR has been identified, registrations were jointly submitted by the 2010 registration deadline under other available EC numbers. Letters of access can therefore be purchased for these substances under another EC number, see below.

We would hereby wish to inform you on behalf of LR Lanxess Deutschland GmbH and the Iron Oxides REACH Consortium that Lanxess filed the following joint registrations in 2010:

- EC 215-277-5 (registered) for which 215-169-8 (non-registered) and 235-442-5 (non-registered) are considered as synonyms for REACH registration purposes
- EC 257-098-5 (registered) for which 215-176-6 (non-registered) and 243-746-4 (non-registered) are considered as synonyms for REACH registration purposes
- EC 215-168-2 (registered) for which 215-275-4 (non-registered) is considered as synonym for REACH registration purposes.

For more details please see at <http://www.mlalaw.eu/Home/DownloadSubstanceDescription/26>. However, please check also carefully the substance identity profile to see whether your substance is covered in the joint registration dossier.

Kind regards,

Ursula Schliessner  
Partner  
McKenna Long & Aldridge LLP

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September 16, 2013

**TO WHOM IT MAY CONCERN**

- SIEF Communication on behalf of Iron Oxides REACH Consortium  
and Lead Registrant Lanxess Deutschland GmbH –

**Re: REACH: SIEF Communication Iron Oxides and Related Substances EC 257-098-5  
(synonyms 243-746-4; 215-176-6); EC 215-277-5 (synonyms 235-442-5; 215-169-8); EC  
215-168-2 (synonyms 215-570-8; 215-275-4); EC 235-049-9; EC 269-056-3; EC 269-103-8**

**Recalculation of all LoA Prices for all Tonnage Categories**

Dear SIEF Members,

The Iron Oxides REACH Consortium has recently proceeded to a recalculation of LoA prices for the 1000t and 100t+ LoA categories and has determined the prices for the lower categories, please see overleaf. The calculation is based on a division factor of 90 (all LoAs sold in all tonnage categories by the 2013 registration deadline). Due to the unexpectedly high number of LoAs sold, IORC has also been able to renegotiate with the data owner the price per SIEF member of the Pauluhn study. The new price calculations are **attached**. These take into account also post 2010 expenditures either spent already or expected to be spent until 2018.

IORC does currently not envisage to revisit these calculations in the future. Any future income from LoAs will be used to offset the LoA price deductions in the lower tonnage categories and conduct additional work on the dossier where considered necessary or required.

Kind regards,

Ursula Schliessner  
Partner  
McKenna Long & Aldridge LLP



**Iron Oxides REACH Consortium : LoA price calculation for 6 substances combined**

**1 to 10 tons**

	Assumption : 90 SIEF members	
	Consortium Budgets	LOA Calculation
2009 Budget - Consortium Management & Dossier Preparation	€ 469,600	€ 5,218
2010 Budget Consortium Management (excl. LoAs) & Dossier Preparation	€ 495,253	€ 5,503
2011 Budget - Consortium Management & Dossier Preparation	€ 152,000	€ 1,689
2012 Budget - Consortium Management & Dossier Preparation	€ 46,000	€ 511
2013 Budget - Consortium Management (excl. LoAs) & Dossier Preparation	€ 67,000	€ 744
2014 Budget - Consortium Management (excl. LoAs) & Dossier Preparation	€ 17,000	€ 189
2015 Budget - Consortium Management & Dossier Preparation	€ 17,000	€ 189
2016 Budget - Consortium Management & Dossier Preparation	€ 17,000	€ 189
2017 Budget - Consortium Management & Dossier Preparation	€ 17,000	€ 189
2018 Budget - Consortium Management & Dossier Preparation	€ 17,000	€ 189
Expenses	€ 4,000	€ 44
Income Licence Agreements with Third Parties	€ (448,001)	€ (4,978)
<b>TOTAL</b>	<b>€ 870,852</b>	<b>€ 9,676</b>
Price reduction for 1 to 10 tons dossier (-80%)		€ (7,741)
<b>TOTAL PRICE</b>		<b>€ 1,935</b>
Admin cost (15%)		€ 290
<b>TOTAL WITH ADMIN COST</b>		<b>€ 2,226</b>
Handling Fee		€ 1,200
<b>LOA PRICE</b>		<b>€ 3,426</b>
Pauluhn study license fee (to be forwarded to HPV Consortium)		€ -
<b>TOTAL LOA PRICE</b>		<b>€ 3,426</b>

**Iron Oxides REACH Consortium : LoA price calculation for 6 substances combined**

**10 to 100 tons**

	Assumption : 90 SIEF members	
	Consortium Budgets	LOA Calculation
2009 Budget - Consortium Management & Dossier Preparation	€ 469,600	€ 5,218
2010 Budget Consortium Management (excl. LoAs) & Dossier Preparation	€ 495,253	€ 5,503
2011 Budget - Consortium Management & Dossier Preparation	€ 152,000	€ 1,689
2012 Budget - Consortium Management & Dossier Preparation	€ 46,000	€ 511
2013 Budget - Consortium Management (excl. LoAs) & Dossier Preparation	€ 67,000	€ 744
2014 Budget - Consortium Management (excl. LoAs) & Dossier Preparation	€ 17,000	€ 189
2015 Budget - Consortium Management & Dossier Preparation	€ 17,000	€ 189
2016 Budget - Consortium Management & Dossier Preparation	€ 17,000	€ 189
2017 Budget - Consortium Management & Dossier Preparation	€ 17,000	€ 189
2018 Budget - Consortium Management & Dossier Preparation	€ 17,000	€ 189
Expenses	€ 4,000	€ 44
Income Licence Agreements with Third Parties	€ (448,001)	€ (4,978)
<b>TOTAL</b>	<b>€ 870,852</b>	<b>€ 9,676</b>
Price reduction for 10 to 100 tons dossier (-40%)		€ (3,870)
<b>TOTAL PRICE</b>		<b>€ 5,806</b>
Admin cost (15%)		€ 871
<b>TOTAL WITH ADMIN COST</b>		<b>€ 6,677</b>
Handling Fee		€ 1,200
<b>LOA PRICE</b>		<b>€ 7,877</b>
Pauluhn study license fee (to be forwarded to HPV Consortium)		€ 1,724
<b>TOTAL LOA PRICE</b>		<b>€ 9,601</b>

Iron Oxides REACH Consortium : LoA price calculation for 6 substances combined		
100 to 1000 tons		
	Assumption : 90 SIEF members	
	Consortium Budgets	LOA Calculation
2009 Budget - Consortium Management & Dossier Preparation	€ 469,600	€ 5,218
2010 Budget Consortium Management (excl. LoAs) & Dossier Preparation	€ 495,253	€ 5,503
2011 Budget - Consortium Management & Dossier Preparation	€ 152,000	€ 1,689
2012 Budget - Consortium Management & Dossier Preparation	€ 46,000	€ 511
2013 Budget - Consortium Management (excl. LoAs) & Dossier Preparation	€ 67,000	€ 744
2014 Budget - Consortium Management (excl. LoAs) & Dossier Preparation	€ 17,000	€ 189
2015 Budget - Consortium Management & Dossier Preparation	€ 17,000	€ 189
2016 Budget - Consortium Management & Dossier Preparation	€ 17,000	€ 189
2017 Budget - Consortium Management & Dossier Preparation	€ 17,000	€ 189
2018 Budget - Consortium Management & Dossier Preparation	€ 17,000	€ 189
Expenses	€ 4,000	€ 44
Licence Agreements with Third Parties	€ (448,001)	€ (4,978)
<b>TOTAL</b>	<b>€ 870,852</b>	<b>€ 9,676</b>
Price reduction for 100 to 1000 tons dossier (-20%)		€ (1,935)
<b>TOTAL PRICE</b>		<b>€ 7,741</b>
Admin cost (15%)		€ 1,161
<b>TOTAL WITH ADMIN COST</b>		<b>€ 8,902</b>
Handling Fee		€ 1,200
<b>LOA PRICE</b>		<b>€ 10,102</b>
Pauluhn study license fee (to be forwarded to HPV Consortium)		€ 5,846
<b>TOTAL LOA PRICE</b>		<b>€ 15,948</b>



**Iron Oxides REACH Consortium : LoA price calculation for 6 substances combined**

**Above 1000 tons**

	Assumption : 90 SIEF members	
	Consortium Budgets	LOA Calculation
2009 Budget - Consortium Management & Dossier Preparation	€ 469,600	€ 5,218
2010 Budget Consortium Management (excl. LoAs) & Dossier Preparation	€ 495,253	€ 5,503
2011 Budget - Consortium Management & Dossier Preparation	€ 152,000	€ 1,689
2012 Budget - Consortium Management & Dossier Preparation	€ 46,000	€ 511
2013 Budget - Consortium Management (excl. LoAs) & Dossier Preparation	€ 67,000	€ 744
2014 Budget - Consortium Management (excl. LoAs) & Dossier Preparation	€ 17,000	€ 189
2015 Budget - Consortium Management & Dossier Preparation	€ 17,000	€ 189
2016 Budget - Consortium Management & Dossier Preparation	€ 17,000	€ 189
2017 Budget - Consortium Management & Dossier Preparation	€ 17,000	€ 189
2018 Budget - Consortium Management & Dossier Preparation	€ 17,000	€ 189
Expenses	€ 4,000	€ 44
Income Licence Agreements with Third Parties	€ (448,001)	€ (4,978)
<b>TOTAL PRICE</b>	<b>€ 870,852</b>	<b>€ 9,676</b>
Admin cost (15%)		€ 1,451
<b>TOTAL WITH ADMIN COST</b>		<b>€ 11,128</b>
Handling Fee		€ 1,200
<b>LOA PRICE</b>		<b>€ 12,328</b>
Pauluhn study license fee (to be forwarded to HPV Consortium)		€ 5,846
<b>TOTAL LOA PRICE</b>		<b>€ 18,174</b>

# JONES DAY

MICHÈLE GRÉGOIRE<sup>(6)</sup>  
WERNER DERIJCKE  
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Members of the Belgian Supreme Court Bar

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<sup>(5)</sup>Member of the District of Columbia Bar  
<sup>(6)</sup>Admitted to the Paris Bar  
<sup>(7)</sup>Member of the Berlin Bar

January 12, 2016

BY ELECTRONIC MAIL

TO WHOM IT MAY CONCERN

**Re: REACH SIEF Communication Iron Oxides: Iron hydroxide oxide yellow EC 257-098-5 (synonyms 243-746-4; 215-176-6); triiron tetraoxide EC 215-277-5 (synonyms 235-442-5; 215-169-8); Diiron trioxide EC 215-168-2 (synonyms 215-570-8; 215-275-4); Iron manganese (tri)oxide EC 235-049-9; manganese ferrite EC 269-056-3; Zinc ferrite EC 269-103-8**

Dear SIEF Member,

We are writing to you today on behalf of Lead Registrant LANXESS Deutschland GmbH and the members of the Iron Oxides REACH Consortium (the 'Consortium') to inform you that earlier this month, the Consortium has completed a REACH registration dossier update with ECHA.

The dossier update consists of, among others, (i) a general update of the dossier including implementation of Commission Recommendation 2011/696 on the definition of nanomaterials and various ECHA Guidance on nanomaterials; (ii) integration of new data and literature search; (iii) development of a new document on the product family approach intended to assist in substance identification; (iv) an overhauled CSR; and (v) an update of the category justification. The Consortium has also updated the list of uses (see at the end of this document).

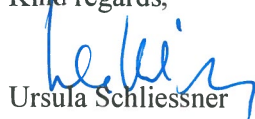
The work conducted on substance identity has concluded that pigments made of iron hydroxide oxide yellow should be considered as nanomaterials according to Recommendation 2011/696 due to the rod shape of the particles. Red iron(III)oxide pigments can consist of particle sizes which warrant a declaration as nano-material or not, depending on the shade of red of the respective material. The laws of physics and chemistry necessitate the particle size being in the order of 100 to 500 nm causing some materials to be considered as nanomaterials and some not. As the differences between the particle sizes are within approximately one order of magnitude there will be no changes in phys./chem. data with the exception of those trivially connected with the particle size, i.e. the specific surface area. Triiron tetraoxide colour pigments, due to physical and chemical constraints, will normally not be considered as nano-materials according to Recommendation 2011/696. However, Triiron tetraoxide for magnetic storage which were mainly used in the '80s and '90s of the 20<sup>th</sup> century had characteristic needle shaped particles necessary for their task.

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DETROIT • DUBAI • DÜSSELDORF • FRANKFURT • HONG KONG • HOUSTON • IRVINE • JEDDAH • LONDON • LOS ANGELES  
MADRID • MEXICO CITY • MIAMI • MILAN • MOSCOW • MUNICH • NEW YORK • PARIS • PERTH • PITTSBURGH • RIYADH  
SAN DIEGO • SAN FRANCISCO • SÃO PAULO • SHANGHAI • SILICON VALLEY • SINGAPORE • SYDNEY • TAIPEI • TOKYO • WASHINGTON

As per the SIEF Agreement and consistent with the approach taken previously, LANXESS has also jointly filed the updated CSR. Those of you that are Letter of Access ('LoA') licensees and would wish to receive a copy of the CSR, or would wish to receive a copy of the Product Family Approach document, please write an email to amccabe@jonesday.com and indicate the legal entity name mentioned in your earlier LoA application, and the date when you applied for the LoA. We will subsequently send you the requested documents by email. Given the large number of LoAs, it may take us a couple of days to send you the requested documents.

Any SIEF Members who wish to purchase LoAs may apply for an LoA at www.jonesdayreach.com.

Kind regards,



Ursula Schliessner

(Excerpt CSR Diiron trioxide):

## 2.2. Identified uses

**Table 1. Formulation**

Identifiers	Use descriptors	Other information
F-1: mainly as colorants and some other technical applications	<p><b>Environmental release category (ERC):</b></p> <p>ERC 2: Formulation of preparations                      ERC 3: Formulation in materials</p> <p><b>Process category (PROC):</b></p> <p>PROC 2: Use in closed, continuous process with occasional controlled exposure                      PROC 3: Use in closed batch process (synthesis or formulation)                      PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities                      PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities                      PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing)                      PROC 14: Production of preparations or articles by tableting, compression, extrusion, pelletisation                      PROC 15: Use as laboratory reagent                      PROC 19: Hand-mixing with intimate contact and only PPE available.                      PROC 26: Handling of solid inorganic substances at ambient temperature                      PROC 22: Potentially closed processing operations</p>	<p>Substance supplied to that use:</p> <p>As such                      In a mixture</p> <p>Remarks:</p> <p>The "Synthetic Iron Oxides for non-metallurgical applications" are used by industry, mostly by professionals,                      a) as pigments mainly but not exclusively in paints and varnishes, plastics, printing inks, construction materials, cosmetics, ceramics and toners.                      b) There are also a multitude of technical applications where other properties of the substances are used, for example when applied as a raw material for chemical synthesis, as catalysts and others, e.g.:                      glazes, frits, ceramic bricks and tiles,</p>

Identifiers	Use descriptors	Other information
	<p>with minerals/metals at elevated temperature.                      Industrial setting                      PROC 23: Open processing and transfer operations with minerals/metals at elevated temperature                      PROC 25: Other hot work operations with metals                      PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)</p> <p><b>Product Category formulated:</b></p> <p>PC 1: Adhesives, sealants                      PC 2: Adsorbents                      PC 3: Air care products                      PC 7: Base metals and alloys                      PC 8: Biocidal products (e.g. disinfectants, pest control)                      PC 9a: Coatings and paints, thinners, paint removes                      PC 9b: Fillers, putties, plasters, modelling clay                      PC 9c: Finger paints                      PC 12: Fertilisers                      PC 14: Metal surface treatment products, including galvanic and electroplating products                      PC 15: Non-metal-surface treatment products                      PC 18: Ink and toners                      PC 21: Laboratory chemicals                      PC 23: Leather tanning, dye, finishing, impregnation and care products                      PC 25: Metal working fluids                      PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents                      PC 24: Lubricants, greases, release products                      PC 26: Paper and board dye, finishing and impregnation products: including bleaches and other processing aids                      PC 27: Plant protection products                      PC 28: Perfumes, fragrances                      PC 29: Pharmaceuticals                      PC 30: Photo-chemicals                      PC 32: Polymer preparations and compounds                      PC 34: Textile dyes, finishing and impregnating products; including bleaches and other processing aids                      PC 35: Washing and cleaning products (including solvent based products)                      PC 36: Water softeners                      PC 37: Water treatment chemicals                      PC 38: Welding and soldering products (with flux</p>	<p>drilling fluids, casting fluxes, exothermic risers (foundries), carbon electrodes, graphite electrodes, casting powders, catalysts, ferrites, magnets and magnetic materials, matches, iron and steel applications as well as metallurgical processes, anti-vibrations materials for the automotive industry, intermediates for the production of substances, waste water treatment, and biogas installations animal feed, fertilizer additives.</p>

Identifiers	Use descriptors	Other information
	<p>coatings or flux cores.), flux products                      PC 39: Cosmetics, personal care products                      PC 31: Polishes and wax blends                      PC 11: Explosives                      PC 16: Heat transfer fluids                      PC 17: Hydraulic fluids                      PC 33: Semiconductors                      PC 0: Other: PC5 Artists supply and Hobby preparations PC6: Automotive Care Products PC10 Buildings and construction preparations, UCN code 62 – electromechanical components, UCN code 26 – Food / Feedstuff flavourings and nutrients, UCN code P15500 - catalysts</p> <p><b>Technical function of the substance during formulation:</b>                      ingredient</p>	

**Table 2. Uses at industrial sites**

Identifiers	Use descriptors	Other information
<p>IW-1: mainly as colorants and some other technical applications</p>	<p><b>Environmental release category (ERC):</b></p> <p>ERC 4: Industrial use of processing aids in processes and products, not becoming part of articles                      ERC 5: Industrial use resulting in inclusion into or onto a matrix                      ERC 6a: Industrial use resulting in manufacture of another substance (use of intermediates)                      ERC 6b: Industrial use of reactive processing aids                      ERC 6d: Industrial use of process regulators for polymerisation processes in production of resins, rubbers, polymers                      ERC 7: Industrial use of substances in closed systems</p> <p><b>Process category (PROC):</b></p> <p>PROC 1: Use in closed process, no likelihood of exposure                      PROC 2: Use in closed, continuous process with occasional controlled exposure                      PROC 3: Use in closed batch process (synthesis or formulation)                      PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises                      PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)</p>	<p>Substance supplied to that use:                      As such                      In a mixture</p> <p>Remarks:                      The “Synthetic Iron Oxides for non-metallurgical applications“ are used by industry, mostly by professionals,                      a) as pigments mainly but not exclusively in paints and varnishes, plastics, printing inks, construction materials, cosmetics, ceramics and toners.                      b) There are also a multitude of technical applications where other properties of the substances are used, for example when applied as a raw material for chemical synthesis, as catalysts and others, e.g.:                      glazes, frits, ceramic bricks and tiles,                      drilling fluids, casting fluxes,</p>



Identifiers	Use descriptors	Other information
	<p>PROC 6: Calendering operations                      PROC 7: Industrial spraying                      PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities                      PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities                      PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing)                      PROC 10: Roller application or brushing                      PROC 12: Use of blowing agents in manufacture of foam                      PROC 13: Treatment of articles by dipping and pouring                      PROC 14: Production of preparations or articles by tableting, compression, extrusion, pelletisation                      PROC 15: Use as laboratory reagent                      PROC 17: Lubrication at high energy conditions and in partly open process                      PROC 19: Hand-mixing with intimate contact and only PPE available.                      PROC 21: Low energy manipulation of substances bound in materials and/or articles                      PROC 22: Potentially closed processing operations with minerals/metals at elevated temperature. Industrial setting                      PROC 23: Open processing and transfer operations with minerals/metals at elevated temperature                      PROC 24: High (mechanical) energy work-up of substances bound in materials and/or articles                      PROC 25: Other hot work operations with metals                      PROC 26: Handling of solid inorganic substances at ambient temperature                      PROC 27a: Production of metal powders (hot processes)                      PROC 27b: Production of metal powders (wet processes)</p> <p><b>Product Category used:</b></p> <p>PC 1: Adhesives, sealants                      PC 2: Adsorbents                      PC 3: Air care products                      PC 7: Base metals and alloys                      PC 8: Biocidal products (e.g. disinfectants, pest control)</p>	<p>exothermic risers (foundries), carbon electrodes, graphite electrodes, casting powders, catalysts, ferrites, magnets and magnetic materials, matches, iron and steel applications as well as metallurgical processes, anti-vibrations materials for the automotive industry, intermediates for the production of substances, waste water treatment, and biogas installations animal feed, fertilizer additives.</p>

Identifiers	Use descriptors	Other information
	<p>PC 9a: Coatings and paints, thinners, paint removes            PC 9b: Fillers, putties, plasters, modelling clay            PC 9c: Finger paints            PC 12: Fertilisers            PC 14: Metal surface treatment products, including galvanic and electroplating products            PC 15: Non-metal-surface treatment products            PC 18: Ink and toners            PC 19: Intermediate            PC 21: Laboratory chemicals            PC 23: Leather tanning, dye, finishing, impregnation and care products            PC 25: Metal working fluids            PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents            PC 24: Lubricants, greases, release products            PC 26: Paper and board dye, finishing and impregnation products: including bleaches and other processing aids            PC 27: Plant protection products            PC 28: Perfumes, fragrances            PC 29: Pharmaceuticals            PC 30: Photo-chemicals            PC 32: Polymer preparations and compounds            PC 34: Textile dyes, finishing and impregnating products; including bleaches and other processing aids            PC 35: Washing and cleaning products (including solvent based products)            PC 36: Water softeners            PC 37: Water treatment chemicals            PC 38: Welding and soldering products (with flux coatings or flux cores.), flux products            PC 39: Cosmetics, personal care products            PC 31: Polishes and wax blends            PC 11: Explosives            PC 16: Heat transfer fluids            PC 17: Hydraulic fluids            PC 33: Semiconductors            PC 0: Other: PC5 Artists supply and Hobby preparations PC6: Automotive Care Products PC10 Buildings and construction preparations, UCN code 62 – electromechanical components, UCN code 26 – Food / Feedstuff flavourings and nutrients, UCN code P15500 - catalysts</p> <p><b>Sector of end use:</b></p>	

Identifiers	Use descriptors	Other information
	<p>SU 1: Agriculture, forestry and fishing            SU 2a: Mining (without offshore industries)            SU 2b: Offshore industries            SU 4: Manufacture of food products            SU 5: Manufacture of textiles, leather, fur            SU 6a: Manufacture of wood and wood products            SU 6b: Manufacture of pulp, paper and paper products            SU 7: Printing and reproduction of recorded media            SU 8: Manufacture of bulk, large scale chemicals (including petroleum products)            SU 9: Manufacture of fine chemicals            SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys)            SU 11: Manufacture of rubber products            SU 12: Manufacture of plastics products, including compounding and conversion            SU 13: Manufacture of other non-metallic mineral products, e.g. plasters, cement            SU 14: Manufacture of basic metals, including alloys            SU 15: Manufacture of fabricated metal products, except machinery and equipment            SU 16: Manufacture of computer, electronic and optical products, electrical equipment            SU 17: General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment            SU 18: Manufacture of furniture            SU 19: Building and construction work            SU 20: Health services            SU 23: Electricity, steam, gas water supply and sewage treatment            SU 24: Scientific research and development</p> <p><b>Technical function of the substance during formulation:</b></p> <p>Laboratory chemicals            Intermediates            Impregnation agents            Fillers            Colouring agents, pigments            Fertilisers            Food/feedstuff additives            Processing aid, not otherwise listed            Catalyst            Binding agents            Agents adsorbing and absorbing gases or liquids</p>	

Identifiers	Use descriptors	Other information
	Process regulators, other than polymerisation or vulcanisation processes	

**Table 3. Uses by professional workers**

Identifiers	Use descriptors	Other information
PW-1: mainly as colorants and some other technical applications	<p><b>Environmental release category (ERC):</b></p> <p>ERC 8a: Wide dispersive indoor use of processing aids in open systems</p> <p>ERC 8b: Wide dispersive indoor use of reactive substances in open systems</p> <p>ERC 8c: Wide dispersive indoor use resulting in inclusion into or onto a matrix</p> <p>ERC 8d: Wide dispersive outdoor use of processing aids in open systems</p> <p>ERC 8e: Wide dispersive outdoor use of reactive substances in open systems</p> <p>ERC 8f: Wide dispersive outdoor use resulting in inclusion into or onto a matrix</p> <p>ERC 9a: Wide dispersive indoor use of substances in closed systems</p> <p>ERC 9b: Wide dispersive outdoor use of substances in closed systems</p> <p><b>Process category (PROC):</b></p> <p>PROC 1: Use in closed process, no likelihood of exposure</p> <p>PROC 2: Use in closed, continuous process with occasional controlled exposure</p> <p>PROC 3: Use in closed batch process (synthesis or formulation)</p> <p>PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises</p> <p>PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)</p> <p>PROC 6: Calendering operations</p> <p>PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities</p> <p>PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities</p> <p>PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing)</p> <p>PROC 10: Roller application or brushing</p> <p>PROC 11: Non industrial spraying</p>	<p>Substance supplied to that use:</p> <p>As such</p> <p>In a mixture</p> <p>Remarks:</p> <p>The “Synthetic Iron Oxides for non-metallurgical applications“ are used by industry, mostly by professionals,</p> <p>a) as pigments mainly but not exclusively in paints and varnishes, plastics, printing inks, construction materials, cosmetics, ceramics and toners.</p> <p>b) There are also a multitude of technical applications where other properties of the substances are used, for example when applied as a raw material for chemical synthesis, as catalysts and others, e.g.:</p> <p>glazes, frits, ceramic bricks and tiles,</p> <p>drilling fluids, casting fluxes, exothermic risers (foundries), carbon electrodes, graphite electrodes,</p> <p>casting powders,</p> <p>catalysts,</p> <p>ferrites, magnets and magnetic materials,</p> <p>matches,</p> <p>iron and steel applications as well as metallurgical processes,</p> <p>anti-vibrations materials for the automotive industry,</p> <p>intermediates for the production of substances,</p>



Identifiers	Use descriptors	Other information
	<p>PROC 12: Use of blowing agents in manufacture of foam</p> <p>PROC 13: Treatment of articles by dipping and pouring</p> <p>PROC 14: Production of preparations or articles by tableting, compression, extrusion, pelletisation</p> <p>PROC 15: Use as laboratory reagent</p> <p>PROC 17: Lubrication at high energy conditions and in partly open process</p> <p>PROC 19: Hand-mixing with intimate contact and only PPE available.</p> <p>PROC 21: Low energy manipulation of substances bound in materials and/or articles</p> <p>PROC 22: Potentially closed processing operations with minerals/metals at elevated temperature. Industrial setting</p> <p>PROC 23: Open processing and transfer operations with minerals/metals at elevated temperature</p> <p>PROC 24: High (mechanical) energy work-up of substances bound in materials and/or articles</p> <p>PROC 25: Other hot work operations with metals</p> <p>PROC 26: Handling of solid inorganic substances at ambient temperature</p> <p>PROC 27a: Production of metal powders (hot processes)</p> <p>PROC 27b: Production of metal powders (wet processes)</p> <p><b>Product Category used:</b></p> <p>PC 1: Adhesives, sealants</p> <p>PC 2: Adsorbents</p> <p>PC 3: Air care products</p> <p>PC 7: Base metals and alloys</p> <p>PC 8: Biocidal products (e.g. disinfectants, pest control)</p> <p>PC 9a: Coatings and paints, thinners, paint removes</p> <p>PC 9b: Fillers, putties, plasters, modelling clay</p> <p>PC 9c: Finger paints</p> <p>PC 12: Fertilisers</p> <p>PC 14: Metal surface treatment products, including galvanic and electroplating products</p> <p>PC 15: Non-metal-surface treatment products</p> <p>PC 18: Ink and toners</p> <p>PC 19: Intermediate</p> <p>PC 21: Laboratory chemicals</p> <p>PC 23: Leather tanning, dye, finishing, impregnation and care products</p>	<p>waste water treatment, and biogas installations</p> <p>animal feed, fertilizer additives.</p>

Identifiers	Use descriptors	Other information
	<p>PC 25: Metal working fluids            PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents            PC 24: Lubricants, greases, release products            PC 26: Paper and board dye, finishing and impregnation products: including bleaches and other processing aids            PC 27: Plant protection products            PC 28: Perfumes, fragrances            PC 29: Pharmaceuticals            PC 30: Photo-chemicals            PC 32: Polymer preparations and compounds            PC 34: Textile dyes, finishing and impregnating products; including bleaches and other processing aids            PC 35: Washing and cleaning products (including solvent based products)            PC 36: Water softeners            PC 37: Water treatment chemicals            PC 38: Welding and soldering products (with flux coatings or flux cores.), flux products            PC 39: Cosmetics, personal care products            PC 11: Explosives            PC 16: Heat transfer fluids            PC 17: Hydraulic fluids            PC 33: Semiconductors            PC 0: Other: PC5 Artists supply and Hobby preparations PC6: Automotive Care Products PC10 Buildings and construction preparations, UCN code 62 – electromechanical components, UCN code 26 – Food / Feedstuff flavourings and nutrients, UCN code P15500 - catalysts</p> <p><b>Sector of end use:</b></p> <p>SU 1: Agriculture, forestry and fishing            SU 2a: Mining (without offshore industries)            SU 2b: Offshore industries            SU 5: Manufacture of textiles, leather, fur            SU 4: Manufacture of food products            SU 6a: Manufacture of wood and wood products            SU 6b: Manufacture of pulp, paper and paper products            SU 7: Printing and reproduction of recorded media            SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys)            SU 11: Manufacture of rubber products            SU 12: Manufacture of plastics products, including</p>	

Identifiers	Use descriptors	Other information
	<p>compounding and conversion                      SU 13: Manufacture of other non-metallic mineral products, e.g. plasters, cement                      SU 14: Manufacture of basic metals, including alloys                      SU 15: Manufacture of fabricated metal products, except machinery and equipment                      SU 16: Manufacture of computer, electronic and optical products, electrical equipment                      SU 17: General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment                      SU 18: Manufacture of furniture                      SU 19: Building and construction work                      SU 20: Health services                      SU 23: Electricity, steam, gas water supply and sewage treatment                      SU 24: Scientific research and development</p> <p><b>Technical function of the substance during formulation:</b></p> <p>Laboratory chemicals                      Intermediates                      Impregnation agents                      Fillers                      Colouring agents, pigments                      Fertilisers                      Food/feedstuff additives                      Processing aid, not otherwise listed                      Catalyst                      Agents adsorbing and absorbing gases or liquids                      Binding agents</p>	

**Table 4. Consumer uses**

Identifiers	Use descriptors	Other information
<p>C-1: mainly as colorants and some other technical applications</p>	<p><b>Environmental release category (ERC):</b></p> <p>ERC 8a: Wide dispersive indoor use of processing aids in open systems                      ERC 8b: Wide dispersive indoor use of reactive substances in open systems                      ERC 8c: Wide dispersive indoor use resulting in inclusion into or onto a matrix                      ERC 8d: Wide dispersive outdoor use of processing aids in open systems                      ERC 8e: Wide dispersive outdoor use of reactive substances in open systems                      ERC 8f: Wide dispersive outdoor use resulting in inclusion into or onto a matrix</p>	<p>Substance supplied to that use:</p> <p>In a mixture</p>

Identifiers	Use descriptors	Other information
	<p>ERC 9a: Wide dispersive indoor use of substances in closed systems</p> <p>ERC 9b: Wide dispersive outdoor use of substances in closed systems</p> <p><b>Product Category used:</b></p> <p>PC 1: Adhesives, sealants</p> <p>PC 2: Adsorbents</p> <p>PC 3: Air care products</p> <p>PC 4: Anti-freeze and de-icing products</p> <p>PC 7: Base metals and alloys</p> <p>PC 8: Biocidal products (e.g. disinfectants, pest control)</p> <p>PC 9a: Coatings and paints, thinners, paint removers</p> <p>PC 9b: Fillers, putties, plasters, modelling clay</p> <p>PC 9c: Finger paints</p> <p>PC 12: Fertilisers</p> <p>PC 14: Metal surface treatment products, including galvanic and electroplating products</p> <p>PC 15: Non-metal-surface treatment products</p> <p>PC 18: Ink and toners</p> <p>PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents</p> <p>PC 23: Leather tanning, dye, finishing, impregnation and care products</p> <p>PC 24: Lubricants, greases, release products</p> <p>PC 26: Paper and board dye, finishing and impregnation products: including bleaches and other processing aids</p> <p>PC 27: Plant protection products</p> <p>PC 28: Perfumes, fragrances</p> <p>PC 29: Pharmaceuticals</p> <p>PC 30: Photo-chemicals</p> <p>PC 31: Polishes and wax blends</p> <p>PC 32: Polymer preparations and compounds</p> <p>PC 34: Textile dyes, finishing and impregnating products; including bleaches and other processing aids</p> <p>PC 35: Washing and cleaning products (including solvent based products)</p> <p>PC 36: Water softeners</p> <p>PC 37: Water treatment chemicals</p> <p>PC 38: Welding and soldering products (with flux coatings or flux cores.), flux products</p> <p>PC 39: Cosmetics, personal care products</p> <p>PC 0: Other: PC5 Artists supply and Hobby preparations PC6: Automotive Care Products PC10</p>	



Identifiers	Use descriptors	Other information
	<p>Buildings and construction preparations, UCN code 62 – electromechanical components, UCN code 26 – Food / Feedstuff flavourings and nutrients                      PC 11: Explosives</p> <p><b>Technical function of the substance during formulation:</b></p> <ul style="list-style-type: none"> <li>Impregnation agents</li> <li>Fillers</li> <li>Colouring agents, pigments</li> <li>Fertilisers</li> <li>Food/feedstuff additives</li> <li>Binding agents</li> <li>Agents adsorbing and absorbing gases or liquids</li> </ul>	

**2.3. Uses advised against**

**Table 5. Uses at industrial sites**

Identifiers	Use descriptors	Other information
IW-1: not applicable		

# JONES DAY

AVOCATS – ADVOCATEN

MICHÈLE GRÉGOIRE<sup>(6)</sup>  
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<sup>(1)</sup>Member of the Rome Bar  
<sup>(2)</sup>Member of the Paris Bar  
<sup>(3)</sup>Member of the New York Bar  
<sup>(4)</sup>Member of the District of  
Columbia Bar  
<sup>(5)</sup>Member of the Düsseldorf Bar  
<sup>(6)</sup>Admitted to the Paris Bar  
<sup>(7)</sup>Member of the Naples Bar  
<sup>(8)</sup>Member of the Berlin Bar  
<sup>(9)</sup>Member of the  
Frankfurt am Main Bar  
<sup>(10)</sup>Member of the Swedish Bar

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

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March 23, 2020

BY ELECTRONIC MAIL

## TO WHOM IT MAY CONCERN

**Re: Implementation of Amendment REACH; Regulation 2018/1881 - REACH SIEF Communication Iron Oxides: Iron hydroxide oxide yellow EC 257-098-5 (synonyms 243-746-4; 215-176-6); triiron tetraoxide EC 215-277-5 (synonyms 235-442-5; 215-169-8); Diiron trioxide EC 215-168-2 (synonyms 215-570-8; 215-275-4); Iron manganese (tri)oxide EC 235-049-9; manganese ferrite EC 269-056-3; Zinc ferrite EC 269-103-8**

Dear Joint Registrants and SIEF Members,

On December 3, 2018, the European Commission adopted Regulation 2018/1881 modifying, among others REACH Annexes I, III and VI-XII introducing nano-specific ‘clarifications’. Nanoforms of substances covered by a registration must be identified and characterized individually by each registrant. They can be documented individually or jointly in sets of similar nanoforms by providing clear identification of size, number size distribution and range, shape, crystallinity, specific surface area and surface chemistry. Please also see the relevant [ECHA Guidance](#). Existing registrations covering nanoforms must be brought in compliance by January 1, 2020.

To this end, the Lead Registrant LANXESS Deutschland GmbH and the Iron Oxides REACH Registration Consortium (‘IORC’) have converted the joint registration dossiers to IUCLID 6.4 and have updated the joint registration dossiers of iron hydroxide oxide yellow and diiron trioxide (red) with the nano specific substance specifications in Annex 1 for the boundaries of the set of nanoforms which will be covered by the joint submission. Please review these specifications to verify whether your substances fit into the joint registration. Please be advised that each registrant must report its nanoforms and its own characterization in the registration dossier. For this purpose, please check whether you need to update the individual parts of your joint registration dossiers.

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SIEF Communication Iron Oxides  
March 23, 2020  
Page 2

In addition, the IORC Consortium is planning a second joint registration dossier update for all six substances covered by the IORC Consortium during 2020, including a literature review and the inclusion of new data. The letter of access prices may increase for reasons of gathering this new data for the dossier updates.

Kind regards,



Ursula Schliessner

Annex

---

# Diiron trioxide (for members)

## CORE

### General information

#### Composition

FLEXIBLE\_RECORD: BC\_Nano Set - alpha Fe2O3\_AR<7

---

**UUID:** 8b2096bc-66f2-457e-b422-92ee22231fa3

**Dossier UUID:**

**Author:** LANXESS

**Date:** 2020-03-17T17:17:15.538+01:00

**Remarks:**

---

### General Information

---

#### Name

Diiron trioxide -Nano Set - alpha Fe2O3 \_ AR<7

#### Type of composition

boundary composition of the substance

#### State / form

solid: nanoform

#### Description

Due to the raw material used for production of diiron trioxide, the substance contains minor amounts of non-iron metals, predominantly Si, Al, which are incorporated in the crystal lattice.

Boundary composition contains all impurities and additives > 0.1%

No impurities affecting the classification and labelling are allowed.

### Degree of purity

---

>= 80

<= 100

% (w/w)

### Constituents

---

#### Reference substance

[diiron trioxide / diiron\(3+\) trioxidandiide / 1309-37-1 / 215-168-2](#)

#### EC number

215-168-2

#### EC name

EC Inventory

#### CAS number

1309-37-1

#### CAS name

Iron oxide (Fe2O3)

#### IUPAC name

diiron(3+) trioxidandiide

---

**Typical concentration**

>= 92 % (w/w)

**Concentration range**

>= 80 <= 100 % (w/w)

---

**Impurities****Reference substance**

[carbon / carbon / 7440-44-0 / 231-153-3](#)

**EC number**

231-153-3

**EC name**

EC Inventory

**CAS number**

7440-44-0

**CAS name**

carbon

**IUPAC name**

carbon

**Typical concentration**

<= 2 % (w/w)

**Concentration range**

>= 0 <= 4 % (w/w)

**This impurity is considered relevant for the classification and labelling of the substance**  
false

**Reference substance**

[aluminium oxide / aluminium oxide / 1344-28-1 / 215-691-6](#)

**EC number**

215-691-6

**EC name**

EC Inventory

**CAS number**

1344-28-1

**CAS name****IUPAC name**

aluminium oxide

**Typical concentration**

<= 0.4 % (w/w)

**Concentration range**

>= 0 <= 2 % (w/w)

**Remarks**

No free aluminium dioxide in the substance: aluminium is incorporated in the crystal lattice

Concentration calculated as Al<sub>2</sub>O<sub>3</sub>

**This impurity is considered relevant for the classification and labelling of the substance**  
false

**Reference substance**

[Manganese dioxide / Dioxomanganese / 1313-13-9 / 215-202-6](#)

<b>EC number</b>	<b>EC name</b>
215-202-6	EC Inventory

<b>CAS number</b>	<b>CAS name</b>
1313-13-9	

**IUPAC name**  
Dioxomanganese

**Typical concentration**

<= 1 % (w/w)

**Concentration range**

>= 0 <= 2 % (w/w)

**Remarks**

No free manganese dioxide in the substance: manganese is incorporated in the crystal lattice  
Concentration calculated as MnO<sub>2</sub>

**This impurity is considered relevant for the classification and labelling of the substance**  
false

**Reference substance**

[silicon dioxide / Silicon dioxide \(amorphous\) / 7631-86-9 / 231-545-4](#)

<b>EC number</b>	<b>EC name</b>
231-545-4	EC Inventory

<b>CAS number</b>	<b>CAS name</b>
7631-86-9	Silica

**IUPAC name**  
Silicon dioxide (amorphous)

**Typical concentration**

<= 1 % (w/w)

**Concentration range**

>= 0 <= 2 % (w/w)

**Remarks**

No free silicon dioxide in the substance: silicon is incorporated in the crystal lattice  
Concentration calculated as SiO<sub>2</sub>

**This impurity is considered relevant for the classification and labelling of the substance**  
false

**Reference substance**

[Calcium sulphate / calcium sulfate / 7778-18-9 / 231-900-3](#)

**EC number**

231-900-3

**EC name**

EC Inventory

**CAS number**

7778-18-9

**CAS name****IUPAC name**

calcium sulfate

**Typical concentration**

<= 1 % (w/w)

**Concentration range**

>= 0 <= 2 % (w/w)

**This impurity is considered relevant for the classification and labelling of the substance**

false

**Reference substance**

[sodium sulphate / disodium sulfate / 7757-82-6 / 231-820-9](#)

**EC number**

231-820-9

**EC name**

EC Inventory

**CAS number**

7757-82-6

**CAS name**

Sulfuric acid sodium salt (1:2)

**IUPAC name**

disodium sulfate

**Typical concentration**

<= 1 % (w/w)

**Concentration range**

>= 0 <= 2 % (w/w)

**This impurity is considered relevant for the classification and labelling of the substance**

false

**Reference substance**

[Magnesium sulfate / Magnesium sulphate / 7487-88-9 / 231-298-2](#)

**EC number**

231-298-2

**EC name**

EC Inventory

**CAS number**

7487-88-9

**CAS name**

Magnesium sulphate

**IUPAC name**

Magnesium sulphate

---

**Typical concentration**

<= 1 % (w/w)

**Concentration range**

>= 0 <= 2 % (w/w)

**This impurity is considered relevant for the classification and labelling of the substance**  
false

---

**Characterisation of nanoforms****Type of information reported**

set of nanoforms

**Justification for reporting set of similar nanoforms**

Please refer to the attached justification for the reporting a set of similar nanoforms.

**Attached information****Attached information**

Fe2O3-JUSTIFICATION FOR REPORTING SET OF SIMILAR NANOFORMS.pdf / 544.144 KB  
( application/pdf)

---

**Shape****Shape description****Shape category**

elongated

**Shape**

rod

**Pure shape**

yes

**Range**

>= 95 <= 100 %

**Shape category**

spheroidal

**Shape**

other: spheres/cubes/globular

**Pure shape**

yes

**Range**

> 95 <= 100 %

**Justification for set containing multiple shape categories or shapes**

Please refer to the attached justification for the reporting a set of similar nanoforms.







---

## Characterisation of polymers

---

## Reactive functional groups

---

Polymer contains only low concern reactive functional groups  
false



**Reference substance**[carbon / carbon / 7440-44-0 / 231-153-3](#)

<b>EC number</b>	<b>EC name</b>
231-153-3	EC Inventory
<b>CAS number</b>	<b>CAS name</b>
7440-44-0	carbon
<b>IUPAC name</b>	
carbon	

**Typical concentration**

<= 2 % (w/w)

**Concentration range**

>= 0 <= 4 % (w/w)

**This impurity is considered relevant for the classification and labelling of the substance**  
false

**Reference substance**[aluminium oxide / aluminium oxide / 1344-28-1 / 215-691-6](#)

<b>EC number</b>	<b>EC name</b>
215-691-6	EC Inventory
<b>CAS number</b>	<b>CAS name</b>
1344-28-1	
<b>IUPAC name</b>	
aluminium oxide	

**Typical concentration**

<= 0.4 % (w/w)

**Concentration range**

>= 0 <= 2 % (w/w)

**Remarks**

No free aluminium dioxide in the substance: aluminium is incorporated in the crystal lattice.  
Concentration calculated as Al<sub>2</sub>O<sub>3</sub>

**This impurity is considered relevant for the classification and labelling of the substance**  
false

**Reference substance**[Manganese dioxide / Dioxomanganese / 1313-13-9 / 215-202-6](#)

<b>EC number</b>	<b>EC name</b>
215-202-6	EC Inventory

**CAS number**                      **CAS name**

1313-13-9

**IUPAC name**

Dioxomanganese

**Typical concentration**

&lt;= 1    % (w/w)

**Concentration range**

&gt;= 0    &lt;= 2    % (w/w)

**Remarks**

No free manganese dioxide in the substance: manganese is incorporated in the crystal lattice  
Concentration calculated as MnO<sub>2</sub>

**This impurity is considered relevant for the classification and labelling of the substance**  
false

**Reference substance**[silicon dioxide / Silicon dioxide \(amorphous\) / 7631-86-9 / 231-545-4](#)**EC number**

231-545-4

**EC name**

EC Inventory

**CAS number**

7631-86-9

**CAS name**

Silica

**IUPAC name**

Silicon dioxide (amorphous)

**Typical concentration**

&lt;= 1    % (w/w)

**Concentration range**

&gt;= 0    &lt;= 2    % (w/w)

**Remarks**

No free silicon dioxide in the substance: silicon is incorporated in the crystal lattice  
Concentration calculated as SiO<sub>2</sub>

**This impurity is considered relevant for the classification and labelling of the substance**  
false

**Reference substance**[Calcium sulphate / calcium sulfate / 7778-18-9 / 231-900-3](#)**EC number**

231-900-3

**EC name**

EC Inventory

**CAS number**

7778-18-9

**CAS name****IUPAC name**

calcium sulfate

**Typical concentration**

<= 1 % (w/w)

**Concentration range**

>= 0 <= 2 % (w/w)

**This impurity is considered relevant for the classification and labelling of the substance**  
false

**Reference substance**

[sodium sulphate / disodium sulfate / 7757-82-6 / 231-820-9](#)

**EC number**

231-820-9

**EC name**

EC Inventory

**CAS number**

7757-82-6

**CAS name**

Sulfuric acid sodium salt (1:2)

**IUPAC name**

disodium sulfate

**Typical concentration**

<= 1 % (w/w)

**Concentration range**

>= 0 <= 2 % (w/w)

**This impurity is considered relevant for the classification and labelling of the substance**  
false

**Reference substance**

[Magnesium sulfate / Magnesium sulphate / 7487-88-9 / 231-298-2](#)

**EC number**

231-298-2

**EC name**

EC Inventory

**CAS number**

7487-88-9

**CAS name**

Magnesium sulphate

**IUPAC name**

Magnesium sulphate

**Typical concentration**

<= 1 % (w/w)

**Concentration range**

>= 0 <= 2 % (w/w)

**This impurity is considered relevant for the classification and labelling of the substance**  
false

## Characterisation of polymers

---

# Iron hydroxide oxide yellow (for members)

## CORE

### General information

#### Composition

FLEXIBLE\_RECORD: BC\_Nano Set\_alpha-FeOOH

---

**UUID:** dcf6ad82-07e2-41eb-8ce3-8a615490241e

**Dossier UUID:**

**Author:** LANXESS

**Date:** 2020-03-17T17:33:49.293+01:00

**Remarks:**

---

### General Information

---

#### Name

Iron hydroxide oxide yellow - BC\_Nano Set\_alpha-FeOOH

#### Type of composition

boundary composition of the substance

#### State / form

solid: nanoform

### Degree of purity

---

>= 80

<= 100

% (w/w)

### Constituents

---

#### Reference substance

[Iron hydroxide oxide yellow / Iron hydroxide oxide / 51274-00-1 / 257-098-5](#)

#### EC number

257-098-5

#### EC name

EC Inventory

#### CAS number

51274-00-1

#### CAS name

Iron hydroxide oxide (Fe(OH)O)

#### IUPAC name

Iron hydroxide oxide

#### Typical concentration

>= 92

% (w/w)





**Reference substance**

[aluminium oxide](#) / [aluminium oxide](#) / [1344-28-1](#) / [215-691-6](#)

**EC number**

215-691-6

**EC name**

EC Inventory

**CAS number**

1344-28-1

**CAS name****IUPAC name**

aluminium oxide

**Typical concentration**

<= 0.4 % (w/w)

**Concentration range**

>= 0 <= 2 % (w/w)

**Remarks**

No free aluminium dioxide in the substance: aluminium is incorporated in the crystal lattice  
Calculated as Al<sub>2</sub>O<sub>3</sub>

**This impurity is considered relevant for the classification and labelling of the substance**

false

**Reference substance**

[carbon](#) / [carbon](#) / [7440-44-0](#) / [231-153-3](#)

**EC number**

231-153-3

**EC name**

EC Inventory

**CAS number**

7440-44-0

**CAS name**

carbon

**IUPAC name**

carbon

**Typical concentration**

<= 2 % (w/w)

**Concentration range**

>= 0 <= 4 % (w/w)

**This impurity is considered relevant for the classification and labelling of the substance**

false

**Reference substance**

[sodium sulphate](#) / [disodium sulfate](#) / [7757-82-6](#) / [231-820-9](#)

**EC number**

231-820-9

**EC name**

EC Inventory

**CAS number**

7757-82-6

**CAS name**

Sulfuric acid sodium salt (1:2)

**IUPAC name**

disodium sulfate

**Typical concentration**

&lt;= 1 % (w/w)

**Concentration range**

&gt;= 0 &lt;= 2 % (w/w)

**This impurity is considered relevant for the classification and labelling of the substance**  
false**Reference substance**[Calcium sulphate / calcium sulfate / 7778-18-9 / 231-900-3](#)**EC number**

231-900-3

**EC name**

EC Inventory

**CAS number**

7778-18-9

**CAS name****IUPAC name**

calcium sulfate

**Typical concentration**

&lt;= 1 % (w/w)

**Concentration range**

&gt;= 0 &lt;= 2 % (w/w)

**This impurity is considered relevant for the classification and labelling of the substance**  
false**Reference substance**[Magnesium sulfate / Magnesium sulphate / 7487-88-9 / 231-298-2](#)**EC number**

231-298-2

**EC name**

EC Inventory

**CAS number**

7487-88-9

**CAS name**

Magnesium sulphate

**IUPAC name**

Magnesium sulphate

**Typical concentration**

&lt;= 1 % (w/w)

**Concentration range**

&gt;= 0 &lt;= 2 % (w/w)

**This impurity is considered relevant for the classification and labelling of the substance**  
false**Characterisation of nanoforms**

---

**Type of information reported**

set of nanoforms

**Justification for reporting set of similar nanoforms**

Please refer to the attached justification for the reporting a set of similar nanoforms.

**Attached information****Attached information**FeOOH-JUSTIFICATION FOR REPORTING SET OF SIMILAR NANOFORMS.pdf / 484.949 KB  
( application/pdf)

---

**Shape****Shape description****Shape category**

elongated

**Shape**

rod

**Pure shape**

yes

**Range**

>= 95	<= 100	%
-------	--------	---

**Justification for set containing multiple shape categories or shapes**

not relevant

---

**Particle size distribution and range****Particle size distribution and range****Shape category**

elongated

**Percentile****Percentile**

D10

**Range**

>= 5	<= 100	nm
------	--------	----

**Percentile**

D50

**Range**

>= 10	<= 100	nm
-------	--------	----

---

**Percentile**

D90

**Range**

>= 10	<= 200	nm
-------	--------	----

**Range of length**

>= 20	<= 600	nm
-------	--------	----

**Range of aspect ratio (:1)**

>= 4	<= 10
------	-------

**Fraction of constituent particles in the size range 1-100 nm**

>= 50	<= 100	%
-------	--------	---

---

**Crystallinity****Structures****Structure**

crystalline

**Name**

alpha-FeOOH

**Pure structure**

yes

---

**Specific surface area****Range of specific surface area**

>= 5	<= 350	m <sup>2</sup> /g
------	--------	-------------------

---

**Surface functionalisation / treatment****Surface treatment applied**

no

**Does the set contain both treated and non-surface treated nanoforms?**

no

---

**Characterisation of polymers**

---

**Reactive functional groups****Polymer contains only low concern reactive functional groups**

false

# JONES DAY

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USCHLISSNER@JONESDAY.COM

July 28, 2020

BY ELECTRONIC MAIL

## TO WHOM IT MAY CONCERN

**Re: SIEF Communication – Iron Oxides – Nano boundary composition Yellow and Red Iron Oxide (Iron Hydroxide Oxide Yellow EC 257-098-5, CAS 51274-00-1; Diiron Trioxide (Red Iron Oxide) EC 215-168-2, CAS 1309-37-1) – Dossier update to be filed by Lead Registrant LANXESS Deutschland GmbH on July 28/29, 2020.**

Dear SIEF Members and Joint Registrants,

Following the last SIEF communication of March 23, 2020 about the nano dossier update and pursuant to the failure of this update in the ECHA manual completeness check, the Lead Registrant LANXESS Deutschland GmbH will file a new dossier update July 28/29, 2020 containing the attached boundary composition and linking all available study records to the nano forms of the two substances.

The overall 2nd dossier update for all six substances and all end points and including the waste stage of the substances is now planned in the course of 2021 rather than mid 2020 as planned originally.

Kind regards,

Ursula Schliessner

Annex

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**Name:** Diiron trioxide - BC

---

**Legal entity owner:** EBRC Consulting GmbH / Hannover / Germany

---

**Printing date:** 2020-07-27T14:33:16.815+02:00

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---

# Diiron trioxide - BC

## CORE

### General information

#### Composition

FLEXIBLE\_RECORD: BC\_powder

---

UUID: 8c5a9f16-9ffa-4433-9139-1337f424e7a8

Dossier UUID:

Author: ebrc02

Date: 2020-07-22T11:08:52.447+02:00

Remarks:

---

### General Information

---

#### Name

Diiron trioxide - powder

#### Type of composition

boundary composition of the substance

#### State / form

solid: particulate/powder

#### Description

Due to the raw material used for production of diiron trioxide, the substance contains minor amounts of non-iron metals, predominantly Si, Al, which are incorporated in the crystal lattice.

Boundary composition contains all impurities and additives > 0.1%

No impurities affecting the classification and labelling are allowed.

### Degree of purity

---

>= 80

<= 100

% (w/w)

### Constituents

---

#### Reference substance

[diiron trioxide / diiron trioxide / 1309-37-1 / 215-168-2](#)

#### EC number

215-168-2

#### EC name

#### CAS number

1309-37-1

#### CAS name

Iron oxide, (Fe<sub>2</sub>O<sub>3</sub>)

#### IUPAC name

diiron trioxide

---

**Typical concentration**

>= 92 % (w/w)

**Concentration range**

>= 80 <= 100 % (w/w)

---

**Impurities****Reference substance**

[carbon / carbon / 7440-44-0 / 231-153-3](#)

**EC number**                      **EC name**

231-153-3

**CAS number**                      **CAS name**

7440-44-0

carbon

**IUPAC name**

carbon

**Typical concentration**

<= 2 % (w/w)

**Concentration range**

>= 0 <= 4 % (w/w)

**This impurity is considered relevant for the classification and labelling of the substance**  
false

**Reference substance**

[aluminium oxide / aluminium oxide / 1344-28-1 / 215-691-6](#)

**EC number**                      **EC name**

215-691-6

**CAS number**                      **CAS name**

1344-28-1

**IUPAC name**

aluminium oxide

**Typical concentration**

<= 0.4 % (w/w)

**Concentration range**

>= 0 <= 2 % (w/w)

**Remarks**

No free aluminium dioxide in the substance: aluminium is incorporated in the crystal lattice.

Concentration calculated as Al<sub>2</sub>O<sub>3</sub>

**This impurity is considered relevant for the classification and labelling of the substance**  
false

**Reference substance**

[Manganese dioxide / Dioxomanganese / 1313-13-9 / 215-202-6](#)

**EC number**                      **EC name**

215-202-6

**CAS number**                      **CAS name**

1313-13-9

**IUPAC name**

Dioxomanganese

**Typical concentration**

<= 1    % (w/w)

**Concentration range**

>= 0                                      <= 2                                      % (w/w)

**Remarks**

No free manganese dioxide in the substance: manganese is incorporated in the crystal lattice  
Concentration calculated as MnO<sub>2</sub>

**This impurity is considered relevant for the classification and labelling of the substance**  
false

**Reference substance**

[silicon dioxide / Silicon dioxide \(amorphous\) / 7631-86-9 / 231-545-4](#)

**EC number**                      **EC name**

231-545-4

**CAS number**                      **CAS name**

7631-86-9

Silica

**IUPAC name**

Silicon dioxide (amorphous)

**Typical concentration**

<= 1    % (w/w)

**Concentration range**

>= 0                                      <= 2                                      % (w/w)

**Remarks**

No free silicon dioxide in the substance: silicon is incorporated in the crystal lattice  
Concentration calculated as SiO<sub>2</sub>

**This impurity is considered relevant for the classification and labelling of the substance**  
false

**Reference substance**[Calcium sulphate / calcium sulfate / 7778-18-9 / 231-900-3](#)**EC number**

231-900-3

**EC name****CAS number**

7778-18-9

**CAS name****IUPAC name**

calcium sulfate

**Typical concentration**

&lt;= 1 % (w/w)

**Concentration range**

&gt;= 0 &lt;= 2 % (w/w)

**This impurity is considered relevant for the classification and labelling of the substance**  
false**Reference substance**[sodium sulphate / disodium sulfate / 7757-82-6 / 231-820-9](#)**EC number**

231-820-9

**EC name****CAS number**

7757-82-6

**CAS name**

sulfuric acid sodium salt (1:2)

**IUPAC name**

disodium sulfate

**Typical concentration**

&lt;= 1 % (w/w)

**Concentration range**

&gt;= 0 &lt;= 2 % (w/w)

**This impurity is considered relevant for the classification and labelling of the substance**  
false**Reference substance**[Magnesium sulfate / Magnesium sulphate / 7487-88-9 / 231-298-2](#)**EC number**

231-298-2

**EC name****CAS number**

7487-88-9

**CAS name**

Magnesium sulphate

**IUPAC name**

Magnesium sulphate

---

**Typical concentration**

$\leq 1$  % (w/w)

**Concentration range**

$\geq 0$                        $\leq 2$  % (w/w)

**This impurity is considered relevant for the classification and labelling of the substance**  
false

**Characterisation of polymers** \_\_\_\_\_

**Reactive functional groups** \_\_\_\_\_

**Polymer contains only low concern reactive functional groups**  
false



**Reference substance**[carbon / carbon / 7440-44-0 / 231-153-3](#)**EC number**

231-153-3

**EC name****CAS number**

7440-44-0

**CAS name**

carbon

**IUPAC name**

carbon

**Typical concentration**

&lt;= 2 % (w/w)

**Concentration range**

&gt;= 0 &lt;= 4 % (w/w)

**This impurity is considered relevant for the classification and labelling of the substance**

false

**Reference substance**[aluminium oxide / aluminium oxide / 1344-28-1 / 215-691-6](#)**EC number**

215-691-6

**EC name****CAS number**

1344-28-1

**CAS name****IUPAC name**

aluminium oxide

**Typical concentration**

&lt;= 0.4 % (w/w)

**Concentration range**

&gt;= 0 &lt;= 2 % (w/w)

**Remarks**No free aluminium dioxide in the substance: aluminium is incorporated in the crystal lattice  
Concentration calculated as Al<sub>2</sub>O<sub>3</sub>**This impurity is considered relevant for the classification and labelling of the substance**

false

**Reference substance**[Manganese dioxide / Dioxomanganese / 1313-13-9 / 215-202-6](#)**EC number**

215-202-6

**EC name**

**CAS number**                      **CAS name**

1313-13-9

**IUPAC name**

Dioxomanganese

**Typical concentration**

&lt;= 1    % (w/w)

**Concentration range**

&gt;= 0    &lt;= 2    % (w/w)

**Remarks**

No free manganese dioxide in the substance: manganese is incorporated in the crystal lattice  
Concentration calculated as MnO<sub>2</sub>

**This impurity is considered relevant for the classification and labelling of the substance**  
false

**Reference substance**[silicon dioxide / Silicon dioxide \(amorphous\) / 7631-86-9 / 231-545-4](#)**EC number**                      **EC name**

231-545-4

**CAS number**                      **CAS name**

7631-86-9                      Silica

**IUPAC name**

Silicon dioxide (amorphous)

**Typical concentration**

&lt;= 1    % (w/w)

**Concentration range**

&gt;= 0    &lt;= 2    % (w/w)

**Remarks**

No free silicon dioxide in the substance: silicon is incorporated in the crystal lattice  
Concentration calculated as SiO<sub>2</sub>

**This impurity is considered relevant for the classification and labelling of the substance**  
false

**Reference substance**[Calcium sulphate / calcium sulfate / 7778-18-9 / 231-900-3](#)**EC number**                      **EC name**

231-900-3

**CAS number**                      **CAS name**

7778-18-9

**IUPAC name**

calcium sulfate



**Typical concentration**

<= 1 % (w/w)

**Concentration range**

>= 0 <= 2 % (w/w)

**This impurity is considered relevant for the classification and labelling of the substance**  
false

**Reference substance**

[sodium sulphate / disodium sulfate / 7757-82-6 / 231-820-9](#)

**EC number**

231-820-9

**EC name****CAS number**

7757-82-6

**CAS name**

sulfuric acid sodium salt (1:2)

**IUPAC name**

disodium sulfate

**Typical concentration**

<= 1 % (w/w)

**Concentration range**

>= 0 <= 2 % (w/w)

**This impurity is considered relevant for the classification and labelling of the substance**  
false

**Reference substance**

[Magnesium sulfate / Magnesium sulphate / 7487-88-9 / 231-298-2](#)

**EC number**

231-298-2

**EC name****CAS number**

7487-88-9

**CAS name**

Magnesium sulphate

**IUPAC name**

Magnesium sulphate

**Typical concentration**

<= 1 % (w/w)

**Concentration range**

>= 0 <= 2 % (w/w)

**This impurity is considered relevant for the classification and labelling of the substance**  
false

## Characterisation of nanoforms

**Type of information reported**

single nanoform



<b>Percentile</b> D90			
<b>Range</b>			
>= 15	<= 110		nm

<b>Range of length</b>			
>= 10	<= 150		nm
<b>Range of aspect ratio (:1)</b>			
>= 1	<= 5		
<b>Fraction of constituent particles in the size range 1-100 nm</b>			
>= 50	<= 100		%

**Shape category**  
spheroidal

<b>Percentile</b> D10			
<b>Range</b>			
> 5	< 90		nm

<b>Percentile</b> D50			
<b>Range</b>			
> 10	< 100		nm

<b>Percentile</b> D90			
<b>Range</b>			
> 20	< 200		nm

<b>Range of aspect ratio (:1)</b>			
>= 1	<= 5		
<b>Fraction of constituent particles in the size range 1-100 nm</b>			
>= 50	<= 100		%

**Crystallinity** \_\_\_\_\_

---

## Structures

**Structure**

crystalline

**Name**

alpha-Fe<sub>2</sub>O<sub>3</sub> (Hematite)

**Pure structure**

yes

## Specific surface area

---

**Range of specific surface area**

> 5 < 380 m<sup>2</sup>/g

## Surface functionalisation / treatment

---

**Surface treatment applied**

no

**Does the set contain both treated and non-surface treated nanoforms?**

no

## Characterisation of polymers

---

## Reactive functional groups

---

**Polymer contains only low concern reactive functional groups**

false

---

# DOMAIN

## SUBSTANCE: Diiron trioxide - BC

---

**UUID:** 24987906-b90e-41c4-abcd-3f7f88d6603d

**Dossier UUID:**

**Author:** ebrc84

**Date:** 2020-07-27T14:26:37.580+02:00

**Remarks:**

---

**Substance name**

Diiron trioxide - BC

**Legal entity**

[EBRC Consulting GmbH / Hannover / Germany](#)

## Role in the supply chain

---

**Manufacturer**

false

**Importer**

false

**Only representative**

false

**Downstream user**

false

---

# References

## REFERENCE\_SUBSTANCE: aluminium oxide

---

**UUID:** IUC5-10f9e3b6-26b3-4cbc-99f9-f9dfd98a9a9a

**Dossier UUID:**

**Author:** ebrc02

**Date:** 2012-12-11T14:46:29.000+01:00

**Remarks:**

---

### General information

---

**Reference substance name**

aluminium oxide

### Inventory

---

**Inventory name**

**Inventory**

EC

**Inventory number**

215-691-6

**CAS number**

**Molecular formula**

**Description**

### Reference substance information

---

EU: REACH

**IUPAC name**

aluminium oxide

### CAS information

---

**CAS number**

1344-28-1

### Molecular and structural information

---

EU: REACH

**Molecular formula**

Al<sub>2</sub>O<sub>3</sub>

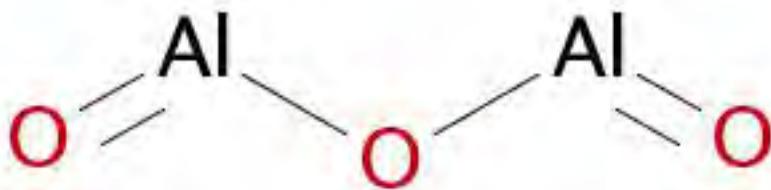
**Molecular weight**

101.96

---

---

Structural formula



---

# REFERENCE\_SUBSTANCE: Calcium sulphate

---

**UUID:** 80b6fdf0-470a-4656-8ef1-9b0241bc3eb3

**Dossier UUID:**

**Author:** ebrc02

**Date:** 2019-12-19T21:20:47.000+01:00

**Remarks:**

---

## General information

---

**Reference substance name**

Calcium sulphate

## Inventory

---

**Inventory name**

**Inventory**

EC

**Inventory number**

231-900-3

**CAS number**

**Molecular formula**

**Description**

## Reference substance information

---

**IUPAC name**

calcium sulfate

## CAS information

---

**CAS number**

7778-18-9

## Molecular and structural information

---

**Molecular formula**

CaSO<sub>4</sub>



---

# REFERENCE\_SUBSTANCE: carbon

---

**UUID:** ECB5-b15b8130-da39-4ec1-b36f-932b1b3de15e

**Dossier UUID:**

**Author:** ebrc09

**Date:** 2017-12-18T12:28:07.000+01:00

**Remarks:**

---

## General information

---

**Reference substance name**

carbon

## Inventory

---

**Inventory name**

**Inventory**

EC

**Inventory number**

231-153-3

**CAS number**

**Molecular formula**

**Description**

## Reference substance information

---

**IUPAC name**

carbon

**Synonyms**

**Identity**

Carbon

## CAS information

---

**CAS number**

7440-44-0

**CAS name**

carbon

## Related substances

---

**Group / category information**

DSL Category: Inorganics

## Molecular and structural information

---

---

**Molecular formula**

C

**Molecular weight**

16.0425

**SMILES notation**

[C]

**Structural formula**

C

---

# REFERENCE\_SUBSTANCE: diiron trioxide

---

**UUID:** ECB5-16d1616d-21e5-4712-98d6-739bde588e80

**Dossier UUID:**

**Author:** ebrc02

**Date:** 2020-05-08T11:13:43.000+02:00

**Remarks:**

---

## General information

---

**Reference substance name**

diiron trioxide

## Inventory

---

**Inventory name**

**Inventory**

EC

**Inventory number**

215-168-2

**CAS number**

**Molecular formula**

**Description**

## Reference substance information

---

EU: REACH

**IUPAC name**

diiron trioxide

**Synonyms**

**Identity**

Iron oxide (Fe<sub>2</sub>O<sub>3</sub>)

## CAS information

---

**CAS number**

1309-37-1

**CAS name**

Iron oxide, (Fe<sub>2</sub>O<sub>3</sub>)

## Molecular and structural information

---

EU: REACH

**Molecular formula**

Fe<sub>2</sub>O<sub>3</sub>

---

---

**Molecular weight**

ca. 159.6882

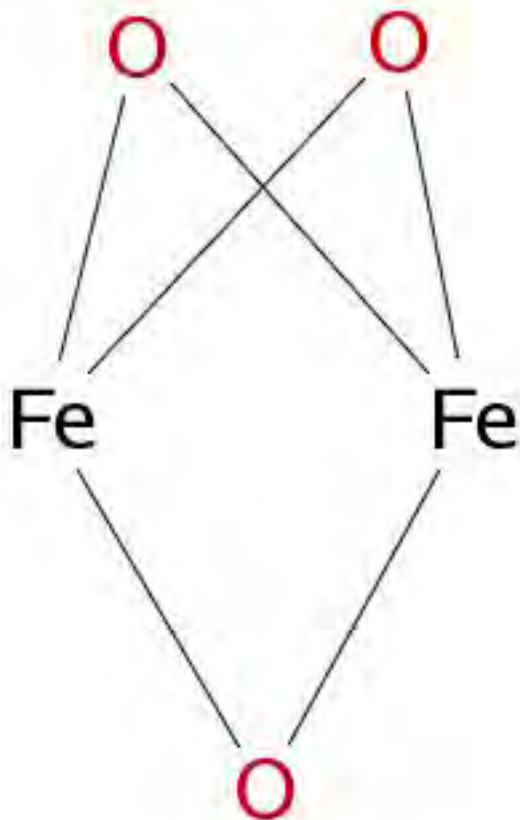
**SMILES notation**

O1[Fe]2O[Fe]1O2

**InChI**

InChI=1/2Fe.3O/rFe2O3/c3-1-4-2(3)5-1

**Structural formula**



---

# LEGAL\_ENTITY: EBRC Consulting GmbH

---

**UUID:** IUC5-ced90d04-9ae3-406e-a31a-6f971125817b

**Dossier UUID:**

**Author:** ebrc86

**Date:** 2017-08-23T14:09:55.000+02:00

**Remarks:**

---

## General information

---

**Legal entity name**

EBRC Consulting GmbH

## Identifiers

---

**Legal entity identifiers**

**Identifier Type**

VAT

**ID**

DE160973087

**Other IT system identifiers**

**IT system**

LEO

**ID**

7900

## Contact information

---

### Contact address

---

**Address 1**

Raffaelstraße 4

**Postal code**

30177

**Town**

Hannover

**Country**

Germany

**Phone**

0049 511 8983890

**Fax**

0049 511 89838910

**E-mail**

info@ebrc.de

---

**Web site**  
[www.ebrc.de](http://www.ebrc.de)

---

# REFERENCE\_SUBSTANCE: Magnesium sulfate

---

**UUID:** 7589d625-fde7-4b54-afb4-3c70c8060cad

**Dossier UUID:**

**Author:** ebrc02

**Date:** 2017-03-06T15:10:07.000+01:00

**Remarks:**

---

## General information

---

**Reference substance name**

Magnesium sulfate

## Inventory

---

**Inventory name**

**Inventory**

EC

**Inventory number**

231-298-2

**CAS number**

**Molecular formula**

**Description**

## Reference substance information

---

**IUPAC name**

Magnesium sulphate

## CAS information

---

**CAS number**

7487-88-9

**CAS name**

Magnesium sulphate

## Molecular and structural information

---

**Molecular formula**

MgO4S

**Molecular weight**

120.361

**SMILES notation**

[O-]S(=O)(=O)[O-].[Mg+2]

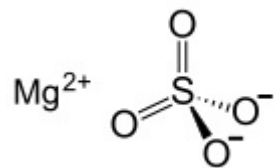
---

---

**InChI**

1S/Mg.H2O4S/c;1-5(2,3)4/h;(H2,1,2,3,4)/q+2;/p-2

**Structural formula**





---

# REFERENCE\_SUBSTANCE: Manganese dioxide

---

**UUID:** 241bc1f5-8bbf-4d62-bc96-6d021ddade67

**Dossier UUID:**

**Author:** ebrc02

**Date:** 2020-03-02T14:31:55.000+01:00

**Remarks:**

---

## General information

---

**Reference substance name**

Manganese dioxide

## Inventory

---

**Inventory name**

**Inventory**

EC

**Inventory number**

215-202-6

**CAS number**

**Molecular formula**

**Description**

## Reference substance information

---

**IUPAC name**

Dioxomanganese

## CAS information

---

**CAS number**

1313-13-9

## Molecular and structural information

---

**Molecular formula**

MnO<sub>2</sub>

---

# REFERENCE\_SUBSTANCE: silicon dioxide

---

**UUID:** ECB5-3ae01078-639b-4d2e-a9e7-ce8b7afaa3c6

**Dossier UUID:**

**Author:** ebrc02

**Date:** 2013-09-20T13:12:06.000+02:00

**Remarks:**

---

## General information

---

**Reference substance name**

silicon dioxide

## Inventory

---

**Inventory name**

**Inventory**

EC

**Inventory number**

231-545-4

**CAS number**

**Molecular formula**

**Description**

## Reference substance information

---

EU: BPD or EU: BPR

**IUPAC name**

Silicon dioxide (amorphous)

**Synonyms**

<b>Identity</b>
Silica
<b>Identity</b>
Silicon oxide
<b>Identity</b>
Silanedione

## CAS information

---

**CAS number**

7631-86-9

**CAS name**

Silica

---

---

## Related substances

---

### Group / category information

DSL Category: Inorganics

## Molecular and structural information

---

EU: BPD or EU: BPR

### Molecular formula

O<sub>2</sub>Si

### Molecular weight

60.0843

### SMILES notation

O=[Si]=O

### InChI

InChI=1/O2Si/c1-3-2

### Structural formula



---

# REFERENCE\_SUBSTANCE: sodium sulphate

---

**UUID:** ECB5-edb493fc-4080-4e80-876f-ec151506fddf

**Dossier UUID:**

**Author:** ebrc02

**Date:** 2019-10-18T12:16:49.000+02:00

**Remarks:**

---

## General information

---

**Reference substance name**

sodium sulphate

## Inventory

---

**Inventory name**

**Inventory**

EC

**Inventory number**

231-820-9

**CAS number**

**Molecular formula**

**Description**

## Reference substance information

---

**IUPAC name**

disodium sulfate

**Synonyms**

<b>Identity</b>
Sulfuric acid disodium salt
<b>Identity</b>
Sulfuric acid disodium salt

## CAS information

---

**CAS number**

7757-82-6

**CAS name**

sulfuric acid sodium salt (1:2)

## Related substances

---

**Group / category information**

DSL Category: Inorganics

---

---

## Molecular and structural information

---

### Molecular formula

H<sub>2</sub>O<sub>4</sub>S.2Na

### Molecular weight

142.0421

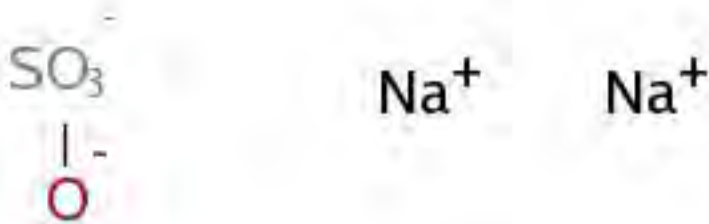
### SMILES notation

[Na+].[Na+].[O-]S(=O)(=O)[O-]

### InChI

InChI=1/2Na.H2O4S/c;;1-5(2,3)4/h;;(H2,1,2,3,4)/q2\*+1;/p-2

### Structural formula





---

**Name:** Iron hydroxide oxide yellow - BC

---

**Legal entity owner:** EBRC Consulting GmbH / Hannover / Germany

---

**Printing date:** 2020-07-27T14:30:09.840+02:00

---

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## Impurities

### Reference substance

[silicon dioxide](#) / [Silicon dioxide \(amorphous\)](#) / [7631-86-9](#) / [231-545-4](#)

**EC number**

231-545-4

**EC name****CAS number**

7631-86-9

**CAS name**

Silica

**IUPAC name**

Silicon dioxide (amorphous)

**Typical concentration**

<= 1 % (w/w)

**Concentration range**

>= 0 <= 2 % (w/w)

**Remarks**

No free silicon dioxide in the substance: silicon is incorporated in the crystal lattice  
Calculated as SiO<sub>2</sub>

**This impurity is considered relevant for the classification and labelling of the substance**  
false

### Reference substance

[Manganese dioxide](#) / [Dioxomanganese](#) / [1313-13-9](#) / [215-202-6](#)

**EC number**

215-202-6

**EC name****CAS number**

1313-13-9

**CAS name****IUPAC name**

Dioxomanganese

**Typical concentration**

<= 1 % (w/w)

**Concentration range**

>= 0 <= 2 % (w/w)

**Remarks**

No free manganese dioxide in the substance: manganese is incorporated in the crystal lattice  
Calculated as MnO<sub>2</sub>

**This impurity is considered relevant for the classification and labelling of the substance**  
false

### Reference substance

[aluminium oxide](#) / [aluminium oxide](#) / [1344-28-1](#) / [215-691-6](#)

**EC number** 215-691-6  
**EC name**  
**CAS number** 1344-28-1  
**CAS name**  
**IUPAC name** aluminium oxide  
**Typical concentration**  
<= 0.4 % (w/w)  
**Concentration range**  
>= 0 <= 2 % (w/w)  
**Remarks**  
No free aluminium dioxide in the substance: aluminium is incorporated in the crystal lattice  
Calculated as Al<sub>2</sub>O<sub>3</sub>  
**This impurity is considered relevant for the classification and labelling of the substance**  
false

**Reference substance**  
[carbon / carbon / 7440-44-0 / 231-153-3](#)  
**EC number** 231-153-3  
**EC name**  
**CAS number** 7440-44-0  
**CAS name** carbon  
**IUPAC name** carbon  
**Typical concentration**  
<= 2 % (w/w)  
**Concentration range**  
>= 0 <= 4 % (w/w)  
**This impurity is considered relevant for the classification and labelling of the substance**  
false

**Reference substance**  
[sodium sulphate / disodium sulfate / 7757-82-6 / 231-820-9](#)  
**EC number** 231-820-9  
**EC name**  
**CAS number** 7757-82-6  
**CAS name** sulfuric acid sodium salt (1:2)  
**IUPAC name** disodium sulfate  
**Typical concentration**  
<= 1 % (w/w)





---

**Structures****Structure**

crystalline

**Name**

alpha-FeOOH (Goethite)

**Pure structure**

yes

**Specific surface area** \_\_\_\_\_**Range of specific surface area**

&gt;= 5

&lt;= 350

m<sup>2</sup>/g**Surface functionalisation / treatment** \_\_\_\_\_**Surface treatment applied**

no

**Characterisation of polymers** \_\_\_\_\_**Reactive functional groups** \_\_\_\_\_**Polymer contains only low concern reactive functional groups**

false

---

## FLEXIBLE\_RECORD: BC\_Nano\_gamma-FeOOH

---

**UUID:** 85bbaeb0-2a3a-4a2a-a9ff-c02edc29c68b

**Dossier UUID:**

**Author:** ebrc02

**Date:** 2020-07-22T11:11:25.110+02:00

**Remarks:**

---

## General Information

---

**Name**

Iron hydroxide oxide yellow - BC\_Nano\_gamma-FeOOH

**Type of composition**

boundary composition of the substance

**State / form**

solid: nanoform

## Degree of purity

---

EU: REACH

>= 92 < 100 % (w/w)

## Constituents

---

EU: REACH

**Reference substance**

[Iron hydroxide oxide yellow / Iron hydroxide oxide / 51274-00-1 / 257-098-5](#)

**EC number**

257-098-5

**EC name**

**CAS number**

51274-00-1

**CAS name**

Iron hydroxide oxide (Fe(OH)O)

**IUPAC name**

Iron hydroxide oxide

**Concentration range**

> 80 < 100 % (w/w)

## Impurities

---















---

# DOMAIN

## SUBSTANCE: Iron hydroxide oxide yellow - BC

---

**UUID:** 1254ba94-4d72-4bc9-adaa-29c9fd98de7c

**Dossier UUID:**

**Author:** ebrc84

**Date:** 2020-07-27T14:23:12.136+02:00

**Remarks:**

---

**Substance name**

Iron hydroxide oxide yellow - BC

**Legal entity**

[EBRC Consulting GmbH / Hannover / Germany](#)

## Role in the supply chain

---

**Manufacturer**

false

**Importer**

false

**Only representative**

false

**Downstream user**

false

---

# References

## REFERENCE\_SUBSTANCE: aluminium oxide

---

**UUID:** IUC5-10f9e3b6-26b3-4cbc-99f9-f9dfd98a9a9a

**Dossier UUID:**

**Author:** ebrc02

**Date:** 2012-12-11T14:46:29.000+01:00

**Remarks:**

---

### General information

---

**Reference substance name**

aluminium oxide

### Inventory

---

**Inventory name**

**Inventory**

EC

**Inventory number**

215-691-6

**CAS number**

**Molecular formula**

**Description**

### Reference substance information

---

EU: REACH

**IUPAC name**

aluminium oxide

### CAS information

---

**CAS number**

1344-28-1

### Molecular and structural information

---

EU: REACH

**Molecular formula**

Al<sub>2</sub>O<sub>3</sub>

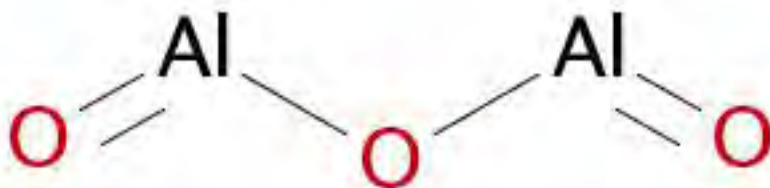
**Molecular weight**

101.96

---

---

Structural formula



---

# REFERENCE\_SUBSTANCE: calcium chloride

---

**UUID:** ECB5-d2485f15-cff1-46a4-a235-3c451dc2fe03

**Dossier UUID:**

**Author:** ebrc02

**Date:** 2010-07-05T10:42:15.000+02:00

**Remarks:**

---

## General information

---

**Reference substance name**

calcium chloride

## Inventory

---

**Inventory name**

**Inventory**

EC

**Inventory number**

233-140-8

**CAS number**

**Molecular formula**

**Description**

## Reference substance information

---

EU: REACH

**IUPAC name**

calcium dichloride

**Synonyms**

<b>Identity</b> Calcium chloride (CaCl <sub>2</sub> )
<b>Identity</b> Calcium chloride (CaCl <sub>2</sub> )

## CAS information

---

**CAS number**

10043-52-4

## Related substances

---

**Group / category information**

DSL Category: Inorganics

---



---

## Molecular and structural information

---

EU: REACH

### Molecular formula

CaCl<sub>2</sub>

### Molecular weight

110.984

### SMILES notation

[Cl-].[Cl-].[Ca+2]

### InChI

InChI=1/Ca.2ClH/h;2\*1H/q+2;;/p-2

### Structural formula



---

# REFERENCE\_SUBSTANCE: calcium sulfate

---

**UUID:** ECB5-9dc36060-c540-4fb4-b037-5940900b425f

**Dossier UUID:**

**Author:** ebrc02

**Date:** 2010-06-25T09:32:14.000+02:00

**Remarks:**

---

## General information

---

**Reference substance name**

calcium sulfate

## Inventory

---

**Inventory name**

**Inventory**

EC

**Inventory number**

231-900-3

**CAS number**

**Molecular formula**

**Description**

## Reference substance information

---

EU: REACH

**IUPAC name**

calcium sulfate

**Synonyms**

**Identity**

Sulfuric acid, calcium salt (1:1)

**Identity**

Sulfuric acid, calcium salt (1:1)

## CAS information

---

**CAS number**

7778-18-9

## Related substances

---

**Group / category information**

DSL Category: Inorganics

---

---

## Molecular and structural information

---

EU: REACH

### Molecular formula

CaSO<sub>4</sub>

### Molecular weight

136.1406

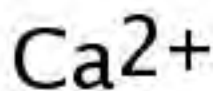
### SMILES notation

[Ca+2].[O-]S(=O)(=O)[O-]

### InChI

InChI=1/Ca.H2O4S/c;1-5(2,3)4/h;(H2,1,2,3,4)/q+2;/p-2

### Structural formula



---

# REFERENCE\_SUBSTANCE: Calcium sulphate

---

**UUID:** 80b6fdf0-470a-4656-8ef1-9b0241bc3eb3

**Dossier UUID:**

**Author:** ebrc02

**Date:** 2019-12-19T21:20:47.000+01:00

**Remarks:**

---

## General information

---

**Reference substance name**

Calcium sulphate

## Inventory

---

**Inventory name**

**Inventory**

EC

**Inventory number**

231-900-3

**CAS number**

**Molecular formula**

**Description**

## Reference substance information

---

**IUPAC name**

calcium sulfate

## CAS information

---

**CAS number**

7778-18-9

## Molecular and structural information

---

**Molecular formula**

CaSO<sub>4</sub>

---

# REFERENCE\_SUBSTANCE: carbon

---

**UUID:** ECB5-b15b8130-da39-4ec1-b36f-932b1b3de15e

**Dossier UUID:**

**Author:** ebrc09

**Date:** 2017-12-18T12:28:07.000+01:00

**Remarks:**

---

## General information

---

**Reference substance name**

carbon

## Inventory

---

**Inventory name**

**Inventory**

EC

**Inventory number**

231-153-3

**CAS number**

**Molecular formula**

**Description**

## Reference substance information

---

**IUPAC name**

carbon

**Synonyms**

**Identity**

Carbon

## CAS information

---

**CAS number**

7440-44-0

**CAS name**

carbon

## Related substances

---

**Group / category information**

DSL Category: Inorganics

## Molecular and structural information

---

---

**Molecular formula**

C

**Molecular weight**

16.0425

**SMILES notation**

[C]

**Structural formula**

C

---

# LEGAL\_ENTITY: EBRC Consulting GmbH

---

**UUID:** IUC5-ced90d04-9ae3-406e-a31a-6f971125817b

**Dossier UUID:**

**Author:** ebrc86

**Date:** 2017-08-23T14:09:55.000+02:00

**Remarks:**

---

## General information

---

**Legal entity name**

EBRC Consulting GmbH

## Identifiers

---

**Legal entity identifiers**

**Identifier Type**

VAT

**ID**

DE160973087

**Other IT system identifiers**

**IT system**

LEO

**ID**

7900

## Contact information

---

### Contact address

---

**Address 1**

Raffaelstraße 4

**Postal code**

30177

**Town**

Hannover

**Country**

Germany

**Phone**

0049 511 8983890

**Fax**

0049 511 89838910

**E-mail**

info@ebrc.de

---

---

**Web site**  
[www.ebrc.de](http://www.ebrc.de)



---

# REFERENCE\_SUBSTANCE: Iron hydroxide oxide yellow

---

**UUID:** IUC5-6206c285-66ce-44db-84b7-371ebdd2de0d

**Dossier UUID:**

**Author:** ebrc02

**Date:** 2019-12-13T10:45:47.000+01:00

**Remarks:**

---

## General information

---

**Reference substance name**

Iron hydroxide oxide yellow

## Inventory

---

**Inventory name**

**Inventory**

EC

**Inventory number**

257-098-5

**CAS number**

**Molecular formula**

**Description**

## Reference substance information

---

**IUPAC name**

Iron hydroxide oxide

## CAS information

---

**CAS number**

51274-00-1

**CAS name**

Iron hydroxide oxide (Fe(OH)O)

## Molecular and structural information

---

**Molecular formula**

Fe(OH)O

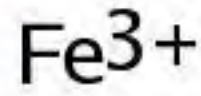
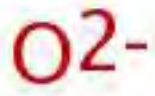
**Molecular weight**

88.85

---

---

Structural formula



---

# REFERENCE\_SUBSTANCE: Magnesium sulfate

---

**UUID:** 7589d625-fde7-4b54-afb4-3c70c8060cad

**Dossier UUID:**

**Author:** ebrc02

**Date:** 2017-03-06T15:10:07.000+01:00

**Remarks:**

---

## General information

---

**Reference substance name**

Magnesium sulfate

## Inventory

---

**Inventory name**

**Inventory**

EC

**Inventory number**

231-298-2

**CAS number**

**Molecular formula**

**Description**

## Reference substance information

---

**IUPAC name**

Magnesium sulphate

## CAS information

---

**CAS number**

7487-88-9

**CAS name**

Magnesium sulphate

## Molecular and structural information

---

**Molecular formula**

MgO4S

**Molecular weight**

120.361

**SMILES notation**

[O-]S(=O)(=O)[O-].[Mg+2]

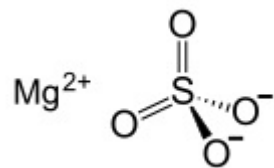
---

---

**InChI**

1S/Mg.H2O4S/c;1-5(2,3)4/h;(H2,1,2,3,4)/q+2;/p-2

**Structural formula**



---

# REFERENCE\_SUBSTANCE: magnesiumsulfat

---

**UUID:** IUC5-bcfbbae9-2f4e-4a30-a2f1-1929c997e77f

**Dossier UUID:**

**Author:** ebrc02

**Date:** 2015-03-24T09:44:05.000+01:00

**Remarks:**

---

## General information

---

**Reference substance name**

magnesiumsulfat

## Inventory

---

**Inventory name**

**Inventory**

EC

**Inventory number**

231-298-2

**CAS number**

**Molecular formula**

**Description**

## Reference substance information

---

EU: REACH

**IUPAC name**

magnesium sulfate

## CAS information

---

**CAS number**

7487-88-9

**CAS name**

magnesium sulfate

## Molecular and structural information

---

**Molecular formula**

H2O4S.Mg

**Remarks**

Structural formula not available: MgSO4

---

---

# REFERENCE\_SUBSTANCE: Manganese dioxide

---

**UUID:** 241bc1f5-8bbf-4d62-bc96-6d021ddade67

**Dossier UUID:**

**Author:** ebrc02

**Date:** 2020-03-02T14:31:55.000+01:00

**Remarks:**

---

## General information

---

**Reference substance name**

Manganese dioxide

## Inventory

---

**Inventory name**

**Inventory**

EC

**Inventory number**

215-202-6

**CAS number**

**Molecular formula**

**Description**

## Reference substance information

---

**IUPAC name**

Dioxomanganese

## CAS information

---

**CAS number**

1313-13-9

## Molecular and structural information

---

**Molecular formula**

MnO<sub>2</sub>

---

# REFERENCE\_SUBSTANCE: manganese dioxide

---

**UUID:** IUC4-25ed219f-012f-35ff-b807-e50534e4c457

**Dossier UUID:**

**Author:** ebrc02

**Date:** 2013-02-15T16:29:53.000+01:00

**Remarks:**

---

## General information

---

**Reference substance name**  
manganese dioxide

## Inventory

---

**Inventory name**

**Inventory**  
EC

**Inventory number**  
215-202-6

**CAS number**

**Molecular formula**

**Description**

## Reference substance information

---

EU: REACH

**IUPAC name**  
Dioxomanganese

**Description**  
The given information is based on IUCLID4 chapter 1.1.0 General Substance Information and the IUCLID4 Substance Definition.

**Synonyms**

<b>Identity</b> Manganese oxide (MnO <sub>2</sub> )
--

## CAS information

---

**CAS number**  
1313-13-9

## Molecular and structural information

---

---

EU: REACH

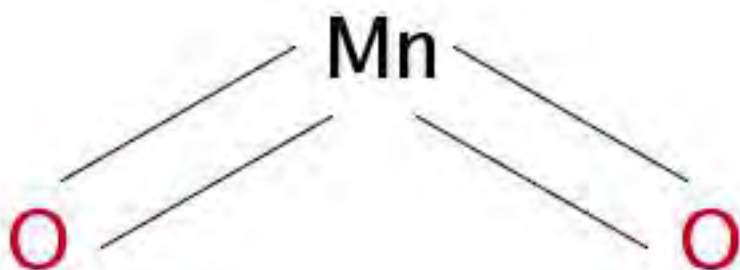
**Molecular formula**

MnO<sub>2</sub>

**Molecular weight**

86.9

**Structural formula**





---

# REFERENCE\_SUBSTANCE: silicon dioxide

---

**UUID:** ECB5-3ae01078-639b-4d2e-a9e7-ce8b7afaa3c6

**Dossier UUID:**

**Author:** ebrc02

**Date:** 2013-09-20T13:12:06.000+02:00

**Remarks:**

---

## General information

---

**Reference substance name**

silicon dioxide

## Inventory

---

**Inventory name**

**Inventory**

EC

**Inventory number**

231-545-4

**CAS number**

**Molecular formula**

**Description**

## Reference substance information

---

EU: BPD or EU: BPR

**IUPAC name**

Silicon dioxide (amorphous)

**Synonyms**

<b>Identity</b>
Silica
<b>Identity</b>
Silicon oxide
<b>Identity</b>
Silanedione

## CAS information

---

**CAS number**

7631-86-9

**CAS name**

Silica

---

---

## Related substances

---

### Group / category information

DSL Category: Inorganics

## Molecular and structural information

---

EU: BPD or EU: BPR

### Molecular formula

O<sub>2</sub>Si

### Molecular weight

60.0843

### SMILES notation

O=[Si]=O

### InChI

InChI=1/O2Si/c1-3-2

### Structural formula



---

# REFERENCE\_SUBSTANCE: sodium chloride

---

**UUID:** ECB5-fdaf2f4f-2a29-4181-ae78-5b5622d4912b

**Dossier UUID:**

**Author:** ebrc02

**Date:** 2019-10-18T12:18:08.000+02:00

**Remarks:**

---

## General information

---

**Reference substance name**

sodium chloride

## Inventory

---

**Inventory name**

**Inventory**

EC

**Inventory number**

231-598-3

**CAS number**

**Molecular formula**

**Description**

## Reference substance information

---

**IUPAC name**

sodium chloride

**Synonyms**

<b>Identity</b>
Sodium chloride (NaCl)
<b>Identity</b>
Sodium chloride (NaCl)

## CAS information

---

**CAS number**

7647-14-5

**CAS name**

sodium chloride (NaCl)

## Related substances

---

**Group / category information**

DSL Category: Inorganics

---

---

## Molecular and structural information

---

### Molecular formula

ClNa

### Molecular weight

58.4428

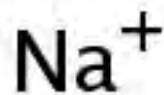
### SMILES notation

[Na+].[Cl-]

### InChI

InChI=1/ClH.Na/h1H;/q;+1/p-1

### Structural formula



---

# REFERENCE\_SUBSTANCE: sodium sulphate

---

**UUID:** ECB5-edb493fc-4080-4e80-876f-ec151506fddf

**Dossier UUID:**

**Author:** ebrc02

**Date:** 2019-10-18T12:16:49.000+02:00

**Remarks:**

---

## General information

---

**Reference substance name**

sodium sulphate

## Inventory

---

**Inventory name**

**Inventory**

EC

**Inventory number**

231-820-9

**CAS number**

**Molecular formula**

**Description**

## Reference substance information

---

**IUPAC name**

disodium sulfate

**Synonyms**

<b>Identity</b>
Sulfuric acid disodium salt
<b>Identity</b>
Sulfuric acid disodium salt

## CAS information

---

**CAS number**

7757-82-6

**CAS name**

sulfuric acid sodium salt (1:2)

## Related substances

---

**Group / category information**

DSL Category: Inorganics

---

---

## Molecular and structural information

---

### Molecular formula

H<sub>2</sub>O<sub>4</sub>S.2Na

### Molecular weight

142.0421

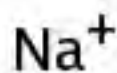
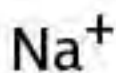
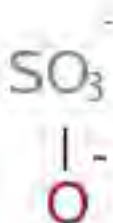
### SMILES notation

[Na+].[Na+].[O-]S(=O)(=O)[O-]

### InChI

InChI=1/2Na.H2O4S/c;;1-5(2,3)4/h;;(H2,1,2,3,4)/q2\*+1;/p-2

### Structural formula



# JONES DAY

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Advocaat bij het Hof van Cassatie  
Member of the Belgian Supreme Court Bar

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

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TELEPHONE: 32.(0)2.645.14.11 • FACSIMILE: 32.(0)2.645.14.45

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HOWARD M. LIEBMAN<sup>(4)</sup>  
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PAUL VAN HOOHTEN

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Columbia Bar  
<sup>(5)</sup>Member of the Düsseldorf Bar  
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<sup>(8)</sup>Member of the Berlin Bar  
<sup>(9)</sup>Member of the  
Frankfurt am Main Bar  
<sup>(10)</sup>Member of the Swedish Bar

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

September 14, 2020

BY ELECTRONIC MAIL

## TO WHOM IT MAY CONCERN


**Re: SIEF Communication – Iron Oxides – Nano boundary composition Yellow and Red Iron Oxide (Iron Hydroxide Oxide Yellow EC 257-098-5, CAS 51274-00-1; Diiron Trioxide (Red Iron Oxide) EC 215-168-2, CAS 1309-37-1) – Dossier update filed by Lead Registrant LANXESS Deutschland GmbH on July 28/29, 2020.**

Dear Joint Registrants,

We are pleased to inform you that based on the written communication of ECHA of September 2 and 3, 2020 respectively, the dossier updates on the above two substances passed the manual completeness check and are considered complete.

If you wish to receive updated CSRs for the two substances, please contact Airi McCabe ([amccabe@jonesday.com](mailto:amccabe@jonesday.com)).

Kind regards,



Ursula Schliessner

# JONES DAY

AVOCATS – ADVOCATEN

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Avocat à la Cour de cassation  
Advocaat bij het Hof van Cassatie  
Member of the Belgian Supreme Court Bar

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SÉBASTIEN CHAMPAGNE  
SERGE CLERCKX  
THOMAS DE MUYNCK<sup>(3)</sup>  
LAURENT DE MUYTER  
CHARLES de NAVACELLE<sup>(2)(3)</sup>  
YVAN DESMEDT  
MATTHIEU DUPLAT  
KAARLI H. EICHHORN<sup>(9)</sup>  
VANESSA FONCKE  
JÖRG HLADJK<sup>(6)</sup>  
URSULA SCHLIESSNER<sup>(4)</sup>  
CRISTIANA SPONTONI<sup>(1)</sup>  
MARIO TODINO<sup>(6)</sup>  
JONAS VAN DEN BOSSCHE  
ALEXANDRE VERHEYDEN<sup>(3)</sup>  
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<sup>(2)</sup>Member of the Paris Bar  
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<sup>(5)</sup>Admitted to the Paris Bar  
<sup>(6)</sup>Member of the Naples Bar  
<sup>(7)</sup>Member of the Berlin Bar  
<sup>(8)</sup>Member of the  
Frankfurt am Main Bar  
<sup>(9)</sup>Member of the Swedish Bar

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

February 9, 2022

**BY ELECTRONIC MAIL**

## TO WHOM IT MAY CONCERN

**Re: REACH SIEF Communication – Iron Oxides – Iron hydroxide oxide yellow EC 257-098-5 (synonyms 243-746-4; 215-176-6); triiron tetraoxide EC 215-277-5 (synonyms 235-442-5; 215-169-8); Diiron trioxide EC 215-168-2 (synonyms 215-570-8; 215-275-4); Iron manganese (tri)oxide EC 235-049-9; manganese ferrite EC 269-056-3; Zinc ferrite EC 269-103-8**

Dear Joint Registrants,

We are pleased to inform you that a registration dossier update for all six substances was submitted to ECHA in December 2021 and has successfully passed the manual completeness check. Dossier changes include, among others, literature update, insertion of new data engaged and/or purchased by the IORC Consortium (incl. bioaccessibility, water solubility, in vitro genotox, toxicokinetic in vivo), new read-across argumentation, and waste life stage argumentation. The Consortium is still working on updating the Life cycle description and shall communicate further on this in the future. There is no change in the joint part of the dossier on classification & labeling (none).

The updated CSR remains 'joint' and was filed 'jointly'.

If you wish to receive updated CSRs with the list of joint uses and / or IUCLIDs, please contact [ReachTeam@jonesday.com](mailto:ReachTeam@jonesday.com).

Due to the acquisition of new data and the considerable work in relation to the dossier update, we will proceed to updating the LoA prices during 2022. We shall communicate on this separately.

Kind regards,



Ursula Schliessner



# JONES DAY

AVOCATS – ADVOCATEN

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1000 BRUSSELS, BELGIUM

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Member of the Belgian Supreme Court Bar

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FERDINAND BRUGHMANS  
SÉBASTIEN CHAMPAGNE  
SERGE CLERCKX  
THOMAS DE MUYNCK<sup>(3)</sup>  
LAURENT DE MUYTER  
CHARLES de NAVACELLE<sup>(2)(3)</sup>  
YVAN DESMEDT  
MATTHIEU DUPLAT  
KAARLI H. EICHHORN<sup>(9)</sup>  
VANESSA FONCKE  
JÖRG HLADJK<sup>(8)</sup>  
NADIYA NYCHAY<sup>(10)</sup>  
URSULA SCHLIESSNER<sup>(4)</sup>  
CRISTIANA SPONTONI<sup>(1)</sup>  
MARIO TODINO<sup>(6)</sup>  
JONAS VAN DEN BOSSCHE  
ALEXANDRE VERHEYDEN<sup>(3)</sup>  
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PRESLAVA DILKOVA  
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<sup>(3)</sup>Member of the New York Bar  
<sup>(4)</sup>Member of the Düsseldorf Bar  
<sup>(5)</sup>Admitted to the Paris Bar  
<sup>(6)</sup>Member of the Naples Bar  
<sup>(7)</sup>Member of the Berlin Bar  
<sup>(8)</sup>Member of the  
Frankfurt am Main Bar  
<sup>(9)</sup>Member of the Swedish Bar  
<sup>(10)</sup>Member of the Ukrainian Bar

DIRECT NUMBER: 26451460  
E-MAIL: USCHLIESSNER@JONESDAY.COM

January 17, 2023

**BY ELECTRONIC MAIL**

## TO WHOM IT MAY CONCERN

**Re: REACH SIEF Communication – Iron Oxides – Iron hydroxide oxide yellow EC 257-098-5 (synonyms 243-746-4; 215-176-6); triiron tetraoxide EC 215-277-5 (synonyms 235-442-5; 215-169-8); Diiron trioxide EC 215-168-2 (synonyms 215-570-8; 215-275-4); Iron manganese (tri)oxide EC 235-049-9; manganese ferrite EC 269-056-3; Zinc ferrite EC 269-103-8**

Dear Joint Registrants,

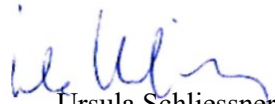
We are pleased to inform you that Lead Registrant LANXESS Deutschland GmbH in October 2022 filed another registration dossier update for all six substances. The following updates were made:

- Change of Boundary Composition for Diiron Trioxide (nano alpha-Fe<sub>2</sub>O<sub>3</sub>) and Iron hydroxide oxide yellow (nano alpha-FeOOH) and change from single nanoform to set of similar nanoforms (as discussed with ECHA), [see attachment](#)
- Inclusion of justifications for set of similar nanoforms as an attachment in IUCLID section 1.2
- Test strategy combined with the test for EOGRT and PNDT, each. These templates are linked to all 6 IUCLID files
- New information on Dispersion stability for gamma-FeOOH
- Inclusion of historical control data for the two 90d oral toxicity studies with yellow and black iron oxide (included in all files except Fe<sub>2</sub>O<sub>3</sub>)
- Update of Pauluhn, 2005, 14 day comparative inhalation study in all 6 dossiers
- Update of BASF 2015, comparative 5d inhalation study in all 6 dossiers
- Reassessment of 28d, oral rat study from Kumari 2012 in the Fe<sub>2</sub>O<sub>3</sub> dossier
- Reassessment of the study by Wang 2010 in the Fe<sub>2</sub>O<sub>3</sub> dossier.

The updated CSR for all six substances remain 'joint' and were filed 'jointly'.

If you wish to receive updated CSRs, please contact [ReachTeam@jonesday.com](mailto:ReachTeam@jonesday.com).

Kind regards,



Ursula Schliessner

Set of nanoforms – Status 30-09-2022

	FeOOH
CAS number	51274-00-1
EC number	257-098-5
IUPAC name	Iron hydroxide oxide
Name	Nano-alpha-FeOOH
Purity	>92% (80-100%)
Impurities	SiO2 (0-2%) MnO2 (0-2%) Al2O3 (0-2%) C (0-4%) Na2SO4 (0-2%) CaSO4 (0-2%) MgSO4 (0-2%)
Crystallinity	Alpha FeOOH (Goethite) Pure structure
Shape category	Elongated
Shap	Rod >= 95%- <= 100
Particle size distribution D10 [nm] D50 [nm] D90 [nm]	>= 5 - <=60 >= 10 - <=100 >= 12 - <=200
Range of length	>= 13 - <= 600 nm
Aspect ratio	>= 3 - <= 10
Fraction of constituent particles in the size range 1 – 100 nm:	50-100 %
Specific surface area [m <sup>2</sup> /g]	10-120
Surface functionalisation/treatment	No

Set of nanoforms – Status 30-09-2022

	Fe2O3	
CAS number	1309-37-1	
EC number	215-168-2	
IUPAC name	Iron(III) oxide	
Name	Nano-alpha-Fe2O3	
Purity	>92% (80-100%)	
Impurities	SiO2 (0-2%) TiO2 (0 - <1%) MnO2 (0-2%) Al2O3 (0-2%) C (0-4%) Na2SO4 (0-2%) CaSO4 (0-2%) MgSO4 (0-2%)	
Crystallinity	Alpha Fe2O3 (Hematite) Pure structure	
Shape category	Multimodal (elongated + spheroidal)	
Shap	Elongated >= 0%- <= 100	Spheroidal >= 0%- <= 100
Particle size distribution		
D10 [nm]	>= 5 - <=40	>= 5 - <=90
D50 [nm]	>= 10 - <=60	>= 15 - <=100
D90 [nm]	>= 15 - <=80	>= 20 - <=300
Range of length	>= 14 - <=240	
Aspect ratio	>= 3 - <= 6	>= 1 - <= 3
Fraction of constituent particles in the size range 1 – 100 nm:	50-100 %	
Specific surface area [m <sup>2</sup> /g]	4 – 130	
Surface functionalisation/treatment	No	

# JONES DAY

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Advocaat bij het Hof van Cassatie  
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<sup>(10)</sup>Member of the Ukrainian Bar  
<sup>(11)</sup>Member of the Plevan Bar

E-MAIL: REACHTeam@JONESDAY.COM

July 25, 2024

BY ELECTRONIC MAIL

## TO WHOM IT MAY CONCERN

**Re: REACH SIEF Communication – Iron Oxides – Iron hydroxide oxide yellow EC 257-098-5 (synonyms 243-746-4; 215-176-6); triiron tetraoxide EC 215-277-5 (synonyms 235-442-5; 215-169-8); Diiron trioxide EC 215-168-2 (synonyms 215-570-8; 215-275-4); Iron manganese (tri)oxide EC 235-049-9; manganese ferrite EC 269-056-3; Zinc ferrite EC 269-103-8; Recalculation of all Letter of Access Prices for all Tonnage Categories; new SIEF / Cooperation Agreement**

Dear Joint Registrants,

This is to let you know that pursuant to the integrated testing strategy on Toxicity to Reproduction and Developmental Toxicity with ensuing testing proposals which was part of the various recent registration dossier updates of the six substances last filed with ECHA in December 2023, and as the Iron Oxides REACH Consortium is making progress with the first Phase of the in-vitro tests, the Consortium under Lead Registrant LANXESS Deutschland GmbH has updated its LoA prices. These had last been recalculated in 2013. The new price calculations are **attached**, divided into LoAs bought before July 15, 2022 and those thereafter. The following parameters and principles have been implemented for this update:

### Background

In the past, the LoA price was calculated on the basis of the following principles which were generally accepted by all co-registrants:

- One LoA price per company including all its affiliates, regardless of the number of legal entities
- One LoA price for all 6 substances together, regardless of the number of substances a registrant wishes to register
- The entire tonnage of the entirety of the individual substances per company (including all its affiliates) was taken into account for tonnage category calculation

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EUI-1218339662v4

- Lower tonnage categories received rebates on the entire price so calculated (including administrative cost, dossier preparation and data cost) of 20% (100-1000t) (all info for 1000t was also needed for 100t but proportional reduction deemed adequate because of lower tonnage), of 40% for 10-100t, and of 80% (1-10t). Tonnages of individual substances per company (including all its affiliates) were added up and had to remain under the respective threshold in total.
- All data initially was third party data. Price of the data had been determined by LANXESS, respectively the HPV Consortium – no percentage reduction for REACH only use had been applied.
- As of 2017, the Consortium generated some own data. That new data and the future substantial new data and third party licensed data (e.g. from E172 Consortium) is not yet included in the LoA price (approx. EUR 4 Million in total).

### **Issues**

- There is a substantial number of registrations for the six substances covered by the Consortium, overall 460.
- The LoA price has not been recalculated since 2013.
- There is a substantial amount of cost (administrative and dossier preparation cost since 2013 and new data cost) that is not yet included in the LoA price.
- There is large uncertainty whether registrants will change their tonnage band or registration status if they have to pay up for their existing LoAs. Hence, the division factor may go down triggering again re-calculation etc. Overall, collection of additional LoA fees from existing registrants will be a significant workload.
- In recent years, a substantial body of case law has emerged on data sharing disputes that must be taken into account for the new LoA price calculation. Among others, ECHA and/or the BoA have set the following principles: (a) “a general and absolute exemption of all affiliates of all registrants from the requirement to pay a share of the costs of the information required for registration purposes is not objectively justified” (BoA A-014-2018 to A-021-2018); It is not possible to apply a “multiplying factor” (premium) without itemisation i.e. how that factor was calculated (ECHA, Decision of April 19, 2022); (c) an existing registrant need not offer a reduced share of costs to another company because it is an SME (ECHA, decision of June 10, 2019); (d) surcharges, discounts and deposits are in principle possible but require explanation/justification (ECHA decision of May 28, 2018).

### **Action Undertaken / To be Undertaken**

- Adoption of a new LoA price based on the current number of LoAs and Consortium Members (216) for administrative and dossier preparation cost. Development of a new LoA price for data cost.
- Notification of the co-registrants that unless they make changes to their registrations by a certain date and communicate this with supporting evidence to Jones Day (cease manufacturing/import or downgrade tonnage) (August 19, 2024) the original information available from them when they purchased their LoA will be applied to calculate their new LoA price.

- A regular recalculation thereafter (e.g., annually) is currently not intended because the annual number of new registrations is low. The Consortium manager will monitor the development of membership/LoA licensee numbers and whether new studies are required to decide if and when a new LoA price calculation will be necessary in the future.

### **Approach to LoA price calculation**

- 1) Divide the administrative cost and the dossier preparation cost (IUCLID, data entries, consultancy, CSR etc.) (= EUR 2,956,278 – of which 50% of third party license income (EUR 275,000) to be deducted) by the number of LoA applicants and Consortium Members (thus initially disregarding number of affiliates) (186 LoAs +30 Consortium Members = 216). Apply a newly developed Excel formula to always arrive at 100% of the dossier and administrative cost despite the changing number of registrants and discounts / premiums applied (doublecheck registrants per tonnage band based on LoAs sold and REACH-IT data). Set premium of 30% for 1000t+ companies that register more than one substance and/or have more than one legal entity. It is considered that multiple legal entities and/or substances create extra work (read-across argumentation, substance identity checks, exposure information, legal entity changes, increased communication needs etc.) Apply a reduction for companies in the lower tonnage categories (price at 90 % 100t+, 80% 10t+, 60% 1t+; - in case of multiple substances covered by one LoA, each substance registration has to be below the respective tonnage category for the reduction factor to be applied). If these lower tonnage companies also have multiple legal entities / substances, a premium of 30% on the reduced price will also be applied.
- 2) Apply a reduction of 20% of the data cost on LoA applicants (for REACH-only use) for all IORC generated data as of 2017. All third party licensed data is charged through fully without reduction (E172, BASF etc.).
- 3) If consultancy cost is related to a specific endpoint (e.g., a compliance check on an Annex X endpoint) then as an exception to the rule above (see (1) dossier preparation cost) that consultancy work is only charged to that tonnage band / endpoint (it is not included in the dossier preparation amount).
- 4) Divide the data cost (with the 20% reduced) (incl. study monitoring) by the number of registrations (per legal entity) that need the data. (The total number of registrations is 460). In other words, a company that needs to have the data for 6 substances has six shares. Registrants only need to pay for the data needed for their tonnage band. Affiliates are counted as separate registrants. Under this rule, indeed, regardless of whether a registrant is an LoA applicant or is a Consortium Member, if he uses a study for 6 substances, he has to pay six times. The 80% study cost are divided through the number of total legal entities that need that study.
- 5) Continue to add the 15% advantage compensation / administrative cost on the total LoA price (including administrative cost, dossier preparation cost, data cost) to account for the substantial work of the Consortium members in relation to elaboration of the dossier (see testing substances working group, selection and submission of substances for testing, consortium meeting participation, provision of exposure and use data, pre-financing of dossier preparation and data cost for several years incl. inflation etc., risk not to recuperate cost from joint registrants; administrative cost for communication with LoA applicants over and above the initial LoA application (estimated at 2 hours per year per registrant at EUR 175 per hour).
- 6) Note: The new cost sharing rules will be applied retroactively to all LoA applicants and Consortium Members.

SIEF Communication Iron Oxides  
July 25, 2024  
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**In execution of the above:**

- (1) Please find attached the preliminary new LoA price calculations based on the currently known registrants per substance and legal entities as well as the number of LoAs / Consortium Members. Once final, existing LoA licensees will have to pay the difference between the price they previously paid and the new price. We will issue the respective invoices for payment in September for payment within 30 days.
- (2) Please proceed to link [Iron Oxides Questionnaire](#) Joint Registrants Survey that we kindly ask you to **complete by August 19, 2024**. If we do not hear back from you by that date, we shall assume that there are no changes to the LoA application that you made initially (i.e. the identity of the substances registered, the number of legal entities identified and the tonnage bands) – unless we find conflicting information on REACH-IT.

Finally, please find **attached** the new SIEF / Cooperation Agreement replacing the previous agreement that has expired.

Thank you for your attention. We look forward to hearing from you.

For further information in this regard, please contact [ReachTeam@jonesday.com](mailto:ReachTeam@jonesday.com).

Kind regards,



Ursula Schliessner

Annexes (2)



**Iron Oxides REACH Consortium: LoA price calculation for 6 substances combined**  
**Post 12 year data protection period (Post-2022) - As of July 2022**

216/460 SIEF members (July 2024)

<b>Consortium Management and Dossier Preparation(*)</b>	<b>Tonnage band</b>	<b>Budget</b>	<b>Above 1000 tons</b>	<b>100 -1000 tons</b>	<b>10 - 100 tons</b>	<b>1 - 10 tons</b>	<b>DF</b>
2009 Budget - Consortium Management	All	€ 49.600	€ 230	€ 230	€ 230	€ 230	216
2009 Budget - Dossier Preparation	All	€ 420.000	€ 1.944	€ 1.944	€ 1.944	€ 1.944	216
2010 Budget Consortium Management (excl. LoAs)	All	€ 174.100	€ 806	€ 806	€ 806	€ 806	216
2010 Budget - Dossier Preparation	All	€ 120.754	€ 559	€ 559	€ 559	€ 559	216
2011 Budget - Consortium Management & Dossier Preparation	All	€ 102.000	€ 472	€ 472	€ 472	€ 472	216
2011 Budget - Dossier Preparation	All	€ 50.000	€ 231	€ 231	€ 231	€ 231	216
2012 Budget - Consortium Management	All	€ 46.000	€ 213	€ 213	€ 213	€ 213	216
2012 Budget - Dossier Preparation	All	€ -	€ -	€ -	€ -	€ -	216
2013 Budget - Consortium Management (excl. LoAs)	All	€ 17.000	€ 79	€ 79	€ 79	€ 79	216
2013 Budget - Dossier Preparation	All	€ 50.000	€ 231	€ 231	€ 231	€ 231	216
2014 Budget - Consortium Management (excl. LoAs) (incl. reimbursement to the Iron Platform for overpaid VAT on the Pauluhn		€ 37.614	€ 174	€ 174	€ 174	€ 174	216
2014 Budget - Dossier Preparation	All	€ -	€ -	€ -	€ -	€ -	216
2015 Budget - Consortium Management	All	€ 67.000	€ 310	€ 310	€ 310	€ 310	216
2015 Budget - Dossier Preparation	All	€ 37.283	€ 173	€ 173	€ 173	€ 173	216
2016 Budget - Consortium Management	All	€ 71.400	€ 331	€ 331	€ 331	€ 331	216
2016 Budget - Dossier Preparation	All	€ -	€ -	€ -	€ -	€ -	216
2017 Budget - Consortium Management	All	€ 67.000	€ 310	€ 310	€ 310	€ 310	216
2017 Budget - Dossier Preparation	All	€ -	€ -	€ -	€ -	€ -	216
2018 Budget - Consortium Management	All	€ 77.000	€ 356	€ 356	€ 356	€ 356	216
2018 Budget - Dossier Preparation	All	€ 25.000	€ 116	€ 116	€ 116	€ 116	216
2019 Budget - Consortium Management (excl. LoAs)	All	€ 92.000	€ 426	€ 426	€ 426	€ 426	216
2019 Budget - Dossier Preparation	All	€ 104.000	€ 481	€ 481	€ 481	€ 481	216
2020 Budget - Consortium Management	All	€ 132.000	€ 611	€ 611	€ 611	€ 611	216
2020 Budget - Dossier Preparation (incl unforeseen EBRC consultancy cost for 2017-2019 testing program and revision of dossier)	All	€ 103.407	€ 479	€ 479	€ 479	€ 479	216
2021 Budget - Consortium Management	All	€ 129.000	€ 597	€ 597	€ 597	€ 597	216
2021 Budget - Dossier Preparation	All	€ 51.000	€ 236	€ 236	€ 236	€ 236	216
2022 Budget - Consortium Management	All	€ 144.000	€ 667	€ 667	€ 667	€ 667	216
2022 Budget - Dossier Preparation	All	€ 118.120	€ 547	€ 547	€ 547	€ 547	216

**Iron Oxides REACH Consortium: LoA price calculation for 6 substances combined**  
**Post 12 year data protection period (Post-2022) - As of July 2022**

**216/460 SIEF members (July 2024)**

2023 Budget - Consortium Management	All	€ 114.000	€ 528	€ 528	€ 528	€ 528	216
2023 Budget - Dossier Preparation	All	€ 105.000	€ 486	€ 486	€ 486	€ 486	216
2024 Budget - Consortium Management	All	€ 131.000	€ 606	€ 606	€ 606	€ 606	216
2024 Budget - Dossier Preparation	All	€ 30.000	€ 139	€ 139	€ 139	€ 139	216
2025 Budget - Consortium Management	All	€ 131.000	€ 618	€ 618	€ 618	€ 618	212
2025 Budget - Dossier Preparation	All	€ 160.000	€ 755	€ 755	€ 755	€ 755	212
<b>SUB-TOTAL - CONSORTIUM MANAGEMENT AND DOSSIER PREPARATION</b>		<b>€ 2.956.278</b>					

<u>DATA (*)</u>	Tonnage band	Budget	Above 1000 tons	100 -1000 tons	10 - 100 tons	1 - 10 tons	DF
2010 - Study data LANXESS - EUR 160,989; End of data protection July 15, 2022 (minus 22 registrations)	All	€ (160.989)	€ -	€ -	€ -	€ -	438
2010 - Study data Iron Platform - EUR 39,410; End of data protection July 15, 2022 (minus 22 registrations)	All	€ (39.410)	€ -	€ -	€ -	€ -	438
2010 - Expenses	All	€ 4.000	€ 19	€ 19	€ 19	€ 19	216
<b>TOTAL - 2010</b>		<b>€ (196.399)</b>	<b>€ 19</b>	<b>€ 19</b>	<b>€ 19</b>	<b>€ 19</b>	
<u>DATA</u>	Tonnage band	Budget	Above 1000 tons	100 -1000 tons	10 - 100 tons	1 - 10 tons	DF
2015 - Study data BASF - EUR 77,000; End of data protection January 1, 2028	All	€ 77.000	€ 167	€ 167	€ 167	€ 167	460
<b>TOTAL - 2015</b>		<b>€ 77.000</b>	<b>€ 167</b>	<b>€ 167</b>	<b>€ 167</b>	<b>€ 167</b>	
<u>DATA</u>	Tonnage band	Budget	Above 1000 tons	100 -1000 tons	10 - 100 tons	1 - 10 tons	DF
2017 - Study data for toxicokinetic & in vitro / in vivo genotox testing - EUR 235,000; End of data protection Sept. 3, 2032 - incl. 20% discount	All	€ 235.000	€ 409	€ 409	€ 409	€ 409	460
<b>TOTAL - 2017</b>		<b>€ 235.000</b>	<b>€ 409</b>	<b>€ 409</b>	<b>€ 409</b>	<b>€ 409</b>	
<u>DATA</u>	Tonnage band	Budget	Above 1000 tons	100 -1000 tons	10 - 100 tons	1 - 10 tons	DF
2019 - Study data for toxicokinetic & in vitro / in vivo genotox testing - EUR 20,000; End of data protection Sept. 3, 2032 - incl. 20% discount	All	€ 20.000	€ 35	€ 35	€ 35	€ 35	460
<b>TOTAL - 2019</b>		<b>€ 20.000</b>	<b>€ 35</b>	<b>€ 35</b>	<b>€ 35</b>	<b>€ 35</b>	
<u>DATA</u>	Tonnage band	Budget	Above 1000 tons	100 -1000 tons	10 - 100 tons	1 - 10 tons	DF
2022 - Study data from E172 Consortium - EUR 53,700; End of data protection period Nov 1, 2034	All	€ 53.700	€ 117	€ 117	€ 117	€ 117	460

**Iron Oxides REACH Consortium: LoA price calculation for 6 substances combined**  
**Post 12 year data protection period (Post-2022) - As of July 2022**

**216/460 SIEF members (July 2024)**

2022 - Study data from Boron (EUR 7,850); End of data protection period ____ 2034	All	€ -	€ -	€ -	€ -	€ -	460
<b>TOTAL - 2022</b>		€ 53.700	€ 117	€ 117	€ 117	€ 117	
<b>DATA</b>	<b>Tonnage band</b>	<b>Budget</b>	<b>Above 1000 tons</b>	<b>100 -1000 tons</b>	<b>10 - 100 tons</b>	<b>1 - 10 tons</b>	<b>DF</b>
2024 - New Study - First step Transwell assay and study monitoring - incl. 20% discount	All	€ 230.000	€ 1.353	€ 1.353	€ 1.353	€ -	136
<b>TOTAL - 2024</b>		€ 230.000	€ 1.353	€ 1.353	€ 1.353	€ -	
<b>DATA</b>	<b>Tonnage band</b>	<b>Budget</b>	<b>Above 1000 tons</b>	<b>100 -1000 tons</b>	<b>10 - 100 tons</b>	<b>1 - 10 tons</b>	<b>DF</b>
2025 - New Study - Second step testing and study monitoring - incl. 20% discount	All	€ 550.000	€ 3.235	€ 3.235	€ 3.235	€ -	136
2025 - New Study - Third step testing (PNDT 1) and study monitoring - incl. 20% discount	All	€ 322.500	€ 1.897	€ 1.897	€ 1.897	€ -	136
2025 - New Study - Third step testing (PNDT 2, EOGRS) and study monitoring - incl. 20% discount	All	€ 2.257.500	€ 32.836	€ -	€ -	€ -	55
<b>TOTAL - 2025</b>		€ 3.130.000	€ 37.969	€ 5.132	€ 5.132	€ -	
<b>SUB-TOTAL DATA</b>		€ 3.549.301	€ 40.068	€ 7.231	€ 7.231	€ 746	DF
Income License Agreements with Third Parties (50% of 550.001)	All	€ (275.000)	€ (598)	€ (598)	€ (598)	€ (598)	460

**Iron Oxides REACH Consortium: LoA price calculation for 6 substances combined**  
**Post 12 year data protection period (Post-2022) - As of July 2022**

216/460 SIEF members (July 2024)

TOTAL DATA		€ 3.274.301	€ 39.470	€ 6.633	€ 6.633	€ 148	
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LOA PRICE CALCULATION	Tonnage band	Budget	Above 1000 tons	100 -1000 tons	10 - 100 tons	1 - 10 tons		Above 1000 tons with extra	100 -1000 tons with extra	10 - 100 tons with extra	1 - 10 tons with extra
<b>SUB-TOTAL - CONSORTIUM MANAGEMENT AND DOSSIER PREPARATION</b>		€ 2.956.278									
Income License Agreements with Third Parties (50% of 550.001)		€ (275.000)									
<b>TOTAL - CONSORTIUM MANAGEMENT AND DOSSIER PREPARATION WITH PRICE REDUCTIONS PER TONNAGE BAND</b>		€ 2.681.278	€ 14.090	€ 12.681	€ 11.272	€ 8.454		€ 14.090	€ 12.681	€ 11.272	€ 8.454
Premium admin and dossier preparation cost (30%) for companies that register <u>more</u> than one <u>substance</u> or have <u>more</u> than one <u>legal entity</u>			€ -	€ -	€ -	€ -		€ 4.227	€ 3.804	€ 3.381	€ 2.536
<b>TOTAL - CONSORTIUM MANAGEMENT AND DOSSIER PREPARATION WITH PREMIUM (30%) (***)</b>			€ 14.090	€ 12.681	€ 11.272	€ 8.454		€ 18.317	€ 16.485	€ 14.653	€ 10.990
<b>TOTAL - CONSORTIUM MANAGEMENT AND DOSSIER PREPARATION AND DATA</b>		€ 5.955.579	€ 53.560	€ 19.314	€ 17.905	€ 8.602		€ 57.786	€ 23.118	€ 21.286	€ 11.138
Administrative/advantage compensation on all cost (15%)			€ 8.034	€ 2.897	€ 2.686	€ 1.290		€ 8.668	€ 3.468	€ 3.193	€ 1.671
<b>TOTAL WITH 15%</b>			€ 61.593	€ 22.211	€ 20.591	€ 9.892		€ 66.454	€ 26.586	€ 24.479	€ 12.809
Handling Fee			€ 1.200	€ 1.200	€ 1.200	€ 1.200		€ 1.200	€ 1.200	€ 1.200	€ 1.200
Pauluhn study license fee (end of data protection on July 15, 2022)			€ -	€ -	€ -	€ -		€ -	€ -	€ -	€ -
<b>TOTAL LOA PRICE (for one substance)</b>			€ 62.793	€ 23.411	€ 21.791	€ 11.092		€ 67.654	€ 27.786	€ 25.679	€ 14.009
Premium cost for additional substance in same tonnage band or other tonnage band (**)			[39,470]	[6,633]	[6,633]	[148]		[39,470]	[6,633]	[6,633]	[148]

(\*) Excluding extra study costs for three small substances

(\*\*) If LoA applicant buys LoA for more than one substance in the same tonnage category, this amount is charged multiple times (= data cost per substance). If LoA applicant buys LoA for more than one substance in different tonnage bands, amount per data per substance is added up.

(\*\*\*) Base prices for tonnage categories calculated on the basis of a "formula" with following parameters: a) total cost dossier preparation and admin; b) number of LoA applicants and Consortium members per tonnage band; c) number of companies per tonnage band that have additional substances/legal entities. These parameters will have to be confirmed by SIEF survey.

**Iron Oxides REACH Consortium : LoA price calculation for 6 substances combined (\*)**  
**Pre-12 year data protection period (pre-July 2022) - Before July 2022**

**216/460 SIEF members (July 2024)**

<b>Consortium Management and Dossier Preparation(*)</b>	<b>Tonnage band</b>	<b>Budget</b>	<b>Above 1000 tons</b>	<b>100 -1000 tons</b>	<b>10 - 100 tons</b>	<b>1 - 10 tons</b>	<b>DF</b>
2009 Budget - Consortium Management	All	€ 49.600	€ 230	€ 230	€ 230	€ 230	216
2009 Budget - Dossier Preparation	All	€ 420.000	€ 1.944	€ 1.944	€ 1.944	€ 1.944	216
2010 Budget Consortium Management (excl. LoAs)	All	€ 174.100	€ 806	€ 806	€ 806	€ 806	216
2010 Budget - Dossier Preparation	All	€ 120.754	€ 559	€ 559	€ 559	€ 559	216
2011 Budget - Consortium Management & Dossier Preparation	All	€ 102.000	€ 472	€ 472	€ 472	€ 472	216
2011 Budget - Dossier Preparation	All	€ 50.000	€ 231	€ 231	€ 231	€ 231	216
2012 Budget - Consortium Management	All	€ 46.000	€ 213	€ 213	€ 213	€ 213	216
2012 Budget - Dossier Preparation	All	€ -	€ -	€ -	€ -	€ -	216
2013 Budget - Consortium Management (excl. LoAs)	All	€ 17.000	€ 79	€ 79	€ 79	€ 79	216
2013 Budget - Dossier Preparation	All	€ 50.000	€ 231	€ 231	€ 231	€ 231	216
2014 Budget - Consortium Management (excl. LoAs) (incl. reimbursement to the Iron Platform for overpaid VAT on the Pauluhn study)		€ 37.614	€ 174	€ 174	€ 174	€ 174	216
2014 Budget - Dossier Preparation	All	€ -	€ -	€ -	€ -	€ -	216
2015 Budget - Consortium Management	All	€ 67.000	€ 310	€ 310	€ 310	€ 310	216
2015 Budget - Dossier Preparation	All	€ 37.283	€ 173	€ 173	€ 173	€ 173	216
2016 Budget - Consortium Management	All	€ 71.400	€ 331	€ 331	€ 331	€ 331	216
2016 Budget - Dossier Preparation	All	€ -	€ -	€ -	€ -	€ -	216
2017 Budget - Consortium Management	All	€ 67.000	€ 310	€ 310	€ 310	€ 310	216
2017 Budget - Dossier Preparation	All	€ -	€ -	€ -	€ -	€ -	216
2018 Budget - Consortium Management	All	€ 77.000	€ 356	€ 356	€ 356	€ 356	216
2018 Budget - Dossier Preparation	All	€ 25.000	€ 116	€ 116	€ 116	€ 116	216
2019 Budget - Consortium Management (excl. LoAs)	All	€ 92.000	€ 426	€ 426	€ 426	€ 426	216
2019 Budget - Dossier Preparation	All	€ 104.000	€ 481	€ 481	€ 481	€ 481	216
2020 Budget - Consortium Management	All	€ 132.000	€ 611	€ 611	€ 611	€ 611	216
2020 Budget - Dossier Preparation (incl unforeseen EBRC consultancy cost for 2017-2019 testing program and revision of dossier)	All	€ 103.407	€ 479	€ 479	€ 479	€ 479	216
2021 Budget - Consortium Management	All	€ 129.000	€ 597	€ 597	€ 597	€ 597	216
2021 Budget - Dossier Preparation	All	€ 51.000	€ 236	€ 236	€ 236	€ 236	216
2022 Budget - Consortium Management	All	€ 144.000	€ 667	€ 667	€ 667	€ 667	216
2022 Budget - Dossier Preparation	All	€ 118.120	€ 547	€ 547	€ 547	€ 547	216

**Iron Oxides REACH Consortium : LoA price calculation for 6 substances combined (\*)**

Pre-12 year data protection period (pre-July 2022) - Before July 2022

**216/460 SIEF members (July 2024)**

2023 Budget - Consortium Management	All	€ 114.000	€ 528	€ 528	€ 528	€ 528	216
2023 Budget - Dossier Preparation	All	€ 105.000	€ 486	€ 486	€ 486	€ 486	216
2024 Budget - Consortium Management	All	€ 131.000	€ 606	€ 606	€ 606	€ 606	216
2024 Budget - Dossier Preparation	All	€ 30.000	€ 139	€ 139	€ 139	€ 139	216
2025 Budget - Consortium Management	All	€ 131.000	€ 618	€ 618	€ 618	€ 618	212
2025 Budget - Dossier Preparation	All	€ 160.000	€ 755	€ 755	€ 755	€ 755	212
<b>SUB-TOTAL - CONSORTIUM MANAGEMENT AND DOSSIER PREPARATION</b>		<b>€ 2.956.278</b>					

<u>DATA (*)</u>	Tonnage band	Budget	Above 1000 tons	100 -1000 tons	10 - 100 tons	1 - 10 tons	DF
2010 - Study data LANXESS - EUR 160,989; End of data protection July 15, 2022 (minus 22 registrations)	All	€ 160.989	€ 368	€ 368	€ 368	€ 368	438
2010 - Study data Iron Platform - EUR 39,410; End of data protection July 15, 2022 (minus 22 registrations)	All	€ 39.410	€ 90	€ 90	€ 90	€ 90	438
2010 - Expenses	All	€ 4.000	€ 19	€ 19	€ 19	€ 19	216
<b>TOTAL - 2010</b>		<b>€ 204.399</b>	<b>€ 476</b>	<b>€ 476</b>	<b>€ 476</b>	<b>€ 476</b>	
<u>DATA</u>	Tonnage band	Budget	Above 1000 tons	100 -1000 tons	10 - 100 tons	1 - 10 tons	DF
2015 - Study data BASF - EUR 77,000; End of data protection January 1, 2028	All	€ 77.000	€ 167	€ 167	€ 167	€ 167	460
<b>TOTAL - 2015</b>		<b>€ 77.000</b>	<b>€ 167</b>	<b>€ 167</b>	<b>€ 167</b>	<b>€ 167</b>	
<u>DATA</u>	Tonnage band	Budget	Above 1000 tons	100 -1000 tons	10 - 100 tons	1 - 10 tons	DF
2017 - Study data for toxicokinetic & in vitro / in vivo genotox testing - EUR 235,000; End of data protection Sept. 3, 2032 - incl. 20% discount	All	€ 235.000	€ 409	€ 409	€ 409	€ 409	460
<b>TOTAL - 2017</b>		<b>€ 235.000</b>	<b>€ 409</b>	<b>€ 409</b>	<b>€ 409</b>	<b>€ 409</b>	
<u>DATA</u>	Tonnage band	Budget	Above 1000 tons	100 -1000 tons	10 - 100 tons	1 - 10 tons	DF
2019 - Study data for toxicokinetic & in vitro / in vivo genotox testing - EUR 20,000; End of data protection Sept. 3, 2032 - incl. 20% discount	All	€ 20.000	€ 35	€ 35	€ 35	€ 35	460
<b>TOTAL - 2019</b>		<b>€ 20.000</b>	<b>€ 35</b>	<b>€ 35</b>	<b>€ 35</b>	<b>€ 35</b>	
<u>DATA</u>	Tonnage band	Budget	Above 1000 tons	100 -1000 tons	10 - 100 tons	1 - 10 tons	DF
2022 - Study data from E172 Consortium - EUR 53,700; End of data protection period Nov 1, 2034	All	€ 53.700	€ 117	€ 117	€ 117	€ 117	460

**Iron Oxides REACH Consortium : LoA price calculation for 6 substances combined (\*)**

Pre-12 year data protection period (pre-July 2022) - **Before July 2022**

**216/460 SIEF members (July 2024)**

2022 - Study data from Boron (EUR 7,850); End of data protection period ____ 2034	All	€ -	€ -	€ -	€ -	€ -	460
<b>TOTAL - 2022</b>		€ 53.700	€ 117	€ 117	€ 117	€ 117	
<b>DATA</b>	<b>Tonnage band</b>	<b>Budget</b>	<b>Above 1000 tons</b>	<b>100 -1000 tons</b>	<b>10 - 100 tons</b>	<b>1 - 10 tons</b>	<b>DF</b>
2024 - New Study - First step Transwell assay and study monitoring - incl. 20% discount	All	€ 230.000	€ 1.353	€ 1.353	€ 1.353	€ -	136
<b>TOTAL - 2024</b>		€ 230.000	€ 1.353	€ 1.353	€ 1.353	€ -	
<b>DATA</b>	<b>Tonnage band</b>	<b>Budget</b>	<b>Above 1000 tons</b>	<b>100 -1000 tons</b>	<b>10 - 100 tons</b>	<b>1 - 10 tons</b>	<b>DF</b>
2025 - New Study - Second step testing and study monitoring - incl. 20% discount	All	€ 550.000	€ 3.235	€ 3.235	€ 3.235	€ -	136
2025 - New Study - Third step testing (PNDT 1) and study monitoring - incl. 20% discount	All	€ 322.500	€ 1.897	€ 1.897	€ 1.897	€ -	136
2025 - New Study - Third step testing (PNDT 2, EOGRTS) and study monitoring - incl. 20% discount	All	€ 2.257.500	€ 32.836	€ -	€ -	€ -	55
<b>TOTAL - 2025</b>		€ 3.130.000	€ 37.969	€ 5.132	€ 5.132	€ -	
<b>SUB-TOTAL DATA</b>		€ 3.950.099	€ 40.525	€ 7.689	€ 7.689	€ 1.204	<b>DF</b>
Income License Agreements with Third Parties (50% of 550.001)	All	€ (275.000)	€ (598)	€ (598)	€ (598)	€ (598)	460

**Iron Oxides REACH Consortium : LoA price calculation for 6 substances combined (\*)**

Pre-12 year data protection period (pre-July 2022) - **Before July 2022**

216/460 SIEF members (July 2024)

TOTAL DATA		€ 3.675.099	€ 39.927	€ 7.091	€ 7.091	€ 606	
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<u>LOA PRICE CALCULATION</u>	Tonnage band	Budget	Above 1000 tons	100 -1000 tons	10 - 100 tons	1 - 10 tons		Above 1000 tons with extra	100 -1000 tons with extra	10 - 100 tons with extra	1 - 10 tons with extra
<b>SUB-TOTAL - CONSORTIUM MANAGEMENT AND DOSSIER PREPARATION</b>		€ 2.956.278									
Income License Agreements with Third Parties (50% of 550.001)		€ (275.000)									
<b>TOTAL - CONSORTIUM MANAGEMENT AND DOSSIER PREPARATION WITH PRICE REDUCTIONS PER TONNAGE BAND</b>		€ 2.681.278	€ 14.090	€ 12.681	€ 11.272	€ 8.454		€ 14.090	€ 12.681	€ 11.272	€ 8.454
Premium admin and dossier preparation cost (30%) for companies that register <u>more</u> than one <u>substance</u> or have <u>more</u> than one <u>legal entity</u>			€ -	€ -	€ -	€ -		€ 4.227	€ 3.804	€ 3.381	€ 2.536
<b>TOTAL - CONSORTIUM MANAGEMENT AND DOSSIER PREPARATION WITH PREMIUM (30%) (***)</b>			€ 14.090	€ 12.681	€ 11.272	€ 8.454		€ 18.317	€ 16.485	€ 14.653	€ 10.990
<b>TOTAL - CONSORTIUM MANAGEMENT AND DOSSIER PREPARATION AND DATA</b>		€ 6.356.377	€ 54.017	€ 19.772	€ 18.363	€ 9.060		€ 58.244	€ 23.576	€ 21.744	€ 11.596
Administrative/advantage compensation on all cost (15%)			€ 8.103	€ 2.966	€ 2.754	€ 1.359		€ 8.737	€ 3.536	€ 3.262	€ 1.739
<b>TOTAL WITH 15%</b>			€ 62.120	€ 22.737	€ 21.117	€ 10.418		€ 66.981	€ 27.112	€ 25.006	€ 13.335
Handling Fee			€ 1.200	€ 1.200	€ 1.200	€ 1.200		€ 1.200	€ 1.200	€ 1.200	€ 1.200
Pauluhn study license fee (end of data protection on July 15, 2022)			€ 5.845	€ 5.846	€ 1.724	€ -		€ 5.845	€ 5.846	€ 1.724	€ -
<b>TOTAL LOA PRICE (for one substance)</b>			€ 69.165	€ 29.783	€ 24.041	€ 11.618		€ 74.026	€ 34.158	€ 27.930	€ 14.535
Premium cost for additional substance in same tonnage band or other tonnage band (**)			[39,927]	[7,091]	[7,091]	[606]		[39,927]	[7,091]	[7,091]	[606]

(\*) Excluding extra study costs for three small substances

(\*\*) If LoA applicant buys LoA for more than one substance in the same tonnage category, this amount is charged multiple times (= data cost per substance). If LoA applicant buys LoA for more than one substance in different tonnage bands, amount per data per substance is added up.

(\*\*\*) Base prices for tonnage categories calculated on the basis of a "formula" with following parameters: a) total cost dossier preparation and admin; b) number of LoA applicants and Consortium members per tonnage band; c) number of companies per tonnage band that have additional substances/legal entities. These parameters will have to be confirmed by SIEF survey.



**Cooperation Agreement for REACH compliance after May 31, 2018  
Applicability as of January 1, 2023**

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

LANXESS Deutschland GmbH, Germany, as Lead Company under the IORC Consortium for REACH registration of six iron oxide substances (hereafter the "**Consortium**"), acting in the name and on behalf of all members of the Consortium and having previously been appointed as Lead Registrant for the registration of the six substances (hereinafter referred to as "**Lead Registrant**")

and

The joint registrant (not being a Consortium member) signatory to the present Agreement (hereinafter referred to as "**Joint Registrant**")

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

**Preamble**

Whereas the Lead Registrant submitted a joint registration dossier and successfully registered six iron oxides, namely

- IRON HYDROXIDE OXIDE YELLOW EC 257-098-5 (SYNONYMS 243-746-4; 215-176-6);
- TRIIRON TETRAOXIDE EC 215-277-5 (SYNONYMS 235-442-5; 215-169-8);
- DIIRON TRIOXIDE EC 215-168-2 (SYNONYMS 215-570-8; 215-275-4);
- IRON MANGANESE (TRI)OXIDE EC 235-049-9;
- MANGANESE FERRITE EC 269-056-3; and
- ZINC FERRITE EC 269-103-8

(as further defined herein to as "**Substances**") before the European Chemicals Agency ("**Agency**") in accordance with Article 10 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**") in 2010;

Whereas numerous legal entities either as Consortium members or by purchasing a letter of access joined the joint registration;

Whereas the Parties to this Agreement agreed on the identity and the sameness of the Substances and were thus participants of the same Substance Information Exchange Fora ("SIEF") as registrants for these Substances under the meaning of Article 29 of REACH;

Whereas for that purpose the Parties concluded a SIEF Agreement on September 29, 2010 with end date December 31, 2022;

Whereas, pursuant to Article 29(3) REACH, SIEFs shall only be operational until June 1, 2018;

Cooperation Agreement for REACH - IORC

Whereas, REACH registration dossiers must be updated from time to time and whereas the Substances may be subject to further regulatory scrutiny, including substance evaluation, by the Agency or Member States;

Whereas, further future Joint Registrants may wish to join the joint registration of the Substances;

Whereas, therefore the cooperation of the Lead Registrant and the Joint Registrants should continue beyond December 31, 2022;

Whereas, the cooperation of the Lead Registrant and the Joint Registrants under the SIEF Agreement was smooth and the principles of the former cooperation under the SIEF Agreement should therefore be maintained where legally possible;

Whereas the Parties agree that the principles of the joint submission of data set out in the SIEF Agreement will continue to apply to the current Agreement;

Whereas the Parties acknowledge that their cooperation should reflect the changes brought in particular by Commission Implementing Regulation (EU) 2016/9 of 5 January 2016 on joint submission of data and data-sharing in accordance with REACH (hereinafter referred to as the “**Implementing Regulation 2016/9**”), Commission Regulation (EU) 2018/1881 of 3 December 2018 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annexes I, III, VI, VII, VIII, IX, X, XI, and XII to address nanoforms of substances, and Commission Implementing Regulation (EU) 2020/1435 of October 2020 on the duties placed on registrants to update their registrations under Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH);

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

Whereas REACH requires existing Joint Registrants and/or potential Joint 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 after the last registration deadline of May 31, 2018 set out in Article 23(3) of REACH in respect to the Substances,

THE PARTIES HAVE AGREED UPON THE FOLLOWING AGREEMENT:

#### **Article I. Scope and General Obligations**

1. The current Agreement replaces the existing SIEF Agreement, which is set out in its entirety as **Annex 1** hereto. However, the Parties shall continue to apply the following terms, conditions and principles laid down in the SIEF Agreement, which become an integral part of the present Agreement, in particular:

- (i) 1. Definitions;
- (ii) 2. Scope;
- (iii) 3. General Rules of Cooperation;
- (iv) 4. Cost Sharing;
- (v) 5. Miscellaneous provisions.

#### **Article II. Compliance**

The following shall be added at the end of 5. (c) of the SIEF Agreement:

The Parties explicitly agree to observe the Implementing Regulation 2016/9 and Section 7 (Information sharing under competition rules) of the ECHA Guidance on data-sharing (Version September 2020), as may be adapted from time to time.<sup>1</sup>

Each Party shall, with respect to such Party's activities in relation to this Agreement, comply with all applicable laws and regulations, including 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 laws and regulations. No Party shall be required to indemnify another Party with regard to legal compliance.

### **Article III. Participation in the joint submission of data by multiple registrants**

The following new point (h) shall be added at the end of 3. of the SIEF Agreement:

- (i) The Lead Registrant shall settle any inquiry or regulatory scrutiny of ECHA 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 Substances 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 Joint Registrants or if there could be a critical impact to the uses of the Substances (e.g. classification, risk management issues, etc.) the Lead Registrant shall inform the Joint Registrants promptly of any inquiry or regulatory scrutiny of ECHA 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 a Joint Registrant 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 Joint Registrants.

### **Article IV. Financial compensation for the Joint Registration Dossier**

The following new language is added at the end of 4. (e) of the SIEF Agreement:

This includes new studies that have to be purchased or performed or other dossier preparation, administrative or other cost engaged after conclusion of this Agreement due to regulatory scrutiny or inquiries of ECHA, other competent authorities, or third parties, or due to requirements pursuant to Article 22(1)(e) of REACH. The resulting costs will be equally divided between all Joint Registrants who are required to incorporate the new information into the Joint Registration Dossiers. For the avoidance of doubt this means, i.e. if ECHA requests a Study only for one Substance or only for the nano form or a particular nano form of a Substance, only those Members that have registered or will register that Substance or the nano form or that nano form as the case may be and that require the Study within their tonnage band equally share that new Study's cost. The same shall apply to consultancy and management expenses related to the update of registration dossiers of such Substance or its nano form or particular nano form pursuant to such Study request and dossier updates of Substances in their nano form or particular nano form in general.

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<sup>1</sup> [https://echa.europa.eu/documents/10162/23036412/guidance\\_on\\_data\\_sharing\\_en.pdf/545e4463-9e67-43f0-852f-35e70a8ead60](https://echa.europa.eu/documents/10162/23036412/guidance_on_data_sharing_en.pdf/545e4463-9e67-43f0-852f-35e70a8ead60)

### **Article V. Term and termination**

This Agreement shall be in force for as long as there is a valid Joint Registration for one of the Substances. The Lead Registrant shall be entitled to terminate this Agreement at any time with prior written notice of one month if he is no longer subject to registration obligations in relation to any or one of the Substances.

### **Article VI. Annexes**

1. The SIEF Agreement shall be set out as **Annex 1** to this Agreement.
2. A new **Annex 2** to this Agreement with the Substance Identity Profile and classification and labelling shall be added. The Lead Registrant may amend this **Annex 2** unless a simple majority of the Joint Registrants expressly objects.
3. A new **Annex 3** to this Agreement is added with the identity of the Project Manager. The Project Manager is Jones Day, Rue de la Régence 4, 1000 Brussels, Belgium.
4. **Annex 2** of the SIEF Agreement laying down the LoA cost calculation shall be replaced by the LoA price calculations periodically published on [www.jonesdayreach.com](http://www.jonesdayreach.com).
5. Since the Letter of Access pricing mechanism has been running smoothly since submission of the Joint Registration Dossier, the Lead Registrant shall reserve its right set out Article 4(5) of the Implementing Regulation 2016/9 not to amend this model. The Joint Registrants will be provided with a detailed list of studies and related costs upon request.

### **Article VII. Miscellaneous**

The Parties shall be validly bound by this Agreement when the Joint Registrant has either given its consent to this Agreement through the communication IT Platform through which the letters of access are issued, or by signing it, or by paying letters of access; or by not expressly objecting to the Agreement within 30 days of its issuance.

The parties to this Agreement consent to the use of electronic signatures via DocuSign to execute this Agreement. The Parties agree that such electronic signatures shall be considered as original signatures for purposes of this Agreement.

THE PARTIES BY THEIR DULY AUTHORIZED REPRESENTATIVES, SIGN THIS AGREEMENT

#### **For The Joint Registrant**

Name of legal entity:

Street:

ZIP-Code :

City:

Country:

Contact Name:

Contact Email:

Place:

Date:

signed by:

\_\_\_\_\_

**LANXESS Deutschland GmbH** in the name and on behalf of all members of the Consortium

*/s/ i.V. Dr. Krzysztof Chlopek*

*/s/ i.V. Dr. Carola Harbauer*

\_\_\_\_\_

\_\_\_\_\_

15 July 2024

15 July 2024

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APPENDIX 3

**Annex 1****SIEF and Joint Submission AGREEMENT****September 29, 2010****Iron Oxides****1. Definitions**

- (a) *Advantage Compensation* shall mean a fee that covers general costs incurred by the Parties to the Consortium Agreement in relation to their initiative, commitment and any other preliminary performance within the Consortium and for the purposes of preparing the Joint Registration Dossier, such as substantiated and reasonable travel costs, manpower allocated to the work in the Consortium, etc.
- (b) *Affiliate(s)* shall mean a corporation, which controls, is controlled by or is under common control with a Party, with control meaning at least 50% of the voting rights directly or indirectly owned. Unless provided otherwise, when referring to Affiliates in the context of this Agreement it is understood that this also comprises any Only Representative acting on behalf of a non-EU Affiliate of a Party. The corporations named in this Agreement are to be considered as Affiliates of Parties who have obligations to register the Substance(s).
- (c) *Consortium* shall mean the members of the Iron Oxides REACH Consortium (established by the *Consortium Agreement* of 2009), of which Lanxess Deutschland GmbH is a member.
- (d) *Information* shall mean all studies, other scientific, statistical, or technical information or data, including but not limited to composition, characteristics, properties, processes and applications, and any other information in whatever form made available by a Party or generated by the Parties jointly, or licensed by or made available to the Consortium by third parties pursuant to or within the remit of this SIEF Agreement.
- (e) *LoA(s)* shall mean a letter of access to the Joint Registration Dossier granted by the Consortium to individual Parties and as attached as Annex 1 to this SIEF Agreement. The LoA entitles the Party (and its Affiliates) on a non-exclusive basis to refer to the information submitted to ECHA by the Lead Registrant for purposes of REACH registration, but it does not grant any additional rights except those specifically stated therein. In particular, it cannot be used, or transferred or relied upon, either for REACH or for any other purpose, by other legal entities, including affiliates of the Parties other than those named in the SIEF Agreement, unless those other legal entities would qualify for a free update of the original registration(s) pursuant to Article 5 (1) (c) of Commission Regulation (EC) No 340/2008.
- (f) *Party* or *Parties* shall mean the parties to this SIEF Agreement who have *either* (i) signed this SIEF Agreement, and/or have paid for the LoA as laid down in 4, *or* (ii) following notification of this Agreement, have not communicated to the Lead Registrant their objection to become a member of the SIEF Agreement pursuant to 5.(k) and are not listed as 'inactivated' pre-registrants in REACH-IT.
- (g) *Joint Registration Dossier(s)* shall cover the joint mandatory (Article 10 (a) (iv), (vi), (vii) and (ix) REACH) and joint voluntary (Article 10 (a) (v), and (b) REACH) parts of the REACH Registration Dossier for the Substance(s). The Joint Registration Dossier(s) covers IUCLID core data for the data requirements for more than 1000 tonnes and the hazard

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assessment for the Chemical Safety Report(s) for the uses previously identified by the Consortium, as well as guidance on safe use.

- (h) *Project Manager* shall mean an external consultancy responsible for the daily management of the Consortium (e.g. financial issues) engaged by the Consortium members. The current project manager is McKenna Long & Aldridge LLP.
- (i) *REACH* shall mean Regulation (EC) No 1907/2006 and all subsequent Regulations, Decisions, and other measures adopted in connection thereto.
- (j) *Substance(s)* shall mean the substance(s) listed in 2.(a) of this SIEF Agreement.
- (k) All other terms used herein shall have the same meaning as under REACH.

## 2. Scope

- (a) This SIEF Agreement covers the following substances, either by themselves, as part of multi-constituent substances, or as intermediates:

1) **Iron hydroxide oxide – Yellow**

- EC 257-098-5
- CAS 51274-00-1

2) **Triiron tetraoxide**

- EC 215-277-5
- CAS 1317-61-9

3) **Diiron trioxide**

- EC 215-168-2
- CAS 1309-37-1

4) **Iron manganese (tri)oxide**

- EC 235-049-9
- CAS 12062-81-6

5) **Manganese ferrite (black spinel)**

- EC 269-056-3
- CAS 68186-94-7

6) **Zinc ferrite (brown spinel)**

- EC 269-103-8
- CAS 68187-51-9

The Parties have agreed in previous communications on the identity and sameness of the Substances and are thus members of the same SIEF.

- (b) This SIEF Agreement is applicable to all communications, actions and submissions made by the Parties individually or jointly within the scope of REACH in as far as these fall within the remit of SIEFs pursuant to Article 29 REACH.

#### 4. Cost Sharing

The price for the LoA is calculated by taking into account management and administration expenses, costs for existing and new data, costs for the preparation of IUCLID by the Lead Registrant, costs for preparing the Chemical Safety Report and guidance on safe use, and handling fees, *as follows*:

##### (a) Joint Registration Dossier Preparation

###### (i) Expenses

The expenses incurred to manage the Consortium and to prepare the Joint Registration Dossier are set out in Annex 2, as may be amended from time to time by the Project Manager..

###### (ii) Existing and new data

The total value of the data is set out in Annex 2 hereto, whereby for the so-called Pauluhn study, the price is separately fixed per LoA at € 10.375 through a License Agreement with another consortium (the so-called HPV consortium) the members of which co-own the Pauluhn study. This license agreement provides that should more than 100 companies request this study, the price will be proportionally reduced.

###### (iii) Chemical Safety Report ("CSR") and guidance on safe use

The cost for the preparation of the CSR (including the hazard assessment and summaries) and the guidance on safe use part of the Joint Registration Dossier will be shared equally by all Parties..

##### (b) LoA Price Determination

The total amount of (a) above will initially be divided by 30 (number of Consortium members at the time of issuance of this SIEF Agreement, i.e. minimum number of expected registrants of the Substances) to determine the LoA price per Party requesting an LoA. The price so determined will constitute the net 2010 LoA price. If more than 30 registrants register by November 30, 2010, any over-payment collected will be reimbursed to all 2010 1000t registrants thereafter. 1000t and above registrants that register after the 2010 registration deadline will pay the same as those registrants in the same tonnage category that register by November 30, 2010 and will be reimbursed their over-payment, if any, after the 2013 registration deadline has passed.

The price for registrants in the 100-999t category will be calculated mid 2011 based on the declared firm license LoA intentions received by the Project Manager by mid-2011. Any payments collected from those registrants will be reimbursed to the 1000t registrants that have previously registered, after the 2013 registration deadline has passed.

The price for registrants below 100t will be set by the Consortium later based on whether new studies will be conducted after 2010 and how many registrants will register in the higher tonnage categories.



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- (c) This SIEF Agreement is applicable to all members of the SIEF (including the members of the Consortium) of the Substances. Consortium members are represented for purposes of this SIEF Agreement by the Lead Registrant.

### **3. General Rules of Cooperation**

- (a) The Parties agree that Lanxess Deutschland GmbH or its legal successor or another SIEF member assigned by it pursuant to 5. (f) below will act as the Lead Registrant for the Substances and will prepare, within the framework of the Consortium, the Joint Registration Dossiers for REACH registration of the Substances as and in as far as required, and make requests pursuant to Article 10 (a) (xi) REACH as deemed necessary. Upon demand of ECHA, within the requested deadline and to the extent necessary, the Lead Registrant also agrees to complete the Joint Registration Dossiers. Parties that are not members of the Consortium will participate in the joint registration efforts via (g) below in conjunction with a LoA to be granted according to this SIEF Agreement.
- (b) The Joint Registration Dossier will be prepared in time using all reasonable efforts so that Parties can meet the November 30, 2010 registration deadline.
- (c) In view of the tight work schedule, the Parties agree that the Lead Registrant will use its reasonable efforts to develop the Joint Registration Dossiers within the Consortium, and they acknowledge that the Lead Registrant has engaged reputable support to assist it in its efforts. The Parties will therefore not object or call into question the Joint Registration Dossiers so prepared in as far as applicable to them, and the Parties hereby agree to the Joint Registration Dossiers as developed by the Lead Registrant within the Consortium.
- (d) The Lead Registrant undertakes in turn to regularly update the Parties in writing on the progress made on the Joint Registration Dossiers as applicable to the Parties. The Lead Registrant may ask for cooperation and comments as it sees fit.
- (e) The Lead Registrant shall pay the registration fee pursuant to Article 11 (4) REACH as invoiced by ECHA for the submission of the Joint Registration Dossier without undue delay.
- (f) The Lead Registrant shall make the Joint Registration Dossiers available for inspection by the Parties at the premises of its Project Manager McKenna Long & Aldridge LLP, Avenue de Tervueren 2, 1040 Brussels, Belgium, for a two weeks period, probably October 4 – October 18, 2010 during office hours. Any Party joining the SIEF after the inspection period is entitled to inspect the Joint Registration Dossier after having taken an appointment with the Project Manager.
- (g) Provided the Party has fulfilled its payment obligations hereunder, the Lead Registrant shall inform the Party of the creation of a ‘joint submission object’ in REACH-IT and shall provide the valid security token number and the name of the joint submission. The Lead Registrant shall also inform the Parties of the submission of the Joint Registration Dossier to ECHA. The Lead Registrant shall further communicate the confirmation that the Joint Registration Dossier has been accepted as ‘complete’ and the registration number assigned pursuant to Article 20 (3) REACH.

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(c) Advantage Compensation

In addition, there is a fee for Advantage Compensation which is 15% of the net LoA price calculated under (b) above but excluding the Pauluhn study.

(d) Handling fee

The fee for handling the LoA request and the joint submission is expected to be € 1,200 per LoA.

(e) Update of the Joint Registration Dossier after submission of the Joint Registration Dossier in 2010

Any cost for Studies requested by ECHA after the Joint Registration Dossier has been submitted shall be allocated in equal parts to those Members who need the Studies, *i.e.* if ECHA requests a Study only for one Substance, only those Members that have registered **or will register** that Substance and that require the Study within their tonnage band equally share that new Study's cost. Any future expenses to manage the Consortium during the registration and LoA issuing procedures and other additional unexpected costs that might arise through further requirements from ECHA after registration can be charged to all Parties in equal shares later, unless the expenses relate to specific Substances, in which case the special rule above will apply.

(f) Other Rules

The Lead Registrant or the Project Manager will calculate the price of the LoA by September 30, 2010 and will issue a proforma invoice or payment notice accordingly to be paid within 30 days of issuance by each Party; following payment, the joint submission tokens will be issued. Formal invoices will be issued after the respective registration deadlines, and for the first time after November 30, 2010. In case the amounts received from the proforma invoices and payment notices are not sufficient to cover the cost, tokens will only be issued after receipt of the amounts from the final invoices. Should new studies have to be purchased or performed as deemed necessary by the Consortium or pursuant to ECHA's request, or technical responses to ECHA be necessary after registration, the Lead Registrant or the Project Manager will issue instructions to issue additional invoices to be paid under the same terms if the cost cannot be covered by the fees already collected. No interest shall be applicable in either case on both sides. However, a Party that does not pay an invoice or payment notice within the 30 days of issuance shall at no time be entitled to participate in the joint submission and receive an LoA, or its LoA and permission to participate in the joint submission shall be considered as revoked. The final settlement shall be handled by an independent auditor appointed by the Lead Registrant on June 1, 2022.

The Lead Registrant or the Project Manager will issue LoAs after receipt of a Party's payment and after the Party has had the option to inspect the Joint Registration Dossier as far as it is concerned by it pursuant to 3. (f).

The Lead Registrant or the Project Manager shall at all times account for the cost of the Joint Registration Dossier and shall keep records thereof for the duration of this SIEF Agreement. Any Party shall have the right to have the accounts audited at its own cost upon prior notice of at least five working days.

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**5. Miscellaneous Provisions**

- (a) *Assignment.* This SIEF Agreement is linked to the joint registration obligations of REACH and can therefore not be assigned or transferred by the Parties without prior approval of the Lead Registrant unless the assignee is an Affiliate or successor in law subject to REACH registration of the Substance(s), or is an Only Representative or Third Party Representative replacing a previous Only Representative or Third Party Representative of the same principal and the assignment/transfer has been communicated to the Lead Registrant or its Trustee.
- (b) *Communications.* All communications within the framework of this SIEF Agreement shall be done by electronic mail and shall be considered valid upon receipt of an automatic confirmation of receipt received by the sender. The Lead Registrant or the Project Manager shall install an email address or other electronic platform for communication within the SIEF. The parties agree to regularly and proactively communicate within this platform provided, and to answer any information and communication requests of the Lead Registrant within five working days at the latest unless the Lead Registrant expressly provides a longer response time. Unless other contact details are indicated below, the contact details available in REACH-IT shall be used at all times. The Parties shall at all times keep their REACH-IT contact details updated and functional. In case the REACH-IT contact details of a Party are not functional and no other valid and functional contact information has been provided below, the Lead Registrant shall be considered as released from any obligations under this SIEF Agreement.
- (c) *Compliance.* The Parties shall at all times comply with the applicable laws, including EU competition law. The Lead Registrant has used its best efforts to acquire use/referral rights for all key and supporting studies used in the Joint Registration Dossier including for all members of the joint submission. Independent from this Agreement, Parties assert to observe copyrights and access rights of the public domain literature used for the Joint Registration Dossier required for their respective registration purposes under REACH in sufficient time before the submission of their respective individual dossier to ECHA. The Lead Registrant will provide Parties with a list of key and supporting studies and the respective ownership. After this Agreement has been signed and the payment obligation has been fulfilled, the access right to the key and supporting studies owned by the Consortium members individually or jointly is considered as granted. Parties will fully indemnify Lead Registrant in the event Parties have no sufficient access or copyrights to refer to all required key and supporting studies.
- (d) *Confidentiality and Non-Use.* Each Party agrees to: (i) treat all Information as confidential and not disclose it to third parties, unless regulatory disclosure requirements are applicable; (ii) immediately advise the other Parties in writing of any disclosure or misuse by any Party or a third party of Information, as well as any request by competent authorities relating to disclosure of Information; (iii) disclose Information as required for legal and/or regulatory purposes including for purposes of REACH only in a form reflecting the minimum information required to be disclosed; (iv) use the Information only for purposes and as permitted hereunder; (v) not to analyze, test or reverse engineer or have analyzed, tested or reverse engineered any samples, formulas, combination of formulas or any technical or scientific methodology, chemistry or know-how provided by any of the Parties for their components, formulations or processes; (vi) not to file any patent, utility model or design application based upon Information or samples; and (vii) not to disclose Information to their employees, Affiliates, external experts and/or other consultants; unless the Party is an Only Representative or Third Party representative to the non-EU manufacturer or legal entity

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represented by the Third Party Representative, in which case it should only disclose Information on a strictly need-to-know basis to the extent permitted and absolutely necessary hereunder. Each Party shall have in place policies and procedures to ensure compliance herewith and shall ensure that the aforementioned entities and persons also have such policies and procedures in place.

The confidentiality and non-disclosure obligations above shall not apply to Information for which the receiving Party can reasonably demonstrate that such Information (i) was known to the receiving Party on a non-confidential basis prior to its disclosure pursuant to this SIEF Agreement; (ii) is publicly known at the time of disclosure or thereafter becomes publicly known without breach of the terms of this SIEF Agreement on the part of the receiving Party; (iii) becomes known to the receiving Party through disclosure by sources other than the disclosing Party, having a right to disclose such Information; (iv) was independently developed by the receiving Party without access to the disclosing Party's information, as evidenced by documentary records; *or* (v) becomes subject to disclosure to governmental authorities with lawful authority to seek such Information.

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.

The obligations on confidentiality and non-use shall remain in effect and shall survive the duration of this SIEF Agreement. In the event of non-compliance with the duties here above, Parties are entitled to exclude the breaching Party from any further cooperation hereunder by decision of the Consortium. The obligation to render compensation for damages in accordance with the applicable legal provisions shall remain unaffected.

- (e) *Dispute resolution and applicable law.* Any dispute hereunder that cannot be settled amicably shall be resolved by arbitration with a single arbitrator to be appointed by the Brussels Bar. The arbitration rules of the International Court of Arbitration ("ICC") shall be applicable. The arbitration decision, including on the payment of the cost of arbitration, shall be binding on the Parties. The place of any hearing shall be Brussels and the language of the arbitration shall be English. Belgian law shall govern this SIEF Agreement. If at any time any provision of this SIEF Agreement is or becomes invalid or illegal in any respect, this shall have no effect on the validity of the remainder of this SIEF Agreement. The invalid provisions are to be replaced retroactively by provisions which come closest to achieving the objectives.
- (f) *Duration and Termination.* This SIEF Agreement shall be in force until December 31, 2022, although its provisions under 5. (d), (e) and (h) shall survive its term indefinitely. Furthermore, the confidentiality obligations related to studies shall survive for 12 years after their first submission to ECHA, and all other confidentiality obligations shall survive until June 1, 2023.

The Lead Registrant has the right to terminate its functions as Lead Registrant provided another SIEF member has validly agreed to replace it within the SIEF, has agreed to the terms of this SIEF Agreement, and has taken up its functions accordingly. The other Parties must be informed about this replacement without undue delay.

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Parties have the right to terminate this SIEF Agreement at the latest by October 15, 2010. The provisions under 5. (d), (e) and (h) shall survive termination as specified above.

- (g) *Individual Responsibility.* Notwithstanding the cooperation within this SIEF Agreement, the Parties and their Affiliates remain individually responsible for compliance with REACH, in particular, but not limited to, their individual submission of information required under Article 11 (1) REACH.
- (h) *Liability.* The Lead Registrant shall only be liable to the other Parties in connection with the activities contemplated in this SIEF Agreement, including delays in the completion and submission of the Joint Registration Dossier, in case of gross negligence or wilful misconduct. He shall not be liable for consequential damage and lost profits. This limitation of liability does not apply in case of claims for death, personal injury or wilful misconduct. No warranty for acceptance of the Joint Registration Dossier or Information it contains, or acceptance of a study by ECHA at dossier evaluation (according to Title VI REACH) is given.
- (i) *Payments.* 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. 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.
- (j) *Rights.* This SIEF Agreement does not grant any ownership rights or change existing ownership rights to any of the Information provided under this SIEF Agreement to the Parties. Neither this SIEF 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. No legal entity or partnership for legal or tax purposes is created under this SIEF Agreement. The Parties are themselves responsible for any fiscal payments and declarations related to the working of this SIEF Agreement.
- (k) *Validity / Entry into Effect.* This SIEF Agreement enters into effect between the Lead Registrant and the respective Party by (i) the Party filling in the required information below and returning a signed PDF copy of this SIEF Agreement; *and/or* (ii) payment by the Party for the LoA, *or* (iii) the non-objection by the SIEF member to become a Party to this SIEF Agreement, *provided that* not more than half of the SIEF members have communicated their objection to this Agreement by October 15, 2010.

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**COMPANY - SIEF Member:**

\_\_\_\_\_

(Print company name and address)

**(NON-EU/EEA) COMPANIES REPRESENTED:**

\_\_\_\_\_

(In case the Party is an Only Representative (“OR”); indicate here the names of all the affiliated companies of one group represented by the OR to which this SIEF Agreement should be applicable; In case the OR has pre-registered for several groups of companies, he must sign separate SIEF Agreements for each of the groups; Likewise, if a Third Party Representative (“TPR”)<sup>1</sup> represents several independent companies for the Substance(s), he must sign separate SIEF agreements for each of the independent companies represented)

**AUTHORIZED REPRESENTATIVE:**

\_\_\_\_\_

(Print name of Representative authorized to sign this SIEF Agreement)

**SIGNATURE:**

\_\_\_\_\_

(Signature of Authorized Representative)

**Registration scope by group, *i.e.* affiliated companies together (take highest applicable tonnage band in the group total):**

- A: Tonnage band < 100 t
- B: Tonnage band 100 – 1,000 t
- C: Tonnage band > 1,000 t

**CONTACT INFORMATION:**

\_\_\_\_\_

(Print contact details for person responsible for SIEF communication)

<sup>1</sup> Unless the TPR voluntarily discloses the identity of the registrants represented, the Lead Registrant reserves the right and the TPR hereby agrees to have the identity of the registrants represented audited by an independent neutral auditor with appropriate confidentiality obligations.

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**Annex 1 - Model Letter of Access<sup>2</sup>***[address of regulatory authority]***Letter of Access for the registration of the following substances**

- 1) **Iron hydroxide oxide – Yellow**
  - EC 257-098-5
  - CAS 51274-00-1
- 2) **Triiron tetraoxide**
  - EC 215-277-5
  - CAS 1317-61-9
- 3) **Diiron trioxide**
  - EC 215-168-2
  - CAS 1309-37-1
- 4) **Iron manganese (tri)oxide**
  - EC 235-049-9
  - CAS 12062-81-6
- 5) **Manganese ferrite (black spinel)**
  - EC 269-056-3
  - CAS 68186-94-7
- 6) **Zinc ferrite (brown spinel)**
  - EC 269-103-8
  - CAS 68187-51-9

**Note: LoA will be issued for all Substances together, not *per* single Substance.**

Dear Sirs,

The Iron Oxides REACH Consortium (here thereafter referred to as the “Consortium”) agrees that the data, studies, summaries, waiving argumentations, reasoning of testing proposals and/or assessments owned or subject to a use right by the members of the Consortium and submitted by the Consortium in support of the registration under *REACH* of the following Substances:

Iron hydroxide oxide – Yellow

Triiron tetraoxide

Diiron trioxide

<sup>2</sup> For information purposes only. The official Letter of Access will only be issued once payment has been made in accordance with Section 4 of the SIEF Agreement.



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Iron manganese (tri)oxide

Manganese ferrite (black spinel)

Zinc ferrite (brown spinel)

(hereinafter collectively referred to as the “Joint Registration Dossier”), may be referred to

*[Company XYZ / List of Affiliates]* (hereafter the “Applicant”)

in order to support the Applicant’s registration of the above-mentioned substance(s) under REACH.

**In his registration, the Applicant acts: *(please tick appropriate box)***

- for itself
- as an Only Representative pursuant to Article 8 REACH for the following non-EU manufacturer:  
\_\_\_\_\_
- as a Third Party Representative<sup>3</sup> pursuant to Article 4 REACH.

**In the Joint Registration Dossier, the Applicant would like to be covered concerning the following parts/documents: *(please tick appropriate box(es))***

- Mandatory joint parts of the Joint Registration Dossier (Article 10 (a) (iv), (vi), (vii) and (ix) REACH)
- Voluntary joint parts of the Joint Registration Dossier (Article 10 (a) (v) and (b) REACH) in as far as applicable (namely CSR and guidance on safe use)
- ‘Opt-out’ pursuant to Article 11 (3) for the following mandatory joint parts:
- Article 10 (a)
- (iv)
- (vi)
- (vii)
- (ix)

<sup>3</sup> Unless the TPR voluntarily discloses the identity of the registrants represented, the Lead Registrant reserves the right and the TPR hereby agrees to have the identity of the registrants represented audited by an independent neutral auditor with appropriate confidentiality



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On request, the Applicant may receive a summary of the *Information* submitted by the Consortium in support of the registration under *REACH*.

The right to refer to the Joint Registration Dossier is subject to the following restrictions:

1. The right of referral only gives access to the Joint Registration Dossier of the substances for the registration as specified above.
2. The right of referral is solely granted in favor of the Applicant and the Affiliates listed herein and is not transferable to any other entity or person.
3. Unless otherwise specified below at 6., 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 at ECHA or any related specific document in whole or in part, outside the general inspection period granted by the Consortium and outside the conditions set out in the SIEF 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. Nothing in this Letter of Access shall require *the Consortium members* to file any additional data.
6. In as far as the Joint Registration Dossier may contain CSR, use and exposure scenarios 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.

If the Applicant has chosen to himself prepare the CSR, use and exposure scenarios and guidance on safe use but does otherwise fully participate in the Joint Registration Dossier, he shall receive an electronic copy of parts Article 10 (a) (iv), (vi), (vii) and (ix) 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 and, as well as to refer to the full study reports on which basis the (robust) study summaries have been developed.

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.

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.

Signature: Authorized Representative of the Consortium.

The Applicant hereby declares that he is aware of, agrees and complies with the provisions of the SIEF Agreement issued by the Lead Registrant Lanxess Deutschland GmbH, which shall apply in its entirety in addition to the provisions set out hereunder.

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**Annex 2 - Consortium Budget and LoA Calculation**

<b>IRON OXIDES REACH CONSORTIUM BUDGET</b>			
<b>APPROVED BUDGET : CONSORTIUM MANAGEMENT</b>	<b><u>2009</u></b>	<b><u>2010</u></b>	<b><u>TOTAL</u></b>
Steering Committee meetings - attend & chair, establish agenda and action plan, prepare minutes and maintain a clear record of decisions and votes (1 meeting in 2009 & 3 meetings 2010)	€ 9,600.00	€ 30,600.00	€ 40,200.00
Accounting fee	€ 7,000.00	€ 25,000.00	€ 32,000.00
General Management of the Consortium	€ 8,000.00	€ 27,000.00	€ 35,000.00
Third Party Communication (excluding SIEF)	€ 10,000.00	€ 10,000.00	€ 20,000.00
SIEF Communication (estimate)	-	€ 60,000.00	€ 60,000.00
LoA Management - On Line IT tool	-	€ 1,500.00	€ 1,500.00
Ad-hoc Legal Advice not related to Steering Committee meetings (e.g. cooperation agreements with other consortia, SIEF agreements, license fee agreements etc.) (estimate)	€ 15,000.00	€ 15,000.00	€ 30,000.00
Iron Platform - SIEF survey assistance	-	€ 5,000.00	€ 5,000.00
<b>TOTAL CONSORTIUM MANAGEMENT (excl. LoA)</b>	<b>€ 49,600.00</b>	<b>€ 174,100.00</b>	<b>€ 223,700.00</b>
<b>APPROVED BUDGET : DOSSIER PREPARATION</b>	<b><u>2009</u></b>	<b><u>2010</u></b>	<b><u>2010</u></b>
IUCLID 5 file/CSR Hazard Assessment/Pre-consortium costs Lead Company	€ 420,000.00	-	€ 420,000.00
Finalization of dossier	-	€ 40,000.00	€ 40,000.00
Licensing of studies (Lanxess) (net value)	-	€ 160,989.00	€ 160,989.00
Licensing of data from Iron Platform	-	€ 39,410.00	€ 39,410.00
Update of IUCLID dossier - Iron Platform	-	€ 60,754.00	€ 60,754.00
Update of IUCLID dossier - Lanxess	-	€ 20,000.00	€ 20,000.00
<b>TOTAL DOSSIER PREPARATION COSTS</b>	<b>€ 420,000.00</b>	<b>€ 321,153.00</b>	<b>€ 741,153.00</b>
<b>TOTAL CONSORTIUM MANAGEMENT &amp; DOSSIER PREPARATION COSTS</b>	<b>€ 469,600.00</b>	<b>€ 495,253.00</b>	<b>€ 964,853.00</b>

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**Iron Oxides REACH Consortium :  
LoA price calculation for 6 substances combined**

	Assumption : 30 SIEF members	
	Consortium Budgets	LOA Calculation
2009 budget - Consortium Management	€ 49,600	€ 1,653
2009 budget - Dossier Preparation	€ 420,000	€ 14,000
2010 Budget less LOA - Consortium Management	€ 174,100	€ 5,803
2010 Budget less LoA - Dossier Preparation	€ 321,153	€ 10,705
Expenses	€ 2,800	€ 93
<b>TOTAL</b>	<b>€ 967,653</b>	<b>€ 32,255</b>
Income Cooperation with Iron Platform	€ (434,655)	€ (14,489)
<b>TOTAL</b>	<b>€ 532,998</b>	<b>€ 17,767</b>
Admin cost (15%)		€ 2,665
<b>TOTAL WITH ADMIN COST</b>		<b>€ 20,432</b>
Handling Fee		€ 1,200
<b>LOA PRICE</b>	-	<b>€ 21,632</b>
Pauluhn study license fee (to be forwarded to HPV Consortium)		€ 10,375
<b>TOTAL LOA PRICE</b>		<b>€ 32,007</b>

**ANNEX 2 – Substance Identity Profile – Classification & Labelling**

Joint Boundary composition, Status 10-07-2024 (Extract from IUCLID and how it is currently reported to ECHA)

	Diiron trioxide		Triiron tetraoxide	NANO Iron hydroxide oxide		NANO Iron manganese trioxide	Manganese ferrite black spinel	Zinc ferrite brown spinel
	(Powder)	Set of nano alpha-Fe2O3	(Powder)	Set of nano alpha-FeOOH	Single Nano gamma-FeOOH	Single Nano	(Powder)	(Powder)
<b>EC No.</b>	215-168-2	215-168-2	215-277-5	257-098-5		235-049-9	269-056-3	269-103-8
<b>CAS No.</b>	1309-37-1	1309-37-1	1317-61-9	51274-00-1		12062-81-6	68186-94-7	68187-51-9
<b>Chemical composition</b>	Fe2O3 (80-100% purity)	Fe2O3 (80-100% purity)	Fe3O4 (80-100% purity)	FeOOH (80-100% purity)	FeOOH (80-100% purity)	(Fe,Mn)2O3 (80-100% purity)	(Fe, Mn)3O4 (80-100% purity)	ZnFe2O4 (80-100% purity)
<b>Crystal Phase</b>		alpha-Fe2O3 (Hematite) pure		gamma-FeOOH (Lepidocrocite) pure	alpha-FeOOH (Goethite) pure	0-30% iron manganese oxide 0-30% Jacobsite 0-50% Hematite		
<b>impurities non are relevant for hazard non-iron metal oxides are incorporated in the crystal lattice.</b>	0-1% TiO2 0-4% C 0-2% Al2O3 0-2% MnO2 0-2% SiO2 0-2% Na2SO4 0-2% CaSO4 0-2% MnSO4	0-1% TiO2 0-4% C 0-2% Al2O3 0-2% MnO2 0-2% SiO2 0-2% Na2SO4 0-2% CaSO4 0-2% MnSO4	0-4% C 0-2% Al2O3 0-2% MnO2 0-2% SiO2 0-2% Na2SO4 0-2% CaSO4 0-2% MnSO4	0-1% C 0-5% Al2O3 0-1% MnO2 0-2.5% SiO2 0-0.5% Na2SO4 0-0.5% CaSO4 0-0.5% MnSO4 0-0.5% NaCl2 0-0.5% CaCl2	0-4% C 0-2% Al2O3 0-2% MnO2 0-2% SiO2 0-2% Na2SO4 0-2% CaSO4 0-2% MnSO4	0-2% SiO2 0-2% Al2O3 0-4% C 0-2% Na2SO4 0-2% CaSO4 0-2% MnSO4	0-2% SiO2 0-2% Al2O3 0-4% C 0-2% Na2SO4 0-2% CaSO4 0-2% MnSO4	0-2% MnO2 0-2% SiO2 0-2% Al2O3 0-4% C 0-2% Na2SO4 0-2% CaSO4 0-2% MnSO4
<b>Surface characteristics</b>		unmodified surface			unmodified surface	unmodified surface		
<b>Shape category shape percentage</b>		elongated polymorph (spheres/cubes/globular/rods) 1-100%	spheroidal polymorph (spheres/cubes/globular/rods) 1-100%		elongated rod (pure shape) 95-100%	elongated rod (pure shape) 95-100%	spheroidal cubic pure shape	
<b>Mean Primary Particle size (by number for nanos)</b>		D10 5 - 40 nm D50 10 - 60 nm D90 15 - 80 nm length 14-240 nm 1-100nm 50-100%	D10 5 - 90 nm D50 10 - 100 nm D90 20 - 200 nm 1-100nm 50-100%		D10 5 - 25 nm D50 20 - 60 nm D90 50 - 120 nm length 10 - 120 nm 1-100nm 85-95%	D10 5 - 60 nm D50 10 - 100 nm D90 12 - 200 nm length 13 - 600 nm 1-100nm 50-100%	D10 20 - 40 nm D50 60 - 100 nm D90 140 - 220 nm 1-100 nm 50-80%	
<b>Aspect ratio</b>		3 - 6			1 - 4	3 - 10		
<b>Specific Surface Area (SSA)</b>		50-130 m <sup>2</sup> /g			10 - 25 m <sup>2</sup> /g	10 - 120 m <sup>2</sup> /g	5 - 15 m <sup>2</sup> /g	

**ANNEX 3 – Project Manager**

**The Project Manager is:**

Jones Day, Rue de la Régence 4, 1000 Brussels, Belgium.

Tel: +32 (0) 645.14.11

reachteam@jonesday.com