AVOCATS - ADVOCATEN

MICHÈLE GRÉGOIRE(5) Avocat à la Cour de cassation Advocaat bij het Hof van Cassatie Member of the Belgian Supreme Court Bar

4, RUE DE LA RÉGENCE • REGENTSCHAPSSTRAAT 4 1000 BRUSSELS, BELGIUM

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

PRESLAVA DILKOVA(11) PHILIPPE LACONTE GEOFFROY VAN DE WALLE PAUL VAN HOOGHTEN

Members of the Brussels Bar

(1)Member of the Rome Bar (2)Member of the Paris Bar (3)Member of the New York Bar (4)Member of the Düsseldorf Bar (5)Admitted to the Paris Bar (7)Member of the Berlin Bar (8)Member of the Frankfurt am Main Bar (9)Member of the Swedish Bar (10)Member of the Ukrainian Bar

BERNARD AMORY CHANTAL BIERNAUX CHARLOTTE BREUVART(2) FERDINAND BRUGHMANS SÉBASTIEN CHAMPAGNE SERGE CLERCKX THOMAS DE MUYNCK(3) LAURENT DE MUYTER CHARLES de NAVACELLE(2)(3) YVAN DESMEDT MATTHIFU DUPLAT KAARLI H. EICHHORN(9) VANESSA FONCKE NADIYA NYCHAY(10) URSULA SCHLIESSNER(4) CRISTIANA SPONTONI(1) MARIO TODINO(6) JONAS VAN DEN BOSSCHE

ALEXANDRE VERHEYDEN(3) PHILIPP WERNER(7)

(11)Member of the Pleven Bar

October 12, 2023

#### TO WHOM IT MAY CONCERN

Dear Applicant,

#### Unsaturated Polyester Resins ('UPR') REACH Consortium Re:

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

- SUBSTANCE 2: CAS 36425-15-7; EC 701-308-4 (OLD IDENTIFIER NLP 500-089-0)
- SUBSTANCE 3: CAS 36425-16-8; EC 701-427-1 (OLD IDENTIFIER NLP 500-090-6)

prepared by the UPR REACH CONSORTIUM. 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 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 6 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:

Ursula Schliessner at <u>uschliessner@jonesday.com</u> / Telephone +32-2-645 1460



Version: October 2023

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

# **Unsaturated Polyester Resins ('UPR') REACH Consortium**

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)

### **NOTES:**

- \* 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.
- \* 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.
- \* 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 IUCLID so-called "export file" and must then insert it themselves into their individual REACH registration.

Substances:
Substance 2: CAS 36425-15-7; EC 701-308-4 (old identifier NLP 500-089-0);
Substance 3: CAS 36425-16-8; EC 701-427-1 (old identifier NLP 500-090-6)

Current Price	Options per LoA:
For the total annual tonnage from <b>1 to 10 tons</b> :	
☐ Substance 2 (only) (w/o CSR):	EUR 107,708 (excl. VAT)
☐ Substance 3 (only) (w/o CSR):	EUR 126,216 (excl. VAT)
$\Box$ Substances 2 and 3 (combined) (w/o CSR):	EUR 151,459 (excl. VAT)
For the total annual tonnage <b>above 10 tons</b> :	
☐ Substance 2 (only):	EUR 218,422 (excl. VAT)
☐ Substance 2 (only) (w/o CSR):	EUR 202,998 (excl. VAT)
☐ Substance 3 (only):	EUR 249,234 (excl. VAT)
☐ <b>Substance 3 (only)</b> (w/o CSR):	EUR 227,004 (excl. VAT)
☐ Substances 2 and 3 (combined):	EUR 314,313 (excl. VAT)
☐ Substances 2 and 3 (combined) (w/o CSR)	EUR 276,659 (excl. VAT)

	Restri	ctions (optio	nal):
	☐ 'Opt-out' pursuant to Article☐ Article 10 (a)☐ Article 10 (a) (iv)☐	☐ Article 10 (a) (vi)	☐ Article 10 (a) (ix)
	I	dentification	
Company	<i>/</i> :		
REACH-I	T UUID Number:		
Company	reference name or number (	optional):	
VAT num	ber:		
If you do	not fill out a VAT number,	you will be charged 21%.	
Address:			
			Country:
	ive full details of person au	thorized to make the applic	ation:
Mr □ Ms	□ Dr □		
Last Nam	ne:	First Na	ame:
Phone No	umber:	Fax Number:	
E-mail ad	ldress:		
	ive full company details for The Miracle Chemicals Co. L		
Affiliates:			

	Registration
In his re	egistration, the Applicant acts:
a.	☐ for himself
b.	☐ as <b>Only Representative</b> pursuant to Article 8 REACH <u>for the following non-EU manufacturer</u> ; Please give full contact details of <b>non-EU legal entity</b> 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 <b>Third Party Representative</b> 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 co	ompany 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:**

- 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.
- 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.

This letter of access is issued by the above Lead Registrant or Consortium Members and they have prepared the respective registration dossier(s). No attorney-client relationship with Jones Day is created by signing this LoA application / change form / the SIEF / Cooperation / Joint Submission Agreement or payment of the LoA (proforma) invoice.

Applicant's certifications and undertakings:

- 1. 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.
- 3. 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).
- 4. 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.

l have read and I agree with the legal Terms of the Agreement
---

Signature of LoA applicant:	
Name:	
Date:	

\* \* \*

# **Unsaturated Polyester Resins (UPR) REACH Consortium**

### **SIEF Communications**

- CAS 36425-15-7; EC 701-308-4 (so-called <u>Substance 2</u>, commonly referred to as "small vinyl ester") / Old identifier: EC (NLP) 500-089-0
- CAS 36425-16-8; EC 701-427-1 (so-called <u>Substance 3</u>, commonly referred to as "modified small vinyl ester") / Old identifier: EC (NLP) 500-090-6

- Updated December 23, 2024 -

# **SIEF Communications**:

14th SIEF Communication dated December 23, 2024 (1 page)

13<sup>th</sup> SIEF Communication dated October 10, 2023 (1 page)

12<sup>th</sup> SIEF Communication dated February 4, 2022 (1 page)

11<sup>th</sup> SIEF Communication dated November 6, 2020 (3 pages)

10<sup>th</sup> SIEF Communication dated September 17, 2020 (2 pages)

9<sup>th</sup> SIEF Communication dated June 17, 2019 (1 page)

8<sup>th</sup> SIEF Communication dated May 23, 2019 (1 page)

7<sup>th</sup> SIEF Communication dated December 28, 2018 (2 pages)

6<sup>th</sup> SIEF Communication dated October 29, 2018 (1 pages)

5<sup>th</sup> SIEF Communication dated October 16, 2018 (2 pages)

4<sup>th</sup> SIEF Communication dated June 7, 2018 (2 pages)

3<sup>rd</sup> SIEF Communication dated July 16, 2012 (30 pages)

2<sup>nd</sup> SIEF Communication dated October 15, 2010 (2 pages)

1<sup>st</sup> SIEF Communication dated September 29, 2010 (including SIEF Agreement) (25 pages)

AVOCATS - ADVOCATEN

MICHÈLE GRÉGOIRE<sup>(5)</sup>
Avocat à la Cour de cassation
Advocaat bij het Hof van Cassatie
Member of the Belgian Supreme Court Bar

4, RUE DE LA RÉGENCE • REGENTSCHAPSSTRAAT 4 1000 BRUSSELS, BELGIUM

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

PRESLAVA DILKOVA(11)
DIDIER DE VLIEGHER
PHILIPPE LACONTE
PAUL VAN HOOGHTEN
SARA VANDERSTRAETEN
LAURENT VERCAUTEREN

Members of the Brussels Bar

(1)Member of the Rome Bar

(2)Member of the Paris Bar

(3)Member of the Düsseldorf Bar

(4)Member of the Düsseldorf Bar

(5)Admitted to the Paris Bar

(6)Member of the Naples Bar

(7)Member of the Berlin Bar

(8)Member of the
Frankfurt am Main Bar

(9)Member of the Wedish Bar

(10)Member of the Ukrainian Bar

(11)Member of the Ukrainian Bar

DIRECT NUMBER: +32.2.645.14.53
E-Mail: PDILKOVA@JONESDAY.COM

BERNARD AMORY CHANTAL BIFRNAUX CHARLOTTE BREUVART(2) FERDINAND BRUGHMANS SÉBASTIEN CHAMPAGNE SERGE CLERCKX THOMAS DE MUYNCK(3) LAURENT DE MUYTER CHARLES de NAVACELLE(2)(3) YVAN DESMEDT MATTHIFU DUPLAT KAARLI H. EICHHORN(9) VANESSA FONCKE JÖRG HLADJK(8) NADIYA NYCHAY(10) URSULA SCHLIESSNER(4)

CRISTIANA SPONTONI(1)

MARIO TODINO(6)

JONAS VAN DEN BOSSCHE
GEOFFROY VAN DE WALLE
ALEXANDRE VERHEYDEN(3)
PHILIPP WERNER(7)

December 23, 2024

#### TO WHOM IT MAY CONCERN

**BY E-MAIL** 

Dear Co-Registrants,

Re: UPR REACH Consortium – SIEF Communication: Registration Dossier Update for Substance 2 (EC 701-308-4, commonly referred to as "small vinyl ester") above 1000 t/a

Please be informed that the registration dossier and CSR for Substance 2 in the tonnage band above 1000 t/a have been updated. The update includes the results of the following two studies that were conducted after the compliance check decision of ECHA from 26 August 2021:

- Prenatal Developmental Toxicity ("PNDT", test method: OECD TG 414);
- Extended One-Generation Reproductive Toxicity ("EOGRT"), test method: OECD TG 443).

The dossier update passed the first completeness check on 2 December 2024.

Please contact us (<u>reachteam@jonesday.com</u>) if you have any questions or would like to request the updated dossier and/or CSR.

Kind regards,

Preslava Dilkova

AVOCATS - ADVOCATEN

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

MICHÈLE GRÉGOIRE(5)

BERNARD AMORY

SERGE CLERCKX

NADIYA NYCHAY(10) URSULA SCHLIESSNER(4)

MARIO TODINO(6) JONAS VAN DEN BOSSCHE ALEXANDRE VERHEYDEN(3) PHILIPP WERNER<sup>(7)</sup>

CRISTIANA SPONTONI(1)

CHANTAL BIERNAUX CHARLOTTE BREUVART(2)

FERDINAND BRUGHMANS

SÉBASTIEN CHAMPAGNE

THOMAS DE MUYNCK(3) LAURENT DE MUYTER

4, RUE DE LA RÉGENCE • REGENTSCHAPSSTRAAT 4 1000 BRUSSELS, BELGIUM

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

PRESLAVA DILKOVA(11) PHILIPPE LACONTE GEOFFROY VAN DE WALLE PAUL VAN HOOGHTEN

Members of the Brussels Bar (1)Member of the Rome Bar (2)Member of the Paris Bar (3)Member of the New York Bar (4)Member of the Düsseldorf Bar (8)Member of the Frankfurt am Main Bar (9)Member of the Swedish Bar

(5)Admitted to the Paris Bar (7)Member of the Berlin Bar

(10)Member of the Ukrainian Bar (11)Member of the Pleven Bar

CHARLES de NAVACELLE(2)(3) YVAN DESMEDT MATTHIFU DUPLAT KAARLI H. EICHHORN(9) VANESSA FONCKE

October 10, 2023

DIRECT NUMBER: +32.2.645.14.60 E-Mail: uschliessner@jonesday.com

# TO WHOM IT MAY CONCERN

BY ELECTRONIC MAIL

Dear Co-Registrants,

**UPR REACH Consortium – SIEF Communication – Registration Dossier Update** Re: for Substance 2: Small vinyl ester (EC 701-308-4; CAS 36425-15-7)

Please be informed that pursuant to new IUCLID and technical completeness check rules of ECHA, certain parts of the IUCLID file (Section 3.5.6 on 'Articles Service Life') for Substance 2 have been updated. The CSR has been updated accordingly. Both updated documents are available and will be provided to you by ReachTeam@jonesday.com upon request.

Kind regards,

# JONES DAY AVOCATS - ADVOCATEN

Avocat à la Cour de cassation Advocaat bij het Hof van Cassatie

MICHÈLE GRÉGOIRE(5)

Member of the Belgian Supreme Court Bar

4 RUE DE LA RÉGENCE • REGENTSCHAPSSTRAAT 4 1000 BRUSSELS, BELGIUM

BERNARD AMORY CHANTAL BIERNAUX CHARLOTTE BREUVART(2) FERDINAND BRUGHMANS SÉBASTIEN CHAMPAGNE SERGE CLERCKX THOMAS DE MUYNCK(3) LAURENT DE MUYTER CHARLES de NAVACELLE(2)(3) YVAN DESMEDT MATTHIFU DUPLAT KAARII H. FICHHORN(9) VANESSA FONCKE JÖRG HLADJK(8) URSULA SCHLIESSNER(4) CRISTIANA SPONTONI(1)

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

PHILIPPE LACONTE GEOFFROY VAN DE WALLE PAUL VAN HOOGHTEN

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

February 4, 2022

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

# TO WHOM IT MAY CONCERN

MARIO TODINO(6) JONAS VAN DEN BOSSCHE ALEXANDRE VERHEYDEN® PHILIPP WERNER

Dear SIEF Members and Co-Registrants,

Re: **UPR REACH Consortium- Substance Identifier Change for Substance 3: Modified Small** vinvl ester (EC: 500-090-6; CAS: 36425-16-8)

Following our communication of December 23, 2020 sent individually to registrants, we would like to inform you that the European Chemicals Agency ("ECHA") has accepted to modify the chemical identity of the substance Modified Small vinyl ester ("S3")

# from

4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane, reaction products with maleic anhydride and methacrylic acid

to

2,2'-[(1-methylethylidene)bis(4,1-phenyleneoxymethylene)]bisoxirane, reaction products with maleic anhydride and methacrylic acid.

The EC number of S3 was changed from 500-090-6 to 701-427-1.

In relation to this procedure, every registrant of S3 received a communication from ECHA dated December 3, 2021. In order to reflect on the substance identifier changes for S3, ECHA requires from the Lead Registrant to update the joint registration dossier and from the joint registrants to update their respective individual parts.

We confirm that the Lead Registrant submitted the updated joint dossier on January 12, 2022.

Upon your request, we will provide you with a copy of the documents necessary to update your individual parts of the dossier, i.e.

- updated IUCLID file (i)
- (ii) a document on changes to the reference substance
- (iii) update to the common part of the Chemical Safety Report (only if you have previously paid for a copy of it).

Kind regards.

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

4 RUE DE LA RÉGENCE • REGENTSCHAPSSTRAAT 4 1000 BRUSSELS, BELGIUM

BERNARD AMORY RENATO ANTONINI(1) CHANTAL BIERNAUX CHARLOTTE BREUVART(2) FERDINAND BRUGHMANS SÉBASTIEN CHAMPAGNE SERGE CLERCKX THOMAS DE MUYNCK(3) LAURENT DE MUYTER CHARLES de NAVACELLE(2)(3) YVAN DESMEDT MATTHIEU DUPLAT KAARLI H. EICHHORN(10) VANESSA FONCKE JÖRG HLADJK<sup>(9)</sup> URSULA SCHLIESSNER(5) CRISTIANA SPONTONI(1) MARIO TODINO(7)

ALEXANDRE VERHEYDEN(3) PHILIPP WERNER(8)

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

PHILIPPE LACONTE HOWARD M LIEBMAN(4) EVA MONARD IONAS VAN DEN BOSSCHE PAUL VAN HOOGHTEN

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

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

November 6, 2020

#### TO WHOM IT MAY CONCERN

BY ELECTRONIC MAIL

Dear SIEF Members and Joint Registrants,

REACH: 11th SIEF Communication; Dossier Update EC 701-308-4 (formerly Re: CAS 36425-15-7; EC (NLP) 500-089-0) (so-called Substance 2, commonly referred to as "small vinyl ester")

Pursuant to our previous communication of September 17, 2020, please note that the dossier update for S2 has been completed. The new SIP (S2) is attached. A new CSR is also available and will be provided to you upon request. We invite you to contact Jones Day to request the new CSR.

Kind regards,

Ursula Schliessner

Encl (1)



# 1. IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

# 1.1. Name and other identifiers of the substance

The substance Small vinyl ester is a UVCB (organic) having the following characteristics and physical-chemical properties (see the IUCLID dataset for further details). The following public name is used: Small Vinyl Ester

# Table 1.1. Substance identity

EC number:	701-308-4
EC name:	Reaction products of methacrylic acid and 2,2'-[(1-methylethylidene)bis(4,1-phenyleneoxymethylene)]bisoxirane
CAS number (EC inventory):	N/A
CAS number:	
CAS name:	
IUPAC name:	Reaction products of methacrylic acid and 2,2'-[(1-methylethylidene)bis(4,1-phenyleneoxymethylene)]bisoxirane
Description:	2,2'-[(1-methylethylidene)bis(4,1-phenyleneoxymethylene)]bisoxirane (EC 216-823-5) is heated in a closed reactor to between 100 and 150°C at atmospheric pressure. Methacrylic acid is dosed and the reaction left for up to 24 hours. The ratio of reactants is 1:2 moles. Once conversion to Small Vinyl Ester is greater than 96%, the reaction is stopped and the material blended with a reactive diluent, ready to be placed on the market.

Other identifiers: Substance 2

S2

CAS Number: 36425-15-7

#### Remarks:

The substance is a UVCB which predominantly consists of a number of structural and (racemic) optical isomers of bis-GMA (Bisphenol A-Glycidyl Methacrylate), including a number of dimeric and trimeric species. As such, an accurate molecular or structural formula and molecular weight range cannot be provided given the nature of the main constituents.

# 1.2. Composition of the substance

Overall information on composition

Composition	Related composition(s)
Small Vinyl Ester (legal entity composition of the substance)	
Small Vinyl Ester (boundary composition of the substance)	

#### **Name: Small Vinyl Ester**

State/form: liquid

Degree of purity: 100 % (w/w)

Description:

Reaction products of methacrylic acid and 2,2'-[(1-methylethylidene)bis (4,1-phenyleneoxymethyl ene)]bisoxirane

# Reaction products of methacrylic acid and 2,2'-[(1-methylethylidene)bis(4,1-phenyleneoxymethylene)]bisoxirane

Methods of manufacture of substance: 2,2'-[(1-methylethylidene)bis(4,1-phenyleneoxymethylene)]bisoxirane (EC 216-823-5) is heated in a closed reactor to between 100 and 150°C at atmospheric pressure. Methacrylic acid is dosed and the reaction left for up to 24 hours. The ratio of reactants is 1:2 moles. Once conversion to Small Vinyl Ester is greater than 96%, the reaction is stopped and the material blended with a reactive diluent, ready to be placed on the market.

**Table 1.2. Constituents (Small Vinyl Ester)** 

Constituent	Typical concentration	Concentration range	Remarks
Bis-GMA EC no.: 216-367-7	% (w/w)	>=70 - <=95 % (w/w)	
Bis-GMA Dimer EC no.:	<mark>% (w/w)</mark>	>=2 - <=20 % (w/w)	
Bis-GMA Trimer EC no.:	% (w/w)	>=1 - <=10 % (w/w)	
Epoxy monoBis-GMA EC no.:	% (w/w)	>=0 - <=5 % (w/w)	No EC number/name is allocated
Dihydroxy monoBisGMA EC no.:	% (w/w)	>=0 - <=5 % (w/w)	No EC number/name is allocated
BisGMA TriMABisGMA TriMA EC No.:	% (w/w)	>=0 - <=1.5 % (w/w)	No EC number/name is allocated
methacrylic acid EC no.: 201-204-4	% (w/w)	>=0 - <=1 % (w/w)	Residual monomer
Unknown Constituents EC no.:	% (w/w)	>=0 - <=5 % (w/w)	

### Name: Small Vinyl Ester

State/form: liquid

Degree of purity: 100 % (w/w)

Description: Reaction products of methacrylic acid and 2,2'-[(1-methylethylidene)bis (4,1-phenyleneoxymethyl

ene)]bisoxiraneReaction

Methods of manufacture of substance: 2,2'-[(1-methylethylidene)bis(4,1-phenyleneoxymethylene)]bisoxirane (EC 216-823-5) is heated in a closed reactor to between 100 and 150°C at atmospheric pressure. Methacrylic acid is dosed and the reaction left for up to 24 hours. The ratio of reactants is 1:2 moles. Once conversion to Small Vinyl Ester is greater than 96%, the reaction is stopped and the material blended with a reactive diluent, ready to be placed on the market.

**Table 1.3. Constituents (Small Vinyl Ester)** 

Constituent	Typical concentration	Concentration range	Remarks
Bis-GMA EC no.: 216-367-7		>=70 - <=95 % (w/w)	
Bis-GMA Dimer EC no.:		>=2 - <=20 % (w/w)	
Bis-GMA Trimer EC no.:		>=1 - <=10 % (w/w)	
Epoxy monoBis-GMA EC no.:		>=0 - <=5 % (w/w)	No EC number/name is allocated
Dihydroxy monoBisGMA EC no.:		>=0 - <=5 % (w/w)	No EC number/name is allocated
BisGMA TriMA		>=0 - <=1.5 % (w/w)	No EC number/name is allocated
methacrylic acid EC no.: 201-204-4		>=0 - <=1 % (w/w)	Residual monomer
Unknown Constituents EC no.:		>=0 - <=5 % (w/w)	

# 1.3. Physicochemical properties

AVOCATS - ADVOCATEN

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

4, RUE DE LA RÉGENCE • REGENTSCHAPSSTRAAT 4 1000 BRUSSELS, BELGIUM

BERNARD AMORY RENATO ANTONINI(1) CHANTAL BIERNAUX CHARLOTTE BREUVART(2) FERDINAND BRUGHMANS SÉBASTIEN CHAMPAGNE SERGE CLERCKX THOMAS DE MUYNCK(3) LAURENT DE MUYTER CHARLES de NAVACELLE(2)(3) YVAN DESMEDT MATTHIEU DUPLAT KAARLI H. EICHHORN(10) VANESSA FONCKE JÖRG HLADJK<sup>(9)</sup> URSULA SCHLIESSNER(5) CRISTIANA SPONTONI(1) MARIO TODINO(7)

ALEXANDRE VERHEYDEN(3)
PHILIPP WERNER(8)

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

PHILIPPE LACONTE
HOWARD M LIEBMAN(4)
EVA MONARD
JONAS VAN DEN BOSSCHE
PAUL VAN HOOGHTEN

Members of the Brussels Bar

(1)Member of the Rome Bar

(2)Member of the Paris Bar

(3)Member of the New York Bar

(4)Member of the District of

Columbia Bar

(5)Member of the Düsseldorf Bar

(6)Admitted to the Paris Bar

(7)Member of the Naples Bar

(8)Member of the Berlin Bar

(9)Member of the

Frankfurt am Main Bar

(10)Member of the Swedish Bar

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

September 17, 2020

#### TO WHOM IT MAY CONCERN

BY ELECTRONIC MAIL

Dear SIEF Members and Joint Registrants,

Re: REACH: SIEF Communication; CAS no. 36425-15-7; EC 701-308-4 (new) (so-called <u>Substance 2</u>, commonly referred to as "small vinyl ester") / Old identifier EC 500-089-0

Please note the attached new substance identity information for small vinyl ester (*Annex 1*). This change will be notified to ECHA latest in October 2020. At that time, we invite you to contact <u>Jones Day</u> to request new CSRs, if these are part of your Letter of Access.

Kind regards,

Ursula Schliessne

Encl (1)

Substance name:	: Small Vinyl Ester								
EC no.	T								
CAS RN	36425-15-7	Complex reaction mixture							
origin	organic								
IUPAC name	Reaction products of methacrylic acid and 2,2'-[(	acrylic acid and 2,2'-[(1-methylethylidene)bis(4,1-phenyleneoxymethylene)]bisoxirane	oxirane						
Composition	Name	Structure	IJPAC name	EC NR	EC Name	CAS RN	CAS Name	Rande	Typical
									2 2 2
	Bis-GMA	HO HO O	((propane-2,2-diylbis(4,1-phenylene))bis(oxy))bis(2-hydroxypropane-3,1-diyl) is (2-methylacrylate)	216-367-7	<del></del>	1595-94-2	(1-methylethylidene)bis[4,1-phenyleneoxy(2- 70 hydroxy-3,1-propanediyl)] bismethacrylate	70-95	71,1
		Mixture of structural isomers (2 possible ways for opening the epoxide ring) and optical isomers							
	Bis-GMA-dimer	HO HO	(((((2-hydroxypropane-1,3-diyl)bis(oxy))bis(4,1-phenylene))bis(propane-2,2-diyl))bis(4,1-phenylene))bis(oxy))bis(2-hydroxypropane-3,1-diyl) bis(2-methylacrylate)				.2	2-20	16,0
		Mixture of structural isomers (2 possible ways for opening the epoxide ing) and optical isomers							
	Bis-GMA-trimer		((((((propane-2,2-diylbis(4,1-phenylene))bis(oxy))bis(2-hydroxypropane-3,1-diyl))bis(oxy))bis(4,1-phenylene))bis(propane-2,2-diyl))bis(4,1-phenylene))bis(oxy))bis(2-hydroxypropane-3,1-diyl) bis(2-methylacrylate)				<del></del>	1-10	5,4
		Mixture of structural isomers (2 possible ways for opening the epoxide ring) and optical isomers							
	Epoxymono Bis-GMA	O HO O O	2-hydroxy-3-(4-(2-(4-(oxiran-2-ylmethoxy)phenyl)propan-2-yl)phenoxy)propyl methacrylate		<u></u>	96128-39-1	2-Propenoic acid, 2-methyl-, 2-hydroxy-3-[4-(1-methyl-[4]0-5 (2-oxiranylmethoxy)phenyl]ethyl]phenoxy]propyl ester	<del>ن</del>	4
	Dihydroxymono Bis-GMA	HO HO HO OH	3-(4-(2-(4-(2,3-dihydroxypropoxy)phenyl)propan-2-yl)phenoxy)-2-hydroxypropyl methacrylate		8	323177-93-1	2-Propenoic acid, 2-methyl-, 2-hydroxy-3-{4-[1-[4-(2,3- ofihydroxypropoxy)phenyl]-1-methylethyl]phenoxy]-2-hydroxypropyl ester	0-5	2
	Bis-GMA TriMA	H <sub>3</sub> C + 1 CH <sub>3</sub> CH <sub>3</sub> CH <sub>3</sub>					ne -O	0-1.5 proposed new entry all toghether	
	Methacrylic acid	HO	2-methylpropenoic acid	201-204-4	methacrylic  7/	79-41-4	2-Propenoic acid, 2-methyl-	0-1	8'0
	Unknown		Unknown components				-0	0-5	۲۷
									66,3

AVOCATS - ADVOCATEN 4 RUE DE LA RÉGENCE • REGENTSCHAPSSTRAAT 4

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

1000 BRUSSELS, BELGIUM

BERNARD AMORY RENATO ANTONINI(1) CHANTAL BIERNAUX CHARLOTTE BREUVART(2) FERDINAND BRUGHMANS SÉBASTIEN CHAMPAGNE SERGE CLERCKX THOMAS DE MUYNCK(3) LAURENT DE MUYTER CHARLES de NAVACELLE(2)(3) YVAN DESMEDT MATTHIEU DUPLAT KAARLI H. EICHHORN(10) VANESSA FONCKE JÖRG HLADJK<sup>(9)</sup> URSULA SCHLIESSNER(5) CRISTIANA SPONTONI(1)

MARIO TODINO(7)

ALEXANDRE VERHEYDEN(3) PHILIPP WERNER(8)

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

PHILIPPE LACONTE HOWARD M LIEBMAN(4) DAVID ROGER

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

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

June 17, 2019

# TO WHOM IT MAY CONCERN

BY E-MAIL

Dear SIEF Members and Joint Registrants,

Re: **REACH: SIEF Communication** 

CAS no. 36425-15-7; NLP no. 701-308-4 (so-called Substance 2, commonly referred to as "small vinyl ester")

As we informed you in our SIEF communication of May 23, 2019, as a result of the submission of the Joint Submission Plan to ECHA on behalf of all registrants of Substance 2, ECHA has updated the ID of Substance 2 to:

- Reaction products of methacrylic acid and 2,2'-[(1-methylethylidene)bis(4,1phenyleneoxymethylene)]bisoxirane, and
- EC 701-308-4

Please be informed that the update of the lead registration dossier of Substance 2 has been submitted by the lead registrant in accordance with ECHA's instructions. All registrants are therefore invited to contact Jones Day to receive the access token.

Kind regards,

MICHÈLE GRÉGOIRE(6) Avocat à la Cour de cassation Advocaat hij het Hof van Cassatie

Member of the Belgian Supreme Court Bar BERNARD AMORY

RENATO ANTONINI(1) CHANTAL BIERNAUX CHARLOTTE BREUVART(2) FERDINAND BRUGHMANS SÉBASTIEN CHAMPAGNE SERGE CLERCKX THOMAS DE MUYNCK(3) LAURENT DE MUYTER CHARLES de NAVACELLE(2)(3) YVAN DESMEDT MATTHIEU DUPLAT KAARLI H. EICHHORN(10) VANESSA FONCKE JÖRG HLADJK<sup>(9)</sup> URSULA SCHLIESSNER(5) CRISTIANA SPONTONI(1) MARIO TODINO(7)

ALEXANDRE VERHEYDEN(3) PHILIPP WERNER(8)

4 RUE DE LA RÉGENCE • REGENTSCHAPSSTRAAT 4 1000 BRUSSELS, BELGIUM

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

PHILIPPE LACONTE HOWARD M LIEBMAN(4) DAVID ROGER

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

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

May 23, 2019

# TO WHOM IT MAY CONCERN

BY E-MAIL

Dear SIEF Members and Joint Registrants,

Re: **REACH: SIEF Communication** 

CAS no. 36425-15-7; NLP no. 500-089-0 (so-called Substance 2, commonly referred to as "small vinyl ester")

As a result of the submission of the Joint Submission Plan to ECHA on behalf of all registrants of S2, ECHA has updated the ID of Substance 2 to:

- Reaction products of methacrylic acid and 2,2'-[(1-methylethylidene)bis(4,1phenyleneoxymethylene)]bisoxirane, and
- EC 701-308-4

ECHA is now sending a letter to all registrants, inviting them to update their individual registrations accordingly. The lead registration dossier must be updated before members can submit their dossier updates.

Please be informed that Aliancys France SAS are now preparing such an update. Once the update will be completed, we will issue another SIEF communication informing registrants of the update and inviting them to contact Jones Day to receive the access token.

Kind regards,

AVOCATS - ADVOCATEN

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

BERNARD AMORY RENATO ANTONINI(1) CHANTAL BIERNAUX

CHARLOTTE BREUVART(2) FERDINAND BRUGHMANS

SÉBASTIEN CHAMPAGNE SERGE CLERCKX THOMAS DE MUYNCK(3)

YVAN DESMEDT MATTHIEU DUPLAT KAARLI H. EICHHORN(10)

VANESSA FONCKE URSULA SCHLIESSNER (5) CRISTIANA SPONTONI(1)

MARIO TODINO(7) ALEXANDRE VERHEYDEN(3)

PHILIPP WERNER(8)

4 RUE DE LA RÉGENCE • REGENTSCHAPSSTRAAT 4 1000 BRUSSELS, BELGIUM

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

LAURENT DE MUYTER CHARLES de NAVACELLE(2)(3) JÖRG HLADJK(9) LUC G HOUBEN(3) HOWARD M LIEBMAN(4) DAVID ROGER

Members of the Brussels Bar (1)Member of the Rome Bar (2)Member of the Paris Bar (3)Member of the New York Bar (4)Member of the District of Columbia Bar (5)Member of the Düsseldorf Bar (6)Admitted to the Paris Bar (7)Member of the Nanles Bar (8)Member of the Berlin Bar

(9)Member of the

(10)Member of the Swedish Bar

December 28, 2018

# TO WHOM IT MAY CONCERN

BY E-MAIL

Dear SIEF Members and Joint Registrants,

Re: **REACH: SIEF Communication** 

CAS no. 36425-15-7; NLP no. 500-089-0 (so-called Substance 2, commonly referred to as "small vinyl ester")

We hereby wish to notify you that on December 17, 2018, the Lead Registrant of Substance 2 made the update of the joint registration dossier of Substance 2 dossier as outlined below.

# **Background**

You have already been informed in the SIEF communication of October 8, 2018 that during the conference call with ECHA of August 28, 2018, ECHA had requested the Lead Registrant of Substance 2 to make the following update of the Substance 2 registration dossier by December 31, 2018:

- details of the analytical method used to determine the methacrylic acid content
- clarification of the identity of the epoxy-functionalised starting material of Substance 2. This request was made in light of the fact that the registrants of the UVCB substance with EC# 500-033-5 (EC name: 4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3epoxypropane) that had been mentioned in the SIP of Substance 2 as a starting material have switched their registrations to the well-defined substance with EC# 216-823-5 (EC name: 2,2'-[(1-methylethylidene)bis(4,1-phenyleneoxymethylene)]bisoxirane).

# Update of the registration dossier

In order to address the ECHA request, the Lead Registrant has made the following update of the joint registration dossier of Substance 2 and of the joint CSR:

(i) Change of the EC Name

# From

4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3epoxypropane, reaction products with methacrylic acid

ALKHOBAR • AMSTERDAM • ATLANTA • BELING • BOSTON • BRISBANE • BRUSSELS • CHICAGO • CLEVELAND • COLUMBUS • DALLAS DETROIT • DUBAI • DÜSSELDORF • FRANKFURT • HONG KONG • HOUSTON • IRVINE • LONDON • LOS ANGELES • MADRID • MELBOURNE MEXICO CITY • MIAMI • MILAN • MINNEAPOLIS • MOSCOW • MUNICH • NEW YORK • PARIS • PERTH • PITTSBURGH • RIYADH SAN DIEGO • SAN FRANCISCO • SÃO PAULO • SHANGHAL • SILICON VALLEY • SINGAPORE • SYDNEY • TAIPEL • TOKYO • WASHINGTON

TO WHOM IT MAY CONCERN December 28, 2018 Page 2

#### To

2,2'-[(1-methylethylidene)bis(4,1-phenyleneoxymethylene)]bisoxirane, reaction products with methacrylic acid

# (ii) Change of the description

#### From

4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane (EC 500-033-5) is heated in a closed reactor to between 100 and 150°C at atmospheric pressure. Methacrylic acid is dosed and the reaction left for up to 24 hours. The ratio of reactants is 1:2 moles. Once conversion to Small Vinyl Ester is greater than 96%, the reaction is stopped and the material blended with a reactive diluent, ready to be placed on the market.

#### To

2,2'-[(1-methylethylidene)bis(4,1-phenyleneoxymethylene)]bisoxirane (EC 216-823-5) is heated in a closed reactor to between 100 and 150°C at atmospheric pressure. Methacrylic acid is dosed and the reaction left for up to 24 hours. The ratio of reactants is 1:2 moles. Once conversion to Small Vinyl Ester is greater than 96%, the reaction is stopped and the material blended with a reactive diluent, ready to be placed on the market.

### (iii) <u>Initiation of the change of the EC number of S2</u>

As part of the update, the Lead Registrant has initiated the change of the EC number of S2. In 2019, ECHA is expected to contact the Lead Registrant and invite him to request ECHA through the webform to make the change. Since the change concerns and affects a joint registration, the Lead Registrant will need to attach a "Joint submission plan" to the webform that covers all the co-registrants' agreements on the substance identifier adaptation. For this, you will be contacted by the Lead Registrant in due time. The minimum ECHA charge for this change is €300 for each registrant requiring the correction of a substance identifier. The description of the process to change an EC Number is provided here: <a href="https://echa.europa.eu/support/how-to-improve-your-dossier/how-to-change-your-substance-identifier">https://echa.europa.eu/support/how-to-improve-your-dossier/how-to-change-your-substance-identifier</a>.

### Update regarding methacrylic acid

The Lead Registrant updated the lead dossier with a reference to the general method used for quantifying the methacrylic acid (ISO 2114:2000). ECHA requested that each registrant should update their individual dossier with a specific test method, if applicable.

Kind regards,



AVOCATS - ADVOCATEN

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

4, RUE DE LA RÉGENCE • REGENTSCHAPSSTRAAT 4 1000 BRUSSELS, BELGIUM

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

BERNARD AMORY
RENATO ANTONINI(1)
CHANTAL BIERNAUX
CHARLOTTE BREUVART(2)
FERDINAND BRUGHMANS
SÉBASTIEN CHAMPAGNE
SERGE CLERCKX
THOMAS DE MUYNCK(3)
YVAN DESMEDT
MATTHIEU DUPLAT
KAARLI H. EICHHORN(10)
VANESSA FONCKE
URSULA SCHLIESSNER(5)
CRISTIANA SPONTONI(1)
MARIO TODINO(7)

ALEXANDRE VERHEYDEN(3)

PHILIPP WERNER(8)

LAURENT DE MUYTER
CHARLES de NAVACELLE(2)(3)
JÖRG HLADJK(8)
LUC G. HOUBEN(3)
HOWARD M LIEBMAN(4)
DAVID ROGER

Members of the Brussels Bar

(1)Member of the Rome Bar

(2)Member of the Paris Bar

(3)Member of the New York Bar

(4)Member of the District of

Columbia Bar

(5)Member of the Düsseldorf Bar

(6)Admitted to the Paris Bar

(7)Member of the Naples Bar

(8)Member of the Berlin Bar

(9)Member of the

Frankfurt am Main Bar

(10)Member of the Swedish Bar

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

October 29, 2018

JP018852 829424-600001

#### TO WHOM IT MAY CONCERN

BY E-MAIL

Dear SIEF Members of Substance 2,

**Re: REACH: SIEF Communication** 

CAS no. 36425-15-7; NLP no. 500-089-0 (so-called <u>Substance 2</u>, commonly referred to as "small vinyl ester")

We hereby wish to notify you that LR DSM Composite Resins France SAS has been effectively replaced by Aliancys France SAS via a legal entity change due to a transfer of business.

Kind regards,

AVOCATS - ADVOCATEN

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

BERNARD AMORY
RENATO ANTONINI(1)
CHANTAL BIERNAUX

CHARLOTTE BREUVART(2) FERDINAND BRUGHMANS

SÉBASTIEN CHAMPAGNE SERGE CLERCKX THOMAS DE MUYNCK<sup>(3)</sup>

YVAN DESMEDT
MATTHIEU DUPLAT
KAARII H. FICHHORN(10)

VANESSA FONCKE
URSULA SCHLIESSNER (5)
CRISTIANA SPONTONI (1)

MARIO TODINO (7)
ALEXANDRE VERHEYDEN (3)

PHILIPP WERNER(8)

4, RUE DE LA RÉGENCE • REGENTSCHAPSSTRAAT 4

1000 BRUSSELS. BELGIUM

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

LAURENT DE MUYTER
CHARLES de NAVACELLE (2)(3)
JORG HLADJK (9)
LUC G. HOUBEN (3)
HOWARD M LIEBMAN (4)
DAVID ROGER

Members of the Brussels Bar

(1)Member of the Rome Bar

(2)Member of the Paris Bar

(3)Member of the New York Bar

(4)Member of the District of

Columbia Bar

(5)Member of the Düsseldorf Bar

(6)Admitted to the Paris Bar

(7)Member of the Naples Bar

(8)Member of the Berlin Bar

Frankfurt am Main Bar
(10)Member of the Swedish Bar

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

<sup>(9)</sup>Member of the

October 16, 2018

JP018852 829424-600001

#### TO WHOM IT MAY CONCERN

BY E-MAIL

Dear SIEF Members and Joint Registrants,

**Re: REACH: SIEF Communication** 

CAS no. 36425-15-7; NLP no. 500-089-0 (so-called <u>Substance 2</u>, commonly referred to as "small vinyl ester")

We hereby wish to notify you of the results of an informal teleconference with ECHA held on August 22, 2018 related to the substance identity profile ('SIP') of Substance 2.

ECHA has requested the lead registrant of Substance 2 to make the following update of the Substance 2 registration dossier by December 31, 2018:

- details of the analytical method used to determine the methacrylic acid content. The information should include a description of the experimental protocol followed and the results obtained. The method should be suitable to quantify the methacrylic acid at the concentration levels that are found in the substance.
- ECHA has requested that the lead registrant clarify the identity of the epoxy-functionalised starting material of Substance 2. This request has been made in light of the fact that as follows from the ECHA dissemination website, the registrants of the UVCB substance with EC# 500-033-5 (EC name: 4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane) that is currently mentioned in the SIP of Substance 2 as starting material have switched their registrations to the well-defined substance with EC# 216-823-5 (EC name: 2,2'-[(1-methylethylidene)bis(4,1-phenyleneoxymethylene)]bisoxirane). The joint submission for the substance with EC# 500-033-5 currently includes only 4 co-registrants. ECHA informed the registrants of Substance 2 that if the substance covered by the registration is obtained from the well-defined substance with EC# 216-823-5, ECHA is of the view that an adaptation of the list number EC# 500-089-0 currently assigned in the registration dossier for Substance 2 will be necessary.

ALKHOBAR • AMSTERDAM • ATLANTA • BEIJING • BOSTON • BRISBANE • BRUSSELS • CHICAGO • CLEVELAND • COLUMBUS • DALLAS
DETROIT • DUBAI • DÜSSELDORF • FRANKFURT • HONG KONG • HOUSTON • IRVINE • LONDON • LOS ANGELES • MADRID • MELBOURNE
MEXICO CITY • MIAMI • MILAN • MINNEAPOLIS • MOSCOW • MUNICH • NEW YORK • PARIS • PERTH • PITTSBURGH • RIYADH
SAN DIEGO • SAN FRANCISCO • SÃO PAULO • SHANGHAI • SILICON VALLEY • SINGAPORE • SYDNEY • TAIPEI • TOKYO • WASHINGTON

TO WHOM IT MAY CONCERN October 16, 2018 Page 2

Thus, we ask the SIEF members:

- to check the identity of their starting material, and
- to take into account that as a result of the ECHA request, the lead registrant might have to initiate a procedure for the change of the list number EC# 500-089-0 currently assigned to Substance 2. The description of the entire process is provided here <a href="https://echa.europa.eu/support/how-to-improve-your-dossier/how-to-change-your-substance-identifier">https://echa.europa.eu/support/how-to-improve-your-dossier/how-to-change-your-substance-identifier</a>

We will keep you informed about any dossier updates that will be made by the lead registrant in line with the above.

Kind regards,

AVOCATS - ADVOCATEN

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

1000 BRUSSELS, BELGIUM

4 RUE DE LA RÉGENCE • REGENTSCHAPSSTRAAT 4

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

BERNARD AMORY RENATO ANTONINI(1) CHANTAL BIERNAUX CHARLOTTE BREUVART(2) FERDINAND BRUGHMANS SÉBASTIEN CHAMPAGNE SERGE CLERCKX THOMAS DE MUYNCK(3) YVAN DESMEDT MATTHIEU DUPLAT KAARLI H. EICHHORN(10) VANESSA FONCKE URSULA SCHLIESSNER (5) CRISTIANA SPONTONI(1)

MARIO TODINO(7)

PHILIPP WERNER(8)

ALEXANDRE VERHEYDEN(3)

LAURENT DE MUYTER CHARLES de NAVACELLE(2)(3) JÖRG HLADJK(9) LUC G. HOUBEN(3) HOWARD M LIEBMAN(4) DAVID ROGER

Members of the Brussels Bar (1)Member of the Rome Bar (2)Member of the Paris Bar (3)Member of the New York Bar Columbia Bar (5)Member of the Düsseldorf Bar (6)Admitted to the Paris Bar (7)Member of the Naples Bar (8)Member of the Berlin Bar <sup>(9)</sup>Member of the (10)Member of the Swedish Bar

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

June 7, 2018

JP018852 829424-600001

#### TO WHOM IT MAY CONCERN

**BY E-MAIL** 

Dear SIEF Members and Joint Registrants,

Re: **REACH: SIEF Communication** 

- CAS no. 36425-15-7; NLP no. 500-089-0 (so-called Substance 2, commonly referred to as "small vinyl ester")
- CAS no. 36425-16-8; NLP no. 500-090-6 (so-called Substance 3, commonly referred to as "modified small vinyl ester")

We hereby wish to notify you of the following changes to the joint registration made last year.

1.

Substance 2 only: new range of unknown constituents (0-2 % instead of 0-1%) in the boundary composition of S2, followed by a note that the unknown constituents do not contribute to classification and labeling of S2. The changes are below in bold.

Constituent	Typical concentration	Concentration range	Remarks
Bis-GMA EC no.: 216-367-7	71.1 % (w/w)	>=70 - <=95 % (w/w)	
Bis-GMA Dimer EC no.:	16 % (w/w)	>=5 - <=20 % (w/w)	
Bis-GMA Trimer EC no.:	5.4 % (w/w)	>=1 -<=10 % (w/w)	
Epoxy monoBis-GMA EC no.:	4 % (w/w)	>=0 - <=5 % (w/w)	No EC number/name is allocated
Dihydroxy monoBisGMA EC no.:	2 % (w/w)	>=0 - <=5 % (w/w)	No EC number/name is allocated

ALKHOBAR • AMSTERDAM • ATLANTA • BEIJING • BOSTON • BRISBANE • BRUSSELS • CHICAGO • CLEVELAND • COLUMBUS • DALLAS DETROIT • DUBAI • DÜSSELDORF • FRANKFURT • HONG KONG • HOUSTON • IRVINE • LONDON • LOS ANGELES • MADRID • MELBOURNE MEXICO CITY • MIAMI • MILAN • MINNEAPOLIS • MOSCOW • MUNICH • NEW YORK • PARIS • PERTH • PITTSBURGH • RIYADH SAN DIEGO • SAN FRANCISCO • SÃO PAULO • SHANGHAI • SILICON VALLEY • SINGAPORE • SYDNEY • TAIPEI • TOKYO • WASHINGTON

# TO WHOM IT MAY CONCERN June 7, 2018

Page 2

Constituent	Typical concentration	Concentration range	Remarks
methacrylic acid EC no.: 201-204-4	0.8 % (w/w)	>=0 -<=1 % (w/w)	Residual monomer
Unknown Constituents EC no.:	<1 % (w/w)	, ,	Unknown constituents do not contribute to classification and labeling

2.

<u>Substance 2</u> + <u>Substance 3</u>: following an informal request by ECHA and a telephone conference between ECHA and the UPR Consortium Technical Committee, the Consortium has decided to change the SIP of both substances to (i) make it clear that the starting material is BADGE with EC 500-033-5, and (ii) not to take into account a potential excess of metacrylic acid.

# Before the change:

"Bisphenol A Diglycidyl Ether is heated in a closed reactor to between 100 and 150 °C at atmospheric pressure. Methacrylic acid is dosed and the reaction left for up to 24 hours. The ratio of Bisphenol A Diglycidyl Ether: Methacrylic acid is 1:2-5 mols. Once conversion to Small Vinyl Ester is greater than 96%, the reaction is stopped and the product blended with a reactive diluent, ready to be placed on the market".

#### After the change:

"4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane (EC 500-033-5) is heated in a closed reactor to between 100 and 150°C at atmospheric pressure. Methacrylic acid is dosed and the reaction left for up to 24 hours. The ratio of reactants is 1:2 moles. Once conversion to Small Vinyl Ester is greater than 96%, the reaction is stopped and the material blended with a reactive diluent, ready to be placed on the market".

3.

The consumer use has been deleted from the joint registration of <u>Substance 2 and Substance 3</u> and from the CSR as this use is not supported any longer. If you have any questions concerning this deletion, please do not hesitate to contact us.

Kind regards,

Albany
Atlanta
Brussels
Denver
Los Angeles
New York
Orange County

Rancho Santa Fe San Diego San Francisco Washington, DC McKenna Long & Aldridge...

Member of the Düsseldorf Bar
Advocaat-Avocat - Member of the Brussels Bar

Ursula Schliessner 1

Nora Wouters<sup>2</sup>

2, Avenue de Tervueren 1040 Brussels, Belgium Telephone: (32-2) 278-1211 mckennalong.com

EMAIL ADDRESS uschliessner@mckennalong.com

URSULA SCHLIESSNER 32.2.278.1224

July 16, 2012

By ELECTRONIC MAIL

#### TO WHOM IT MAY CONCERN

Re: REACH: SIEF Communication

- CAS no. 36425-15-7; NLP no. 500-089-0 (so-called <u>Substance 2</u>, commonly referred to as "small vinyl ester")
- CAS no. 36425-16-8; NLP no. 500-090-6 (so-called <u>Substance 3</u>, commonly referred to as "modified small vinyl ester")

Dear SIEF Member,

As you are aware from previous SIEF communications, and in particular the SIEF communication of September 29, 2010, available at <a href="www.mlalaw.eu">www.mlalaw.eu</a>, <a href="www.mlalaw.eu">DSM Composite Resins France S.A.S.</a> (for Substance 2) and <a href="Reichhold UK Ltd.">Reichhold UK Ltd.</a> (for Substance 3) have been appointed as Lead Registrants for the respective substances. <a href="https://www.mlalaw.eu">McKenna Long & Aldridge LLP</a> act as Consortium Manager for the UPR REACH Consortium covering both Substances, to which both Lead Registrants are Members.

We are writing to you today to notify you that

- (a) the joint registration dossier for <u>Substance 3</u> has been finalized, submitted to ECHA and the Business Rules and the overall completeness check have been passed successfully in May 2012. SIEF members may therefore purchase letters of access for joint submission at <u>www.mlalaw.eu</u>. The application forms on <u>www.mlalaw.eu</u> for Substance 3 will be made available in due course.
- (b) the registration dossier submitted for <u>Substance 2</u> in September 2010 has been updated with ECHA in May 2012, in particular with read-across of data from Substance 3.

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

# **Substance 3**

# 1) Joint Registration Dossier - Inspection Period

The final joint registration dossier for Substance 3 shall be made available for inspection at the offices of McKenna Long & Aldridge LLP (Consortium Manager UPR Consortium) during office hours upon appointment taken.

### 2) Substance ID

The Substance ID for Substance 3 is set out in **Annex 1**.

# 3) <u>Classification & Labeling</u>

# According to CLP Regulation 1272/2008:

Skin Sens. 1B (Hazard statement: H317: May cause an allergic

sensitization: skin reaction.)

# Hazard pictogram:

GHS07: exclamation mark



# Hazard statements:

H317: May cause an allergic skin reaction.

### **Precautionary statements:**

P261: Avoid breathing dust/fume/gas/mist/vapours/spray.

*P272: Contaminated work clothing should not be allowed out of the workplace.* 

P302+P352: IF ON SKIN: Wash with plenty of soap and water.

P333+P313: If skin irritation or rash occurs: Get medical advice/attention.

P501: Dispose of contents/container to...

### According to Directive 67/548:

Sensitization	R43 May cause
	sensitization by skin
	contact.

# Labelling:

# *Indication of danger:*

#### TO WHOM IT MAY CONCERN

July 16, 2012

Page 3

Xi irritant

### R-phrases:

R43 - may cause sensitization by skin contact

### *S-phrases:*

S36/37 - wear suitable protective clothing and gloves

S60 - this material and its container must be disposed of as hazardous waste

SIEF members are considered as having agreed to the above classification & labeling if they do not object within 30 calendar days after issue date of this SIEF communication.

### 4) DNELs & PNECs

Derived no-effect levels ("DNELs") and predicted no-effect concentrations ("PNECs") were not necessary for Substance 3 (see Annex 2 for justification).

# 5) Chemical Safety Report ("CSR")

The CSR was prepared jointly but shall be submitted individually. A copy of the CSR will be provided to interested SIEF members upon LoA application simultaneously with the joint submission name and token.

# 6) <u>Uses and Guidance on safe use</u>

Guidance on safe use has been included in the Joint Registration Dossier and will be made available to SIEF members upon request. The uses and uses advised against are set out at **Annex 3**.

### **Substance 2**

# 1) <u>Substance ID</u>

Updated substance identity information is set out in **Annex 4**. There are no material changes from the September 2010 version communicated.

# 2) <u>Classification & Labeling</u>

No classification and therefore no change from September 2010.

### 3) DNELs & PNECs

DNELs and PNECs were not necessary for Substance 2 (see Annex 5 for justification, updated from September 2010).

# 4) Chemical Safety Report ("CSR")

The CSR was updated from September 2010 and prepared jointly but shall be submitted individually. A copy of the CSR will be provided to interested SIEF members upon LoA application simultaneously with the joint submission name and token.

# 5) <u>Uses and Guidance on safe use</u>

Guidance on safe use has been included in the Joint Registration Dossier and will be made available to SIEF members upon request. No uses are identified, since the substance is not classified. The substance is used for manufacturing of UP/VE resins. Consumer use is advised against.

# <u>Information for both Substances 2 and 3</u>

# 1) <u>SIEF Agreement</u>

We ask that those SIEF members that wish to participate in the joint registration **of either Substance 2 or 3 or both** sign and return to us the signature page of the SIEF Agreement which was made available in the SIEF communication of September 29, 2010.

# 2) <u>Participation in Joint Submission - Letters of Access</u>

We kindly ask those SIEF members of Substance 2 and Substance 3 who wish to participate in joint submission to fill in the respective letter of access (LoA) application at <a href="www.mlalaw.eu">www.mlalaw.eu</a>, which will be active by the end of July 2012. An on-line tool will guide you through the procedure, options and payment requirements. Once your LoA application has been duly accepted and payment has been made, you shall automatically receive the joint submission token to file the individual parts of your registration dossier. Participation in joint submission is conditional upon completing the procedure and obtaining an LoA at <a href="www.mlalaw.eu">www.mlalaw.eu</a>.

### 3) Cost

Updated cost information for Substances 2 and 3 is set out at **Annex 6**.

Thank you very much for your attention.

Kind regards,

Ursula Schliessner

Partner

McKenna Long & Aldridge LLP

La Wiz

Annexes (6)

# **Annex 1- Substance Identity Substance 3**

The substance **Modified Small Vinyl Ester** is a multi constituent substance (origin: organic) having the following characteristics and physical—chemical properties.

The following public name is used: Modified Small Vinyl Ester.

Table 1. Substance identity

EC number:	500-090-6
EC name:	4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane, reaction products with maleic anhydride and methacrylic acid
CAS number (EC inventory):	36425-16-8
Molecular formula:	С29Н36О8 - С33Н38О11
Molecular weight range:	>= 512.6 <= 610.6

**Table 2. Constituents** 

Constituent	Typical concentration	Concentration range	Remarks
(1-	ca. 70.0 % (w/w)	> 60.0 — < 90.0 %	
methylethylidene)bis[4,		(w/w)	
1-phenyleneoxy(2-			
hydroxy-3,1-			
propanediyl)]			
bismethacrylate			
EC no.: 216-367-7			
Monomaleic bisGMA	ca. 18.0 % (w/w)	ca. 5.0 — ca. 30.0 %	
		(w/w)	
4,4'-	ca. 10.0 % (w/w)	> 2.0 - < 20.0 % (w/w)	
Isopropylidenediphenol,			
polymeric reaction			
products with 1-chloro-			
2,3-epoxypropane,			
reaction products with			
methacrylic acid			

# TO WHOM IT MAY CONCERN July 16, 2012 Page 6

# **Table 3. Impurities**

Impurity	Typical concentration	Concentration range	Remarks
Epoxy monoGMA	ca. 0.8 % (w/w)	> 0.0 — < 1.0 % (w/w)	
Dihydroxy monoGMA	ca. 0.6 % (w/w)	> 0.0 — < 1.0 % (w/w)	
methacrylic acid	< 0.5 % (w/w)	> 0.0 — < 1.0 % (w/w)	
EC no.: 201-204-4			
Catalysts, inhibitors	< 1.0 % (w/w)	> 0.0 — < 1.0 % (w/w)	
Unidentified impurities	< 1.0 % (w/w)	> 0.0 — < 1.0 % (w/w)	

TO WHOM IT MAY CONCERN July 16, 2012 Page 7

# **Annex 2 - DNELs and PNECs Substance 3**

**Substance Name:** Modified Small Vinyl Ester

**EC Number:** 500-090-6

**CAS Number:** 36425-16-8

DNELs and PNEC derivation were not considered necessary. For justification, please see below tables.

# DN(M)ELs for workers

Table 4. DN(M)ELs for workers

Exposure pattern	Route	Descriptor	(Corrected) Dose descriptor *)	Most sensitive endpoint	Justification
Acute - systemic effects	Dermal				No acute dermal DNEL for systemic effects is derived. A DNEL could have been derived based on the sensitization studies and the LOAEL from the LLNA study. However, as dermal bioavailability and exposure is considered negligible based on the physicochemical properties and use of the substance, a DNEL was not derived. In addition, RMMs and OCs will be in place considering the classification with H317.
Acute - systemic effects	Inhalation				No acute inhalation DNEL for systemic effects is derived, considering negligible inhalation exposure based on the physicochemical properties and use of the substance.
Acute - local effects	Dermal				No acute dermal DNEL for local effects is derived, since no local effects were observed in the skin irritation study. In addition, RMMs and OCs will be in place considering the classification with H317.
Acute - local effects	Inhalation				No acute inhalation DNEL for local effects is derived, since there are no indications for local effects after inhalation exposure and

Exposure pattern	Route	Descriptor	DNEL / DMEL	(Corrected) Dose descriptor *)	Most sensitive endpoint	Justification
						considering negligible inhalation exposure based on the physico-chemical properties and use of the substance.
Long-term - systemic effects	Dermal					No long-term dermal DNEL for systemic effects was derived. A DNEL could have been derived based on the sensitization studies and the LOAEL from the LLNA study. However, as dermal bioavailability and exposure is considered negligible based on the physicochemical properties and use of the substance, a DNEL was not derived. In addition, RMMs and OCs will be in place considering the classification with H317.
Long-term - systemic effects	Inhalation					No long-term inhalation DNEL for systemic effects is derived, considering negligible inhalation exposure based on the physicochemical properties and use of the substance.
Long-term - local effects	Dermal					No long-term dermal DNEL for local effects is derived, considering the absence of local effects in the skin irritation study. In addition, RMMs and OCs will be in place considering the classification with H317. Bioavailability and exposure is considered negligible based on the physico-chemical properties and use of the substance, a DNEL was not derived. In addition, RMMs and OCs will be in place considering the classification with H317.

Exposure pattern	Route	Descriptor	descriptor *)	Most sensitive endpoint	Justification
Long-term - local effects	Inhalation				No long-term inhalation DNEL for local effects is derived, considering negligible inhalation exposure based on the physicochemical properties and use of the substance.

<sup>\*)</sup> The (corrected) dose descriptor starting points have been automatically calculated by multiplying the values of the fields "D(N)MEL" and "Assessment factor" provided in the Endpoint summary of IUCLID section 7. Toxicological information. It reflects the value after any corrections, e.g. route-to-route extrapolation. See column "Justification" for the rationale behind such modifications and the use of assessment factors.

Table 5. DN(M)ELs for the general population

Exposure pattern	Route	Descriptor	(Corrected) Dose descriptor *)	Most sensitive endpoint	Justification
Acute - systemic effects	Dermal				No acute dermal DNEL for systemic effects is derived for the general population, since there will be no exposure of the general population since consumer use of Modified Small Vinyl Ester is excluded and the general population will not be exposed through the environment.
Acute - systemic effects	Inhalation				No acute inhalation DNEL for systemic effects is derived for the general population, since there will be no exposure of the general population since consumer use of Modified Small Vinyl Ester is excluded and the general population will not be exposed through the environment.
Acute - systemic effects	Oral				No acute oral DNEL for systemic effects is derived for the general population, since there will be no exposure of the general population since consumer use of Modified Small Vinyl Ester is excluded and the general population will not be exposed through the environment.
Acute - local effects	Dermal				No acute dermal DNEL for local effects is derived for the general population, since there will be no exposure of the general population since consumer use of Modified Small Vinyl Ester is excluded and the general population will not be exposed through the environment.
Acute - local	Inhalation				No acute inhalation DNEL for local effects is

Exposure pattern	Route	Descriptor	DNEL / DMEL	(Corrected) Dose descriptor *)	Most sensitive endpoint	Justification
effects						derived for the general population, since there will be no exposure of the general population since consumer use of Modified Small Vinyl Ester is excluded and the general population will not be exposed through the environment.
Long-term - systemic effects	Dermal					No long-term dermal DNEL for systemic effects is derived for the general population, since there will be no exposure of the general population since consumer use of Modified Small Vinyl Ester is excluded and the general population will not be exposed through the environment.
Long-term - systemic effects	Inhalation					No long-term inhalation DNEL for systemic effects is derived for the general population, since there will be no exposure of the general population since consumer use of Modified Small Vinyl Ester is excluded and the general population will not be exposed through the environment.
Long-term - systemic effects	Oral					No long-term oral DNEL for systemic effects is derived for the general population, since there will be no exposure of the general population since consumer use of Modified Small Vinyl Ester is excluded and the general population will not be exposed through the environment.
Long-term - local effects	Dermal					No long-term dermal DNEL for local effects is derived for the general population, since there will be no exposure of the general population

Exposure pattern	Route	Descriptor		Most sensitive endpoint	Justification
					since consumer use of Modified Small Vinyl Ester is excluded and the general population will not be exposed through the environment.
Long-term - local effects	Inhalation				No long-term inhalation DNEL for local effects is derived for the general population, since there will be no exposure of the general population since consumer use of Modified Small Vinyl Ester is excluded and the general population will not be exposed through the environment.

<sup>\*)</sup> The (corrected) dose descriptor starting points have been automatically calculated by multiplying the values of the fields "D(N)MEL" and "Assessment factor" provided in the Endpoint summary of IUCLID section 7. Toxicological information. It reflects the value after any corrections, e.g. route-to-route extrapolation. See column "Justification" for the rationale behind such modifications and the use of assessment factors.

Table 6. PNEC water

PNEC	Assessment factor	Remarks/Justification
		A PNEC aqua (freshwater) cannot be derived since there are no fixed EC50 values from the studies available. At the water solubility limit no toxicological effects were found.
		A PNEC aqua (marine water) cannot be derived since there are no fixed EC50 values from the studies available. At the water solubility limit no toxicological effects were found.
		A PNEC aqua (intermittent release) cannot be derived since there are no fixed EC50 values from the studies available. At the water solubility limit no toxicological effects were found. Furthermore, a separate PNEC for intermittent release is not considered required.

Table 7. PNEC sediment

PNEC	Assessment factor	Remarks/Justification
		PNEC sediment (freshwater) cannot be derived, since there are no studies on sediment organisms. Furthermore, derivation using the EPM (equilibrium partition method) cannot be used as there is no PNEC aqua.
		PNEC sediment (marine water) cannot be derived, since there are no studies on sediment organisms. Furthermore, derivation using the EPM (equilibrium partition method) cannot be used as there is no PNEC aqua.

Table 8. PNEC soil

PNEC	Assessment factor	Remarks/Justification
		PNEC soil cannot be derived, since there are no terrestrial studies available. Furthermore, derivation using the EPM is not possible since there is no PNEC aqua available.

### Table 9. PNEC sewage treatment plant

Value	Assessment factor	Remarks/Justification
PNEC STP: 10 mg/L	10	Extrapolation method: assessment factor  The PNEC STP is derived by applying an assessment factor of 10 to the NOEC of 100 mg/L from the activated sludge inhibition study.

### Table 10. PNEC oral

PNEC	Assessment factor	Remarks/Justification
		The substance is not classified as H373, H372, H360, H361 or H362 under the CLP Regulation. Therefore, exposure assessment regarding secondary poisoning is not required and thus no PNEC oral is derived.

### **Annex 3 – Uses Substance 3**

Table 11. Uses by workers in industrial settings

Confidential	IU number	Identified Use (IU) name	Substance supplied to that use	Use descriptors
	1	Manufacturing of the substance/Mo dified Small Vinyl Ester	as such (substance itself)	Process category (PROC):  PROC 3: Use in closed batch process (synthesis or formulation)  Environmental release category (ERC):  ERC 1: Manufacture of substances  Subsequent service life relevant for that use?: no
	2	Formulation – manufacturing of formulated resins	as such (substance itself)	Process category (PROC):  PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 15: Use as laboratory reagent 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 1: Use in closed process, no likelihood of exposure  Market sector by type of chemical product: PC 32: Polymer preparations and compounds  Environmental release category (ERC): ERC 2: Formulation of preparations

Confidential	IU number	Identified Use (IU) name	Substance supplied to that use	Use descriptors
	3	Industrial FRP	as such	Sector of end use (SU): SU 3: Industrial uses Subsequent service life relevant for that use?: no Process category (PROC):
	3	manufacturing using UP/VE resins and/or formulated resins		PROC 10: Roller application or brushing PROC 7: Industrial spraying PROC 13: Treatment of articles by dipping and pouring PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 3: Use in closed batch process (synthesis or formulation) PROC 14: Production of preparations or articles by tabletting, compression, extrusion, pelletisation  Market sector by type of chemical product: PC 32: Polymer preparations and compounds  Environmental release category (ERC): ERC 6d: Industrial use of process regulators for polymerisation processes in production of
	4	Industrial FRP	as such	resins, rubbers, polymers  Sector of end use (SU): SU 3: Industrial uses  Subsequent service life relevant for that use?: no  Process category (PROC):

Confidential	IU number	Identified Use (IU) name	Substance supplied to that use	Use descriptors
		manufacturing – related activities	(substance itself) in a mixture	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 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 15: Use as laboratory reagent  Market sector by type of chemical product: PC 32: Polymer preparations and compounds  Environmental release category (ERC): ERC 6d: Industrial use of process regulators for polymerisation processes in production of resins, rubbers, polymers  Sector of end use (SU): SU 3: Industrial uses  Subsequent service life relevant for that use?: no

Table 12. Uses by professional workers

Confide	ential		1	Substance supplied to that use	Use descriptors
		5		(substance	Process category (PROC): PROC 3: Use in closed batch process (synthesis or formulation)

Confidential	IU number	Identified Use (IU) name	Substance supplied to that use	Use descriptors
		using UP/VE resins and/or formulated resins	in a mixture	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) PROC 10: Roller application or brushing PROC 11: Non industrial spraying
				Market sector by type of chemical product:
				PC 9b: Fillers, putties, plasters, modelling clay PC 32: Polymer preparations and compounds
				Environmental release category (ERC):
				ERC 8c: Wide dispersive indoor use resulting in inclusion into or onto a matrix ERC 8f: Wide dispersive outdoor use resulting in inclusion into or onto a matrix
				Sector of end use (SU):
				SU22: Professional uses
				Subsequent service life relevant for that use?: no
	6	Professional	as such	Process category (PROC):
		FRP manufacturing – related activities	(substance itself) in a mixture	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 15: Use as laboratory reagent
				Market sector by type of chemical product:
				PC 9b: Fillers, putties, plasters, modelling clay PC 32: Polymer preparations and compounds

Confidentia	l IU number	3	Substance supplied to that use	Use descriptors
				Environmental release category (ERC):  ERC 8c: Wide dispersive indoor use resulting in inclusion into or onto a matrix ERC 8f: Wide dispersive outdoor use resulting in inclusion into or onto a matrix  Sector of end use (SU):  SU 22: Professional uses  Subsequent service life relevant for that use?: no

### <u>Most common technical function of substance (what it does):</u>

manufacturing of UP/VE resins

### Uses advised against

Consumer use is advised against.

### **Annex 4 – Substance Identity Substance 2**

The substance **Small Vinyl Ester** is a multi constituent substance (origin: organic) having the following characteristics and physical—chemical properties (see the IUCLID dataset for further details).

The following public name is used: Small Vinyl Ester.

Table 13. Substance identity

EC number:	500-089-0
EC name:	4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane, reaction products with methacrylic acid
CAS number (EC inventory):	36425-15-7
Molecular formula:	C29H36O8
Molecular weight range:	512.6

Description: Oligomeric reaction products of 4,4'-isopropylidenediphenol with 1-chloro-2,3-epoxypropane, reaction products with methacrylic acid

Degree of purity: > 70.0 - < 95.0 % (w/w)

**Table 14. Constituents** 

Constituent	Typical concentration	Concentration range	Remarks
bisGMA	ca. 80.0 % (w/w)	> 70.0 — < 95.0 %	
EC no.: 216-367-7		(w/w)	
4,4'-	ca. 13.0 % (w/w)	> 3.0 — < 25.0 % (w/w)	No EC number/name,
Isopropylidenediphenol,			CAS number/name or
polymeric reaction			IUPAC name is
products with 1-chloro-			allocated.
2,3-epoxypropane,			
reaction products with			
methacrylic acid			

Table 15. Impurities

Impurity	Typical concentration	Concentration range	Remarks
Epoxy monoGMA	ca. 3.0 % (w/w)	> 0.0 — < 5.0 % (w/w)	No EC number/name is allocated
Dihydroxy monoGMA	ca. 2.0 % (w/w)	> 0.0 — < 5.0 % (w/w)	No EC number/name is allocated
methacrylic acid	< 1.0 % (w/w)	> 0.0 — < 1.0 % (w/w)	Residual monomer
EC no.: 201-204-4			
Catalysts, inhibitors	< 1.0 % (w/w)	> 0.0 — < 1.0 % (w/w)	
Unidentified impurities	< 1.0 % (w/w)	> 0.0 — < 1.0 % (w/w)	

### **Annex 5 – DNELs & PNECs Substance 2**

### Table 16. DN(M)ELs for workers

Exposure pattern	Route	Descriptor	DNEL / DMEL	(Corrected) Dose descriptor *)	Most sensitive endpoint	Justification
Acute - systemic effects	Dermal					As an acute toxicity hazard leading to classification and labelling of the substance has not been identified, the long-term DNEL is considered sufficient to ensure that effects from acute exposure to the substance do not occur (in accordance with ECHA guidance on information requirements and chemical safety assessment: Chapter R.*: characterisation of dose [concentration]-response for human healt, May 2008 and Part B: Hazard Assessment, Draft new chapter B.8 Scope of Exposure Assessment, March 2010).
Acute - systemic effects	Inhalation					As an acute toxicity hazard leading to classification and labelling of the substance has not been identified, the long-term DNEL is considered sufficient to ensure that effects from acute exposure to the substance do not occur (in accordance with ECHA guidance on information requirements and chemical safety assessment: Chapter R.*: characterisation of dose [concentration]-response for human healt, May 2008 and Part B: Hazard Assessment, Draft new chapter B.8 Scope of Exposure Assessment, March 2010).

Exposure pattern	Route	Descriptor	DNEL / DMEL	(Corrected) Dose descriptor *)	Most sensitive endpoint	Justification
Acute - local effects	Dermal					Since no local effects were noted after dermal exposure (skin irritation study), local DNELs were not derived.
Acute - local effects	Inhalation					Since inhalation exposure is considered to be negligible, a local DNEL is not considered applicable. Furthermore, there are no indications from the available data for occurence local effects after exposure to the substance.
Long-term - systemic effects	Dermal	DNEL (Derived No Effect Level)	20.4 mg/kg bw/day	: 44,064.0 mg/kg bw/day (based on AF of 2160)	acute toxicity	See discussion.
Long-term - systemic effects	Inhalation	DNEL (Derived No Effect Level)	3.3 mg/m <sup>3</sup>	: 7,128.0 mg/m³ (based on AF of 2160)	acute toxicity	See discussion.
Long-term - local effects	Dermal					Since no local effects were observed after dermal exposure, local DNELs were not considered applicable.
Long-term - local effects	Inhalation					Since inhalation exposure is considered to be negligible, a local DNEL is not considered applicable. Furthermore, there are no indications from the available data for occurence local effects after exposure to the substance.

<sup>\*)</sup> The (corrected) dose descriptor starting points have been automatically calculated by multiplying the values of the fields "D(N)MEL" and "Assessment factor" provided in the Endpoint summary of IUCLID section 7. Toxicological information. It reflects the value after any corrections, e.g. route-to-route extrapolation. See column "Justification" for the rationale behind such modifications and the use of assessment factors.

Table 17. DN(M)ELs for the general population

Exposure pattern	Route	Descriptor	(Corrected) Dose descriptor *)	Most sensitive endpoint	Justification
Acute - systemic effects	Dermal				As an acute toxicity hazard leading to classification and labelling of the substance has not been identified, the long-term DNEL is considered sufficient to ensure that effects from acute exposure to the substance do not occur (in accordance with ECHA guidance on information requirements and chemical safety assessment: Chapter R.*: characterisation of dose [concentration]-response for human healt, May 2008 and Part B: Hazard Assessment, Draft new chapter B.8 Scope of Exposure Assessment, March 2010).
Acute - systemic effects	Inhalation				As an acute toxicity hazard leading to classification and labelling of the substance has not been identified, the long-term DNEL is considered sufficient to ensure that effects from acute exposure to the substance do not occur (in accordance with ECHA guidance on information requirements and chemical safety assessment: Chapter R.*: characterisation of dose [concentration]-response for human healt, May 2008 and Part B: Hazard Assessment, Draft new chapter B.8 Scope of Exposure Assessment, March 2010).

Exposure pattern	Route	Descriptor	DNEL / DMEL	(Corrected) Dose descriptor *)	Most sensitive endpoint	Justification
Acute - systemic effects	Oral					As an acute toxicity hazard leading to classification and labelling of the substance has not been identified, the long-term DNEL is considered sufficient to ensure that effects from acute exposure to the substance do not occur (in accordance with ECHA guidance on information requirements and chemical safety assessment: Chapter R.*: characterisation of dose [concentration]-response for human healt, May 2008 and Part B: Hazard Assessment, Draft new chapter B.8 Scope of Exposure Assessment, March 2010).
Acute - local effects	Dermal					Since no local effects were noted after dermal exposure (skin irritation study), local DNELs were not derived.
Acute - local effects	Inhalation					Since inhalation exposure is considered to be negligible, a local DNEL is not considered applicable. Furthermore, there are no indications from the available data for occurence local effects after exposure to the substance.
Long-term - systemic effects	Dermal	DNEL (Derived No Effect Level)	15.3 mg/kg bw/day	: 55,080.0 mg/kg bw/day (based on AF of 3600)	acute toxicity	See discussion.
Long-term - systemic effects	Inhalation	DNEL (Derived No Effect Level)	0.99 mg/m³	: 3,564.00 mg/m³ (based on AF of	acute toxicity	See discussion.

Exposure pattern	Route	Descriptor	DNEL / DMEL	(Corrected) Dose descriptor *)	Most sensitive endpoint	Justification
				3600)		
Long-term - systemic effects	Oral	DNEL (Derived No Effect Level)	1.42 mg/kg bw/day	: 5,112.00 mg/kg bw/day (based on AF of 3600)	acute toxicity	See discussion.
Long-term - local effects	Dermal					Since no local effects were noted after dermal exposure (skin irritation study), local DNELs were not derived.
Long-term - local effects	Inhalation					Since inhalation exposure is considered to be negligible, a local DNEL is not considered applicable. Furthermore, there are no indications from the available data for occurence local effects after exposure to the substance.

<sup>\*)</sup> The (corrected) dose descriptor starting points have been automatically calculated by multiplying the values of the fields "D(N)MEL" and "Assessment factor" provided in the Endpoint summary of IUCLID section 7. Toxicological information. It reflects the value after any corrections, e.g. route-to-route extrapolation. See column "Justification" for the rationale behind such modifications and the use of assessment factors.

Table 18. PNEC water

PNEC	Assessment factor	Remarks/Justification
		A PNEC aqua (freshwater) cannot be derived since there are no fixed EC50 values from the studies available. At the water solubility limit no toxicological effects were found.
		A PNEC aqua (marine water) cannot be derived since there are no fixed EC50 values from the studies available. At the water solubility limit no toxicological effects were found.
		A PNEC aqua (intermittend release) cannot be derived since there are no fixed EC50 values from the studies available. At the water solubility limit no toxicological effects were found. Furthermore, a separate PNEC for intermittend release is not considered required.

### Table 19. PNEC sediment

PNEC	Assessment factor	Remarks/Justification
		PNEC sediment (freshwater) cannot be derived, since there are no studies on sediment organisms. Furthermore, derivation using the EPM (equilibrium partition method) cannot be used as there is no PNEC aqua.
		PNEC sediment (marine water) cannot be derived, since there are no studies on sediment organisms. Furthermore, derivation using the EPM (equilibrium partition method) cannot be used as there is no PNEC aqua.

Table 20. PNEC soil

PNEC	Assessment factor	Remarks/Justification
		PNEC soil cannot be derived, since there are no terrestrial studies available. Furthermore, derivation using the EPM is not possible since there is no PNEC aqua available.

Table 21. PNEC sewage treatment plant

Value	Assessment factor	Remarks/Justification
PNEC STP: 10 mg/L		Extrapolation method: assessment factor  The PNEC STP is derived by applying an assessment factor of 10 to the NOEC of 100 mg/L from the activated sludge inhibition study.

### Table 22. PNEC oral

PNEC	Assessment factor	Remarks/Justification
		The substance is not classified as H373, H372, H360, H361 or H362 under the CLP Regulation. Therefore, exposure assessment regarding secondary poisoning is not required and thus no PNECoral is derived.

### UPR/VER REACH Consortium : Annex 6 - LoA price July 2012

Description of costs	(div	eneral Costs vision factor : EF Members)	Costs spe only to Substand (Division fa 4 SIEF Men	o ce 2 actor :	(D	Costs specific only to Substance 3 vivision factor : SIEF Members)	Sub Co	per LoA for ostance 2 (4 onsortium (lembers)	S	ost per LoA for Substance 3 (3 Consortium members)	•	per LoA for ances 2 & 3
Consortium Management 2008	€	57,000	€	-	€	-	€	14,250	€	14,250	€	14,250
Consortium Management 2009	€	66,440	€	-	€	-	€	16,610	€	16,610	€	16,610
Consortium Management 2010	€	87,460	€	-	€	-	€	21,865	€	21,865	€	21,865
Consortium Management 2011	€	55,150	€	-	€	-	€	13,788	€	13,788	€	13,788
Consortium Management 2012	€	49,000	€	-	€	-	€	12,250	€	12,250	€	12,250
Dossier Preparation 2009	€	204,092	€	-	€	-	€	51,023	€	51,023	€	51,023
Dossier Preparation 2010	€	-	€ 102	2,568	€	2,500	€	25,642	€	833	€	26,475
Dossier Preparation 2011	€	-	€	-	€	110,068	€	1	€	36,689	€	36,689
Dossier Preparation 2012	€	-	€ 2	5,000	€	10,000	€	6,250	€	-	€	6,250
Data purchased (Evonik)	€	-	€ 1	3,812			€	3,453	€	-	€	3,453
Data QSAR	€	-	€	6,500	€	6,500	€	1,625	€	2,167	€	3,792
Data generated (testing) 2008 - GPC Analysis (BASF)	€	1,054	€	-	€	-	€	264	€	264	€	264
Data generated (testing) 2009	€	-	€	-	€	-	€	1	€	-	€	-
Data generated (testing) 2010	€	-	€ 7	2,146	€	49,121	€	18,037	€	16,374	€	34,410
Data generated (testing) 2011	€	-	€	-	€	75,628	€	=	€	25,209	€	25,209
Data generated (testing) 2011 - Daphnia acute toxicity test 5 (*)	) €	-	€	3,587	€	3,587	€	897	€	1,196	€	2,092
Data generated (testing) 2011 - Fish acute toxicity test (*)	€	-	€	2,746	€	2,746	€	686	€	915	€	1,602
Expenses	€	9,000	€	-	€	-	€	2,250	€	2,250	€	2,250
TOTAL with CSA/CSR	€	529,196	€ 220	6,358	€	260,149	€	188,889	€	215,682	€	272,272
Admin Cost (15%)							€	28,333	€	32,352	€	40,841
Handling Fee							€	1,200	€	1,200	€	1,200
TOTAL LOA PRICE							€	218,422	€	249,234	€	314,313
	1 -								_			
CSA/CSR	€	-	€ 5	3,649	€	57,991	€	13,412	€	19,330	€	32,743
TOTAL w/o CSA / CSR	€	529,196	€ 17:	2,709	€	202,158	€	175,476	€	196,352	€	239,529
Admin Cost (15%)	Ť	327,170	- 177	_,, , ,	Ť	202,100	€	26,321	€	29,453	€	35,929
Handling Fee	1						€	1,200	€	1,200	€	1,200
TOTAL LOA PRICE (w/o CSA / CSR)	1						€	202,998	€	227,004	€	276,659

<sup>(\*)</sup> read-across from S3 to S2 (previously paid by S3)

Albany Atlanta Brussels Denver Los Angeles

New York

Philadelphia

San Francisco Washington, D.C.

San Diego

McKenna Long

2, Avenue de Tervueren 1040 Brussels, Belgium Telephone: (32-2) 278-1211 ■ Telefax: (32-2) 278-1200

www.mckennalong.com

Flavia Distefano 1 Ursula Schliessner<sup>2</sup> Richard R. Willis 3 Nora Wouters 4 <sup>1</sup> Member of the Rome Bar

<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

October 15, 2010

### TO WHOM IT MAY CONCERN

Re: **REACH: Revised SIEF Communication** 

CAS no. 36425-15-7; NLP no. 500-089-0 (so-called Substance 2, commonly referred to as "small vinyl ester")

Dear SIEF Member,

Further to the SIEF communication dated September 29, 2010 sent by DSM Composite Resins France S.A.S. on October 5, 2010 (see attached), we hereby would like to communicate revised information regarding the LoA price.

The LoA price (1,000 tons) for substance 2 provided in the earlier SIEF Communication was calculated on the basis of 6 SIEF members participating in joint submission in 2010. As to date no additional SIEF members other than the current 4 members of the Consortium have expressed their intention to register in 2010, we have decided to recalculate the LoA pre-payment based on 4 SIEF members only, i.e.:

- € 242,046.51 with CSA/CSR (including handling fee; excl. VAT where applicable)
- € 229,937.01 without CSA/CSR (including handling fee; excl. VAT where applicable)

If more than 4 registrants register by November 30, 2010, any over-payment collected will be reimbursed to all 2010 1,000 tons registrants thereafter.

Thank you very much for your attention.

Kind regards,

Ursula Schliessner

Partner

McKenna Long & Aldridge LLP

La luiz

Attachments: (1) Calculation of LoA price - new estimation October 2010

(2) SIEF Communication of September 29, 2010 and SIEF Agreement

UPRVER REACH Consor		ım : Calculatio	fium: Calculation of LoA price - new estimation October 2010	- new estima	tion October	2010
Security of the second	General Costs	Costs specific only to Substance 2	Costs specific only to Substance 3	Cost per LoA for Substance 2 (4 SIEF members incl. Consortium members)	Cost per LoA for Substance 3 (3 SIEF members incl. Consortium members)	Cost per LoA for Substances 2 & 3
Management expenses*	€ 263,650.00	€	· ·	€ 65,912.50	€ 65,912.50	€ 65,912.50
Test strategy and general technical support	€ 198,640.00	e e	⊕ -	€ 49,660.00	€ 49,660.00	€ 49,660.00
GPC analysis	CHT.	€ 527.00	€ 527.00	€ 131.75	€ 175.67	€ 307.42
Data purchased	, T	€ 13,812.00	-	€ 3,453.00	¥	€ 3,453.00
QSAR data	4	€ 6,500.00	€ 6,500.00	€ 1,625.00	€ 2,166.67	€ 3,791.67
Data testing**	, CE	€ 352,030.00	€ 64,680.00	€ 63,007.50	€ 21,560.00	€ 84,567.50
Total Data (addition of 3 lines above)	د	€ 272,342.00	€ 71,180.00	€ 68,085.50	€ 23,726.67	€ 91,812.17
Preparation of IUCLID by the						
Consortium	€ -	€ 30,448.00	€ 30,448.00	€ 7,612.00	€ 10,149.33	€ 17,761.33
Preparation of the CSA/CSR and	Ų.	00 001 00	45 42 126 00	10 530 00	00 080 KT 3	34570.00
Lead Registrants' costs	- <u>3</u>					
Miscellaneous	en en	€ 20,000.00	€ 20,000.00			€ 11,666.67
Expenses	€ 6,000.00					
TOTAL COSTS	€ 468,290.00	£ 375,437.00	€ 169,275.00	€ 209,431.75	€ 171,997.50	€ 265,856.75
TOTAL General + S2 + S3 costs	€ 1,013,002.00					
Consortium member cost with CSA/CSR				€ 209,431.75	€ 171,997.50	€ 265,856.75
Consortium member cost w/o CSA/CSR				€ 198,901.75	£ 157,957.50	€ 241,286.75
LoA cost with CSA/CSR (incl. 15% admin cost but excl. Handling fee)				£ 240,846.51	£ 197,797.13	€ 305,735.26
LoA cost w/o CSA/CSR (incl. 15% admin cost but excl. Handling fee)				€ 228,737.01	*	€ 277,479.76
Handling fee				€ 1,200.00	€ 1,200.00	€ 1,200.00
and the same of the same and the same of t		the state of the s	0100 3			

<sup>\*</sup> Management expenses will be allocated according to the presumed number of SIEF members for both substances as of 2010.
\*\*Data testing includes critical tests, physchem, tox, and ecotox testing and covers some additional tests on Substance 2.

### TO WHOM IT MAY CONCERN

Re: REACH: SIEF Communication

- CAS no. 36425-15-7; NLP no. 500-089-0 (so-called <u>Substance 2</u>, commonly referred to as "small vinyl ester")
- CAS no. 36425-16-8; NLP no. 500-090-6 (so-called Substance 3)

Dear SIEF Member,

As you are aware from previous SIEF communications, <u>DSM Composite Resins France S.A.S.</u> (for Substance 2) and <u>Reichhold UK Ltd.</u> (for Substance 3) have been appointed as Lead Registrants for the respective substances.

We are writing to you today to notify you that the joint registration dossier for <u>Substance 2</u> has been finalized, submitted to ECHA and the Business Rules and the overall completeness check have been passed successfully. The dossier for Substance 3 is expected to be finalized in 2011. Set out below and overleaf is critical information for your perusal as well as about the <u>next steps to be taken by SIEF members</u>.

### 1) <u>Data</u>

The list of data that was used in Substance 2's joint registration dossier (per Article 11 (1) REACH) shall be communicated to you upon request (per 29 (3) REACH).

### 2) <u>Joint Registration Dossier - Inspection Period</u>

The final joint registration dossier for Substance 2 will be made available for inspection at the offices of McKenna Long & Aldridge LLP (Consortium Manager UPR Consortium) during office hours between October 15 and October 30, 2010, upon appointment taken at least 48 hours in advance.

### 3) <u>Classification & Labeling</u>

No classification & labeling is necessary for Substance 2.

### 4) <u>DNELs & PNECs</u>

The derived no-effect levels ("DNELs") and predicted no-effect concentrations ("PNECs") have been derived for Substance 2 (see Annex 2)

### 5) Chemical Safety Report ("CSR")

The CSR was prepared jointly but shall be submitted individually (*see* Scenario 4.3 of ECHA Data Submission Manual.<sup>1</sup>) A copy of the CSR will be provided to interested SIEF members simultaneously with the joint submission name and token.

http://echa.europa.eu/doc/reachit/dsm 19 how joint csr en.pdf

### 6) Uses and Guidance on safe use

Substance 2 has no specific uses, only general uses. These general uses can be found on the CEFIC website at <a href="http://www.upresins.org/">http://www.upresins.org/</a>. Guidance on safe use has been included in the Joint Registration Dossier and will be made available to SIEF members upon request.

### 7) Substance ID

The Substance ID for Substance 2 has being finalized (see Annex 1)). Based on comments received, the definition of Substance 2 has been made more precise than in earlier SIEF communications.

### 8) SIEF Agreement

We ask that those SIEF members that wish to participate in the joint registration dossier of either Substance 2 or 3 or both sign and return to us the signature page of the SIEF Agreement attached hereto (Annex 3).

### 9) Participation in Joint Submission - Letters of Access

We kindly ask those SIEF members of Substance 2 who wish to participate in joint submission to fill in a letter of access (LoA) application at <a href="www.mlalaw.eu">www.mlalaw.eu</a>, which will be active from October 18, 2010 onwards. An on-line tool will guide you through the procedure, options and payment requirements. Once your LoA application has been duly accepted and payment has been made, you shall automatically receive the joint submission token to file the individual parts of your registration dossier. Participation in joint submission is conditional upon completing the procedure and obtaining an LoA at www.mlalaw.eu.

For your information, the price for an LoA (1,000 tons) for Substance 2 is expected to be approx. € 160,564.34 with CSA/CSR and € 152,491.34 without CSA/CSR (excl. VAT where applicable) if six SIEF members participate in joint submission in 2010. However, please note that testing proposals have been made in the registration dossier so that additional fees are to be expected in 2011. In order to determine the exact number of SIEF members for 2010 registration of Substance 2 and thus the exact price, we kindly ask the concerned SIEF members to notify us by October 31, 2010 of their registration intentions. Additional pricing information is set out in the SIEF Agreement.

Thank you very much for your attention.

Kind regards,

Dr. Bert Handels

REACH Program Manager DSM Composite Resins DSM Powder Coating Resins

Annexes

### Annex 1

### SUBSTANCE IDENTITY

Composition substance 2

	Range (w-%)	Typical (W- %)
EC 216-367-7 (1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate Or also named bisGMA	70-95	80
4,4'-Isopropylidenediphenol, polymeric reaction products with 1-chloro-2,3-epoxypropane, reaction products with methacrylic acid	3-25	13
Epoxy-, mono adduct (CAS No 96128-39-1): 2,2-(4-(2-hydroxy-3-methacryloyloxy-l-propoxy)-4'-(2,3-epoxy-l-propoxy)]diphenylpropane	0-5	3
Dihydroxy-, mono adduct (CAS No 323177-93-1): 2,2-(4-(2-hydroxy-3-methacryloyloxy-l-propoxy)-4'-(2,3-dihydroxy-1-propoxy)]diphenylpropane	0-5	2
EC 201-204-4 Methacrylic acid	0-1	<1
Unidentified impurities	0-1	<1
Catalysts, inhibitors (processing aids)	0-1	<1
Total	73-133	100

### Annex 2

### **DNELs and PNECs**

**Substance Name:** 

Small Vinyl Ester

**EC Number:** 

500-089-0

CAS Number:

36425-15-7

### BR:245129.4

### DN(M)ELs for workers

Exposure pattern	Route	Descriptor	DNEL/DMEL	(Corrected) Dose descriptor*)	Most sensitive endpoint	Justification
Acute - systemic effects	Dermal					As an acute toxicity hazard leading to classification and labeling of Small Vinyl Ester has not been identified, the long-term DNEL is considered sufficient to ensure that effects from acute exposure to Small Vinyl Ester do not occur (in accordance with ECHA guidance on information requirements and chemical safety assessment: Chapter R.8: characterisation of dose [concentration]-response for human health, May 2008 and Part B: Hazard Assessment, Draft new chapter B.8 Scope of Exposure Assessment, March 2010).
Acute - systemic effects	Inhalation		<b>4</b>			As an acute toxicity hazard leading to classification and labeling of Small Vinyl Ester has not been identified, the long-term DNEL is considered sufficient to ensure that effects from acute exposure to Small Vinyl Ester do not occur (in accordance with ECHA guidance on information requirements and chemical safety assessment: Chapter R.8: characterisation of dose [concentration]- response for human health, May 2008 and Part B: Hazard Assessment, Draft new chapter B.8 Scope of Exposure Assessment, March 2010).
Acute - local effects	Dermal					Since no local effects were noted after dermal exposure (skin irritation study), local DNELs

Justification	were not derived.	Since inhalation exposure is considered to be negligible, a local DNEL is not considered applicable. Furthermore, there are no indications from the available data for occurrence local effects after exposure to Small Vinyl Ester.			Since no local effects were observed after dermal exposure, local DNELs were not considered applicable.	Since inhalation exposure is considered to be negligible, a local DNEL is not considered applicable. Furthermore, there are no indications from the available data for occurrence local effects after exposure to Small Vinyl Ester.
Most sensitive endpoint			acute toxicity	acute toxicity	<b>\$</b> .	
L/DMEL (Corrected) Dose descriptor*)			: 44,080 mg/kg bw/day (based on AF of 2160)	: 7,208 mg/m³ (based on acute toxicity AF of 2160)		
DNET / DMET			20.4 mg/kg bw/day	3.3 mg/m³		
Descriptor			DNEL (Derived No Effect Level)	Inhalation DNEL (Derived No Effect Level)	3.	
Route		Inhalation	Dermal	Inhalation	Dermal	Inhalation
Exposure		Acute - local effects	Long-term - systemic effects	Long-term - systemic effects	Long-term - local effects	Long-term - local effects

BR:245129.4

## DN(M)ELs for the general population

Exposure pattern	Route	Descriptor	DNEL / DMEL (Corrected) Dose descriptor *)	(Corrected) Dose descriptor *)	Most sensitive Justification endpoint	Justification
Acute - systemic effects	Dermal					As an acute toxicity hazard leading to classification and labeling of Small Vinyl Ester has not been identified, the long-term DNEL is considered sufficient to ensure that effects from acute exposure to Small Vinyl Ester do not occur (in accordance with ECHA guidance on information requirements and chemical safety assessment: Chapter R.8: characterisation of dose [concentration]-response for human health, May 2008 and Part B: Hazard Assessment, Draft new chapter B.8 Scope of Exposure Assessment,
Acute - systemic effects	Inhalation		် <u>ခ</u> ွ်			As an acute toxicity hazard leading to classification and labeling of Small Vinyl Ester has not been identified, the long-term DNEL is considered sufficient to ensure that effects from acute exposure to Small Vinyl Ester do not occur (in accordance with ECHA guidance on information requirements and chemical safety assessment: Chapter R.8: characterisation of dose [concentration]-response for human health, May 2008 and Part B: Hazard Assessment, Draft new chapter B.8 Scope of Exposure Assessment,
Acute - systemic effects	Oral					As an acute toxicity hazard leading to classification and labeling of Small Vinyl Ester has not been identified, the long-term DNEL is considered sufficient to ensure that effects from

Exposure	Route	Descriptor	DNEL / DMEL (Corrected) Dose descriptor *	(Corrected) Dose descriptor *)	Most sensitive Justification endpoint	Justification
						acute exposure to Small Vinyl Ester do not occur (in accordance with ECHA guidance on information requirements and chemical safety assessment: Chapter R.8: characterisation of dose [concentration]-response for human health, May 2008 and Part B: Hazard Assessment, Draft new chapter B.8 Scope of Exposure Assessment, March 2010).
Acute - local effects	Dermal					Since no local effects were noted after dermal exposure (skin irritation study), local DNELs were not derived.
Acute - local effects	Inhalation				ž	Since inhalation exposure is considered to be negligible, a local DNEL is not considered applicable. Furthermore, there are no indications from the available data for occurrence local effects after exposure to Small Vinyl Ester.
Long-term - systemic effects	Dermal	DNEL (Derived No Effect Level)	15.3 mg/kg bw/day	: 55,100 mg/kg bw/day (based on AF of 3600)	acute toxicity	
Long-term - systemic effects	Inhalation	DNEL (Derived No Effect Level)	0.99 mg/m³	: 3,555 mg/m³ (based on AF of 3600)	acute toxicity	
Long-term - systemic effects	Oral	DNEL (Derived No Effect Level)	1.42 mg/kg bw/day	: 5,110 mg/kg bw/day (based on AF of 3600)	acute toxicity	
Long-term - local effects	Dermal					Since no local effects were noted after dermal exposure (skin irritation study), local DNELs were not derived.

ş

Justification	Since inhalation exposure is considered to be negligible, a local DNEL is not considered applicable. Furthermore, there are no indications from the available data for occurrence local effects after exposure to Small Vinyl Ester.
Most sensitive endpoint	
(Corrected) Nose elescriptor*)	
DNEL/DMEL (Corrected) Most sensitive Justification Dose endpoint descriptor*)	
Descriptor	
	Inhalation
Exposure Route pattern	Long-term - Inl

3.1

9 1

### PNEC water

PNEC	Assessment factor	Remarks/Justification
		A PNEC aqua (freshwater) cannot be derived since there are no fixed EC50 values from the studies available. At the water solubility limit no toxicological effects were found.
		A PNEC aqua (marine water) cannot be derived since there are no fixed EC50 values from the studies available. At the water solubility limit no toxicological effects were found.
		A PNEC aqua (intermittent release) cannot be derived since there are no fixed EC50 values from the studies available. At the water solubility limit no toxicological effects were found. Furthermore, a separate PNEC for intermittent release is not considered required.

### PNEC sediment

PNEC	Assessment factor	Remarks/Justification
		PNEC sediment (freshwater) cannot be derived, since there are no studies on sediment organisms. Furthermore, derivation using the EPM (equilibrium partition method) cannot be used as there is no PNEC aqua.
		PNEC sediment (marine water) cannot be derived, since there are no studies on sediment organisms. Furthermore, derivation using the EPM (equilibrium partition method) cannot be used as there is no PNEC aqua.

### PNEC soil

factor	Remarks/Justification
	PNEC soil cannot be derived, since there are no terrestrial studies available. Furthermore, derivation using the EPM is not possible since there is no PNEC aqua available.

### PNEC sewage treatment plant

11119/17		
mg/L		1
PNEC STP: 10	10	Extrapolation method: assessment factor
Value	Assessment factor	Remarks/Justification

Value Assessmen factor	t Remarks/Justification
	to the NOEC of 100 mg/L from the activated sludge inhibition study.

### PNEC oral

Assessment factor	Remarks/Justification
	PNEC oral is not derived, since no data are available.

Annex 3 - SIEF Agreement

### SIEF AND JOINT SUBMISSION AGREEMENT

### Unsaturated Polyester Resins ("UPR") (Substances 2 and 3)

### 1. <u>Definitions</u>

- (a) Affiliate(s) shall mean any legal person, which directly or indirectly through one or more intermediaries owns, controls, is controlled by, or is under common control with, another legal person. For the purpose of this definition, a legal person shall be deemed to 'control' another legal person if it has the direct or indirect power to direct or cause the direction of the general management and policies of another legal person whether through the ownership of securities or capital stock, voting stock, by contract or otherwise. A legal person shall presumptively be deemed to control another legal person if it owns, directly or indirectly through one or more intermediaries and whether legally or beneficially fifty per cent (50%) or more of the outstanding voting securities or capital stock or other comparable equity or ownership interest of such legal person.
- (b) Consortium shall mean the members of the UPR REACH Consortium (established by the Consortium Agreement of 2009), of which DSM Composite Resins AG and Reichhold, Inc. are members and in the framework of which their Affiliates DSM Composite Resins France S.A.S. and Reichhold UK Ltd. have agreed to act as respective Lead Registrants for the Joint Registration Dossiers being jointly prepared by the members of the Consortium.
- (c) Consortium Expenses shall mean expenses set out under 4(a) (i), (iii), (iv), (v), and (vi).
- (d) Information or Data 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) 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 (Substance 2 only for the time being) and the Chemical Safety Report(s), as well as guidance on safe use.
- (f) LoA(s) shall mean a letter of access to the Joint Registration Dossier(s) 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 the European Chemicals Agency ("ECHA") by the Lead Registrants 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.
- (g) 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 respective 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.
- (h) *REACH* shall mean Regulation (EC) No 1907/2006 and all subsequent Regulations, Decisions, and other measures adopted in connection thereto.

- (i) Substance(s) shall mean the substance(s) listed in 2.(a) of this SIEF Agreement.
- (i) 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 multiconstituent substances, or as intermediates:

### Substance 2:

- CAS no. 36425-15-7
- NLP no. 500-089-0

### Substance 3:

- CAS no. 36425-16-8
- NLP no. 500-090-6

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

- (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 SIEFs (including the members of the Consortium) of the Substances. Consortium members are represented for purposes of this SIEF Agreement by the respective Lead Registrant.

### a.

### 3. General Rules of Cooperation

- The Parties agree that <u>DSM Composite Resins France S.A.S.</u> (for Substance 2) and <u>Reichhold UK Ltd.</u> (for Substance 3), or their legal successors or another member of the respective SIEF assigned by them pursuant to <u>5. (f)</u> below, will act as the respective Lead Registrant for the Substances and will prepare, within the framework of the Consortium, the respective Joint Registration Dossier for REACH registration of the Substances as and in so 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 respective Lead Registrant also agrees to complete the respective Joint Registration Dossier. Parties that are not members of the Consortium will participate in the joint registration efforts via (g) below in conjunction with an LoA to be granted according to this SIEF Agreement.
- (b) The Joint Registration Dossiers will be prepared in time so that Parties can meet the November 30, 2010 registration deadline for Substance 2 and the May 31, 2013 registration deadline for Substance 3.
- (c) In view of the tight work schedule, the Parties agree that the respective Lead Registrant will use its best efforts to develop the respective Joint Registration Dossier within the Consortium, and they acknowledge that the Consortium has engaged reputable support to assist it in its efforts. The Parties will therefore not object or call into question the respective Joint

Registration Dossier so prepared in as far as applicable to them, and the Parties hereby agree to the respective Joint Registration Dossier as developed within the Consortium.

- (d) The respective Lead Registrant undertakes in turn to regularly update the Parties in writing on the progress made on the respective Joint Registration Dossier as applicable to the Parties. The respective Lead Registrant may ask for cooperation and comments as it sees fit.
- (e) The respective Lead Registrant shall pay the registration fee pursuant to Article 11 (4) REACH as invoiced by ECHA for the submission of the respective Joint Registration Dossier without undue delay in compliance with ECHA's payment terms.
- (f) The Lead Registrants within the framework of the Consortium 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 during office hours (for the Joint Registration Dossier for Substance 2, this two weeks period will be in October 2010, and for Substance 3, it will be during the course of 2011 or 2012). Any Party joining the SIEFs after the respective inspection periods is entitled to inspect the Joint Registration Dossier(s) after having taken an appointment with the Project Manager.
- (g) Provided the Party has fulfilled its payment obligations hereunder, the respective 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 respective Lead Registrant shall also inform the Parties of the submission of the respective Joint Registration Dossier to ECHA. The respective Lead Registrant shall further communicate the confirmation that the respective Joint Registration Dossier has been accepted as 'complete' and the registration number assigned pursuant to Article 20 (3) REACH.

### 4. Cost Sharing

(a) The price for the LoA (Data Compensation Price) is calculated by taking into account *inter alia* management and administration expenses, costs for test strategy and general technical support, costs for existing and new data, costs for the preparation of IUCLID by the Consortium, costs for preparing the Chemical Safety Report and guidance on safe use, and handling fees, *as follows*:

### (i) Management expenses

The expenses incurred to manage the Consortium amount to approximately  $\in$  263,650.

### (ii) Administration cost

There is an administration cost of 15% of the LoA for Parties that are not members of the Consortium.

### (iii) Test strategy and general technical support

This amounts to approximately € 198,640.

### (iv) Existing and new data

The total value of the data for Substance 2 is approximately € 272,342. This includes:

- Existing data (data purchased from a non-Consortium member): € 13,812
- OSAR data: € 6,500
- New data (developed by laboratory: on behalf of the Consortium): € 252,030

The total value of the data for Substance 3 is at this time approximately € 71,180. This includes:

- QSAR data: € 6,500
- New data (developed by laboratory on behalf of the Consortium): € 64,680

### (v) Preparation of IUCLID by the Consortium

The approximate cost to prepare the IUCLID 5 dossier is € 30,448 per substance.

### (vi) <u>Chemical Safety Assessment ("CSA"), Chemical Safety Report ("CSR") and guidance</u> on safe use

The cost for the preparation of the CSA/CSR (including the hazard assessment and summaries as well as setting exposure scenarios) and the guidance on safe use part of the Joint Registration Dossier(s) is  $\in$  42,120 per substance.

### (vii) <u>Handling fee</u>

The fee for handling the LoA request and the joint submission is expected to be  $\[ \]$  1,200.

### (b) Overview and Future Cost

The overview of current cost estimates is set out in Annex 2 as may be adapted from time to time. Based on the above estimates, the Consortium currently estimates the Consortium Expenses for the development of its Joint Registration Dossiers at a total of approximately € 1,009,402. This figure excludes the handling fee, administration cost and any ongoing and future expenses to manage the Consortium during the registration and LoA issuing procedures and additional costs that might arise for future testing and through further requirements from the ECHA after registration. In particular, any cost for Studies requested by ECHA after the Joint Registration Dossiers have been submitted shall be allocated in equal parts to those Parties who need the Studies, i.e. if ECHA requests a Study only for one Substance, only those Parties that have registered or will register that Substance and that require the Study within their tonnage band equally share that new Study's cost.

From the detailed break-down of the figures as set out in Annex 2, it is estimated that if a total of 6 and 3 SIEF members (including current Consortium members) were to join the respective Joint Registration Dossier for Substance 2 and Substance 3 respectively, the price of the LoA to the Joint Registration Dossier(s) for the Substance(s) for non-Consortium members (taking into account the handling fee and administration cost) would be approximately the following:

Substances	With CSA/CSR	Without CSA/CSR
Substance 2 and Substance 3	€ 225,453.09	€ 201,234.09
Substance 2 only	€ 160,564.34	€ 152,491.34
Substance 3 only	€ 153,494.33	€ 137,348.33

- (c) The Consortium will calculate the final price of the LoA for each Substance at the latest shortly before the registration dossier submission to ECHA of the respective Substance based on the number of Parties that have confirmed their registration intentions to the Lead Registrants 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. The final price will be calculated based on the amounts received on the proforma invoices and payment notices after the respective registration deadline. Thereafter, final invoices will be issued. 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. The final price will be considered as a lump-sum fee for the future Parties to participate in joint submission or later registration. 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 respective Lead Registrant 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. Due to the administrative burden upon the Consortium and the unlikelihood of new market entrants, no reimbursements shall be made. Should the number of registrants be significantly higher than the calculation, the additional fee originating from new Parties will be used to cover the running cost of the respective SIEF. The final settlement shall be handled by an independent auditor appointed by the Lead Registrants on June 1, 2022.
- (d) The Lead Registrants will issue LoAs after receipt of a Party's payment and after the Party has had the option to inspect the Joint Registration Dossier(s) as far as it is concerned by it pursuant to 3. (f).
- (e) The respective Lead Registrant shall at all times account for the cost of the respective Joint Registration Dossier and shall keep or shall cause records thereof to be kept by the Consortium's Project Manager 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. <u>Miscellaneous Provisions</u>

- (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 Registrants 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 Registrants or their 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 respective Lead Registrant shall install an email address or other electronic platform for communication within the respective SIEF. The parties agree to regularly and proactively communicate within this platform provided, and to answer any information and communication requests of the respective Lead Registrant or his assignees within five working days at the latest unless the respective 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 respective Lead Registrant shall be considered as released from any obligations under this SIEF Agreement.

1

- (c) Compliance. The Parties shall at all times comply with the applicable laws, including EU competition law.
- (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 an independent law firm appointed by the respective Lead Registrant upon recommendation of the Brussels Bar. 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.

In case the respective Lead Registrant informs ECHA that it has ceased to manufacture the Substance, the other SIEF members must be informed without undue delay and appoint a new lead registrant. The new lead registrant must inform ECHA and the other SIEF members of its nomination and the previous Lead Registrant must inactivate its Lead Registrant status in REACH-IT without undue delay, In addition, the respective Lead Registrant has the right to terminate its functions as Lead Registrant provided another SIEF member has validly agreed to replace it within the respective SIEF, has agreed to the terms of this SIEF Agreement, and has taken up its functions accordingly. The other Parties in the respective SIEF must be informed about this replacement without undue delay.

Parties have the right to terminate this SIEF Agreement at the latest by November 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 Registrants 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 respective Joint Registration Dossier, in case of gross negligence or wilful misconduct. The Lead Registrants 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 respective 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 Registrants 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 payment by the Party for the LoA, or
  - (ii) 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 31, 2010.

COMPANY:
Section 1
(Print company name and address)

### **AFFILIATES:**

(Print company names and addresses of all the affiliates companies of the Company mentioned above to which this SIEF Agreement should be applicable)

### (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") 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)
CONTACT INFORMATION:
(Print contact details for person responsible for SIEF communication)

Page 9 of 13

Registration scope by group, *i.e.* affiliated companies together (take highest applicable tonnage band in the group total; intermediate category only applicable if all group members have exclusive intermediate use only):

A: Registering as an intermediate (not applicable)

B: Tonnage band < 10 t

C: Tonnage band 10 - 100 t with CSR

D: Tonnage band 100 - 1,000 t with CSR

E: Tonnage band > 1,000 t with CSR (for the time being only applicable to

Substance 2)

F. No CSR

Substance	Registration Scope A-F // List of Affiliates
Substance 2	
<ul><li>CAS no. 36425-15-7</li><li>NLP no. 500-089-0</li></ul>	
Substance 3	
<ul> <li>CAS no. 36425-16-8</li> <li>NLP no. 500-090-6</li> </ul>	

### MODEL LETTER OF ACCESS<sup>1</sup>

[address of regulatory authority]

Letter o	f Access	for the	registration	of the	following	substance(s)	under	<b>REACH:</b>

(please tick appropriate box)

☐ Substance 2
<ul> <li>CAS no. 36425-15-7</li> <li>NLP no. 500-089-0</li> </ul>
□ Substance 3
<ul> <li>CAS no. 36425-16-8</li> <li>NLP no. 500-090-6</li> </ul>
Dear Sirs,
The UPR 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 <i>REACH</i> of the following <u>Substances:</u>
☐ Substance 2
☐ Substance 3
(hereinafter collectively referred to as the "Joint Registration Dossier(s)"), 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 himself
□ as an Only Representative pursuant to Article 8 REACH for the following non-EU manufacturer
☐ as a Third Party Representative <sup>2</sup> pursuant to Article 4 REACH.
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.

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

- For Su	bstance	2:
☐ Mar REACH	•	joint parts of the Joint Registration Dossier (Article 10 (a) (iv), (vi), (vii) and (ix)
		oint parts of the Joint Registration Dossier (Article 10 (a) (v) and (b) REACH) in as far amely CSR and guidance on safe use)
□ 'Opt	-out' pu	rsuant to Article 11 (3) for the following mandatory joint parts:
	Article	10 (a)
		(iv)
		(vi)
		(vii)
		(ix)
- For Su	bstance	<b>3</b> :
☐ Mar REACH		joint parts of the Joint Registration Dossier (Article 10 (a) (iv), (vi), (vii) and (ix)
		oint parts of the Joint Registration Dossier (Article 10 (a) (v) and (b) REACH) in as far amely CSR and guidance on safe use)
□ 'Opt	-out' pu	rsuant to Article 11 (3) for the following mandatory joint parts:
	Article	10 (a)
		(iv)
		(vi)
		(vii)
		(ix)

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.

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(s) 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(s) nor is the Applicant authorized to inspect or view the Joint Registration Dossier(s) at ECHA or any related specific document in whole or in part, outside the general inspection period granted by the Consortium.
- 4. This Letter of Access shall in no event be construed as granting the Applicant any property rights whatsoever in the Joint Registration Dossier(s).
- 5. Nothing in this letter shall require the Consortium members to file any additional data.
- 6. In as far as the Joint Registration Dossier(s) may contain CSR(s), 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 itself prepare the CSR, use and exposure scenarios and guidance on safe use, it shall receive an electronic copy of parts Article 10 (a) (iv), (vi), (vii) and (ix) REACH of the Joint Registration Dossier(s) and shall have the rights to use for this purpose only the (robust) study summaries and other information contained therein and for which opt-out has been claimed, 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 CSRs, 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 Registrants DSM Composite Resins AG (for Substance 2) and Reichhold, Inc (for Substance 3), which shall apply in its entirety in addition to the provisions set out hereunder.

# UPR/VER REACH Consortium: Calculation of LoA price - estimated September 2010

Description of costs	General Costs	Costs specific only to Substance 2	lly to C	Costs specific only to Substance 3	Cost Sut SIE incl.	Cost per LoA for Substance 2 (6 SIEF members incl. Consortium members)	Cost per LoA for Substance 3 (3 SIEF members incl. Consortium members)	G Grand	Cost per LoA for Substances 2 & 3	or .3
Management expenses*	E 263,650.00	Э	<del>-</del> е	_	e	43,941.67	e 43,941.67	-	e 43,941.67	27
Test strategy and general technical										
support	E 198,640.00	e	<u>е</u>	-	E	33,106.67	€ 33,106.67	-	€ 33,106.67	57
GPC analysis	e -	e 52	527.00   E	527.00	Э	87.83	e 17:	175.67	€ 263.50	20
Data purchased	<i>-</i>	$\epsilon$ 13,81	3,812.00 €	_	Э	2,302.00	$\epsilon$	ı	$\epsilon$ 2,302.00	90
QSAR data	- <i>э</i>	<i>E</i> 6,50	6,500.00	6,500.00	Э	1,083.33	<i>€</i> 2,166.67	_	€ 3,250.00	00
Data testing**	e -	$\epsilon$ 252,030.00	30.00 €	64,680.00	$\epsilon$	42,005.00	<i>€</i> 21,560.00	Н	E 63,565.00	90
Total Data (addition of 3 lines above)		€ 272,342.00	12.00 €	71,180.00	Э	45,390.33	€ 23,726.67	2.67	e 69,117.00	00
Preparation of IUCLID by the Consortium		   E 30,44	30,448.00 E	30,448.00	E	5,074.67	e 10,149.33	9.33	<b>e</b> 15,224.00	8
Preparation of the CSA/CSR and guidance on safe use	υ	E 42.12	42.120.00 E	42.120.00	e)	7.020.00	E 14.040.00		€ 21.060.00	8
Lead Registrants' costs	· ·		+	- Landenstand	E	1,666.67	-	1,666.67	€ 3,333.33	33
Miscellaneous	E	€ 20,00	20,000.00 €	20,000.00	e	3,333.33	€ 6,666.67	29.9	€ 10,000.00	8
Expenses	€ 6,000.00									
TOTAL COSTS	€ 468,290.00	e 375,437.00	7.00 €	169,275.00	$\epsilon$	139,621.17	€ 133,473.33	(.33	€ 196,046.17	[7]
TOTAL General + S2 + S3 costs	E 1,013,002.00									
Consortium member cost with CSA/CSR					Э	139,621.17	€ 133,473.33	33	€ 196,046.17	[7
Consortium member cost w/o CSA/CSR					e	132,601.17	£ 119,433.33	1.33	€ 174,986.17	17
LoA cost with CSA/CSR (incl. 15% admin cost but excl. Handling fee)					9	160,564.34	€ 153,494.33	1.33	€ 225,453.09	99
LoA cost w/o CSA/CSR (incl. 15% admin cost but excl. Handling fee)	:				e	152,491.34	E 137,348.33		€ 201,234.09	60
Handling fee					Э	1,200.00	$\epsilon$ 1,200.00	10000000000	€ 1,200.00	00
* Management expenses will be allocated according to the presumed number of SIEF members for both substances as of 2010	cording to the presumed r	number of SIEF memb	ers for bo	oth substances as of 2010.						

<sup>\*\*</sup>Data testing includes critical tests, physchem, tox, and ecotox testing and covers some additional tests on Substance 2.