

REACH and CLP compliance considerations for importers and recommended solutions



Enabling Chemical Compliance for A Safer World



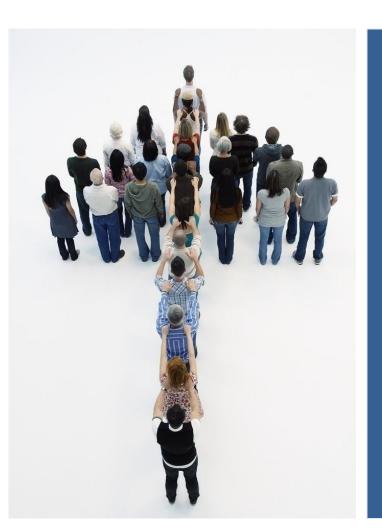
Céad míle fáilte – a warm Irish welcome!





10 July 2014, Free Webinar Louise Halpin, Chief Operations Officer, CIRS Email: <u>louise@cirs-reach.com</u> Connect with me on <u>LinkedIn</u>

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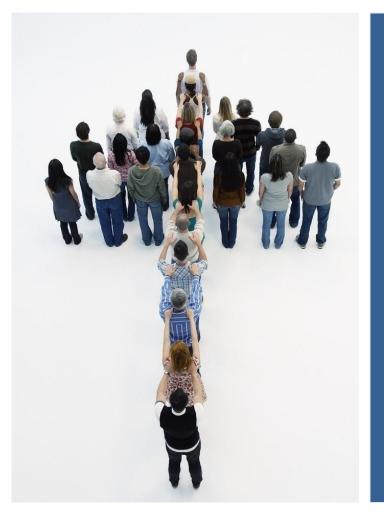




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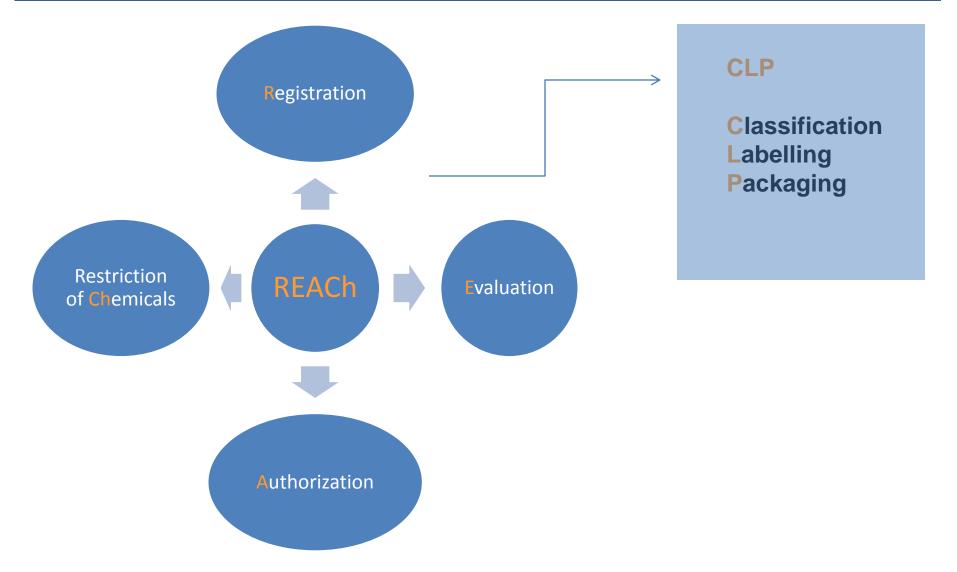
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REACH applies to substances manufactured or **imported** into the EU in quantities of 1 tonne per year or more.





REACh covers:



substances on their own

www.cirs-group.com





in a preparation





or in an article eg. Metal, Paint/ Lacquer/ Pigment/ Ink, Textile, Rubber, Plastic, Paper, Glass, Leather etc







Are you importing any items fitting those descriptions?



If so you need to take steps to comply with REACH or demonstrate compliance within your supply chain



REACH compliance steps depends on a number of factors:

- Date of first import > 1 tonne per annum
- Annual tonnage band
- Company size
- Position in the supply chain
- Substance / mixture classification



Rules are established in REACH and also set out in CLP regulation

Substance / Mixture classification also impacts the labelling and packaging required for the product under CLP regulation

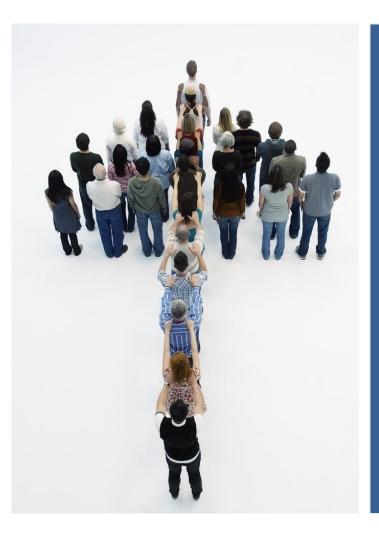
CLP ensures that the hazards presented by chemicals are clearly communicated to workers and consumers in the European Union

<u>and</u>

implements **GHS** (the Globally harmonized system for the labelling of chemicals proposed by the United Nations) within the EU.



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Regulatory:

Advancements in IT infrastructure
Publications of data by ECHA e.g. C&L inventory
Amendments to the legislation
Updates to Annex IV CLP harmonized classification
Growing candidate list of SVHC

Enforcement:

- SME Verification
- •CLP compliance eg SDS
- •Compliance of various organizations eg OR
- Individual Substance evaluations (CoRAP)





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Importers should beware of the growing candidate list of SVHC (substances of very high concern):





Date of recommendation	Amount
28/10/2008	15
13/01/2010	12
30/03/2010	1
18/06/2010	8
15/12/2010	8
20/06/2011	7
19/12/2011	20
18/06/2012	13
19/12/2012	54
19/06/2013	6
16/12/2013	7
16/06/2014	4
Total	155





Regulatory:

Advancements in IT infrastructure
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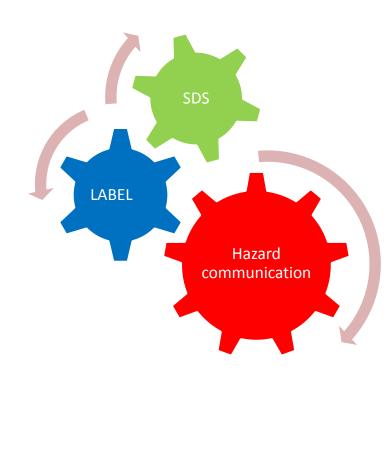
Enforcement:

•SME Verification •CLP compliance eg SDS

•Compliance of various organizations eg OR •Individual Substance evaluations (CoRAP)



Enforcement : CLP example

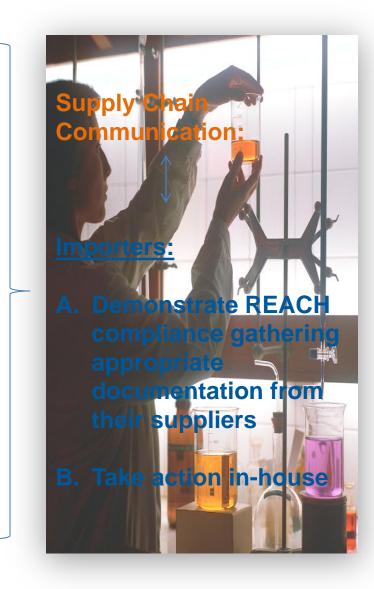


Safety Data Sheet <u>According to Regulation (EU) No. 1907/2006, Annex II,</u> <u>According to Regulation (EU) No. 1272/2008,</u> <u>Amended by REGULATION (EU) No 453/2010</u>					
Ine	thyl orthoformate SDS Record Number: CSSS-TCO-010-******				
Printing date: 16/02/2011	Version 1.1 Revision date: 16/02/2011				
1 Identification of the substance and of the com	pany/undertaking				
1.1 Product identifier:					
Identification on the label/Trade name:	Triethyl orthoformate				
Additional identification:	Triethyl orthoformate				
Identification of the product:	CAS#122-51-0; EC#204-550-4				
Index Number:	Not available				
REACH registration No.:	Not available				
1.2 Relevant identified uses of the substance	e and uses advised against:				
1.2.1 Identified uses: Used in organic synthesis.					
1.2.2 Uses advised against: Not available.					
1.3 Details of the supplier of the safety data	sheet:				
Supplier(Only representative): Supplier(Manufacturer):	Chemical Inspection & Regulation Service Limited				
Address:					
Contact person(E-mail):					
Telephone:					
Fax:					
1.4 Emergency telephone Number:					
+353-41-980 6916					
Available outside office hours?	YES NO X				
2 Hazards Identification					
2.1 Classification of the substance					
2.1.1 Classification:					
The substance is classified as following according to 67/548/EEC and REGULATION (EC) No 1272/2008:					
REGULATION (EC) No 1272/2008					
Hazard classes/Hazard categories	Hazard statement				
Flam. Liq. 3,	H226				
For full text of H- phrases: see section 2.2.					
67/548/FFC					



Key checks for REACH compliance:

- ✓ Evidence of C&L notification
- ✓ Evidence of REACH (pre-)registration
- ✓ Proof that articles do not contain any SVHCs



Enforcement related to evaluation:

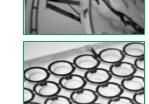
Evaluation under REACH focuses on three different areas:

Examination of testing proposals submitted by registrants
Compliance check of the dossiers submitted by registrants
Substance evaluation

CoRAP – Community Rolling Action Plan, Feb 2012

90 substances for evaluation in years 2012, 2013 and 2014

http://echa.europa.eu/documents/10162/13628/corap_2014-2016_en.pdf







YEAR	MEMBER STATE *	EC NUMBER	CAS NUMBER	SUBSTANCE NAME **	INITIAL GROUNDS FOR CONCERN ***	Member State contact details ****
2012	Sweden	201-289-8	80-54-6	2-(4-tert- butylbenzyl)propionalde hyde	Human health/CMR; Exposure/Wide dispersive use, consumer use (suspected)	Swedish Chemicals Agency Esplanaden 3a, P.O Box 2 SE-172 13 Sundbyberg Swede Katarzyna.Malkiewicz(at)kemi. Tel. +46 8 519 41 358 Lars.Andersson(at)kemi.se Tel. +46 8 519 41 128
2012	Germany	201-983-0	90-30-2	N-1-naphthylaniline	Environment/Suspected PBT; Exposure/Wide dispersive use	Ann Bambauer Federal Institute for Occupatio Safety and Health Division 5 "Federal Office for Chemicals, Authorisation of Biocides" Friedrich-Henkel-Weg 1-25 44149 Dortmund E-mail: chemg(at)baua.bund.d
2012	Finland	202-046-9	91-17-8	decahydronaphthalene	Environment/Suspected PBT; Exposure/High tonnage	Turvallisuus- ja kemikaaliviras (Tukes) / Finnish Safety and Chemicals Agency (Tukes) reach_evaluation(at)tukes.fi
2012	France	203-002-1	102-06-7	1,3-diphenylguanidine	Human health/CMR; Exposure/High tonnage; Risk characterisation ratio >1 (human health)	French Agency for Food, Environmental and Occupation Health Safety (ANSES) Department for Regulated Products (DPR) REACH-CLP Unit henri.bastos(at)anses.fr
2012	Ireland	203-253-7	104-93-8	4-methylanisole	Human health/CMR; Exposure/Wide dispersive use, consumer use; Risk characteriastion ratio close to 1 (human health)	Health and Safety Authority The Metropolitan Building James Joyce Street Dublin 1 Ireland chemicals(at)hsa.ie
2012	Finland	203-625-9	108-88-3	toluene	Human health/CMR and systemic toxicity; Exposure/Wide dispersive use, consumer use, high aggregated tonnage	Turvallisuus- ja kemikaalivirast (Tukes) / Finnish Safety and Chemicals Agency (Tukes) reach_evaluation(at)tukes.fi





Enforcement is strengthening and companies face a dramatic increase in the number of inspection cases by national authorities



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The type of enforcement penalty varies among the EU countries:

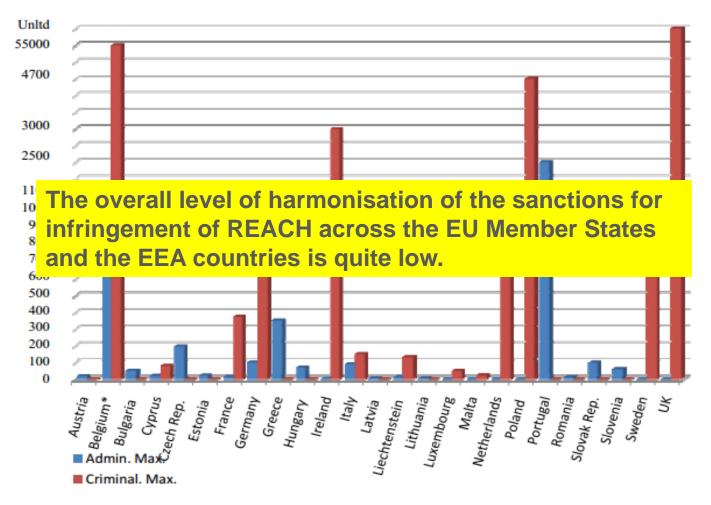
Fines

Injunctions eg market withdrawal
 In Latvia and Lithuania, maximum fine is below 5 000 Euros.

Name and shame methods – non compliance made public In Belgium, fine can go up to 55 000 000 Euros under the federal legislation

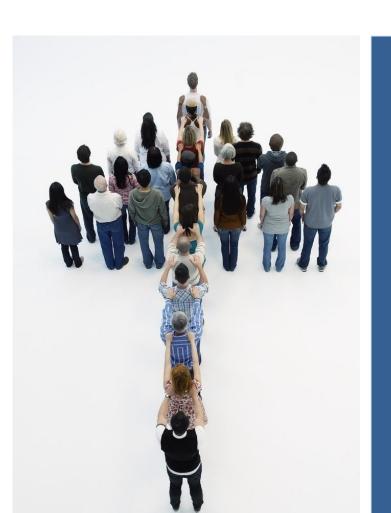
In the UK the fine is unlimited.

Unit= 1000 EUR



Report on penalties applicable for infringement of the provisions of the REACH Regulation in the Member www.cirs-group.com States, Final report 2010

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If you have completed REACH (pre-) registration / CLP notificiation

-Submission(s) report for substance or substances within preparation

- Relevant SDS or eSDS and label in the language of the member state the product is placed on the market
- Test report for articles to demonstrate SVHC screening

If your supplier has completed REACH (pre-) registration / CLP notification

- -REACH Certificate from the supplier OR
- -Tonnage coverage certificate outlining the volume of substance that is allocated to you by the supplier under their registration
- C&L notifications should be carried out if necessary
- Relevant SDS or eSDS and label in the language of the member state the product is placed on the market
- Test report for articles to demonstrate SVHC screening

Overview of documents required



Dear Madam/Sir! We are importers an acrylic paint box from ******* Paints Co. Ltd. We do need some kind of documentation that our tonnage is covered by you as Only Representative. Can you provide us with that? Thank you! Best regards Anon



Overview of documents required



Dear Sirs,

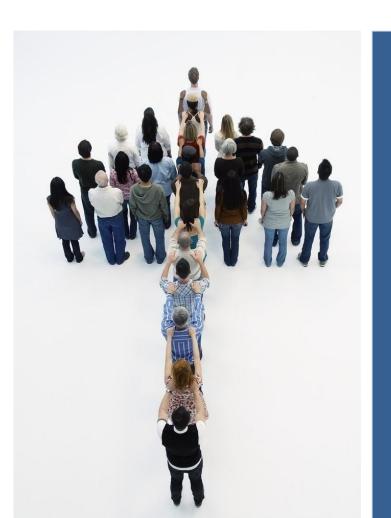
kindly let us have tonnage coverage certificates according to the attached ones from 2011 also for 2012.

For Ammonumpolyphosphate *** I just recognised, that the certificate for 2011 is also missing. So for this product please send it for 2011 + 2012.

Please also send MSDS according to CLP as extended SDS (including the EXPOSURE SCENARIOS, if applicable) for these products.

MSDS must be in English and Greek language please.

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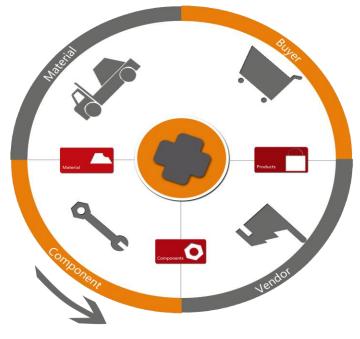


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'The trust of the innocent is the liar's most useful tool.'

We encourage importers to have good supply chain communication, maintain documentation internally regarding the REACH status of all of your imports and monitor this in an ongoing way.



Display of Supply Chain Relations



You shall also contact your suppliers **Only representative** for additional verification of the REACH compliance of your imports.

Tonnage coverage certification

It is important to be cautious about whether your supplier has registered adequate tonnage band and that your volume of product is covered within this registration. Their Only representative can help with this.

REACH COMPLIANC	CE USER MANAGEMENT SYSTEM
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Login User	
Lopin pessi	word
	Forgot Password LOGIN
	powered by





REACH Certificate of Compliance – OR Confirmation and Tonnage Coverage

In compliance with the article 8 of the Regulation (EC) 1907/2006 of 18th December 2006 concerning the registration, evaluation, authorization and restriction of Chemicals (REACH), we hereby confirm that the non-EU manufacturer:

Puji Chemicals Co., L

having its principal place of business at 391 Wener Road, Hangzhou City, P.R of China

as appointed

Chemical Inspection and Regulation Service Limited

having its principal place of business at Singleton House, Laurence Street, Drogheda, Co. Louth, Republic of Ireland

as its Only Representative for REACH compliance of the following substances:

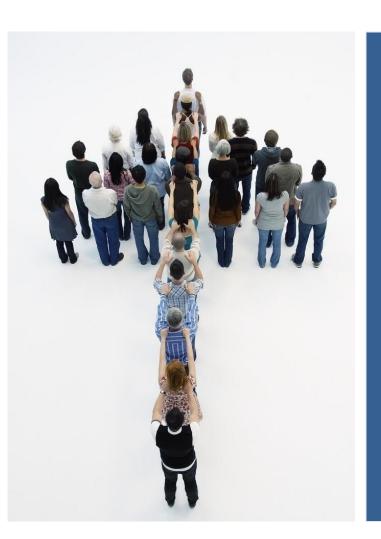
Substance Name	EC No.	CAS No.	Pre-registration / Registration No.	Tonnage (ton/y)	Registration Deadline
Alginic Acid	232-680-1	9005-32-7	05-21136881800-34-0000	1~10	2018
Humic Acid	215-809-6	1415-93-6	05-2115507697-37-0000	10~100	2013
Arginine	205-866-5	74-79-3	05-2115507687-23-0000	1~10	2018
Glycine	200-272-2	36-40-6	05-2115507684-25-0000	1~10	2018
L-serine	200-274-3	56-45-1	05-2115507680-51-0000	1~10	2018
Glutamic Acid	210-522-2	36-86-0	05-2115507683-57-0000	100~1000	2013
Ammonium Sulphate	231-984-1	7783-20-2	05-2115507688-67-0000	1~10	2018

In capacity of the appointed Only Representative, <u>Pull Chemicals Co., Ltd</u> is identified under the Universal Unique Identifier code (UUID):

ECHA-det9-0031-47e8-543157899764

This REACH certificate is not valid unless accompanied by an annex bearing same certificate number This REACH certificate alone should not be used to carry out any kind of import formalities.

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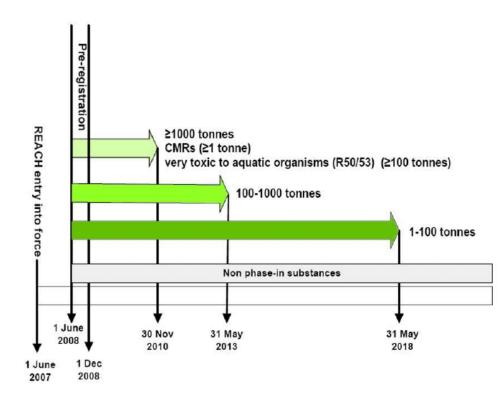
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Check REACH Status & Suppliers intentions:

Before ordering the product ensure you are aware of not only the current REACH status but also the intentions of the manufacturer to continue to maintain REACH compliance.



Example:

Supplier has pre-registered but when full registration is due according to the transitional deadline decides compliance is too expensive.

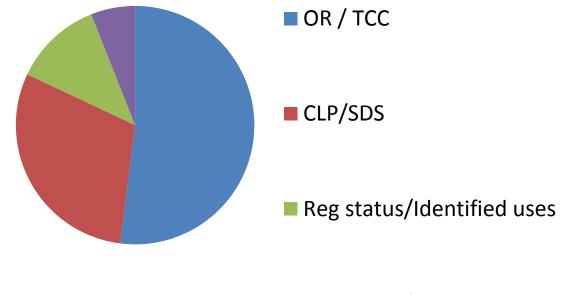
Only EU manufacturers /importers are obliged to comply with REACH. This would cause disruption in your supply chain and should be mitigated.

Supplier compliance checks



Check REACH Status & Suppliers intentions:

6823 emails from EU importers from 2008 to 2014. We've already issued 4276 tonnage coverage certificates to them. Most emails are from Greece, Italy, Germany, France, UK, Portugal and Spain.



SVHC supplier recommendations etc

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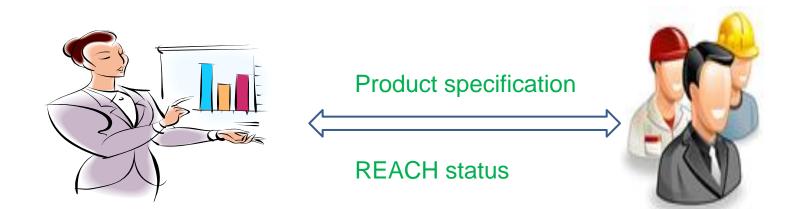


CIRS can assist you with supplier communication and compliance checks. As the largest Only Representative in the world and as a result of our market share, we can also assist you to estimate which suppliers are reliable.





Are you getting what you paid for?





Dear Alice,

thank you for your answer, but unfortunately this information has reached us too late. We have already lived the unpleasant experience as we are victim of a scam made by Hebei *** Chemical Imp against us.

We bought 10.000,00 Kg of Titanium Dioxide, but they sent us 10.000,00 kg of Calcium Carbonate. They sent us a pre shipment sample conform to the first approved sample and then we had this bad surprise.

I think that first it's a REACH problem (are you their OR also for Calcium Carbonate?) and then we can't use this product in our production.

How can we solve this really unpleasant situation? Have you a legal office in China that can help us? Can you suggest us a more reliable TiO2 Chinese manufacturer that you represent for the REACH COMPILANCE?

I hope you'll send us an optimistic answer, Best regards 'Anon'



Dear

We are (were) a customer of a chinese company called *** Hebei who registered a product under the attached registration. We also attached a test report of the product for your reference.

This company is unfortunately a trader who is cheating customers, the pretend having a product by providing documents, then ask for prepayment but do not deliver the goods.

My question is: Is this pre-registration document correct, what's your knowledge about this company ? Have they ever delivered something to Europe under this pre-registration number (which should be known at your side as OR). Finally, do they have any contact person in Europe ?

Regards Peter



Dear Alice

Sorry to contact you once again, but I have to tell you that ***is indeed a company who wants to fraud customers. My first impression was right, but we were not sure and wanted to await the receipt of the goods.

Now we got the ordered goods and found out that the content is not Titanium Dioxide, but some kind of grey-white material for constructions, like a mineral Quartz. We hope that we at least can get the money back we paid, but I' m pessimistic. Can you help us, or can you recommend someone who can help us ?

Of course <u>please give a warning to the other potential customers</u> if you know them and delete them from the REACH pre-registration list.

For us it was too late, and what is more, I expect the other supplier where we ordered, ***-Pigments, is also a cheater. But their goods still have not arrived.

Thanks and regards

Anon



Tips / precautions:

Determine is the supplier newly established

What is the company size of your supplier

Exercise caution and take steps to help estimate whether the supplier is generally reliable.





Check with CIRS incase we have been notified already that this supplier has been involved in trade fraud.

CIRS – Our services





- REACH Only Representative
- REACH (Pre-)Registration/Inquiry Process
- REACH Safety Data Sheet
- CLP Classification/Notification/Labelling
- GHS Strategic Compliance

Regulatory Consulting



- China New Substance Notification
- Hazardous Chemicals Registration
- China GHS(SDS/Labelling/24h Tel. Service)
- SFDA Registration of Cosmetics
- SFDA Registration of New Cosmetic Ingredient
- Pesticide Registration China

If you are interested in regulatory compliance in China, <u>register</u> for our next free focused webinar on <u>Operating Licences for hazardous chemicals in</u> <u>China</u> to be held next week on July 16th.



SUMMARY

- REACH and CLP regulatory summary
- Latest regulatory and enforcement updates
- Overview of document required
- Tips for communication with suppliers
- Supplier compliance checks
- Trade Fraud precautions
- CIRS Services



Thank You!



CIRS Ireland

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