



*Responsibilities under
REACH enforcement:
a case study*

ECHA Forum Open session
05/11/2015

Irantzu Garmendia Aguirre
Technical and Regulatory Affairs Manager, Fecc



Case description

This is the case of a Distributing company that buys a chemical substance from an EU Manufacturer and store and sells it to several Downstream Users.



Case description

When buying the product from the Manufacturer, the Distributor receives the SDS of the chemical substance.

But without the corresponding ES.

The Distributor forwards the SDS with the name of the original supplier.



Case description



Nome del prodotto: [REDACTED]
Data di revisione: 04 Maggio (abbr.) 2012
Pagina 1 di 18

SCHEDA DI SICUREZZA

SEZIONE 1 IDENTIFICAZIONE DELLA SOSTANZA/MISCELA E DELLA COMPAGNIA/IMPRESA

Alla data di revisione, questa SDS è conforme alla legislazione Italiana vigente.

1.1. IDENTIFICATORE DEL PRODOTTO
Nome del prodotto: [REDACTED]
Descrizione del prodotto: Idrocarburo isoparaffinico
Nome registrato: Idrocarburi, C11-C13, isoalcani, <2% aromatici

Numero di registrazione: [REDACTED]

1.2. USI IDENTIFICATI DELLA SOSTANZA O DELLA MISCELA E USI SCONSIGLIATI
Usi previsti: Solvente

usi identificati:
Fabbricazione della sostanza
Distribuzione della sostanza
Formulazione e (ri)confezionamento di sostanze e miscele
Uso nei laboratori - Uso industriale
Uso nei laboratori - Uso professionale

Usi non raccomandati: Questo prodotto non è consigliato per alcun impiego industriale, professionale o da parte dei consumatori diverso dai suddetti Usi identificati.

1.3. Dettagli del fornitore della scheda di dati di sicurezza
Fornitore: [REDACTED]

Contatto locale: [REDACTED]

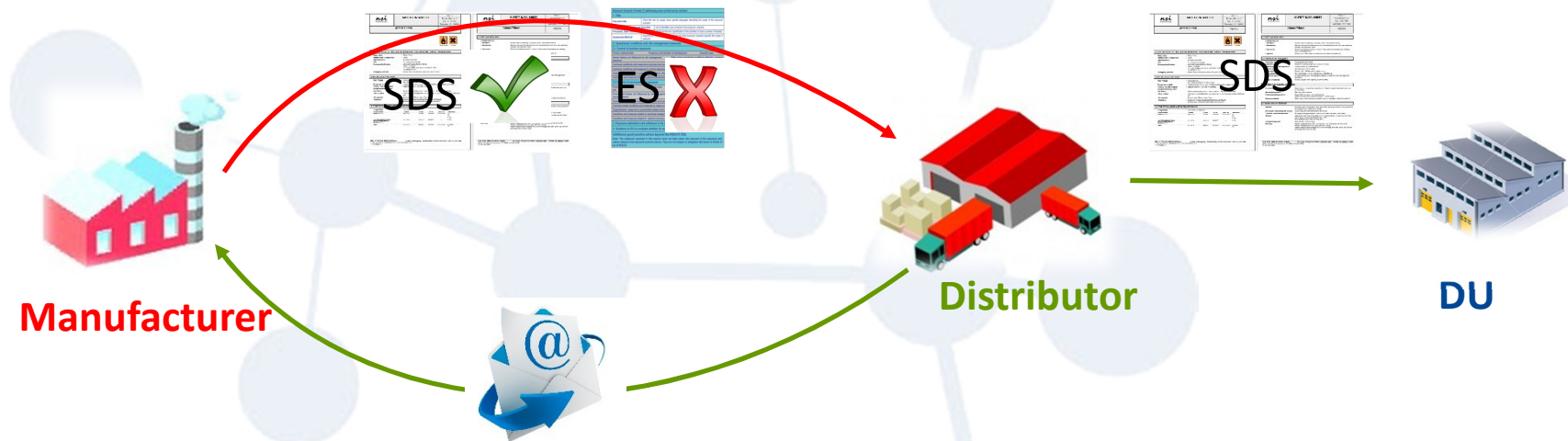
Informazioni generali:
E-Mail: [REDACTED]

1.4. NUMERO TELEFONICO DI EMERGENZA
Servizio Emergenza 24 ore su 24: [REDACTED] Emergenza, ore ufficio 02 8803 333'

- Original Manufacturer's SDS sent to DUs.
- ES completely missing.
- Product properties
 - R65:Harmful: may cause lung damage if swallowed
 - R66:Repeated exposure may cause skin dryness or cracking
 - H304:May be fatal if swallowed and enters airways
 - EUH066:Repeated exposure may cause skin dryness or cracking

Case description

What can the Distributor do?



The Distributor, requests the ES from the Manufacturer.

Case description



REQUEST:

Sent: Tuesday, June 05, 2012 3:08 PM

Dear A,

I hope you are the right person to contact for this request. If not, please let me know.

My colleague from Italy is asking for the **most recent version of extSDS** for XXX. According to her, the version she has currently **contains the uses but without mentioning descriptors and ESs**. May I kindly ask you to provide most recent version in Italian Language and in English. If not available in Italian, English alone would also do.

Many thanks in advance!

Kind regards

M

REPLY:

Sent: Tuesday, June 05, 2012 16:09

Dear M,

Please find attached the latest version of XXXX ext-SDS in Italian and in English.

The ext-SDS of this grade does not contain Exposure Scenario (ES) because it is only classified for Aspiration Hazard (H304) and EUH066.

Below some **background information** to explain why some of our ext-SDS do not have ES:

Hope this helps,

Regards, A

Case description



The answer from the Manufacturer/supplier is that the substance is classified as Asp. Tox1 H304 EUH066 under Regulation 1272/2008, and that there is a common understanding of the industry that for this human hazard no ES is needed.

HSPA HYDROCARBON SOLVENTS PRODUCERS ASSOCIATION

TO WHOM IT MAY CONCERN

Dear Madam, dear Sir,


Within the REACH regulation Exposure Scenarios (ES) are required for products that are classified for health and environment.

According to the Industry legal interpretation exception applies for environmental ES in substances that are not classified for environment, and for health ES in substances that are only classified R65/66 (Aspiration Tox.1 H304 - EUH066).


No ES are required if the product is hazardous due to phys/chem properties.

This exception has been agreed at industry level through the European Chemical Federation (CEFIC) and CONCAWE at the time of REACH registration (Year 2010) and based on the regulation and guidance existing at the time.

Sincerely yours,



HSPA Chairman

 **cefic** Chemistry making a world of difference
sector group
European Chemical Industry Council
Avenue E, van Nieuwenhuyse 4, B-1160 Brussels, Belgium
Tel: +32 2 676 72 11 Fax: +32 2 676 73 01 mail@cefic.be www.cefic.org

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HSPA Chairman





Case description

Fecc

When being inspected the Distributor, provides to the authorities the answer and the document sent by the Manufacturer/supplier.



<p>Nome del prodotto: [REDACTED] Data di revisione: 04 Maggio (abbr.) 2012 Pagina 1 di 18</p> <p>SCHEDA DI SICUREZZA</p> <p>SEZIONE 1 IDENTIFICAZIONE DELLA SOSTANZA/MISCELA COMPAGNIA/IMPRESA</p> <p>Alla data di revisione, questa SDS è conforme alla legislazione Italiana vigente.</p> <p>1.1. IDENTIFICATORE DEL PRODOTTO Nome del prodotto: [REDACTED] Descrizione del prodotto: Idrocarburo isoparaffinico Nome registrato: Idrocarburi, C11-C13, isovalcani, <2% aromatici</p> <p>Numero di registrazione: [REDACTED]</p> <p>1.2. USI IDENTIFICATI DELLA SOSTANZA O DELLA MISCELA E USI SCONSIGLIATI Usi previsti: Solvente</p> <p>usi identificati: Fabbricazione della sostanza Distribuzione della sostanza Formulazione e (ri)condizionamento di sostanze e miscele Uso nei laboratori - Uso industriale Uso nei laboratori - Uso professionale</p> <p>Usi non raccomandati: Questo prodotto non è consigliato per alcun impiego industriale parte dei consumatori diverso dai suddetti Usi identificati.</p> <p>1.3. Dettagli del fornitore della scheda di dati di sicurezza Fornitore: [REDACTED]</p> <p>Contatto locale: [REDACTED]</p> <p>Informazioni generali: E-Mail: [REDACTED]</p> <p>1.4. NUMERO TELEFONICO DI EMERGENZA Servizio Emergenza 24 ore su 24: [REDACTED] Emergenza, ore ufficio 02 8803 333/ [REDACTED]</p>	<p>HSPA HYDROCARBON SOLVENTS PRODUCERS ASSOCIATION</p> <p>TO WHOM IT MAY CONCERN</p> <p>Dear Madam, dear Sir,</p> <p>Within the REACH regulation Exposure Scenarios (ES) are required for products that are classified for health and environment.</p> <p>According to the Industry legal interpretation exception applies for environmental ES in substances that are not classified for environment, and for health ES in substances that are only classified R65/66 (Aspiration Tox.1 H304 - EUH066).</p> <p>No ES are required if the product is hazardous due to phys/chem properties.</p> <p>This exception has been agreed at industry level through the European Chemical Federation (CEFIC) and CONCAWE at the time of REACH registration (Year 2010) and based on the regulation and guidance existing at the time.</p> <p>Sincerely yours,</p> <p> [REDACTED] HSPA Chairman</p> <p> cefic sector group</p> <p>Chemistry making a world of difference European Chemical Industry Council Avenue E. van Nieuwenhuysse 4, B - 1180 Brussels Belgium Tel: +32 2 676 72 11 Fax: +32 2 676 73 01 mail@cefic.be www.cefic.org</p>	<p>3:08 PM</p> <p>to contact for this request. If not, please let me know. ing for the most recent version of extSDS for XXX. she has currently contains the uses but without ES. May I kindly ask you to provide most recent version in n. If not available in Italian, English alone would also do.</p> <p>16:09</p> <p>t version of XXXX ext-SDS in Italian and in English. es not contain Exposure Scenario (ES) because it is only rd (H304) and EUH066. information to explain why some of our ext-SDS do not have</p>
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Case description



After the evaluation of the documents by the authorities, they conclude that distributing company is not complying with Art 31(7) and is fined for that.

*DGR Marche 562 del 15/03/2010
DGR Marche 1499 del 04/11/2013*

Personale che ha effettuato l'accertamento: Gruppo Tecnico Regionale REACH

Verbale di contestazione di illecito amministrativo Prot. n. 9801SPU del 02.10.2013
Notificato/contestato in data 09.10.2013
Memorie difensive presentate in data 25.10.2014 acquisite con Ns. Prot. 10720SPU del 29.10.2013
Audizione effettuata in data 09.12.2013
Ulteriore documentazione fornita:
Documentazione a supporto di Audizione 09.12.2013; Ns. prott. 12330 del 13.12.2013; 12341 del 16.12.2013; 12521 del 18.12.2013
Osservazioni della Ditta [redacted] desumibili dalle memorie difensive acquisite con Ns. Prot. 10720 del 29.10.2013

Violazione articoli Regolamenti (CE) 1907-06 / 1272-08	Applicazione Dd. Lgs. n.133-09 e n.186-11 sulla disciplina sanzionatoria violazione Regolamenti (CE) 1907-06 e 1272-08	Sanzione amministrativa pecuniaria prevista in misura non ridotta da euro a euro	Determinazione importo sanzione	Motivazione
art. 31 paragrafo 7 del Regolamento (CE) 1907/06 in relazione alla mancata redazione degli Scenari di Esposizione per la sostanza [redacted].	Violazione sanzionata dall'art. 10, comma 4 del D.Lgs. 14.09.2009, n. 133	da 10.000 (diecimila) euro a 60.000 (sessantamila) euro	sanzione di euro 10.000 (diecimila), pari al minimo previsto	La necessità di redazione degli scenari di esposizione è stata confermata da ECHA con nota 0657 del 29.03.2011, pervenuta tramite ACN il 03.03.2014 - Ns. prot. 2370 del 10.03.2014. Si applica il minimo in quanto l'Azienda, al momento dell'ispezione, si era già attivata nei confronti del proprio fornitore, come da documentazione a supporto di Audizione - Ns. prot. 12330 del 13.12.2013

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Via Don Antonio Gioia, 8 – 60122 ANCONA - Tel. 071 8067922 Fax 071 8067950

GA



Reasons for bringing the issue to the Forum



1. Under REACH Regulation the requirement for distributors is very clear, to ensure that the information related to the chemical substance is communicated further up and down the supply chain.
2. The responsibility to prepare a chemical safety report is of the registrant.
3. The distributor does not have the obligation to prepare a chemical safety report.
4. According to the generally agreed approach the distributor should, in this case, communicate up the supply chain to request the missing ES on behalf of the DU.

5. The documentation presented to the authorities should have been enough.

Question: My supplier doesn't provide the ES of a substance justifying that solvents with aspiration hazards don't need it. I have it documented via email communication.

If an inspector comes to my company to check our compliance with the REACH regulation as DU. Does this documentation via email validity to justify why we don't have the ES? If not, how can I justify it otherwise? Who is non-compliant with the regulation?

Dear Miss Garmendia,

Thank you for your enquiry to the ECHA Helpdesk concerning the lack of ES for a given substance.

Issues regarding inspection are the responsibility of the national enforcement authority (NEA). However, **the generally agreed approach is that the DU should communicate with his supplier about the issue and record this communication. E-mail is an acceptable form of documentation.** When another party is non-compliant, or suspected of being non-compliant, the DU also has the possibility of informing the NEA. The DU is responsible under other legislation (chemical agent directive) for assessing the risk and ensuring that the use is safe.

In support of this I refer you to section 3.5 of the Guidance for downstream users and frequently asked question (FAQ's are agreed by ECHA, national helpdesks and the Commission) FAQ 0943 which relates to the timing of DU obligations and includes the response: "In cases where the required information has not been provided in the SDS, it is advisable that the DU communicates with his supplier to check why, record this communication, and the date when they receive an ES." Section 3.5 of the guidance relates generally to supplier responses and is partly relevant to your question.

Yours sincerely,

ECHA Helpdesk

Actions from the Forum

1. Clarify the responsibilities of the different actors in the supply chain
2. In this particular case:
 - who is responsible to prepare the exposure scenario and
 - who should be fined

Even more

3. Harmonize MS enforcement

D.Lgs. 133 del 14 settembre 2009, in vigore dal 10 Ottobre 2011, riguardante la “Disciplina sanzionatoria per la violazione delle disposizioni del Regolamento(CE) n. 1907/2006 REACH”

Art. 10.

Violazione degli obblighi derivanti dagli articoli 7, 31, 32, 33, 34, 35 e 36 del regolamento in materia di informazioni all'interno della catena d'approvvigionamento.

4. Salvo che il fatto costituisca reato, **un attore della catena d'approvvigionamento** che in violazione all'articolo 31, paragrafo 7 del regolamento, non riporta i pertinenti scenari di esposizione in allegato alla scheda di dati di sicurezza, e' punito con la sanzione amministrativa pecuniaria da 10.000 a 60.000 euro.

An actor in the supply chain

Article 31

Requirements for safety data sheets

7. Un attore della catena d'approvvigionamento che sia tenuto a predisporre una relazione sulla sicurezza chimica a norma dell'articolo 14 o dell'articolo 37 **riporta i pertinenti scenari di esposizione** (incluse, se del caso, le categorie d'uso e d'esposizione) in un allegato della scheda di dati di sicurezza che contempra gli usi identificati e comprenda le condizioni specifiche derivanti dall'applicazione dell'allegato XI, punto 3.

7. Any actor in the supply chain who is required to prepare a chemical safety report according to Articles 14 or 37 shall place the relevant exposure scenarios (including use and exposure categories where appropriate) in an annex to the safety data sheet covering identified uses and including specific conditions resulting from the application of Section 3 of Annex XI.

*Thank you for your
attention*

www.fecc.org

