National Institute for Public Health
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Ministry of Health, Welfare and Sport

Quality and usefulness of (extended) Safety Data Sheets

RIVM Letter report 110001002/2014
D.Theodori et al.

TNO triskelion bv

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Colophon

H. Marquart (), TNO Triskelion bv
I. Puijk (), TNO Triskelion bv
E. Mulder (), TNO Triskelion bv
D. Theodori (), RIVM

Contact:
Demi Theodori
NAT
demi.theodori@rivm.nl

This investigation has been performed by order and for the account of I-SZW, within the framework of REACH and CLP

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Het veiligheidsinformatieblad (VIB) is het belangrijkste instrument voor het verstrekken van informatie over veilig gebruik van stoffen en chemische mengsels aan professionele en industriële gebruikers. De REACH-wetgeving is de huidige wettelijke basis voor de VIBs in Europa.

Voor geregistreerde stoffen in hoeveelheden van 10 ton of meer per jaar per registrant, moeten registranten ook blootstellingsscenario's (aangeduid als "ES", de afkorting voor "Exposure Scenario") opstellen en deze toevoegen als bijlage aan de VIB's. ES worden vereist voor stoffen die voldoen aan de criteria van een van de gevarenklassen van artikel 14 (4) van REACH of stoffen die als PBT of vPvB zijn aangemerkte en voor alle in de registratie voorziene gebruiken die tot blootstelling kunnen leiden. In de ES worden voor alle geïdentificeerde gebruiken de relevante operationele omstandigheden (OC) en risicobeheersmaatregelen (RMM) omschreven die nodig zijn voor een veilig gebruik. Een dergelijke verplichting voor een ES geldt niet voor mengsels van chemische stoffen. Echter, de informatie uit de blootstellingsscenario's van de stoffen waaruit het mengsel bestaat, moet wél in een bepaalde vorm worden gepresenteerd in het VIB van het mengsel. Met '(e)SDS' worden in dit rapport alle VIBs aangeduid met en zonder ES.

Om diverse signalen uit de praktijk van onvoldoende kwaliteit te verifiëren, en omdat (e)SDS als een primaire bron van informatie voor werkgevers worden beschouwd bij het nakomen van hun arbo-verplichtingen, heeft de Nederlandse Inspectie-SZW (I-SZW) een systematische evaluatie laten uitvoeren van een 50-tal (e)SDS die door de I-SZW inspecteurs zijn verzameld tijdens een REACH inspectieproject in 2012. Het gaat hier om (e)SDS die bepaalde tekortkomingen tonen volgens een snelle scan van de inspecteurs zelf. Het doel is om meer inzicht te krijgen in de stand van zaken rond te kwaliteit van de (e)SDS. De evaluatie is uitgevoerd door TNO Triskelion BV onder begeleiding door Bureau REACH en is bedoeld als input voor de discussie over mogelijke verdere acties voor de verbetering van de kwaliteit en bruikbaarheid van de (e)SDS.

De resultaten voor de bestudeerde (e)SDS zijn globaal als volgt. Voor bijna de helft van de (e)SDS waren er sterke aanwijzingen dat ze niet up-to-date waren. Verder waren er problemen met de Nederlandse taal, en onvolledige of geen specificaties over de wijze van huidbescherming. In sommige (e)SDS, die melding maakten van onverenigbare materialen, troffen we geen verdere specificaties aan over de maatregelen die nodig zijn om mogelijke relevante risico's te voorkomen. Regelmatig werden inconsistenties gevonden tussen rubriek 7, rubriek 8 en de blootstellingsscenario's, en er waren indicaties dat de indeling, vermeld in de (e)SDS, en de geharmoniseerde indeling niet met elkaar overeen kwamen, of dat de indeling van de stoffen als zodanig of in mengsel afweken van de meest voorkomende zelf-classificatie in de C & L-inventaris. Waarschijnlijke blootstellingsroutes werden vaak niet genoemd. Soms miste een ES waar we dat wel zouden verwachten en een aantal bevatte zelfs geen registratienummer. Dit kan wijzen op stoffen afkomstig van leveranciers die (nog) niet hoeven te registreren maar het kan ook wijzen op een non-compliance. Een derde maakte geen melding van de nu geldende grenswaarden voor de werkplek en werden er geen DNELs genoemd. Ook passende technische maatregelen werden niet gemeld bij bijna de helft van de bestudeerde (e)SDS. In sommige gevallen werden deze technische maatregelen in een andere rubriek

genoemd. Voor ongeveer twee derde van de (e) SDS met blootstellingsscenario's in de bijlage, hadden deze blootstellingsscenario's een duidelijke toegevoegde waarde.

Een belangrijke notie hierbij is dat de bestudeerde (e)SDS al twee jaar geleden zijn geselecteerd. Het is de vraag in hoeverre de hier beschreven conclusies nog steeds representatief zijn voor de situatie anno 2014. ECHA heeft inmiddels initiatieven ontplooid met als doel het verbeteren van de kwaliteit van de (e)SDS. We hebben het hier over het uitwisselingsnetwerk voor blootstellingsscenario's ENES (Exchange Network on Exposure Scenario's) en, de daaruit ontstaan CSR/ES Roadmap. Deze initiatieven zijn opgericht door ECHA en worden uitgevoerd in samenwerking met de industrie en een aantal geïnteresseerde landen. De relevante departementen en Inspectie SZW vanuit Nederland alsook Bureau REACH zijn betrokken bij het ENES en de CSR/ES Roadmap. Daarnaast heeft de Nederlandse overheid een nationaal project opgericht samen met het bedrijfsleven dat gericht is op het identificeren en implementeren van oplossingen voor de knelpunten van het MKB m.b.t. de (e)SDS. Het project loopt tot begin 2015. De specifieke focus van het Nederlandse project is om REACH effectiever en nuttiger maken voor vooral het MKB op een wijze die kostenbesparingen oplevert bij de implementatie van de RAECH verplichtingen.

Het rapport sluit af met aanwijzingen voor de werkgevers c.q. DU over hoe ze zelfstandig de kwaliteit en bruikbaarheid van een (e)SDS kunnen controleren.

Abstract

The safety data sheet (SDS) is the main instrument for providing information on the safe use of chemical substances and mixtures to professional and industrial users. The REACH legislation is the current legal basis for the SDS in Europe.

For registered substances in quantities of 10 tons or more per year per registrant, registrants should also describe the various relevant exposure scenarios ("ES"), and annex them to the SDS. ES are required for all identified uses that can lead to exposure. ES are further required for substances that meet the criteria of article 14 (4) of REACH or are identified as PBT or vPvB. For each ES relevant operational conditions (OC) and risk management measures (RMM) need to be described that are necessary for safe use. Such a requirement does not apply to mixtures of chemicals. However, the information from the exposure scenarios of the substances in the mixture must be somehow incorporated in the SDS of the mixture. The abbreviation "(e)SDS" in this report is used for all types of SDSs with or without exposure scenarios.

To verify various field signals of poor quality and because employers use the (e)SDS as a primary source of information to meet their OSH-obligations, the Dutch Labor Inspectorate (I-SZW) commissioned a systematic review of 50 (e)SDS collected during a REACH enforcement project from 2012. These are (e)SDS that the inspectors, based on a quick scan, identified as showing certain shortcomings. The study was conducted by TNO Triskelion BV under the supervision of Bureau REACH and is intended as input into the discussion on possible further actions to improve the quality and usefulness of the (e)SDS.

The results for the studied (e) SDS are summarized as follows. For nearly half of the concerned (e)SDS there were strong indications that they were not up to date. The problems identified were related to the use of the Dutch language and incomplete or no specifications on skin protection. In some (e)SDS that reported incompatibility with certain materials, no further specifications were given on how to avoid the associated risk. Inconsistencies were often found between section 7, section 8 and the annexed exposure scenarios and there were indications that the classification listed on the (e)SDS and the harmonized classification did not correspond well with each other, and there were discrepancies between the classification of substances as such or in mixture and the most common self-classification in the C & L Inventory. Likely routes of exposure were often not mentioned. Sometimes there were no ES for substances where we would have expected one. Some (e)SDS didn’t even contain a registration number. A reason for this omission may be that the registration deadline is not yet met, but it may also point to a non-compliance. A third of the evaluated (e)SDS did not mention the OELin force and there were no DNELs mentioned. Also, appropriate technical measures were not reported in almost half of the studied (e)SDS. In some cases, these technical measures were mentioned in another section. For about two-thirds of the (e) SDS with exposure scenarios in the appendix, these exposure scenarios had a clear added value.

A key notion is that the studied (e) SDS are selected as long as two years ago. The question is whether the conclusions presented here are still representative of the situation in the year 2014. ECHA has already deployed initiatives to improve the quality of the (e)SDS. We refer here to the exchange network for

exposure scenarios ENES and the CSR / EV Roadmap that has resulted within the scope of ENES. These initiatives have been established by ECHA and implemented in collaboration with the industry and a number of interested countries. The relevant departments and Social Affairs Inspectorate from the Netherlands and Bureau REACH are involved in ENES and CSR / ES Roadmap. In addition, the Dutch government is carrying out a national project in cooperation with the industry that focuses on identifying and implementing solutions to the problems of SMEs with regard to the (e)SDS. The project runs until early 2015. The specific focus of the Dutch project is to make REACH more effective and more useful, especially for SMEs and in a manner that yields cost savings in the implementation of the REACH obligations.

The report concludes with guidance for employers/ DU on how they can independently evaluate the quality and usability of an (e)SDS.

Contents

1 Uitgebreide samenvatting

VIB

Het veiligheidsinformatieblad (VIB) is het belangrijkste instrument voor het verstrekken van informatie over veilig gebruik van stoffen en chemische mengsels aan professionele en industriële gebruikers. De REACH-wetgeving is de huidige wettelijke basis voor de VIBs in Europa. Voor geregistreerde stoffen in hoeveelheden van 10 ton of meer per jaar per registrant worden in de regel ook blootstellingsscenario's (aangeduid als "ES", de afkorting voor "Exposure Scenario") toegevoegd aan de VIB's. ES moeten de relevante operationele omstandigheden (OC) en risicobeheersmaatregelen (RMM) omschrijven die nodig zijn voor een veilig gebruik. In het Engels heet het VIB dan "extended SDS" en wordt afgekort als "eSDS". Met de afkorting "(e)SDS" worden in dit rapport alle type VIB's aangeduid met of zonder blootstellingsscenario's. Het opmaken van blootstellingsscenario's is een REACH Registratieverplichting voor stoffen geregistreerd in hoeveelheden van 10 ton of meer per jaar per registrant indien de stoffen voldoen aan de criteria van een van de gevarenklassen van artikel 14 (4) van REACH of stoffen die als PBT of vPvB zijn aangemerkt. ES worden vereist voor alle in de registratie voorziene gebruiken die tot blootstelling kunnen leiden.
Een dergelijke verplichting geldt niet voor mengsels van chemische stoffen. Echter, de informatie uit de blootstellingsscenario's van de stoffen waaruit het mengsel bestaat, moet wél in een bepaalde vorm worden gepresenteerd in het VIB van het mengsel. Dat kan via verwerking van deze informatie in het VIB zelf, via het toevoegen van alle relevante blootstellingsscenario's als bijlage, of via het opstellen van een specifiek blootstellingscenario voor het mengsel.

Vóór de invoering van REACH, was in Nederland de ervaring dat VIB's niet (veel) werden gebruikt, noch door de werkgevers, noch door de werknemers, hoewel die verplichting tot het gebruik van VIB's er toen ook al was. Hun omvang en complexiteit werden gezien als belangrijk reden hiervoor (Van Niftrik en Krop, 2003). Omdat de REACH blootstellingsscenario's kunnen worden gericht op het veilige gebruik van specifieke toepassingen is het aannemelijk om te verwachten dat REACH hier verbetering in zou inbrengen. Een studie van de Finse autoriteiten uit 2012 constateerde echter kwaliteitsproblemen bij bijna de helft van de bestudeerde VIBs (Forsman - Katainen et al. , 2012). Ook in een recente Duitse studie lezen we vergelijkbare conclusies. Het betreft hier een onderzoek naar de mening van registranten , formuleerders , distributeurs , sector groepen , downstreamgebruikers en autoriteiten over de kwaliteit van de (e) SDS (Reihlen en Jepsen , 2013). De meerderheid van de respondenten gaf aan dat de kwaliteit van de (e) SDS moet worden verbeterd. Mogelijke verbeteringen die werden genoemd omvatten meer standaardisatie , best - practice voorbeelden, deskundige begeleiding voor mensen die een (e)SDS moeten opstellen, nationale controles, betere uitleg over de DNEL's en betere registratiedossiers. Evaluatie van de blootstellingsscenario's door ECHA en sectorspecifieke oplossingen behoren tot de meest aanbevolen maatregelen.

Waarom deze studie en reikwijdte
Om deze signalen van onvoldoende kwaliteit te verifiëren, en omdat VIBs als een primaire bron van informatie voor werkgevers worden beschouwd bij het nakomen van hun arbo-verplichtingen, heeft de Nederlandse Inspectie-SZW (I-

SZW) een systematische evaluatie willen uitvoeren van een 50-tal (e)SDS die door inspecteurs zijn verzameld tijdens een REACH inspectieproject in 2012. Het gaat hier om (e)SDS die bepaalde tekortkomingen tonen volgens een snelle scan van de inspecteurs zelf. Het doel van deze evaluatie is om inzicht te krijgen in de stand van zaken rond te kwaliteit van de (e)SDS. De evaluatie, zoals beschreven in dit rapport, is bedoeld als input in de discussie over mogelijke verdere acties voor de verbetering van de kwaliteit en bruikbaarheid van de (e)SDS. De (e) SDS werden getoetst aan de volgende criteria:
1) de formele naleving van de wettelijke vereisten van REACH art. 31 en bijlage II,
2) de kwaliteit van de gegevens,
3) duidelijkheid van de verstrekte informatie, en
4) de bruikbaarheid van deze informatie voor DU.

De evaluatie werd uitgevoerd door TNO Triskelion BV, begeleid door Bureau REACH, in opdracht van I-SZW. Alle (e) SDS betrokken bij dit onderzoek werden geëvalueerd op dezelfde wijze ongeacht de oorspronkelijke evaluatie door de arbeidsinspecteurs.
De (e)SDS werden niet integraal maar slecht op die onderdelen bestudeerd die het meest relevant zijn voor arbeidsomstandigheden. Als meest relevant werden rubriek 7 (Hantering en opslag) en 8 (Maatregelen ter beheersing van blootstelling/persoonlijke bescherming) gezien in combinatie met rubriek 2, alsook de blootstellingsscenario’s, indien aanwezig. Ook andere rubrieken werden erbij betrokken zoals rubriek 9 (Fysische en chemische eigenschappen) en rubriek 11 (Toxicologische informatie).
In deze studie is niet gekeken naar hoe mogelijke tekortkomingen in de (e)SDS doorwerken op de arbeidsomstandigheden in de praktijk. Aangezien de arboverplichtingen onverminderd van toepassing zijn en de werkgever te allen tijde voor een veilige en gezonde werkplek moet zorgen, betekent een gebrekkige (e)SDS niet automatisch dat de werknemer in gevaar komt. Een voorwaarde hierbij is dat de werkgever herkent wanneer de (e)SDS geen goede bron van informatie is. Een doel van deze studie was ook om, mede op basis van de geïdentificeerde problemen, richtlijnen te geven aan de werkgever c.q. DU bij het controleren van de (e)SDS kwaliteit.

Conclusies
De algemene conclusie is dat geen van de onderzochte (e)SDS volledig voldeed aan de specifieke wettelijke eisen dan wel aan de verwachtingen met betrekking tot de kwaliteit en bruikbaarheid van de (e)SDS. Het ging hierbij meestal om tekortkomingen die het gebruik van de (e)SDS als een bron van informatie voor de risicobeoordeling op de werkplek, serieus beperken.

De resultaten voor de bestudeerde (e)SDS zijn in meer detail als volgt:

- voor 40% waren er sterke aanwijzingen dat ze niet up-to-date waren;
- bij 20% waren er problemen met de Nederlandse taal;
- bij meer dan 85% waren er onvolledige of geen specificaties over de wijze van huidbescherming;
- bij 85% van de (e)SDS die melding maakten van onverenigbare materialen, waren er geen verdere specificaties over de maatregelen die nodig zijn om mogelijke relevante risico’s te voorkomen;
- bij 20% werden inconsistenties gevonden tussen rubriek 7, rubriek 8 en de blootstellingsscenario's;

- bij 4% waren er indicaties dat de indeling vermeld op de (e)SDS en de geharmoniseerde classificatie niet met elkaar niet overeen kwamen. In ongeveer een kwart van de (e) SDS week de indeling van de stoffen als zodanig of in mengsel af van de meest voorkomende zelf-classificatie in de C & L-inventaris;
- bij bijna 50% waren er mogelijke inconsistenties tussen de wijze voor veilig hanteren en opslag in rubriek 7 en de gevaren van de stof, zoals weergegeven in rubriek 9 (Fysische en chemische eigenschappen) of rubriek 11 (Toxicologische informatie) - beide situaties zijn aangetroffen: zowel te zwaar als te lichte risicobeheersmaatregelen t.o.v. de maatregelen die werden verwacht op basis van de indeling van de stof
- op één na bevatten de (e)SDS geen advies voor veilige hantering en opslag, dat gericht was op specifieke toepassingen;
- waarschijnlijke blootstellingsroutes werden niet genoemd in 90% van de (e) SDS;
- vijf (e)SDS van ingedeelde stoffen gepubliceerd in 2011 of later bevatten geen bijgevoegde blootstellingsscenario terwijl dat wel was verwacht op basis van de indeling van de stoffen;
- 40% bevatte geen registratienummer. Dit kan wijzen op stoffen afkomstig van leveranciers die (nog) niet hoeven te registreren maar het kan ook wijzen op een non-compliance;
- 30% maakte geen melding van de nu geldende grenswaarden voor de werkplek;
- bij meer dan 30% van de (e)SDS die in 2011 of later werden gepubliceerd, werden geen DNELs genoemd.
- passende technische maatregelen werden niet gemeld bij ongeveer 40% van de bestudeerde (e)SDS. In sommige gevallen werden deze technische maatregelen in een andere rubriek genoemd;
- 10 % van de (e) SDS waren niet in een beknopte en duidelijke manier opgeschreven;
- meer dan 95 % van de (e)SDS voorzag niet in voldoende bruikbare adviezen voor veilig hanteren en risicobeheersmaatregelen. De aanbevelingen waren meestal in zulke algemene bewoordingen beschreven, dat ze niet als bruikbaar kunnen worden beschouwd voor de DU;
- voor de ongeveer twee derde van de (e) SDS met blootstellingsscenario's in de bijlage, hadden deze blootstellingsscenario's een duidelijke toegevoegde waarde in vergelijking met de aanbevelingen in de rubrieken van het hoofdonderdeel van de (e)SDS.

Het is hier echter belangrijk om te beseffen dat de bestudeerde (e)SDS al twee jaar geleden zijn geselecteerd. Het is de vraag in hoeverre de hier beschreven conclusies nog steeds representatief zijn voor de situatie anno 2014. ECHA initiatieven met als doel het verbeteren van de kwaliteit van de (e)SDS zijn al een tijd op gang. We hebben het hier over het uitwisselingsnetwerk voor blootstellingsscenario's ENES (Exchange Network on Exposure Scenario's) en, de daaruit ontstaan CSR/ES Roadmap. Deze initiatieven zijn opgericht door ECHA en worden uitgevoerd in samenwerking met de industrie en een aantal geïnteresseerde landen. Of deze initiatieven op EU niveau, in samenspel met

nationale inspanningen w.o. gerichte inspecties, de kwaliteit en bruikbaarheid van de (e)SDS daadwerkelijk hebben kunnen verbeteren zou bezien moeten worden in vervolgonderzoek.

Het rapport sluit af met aanwijzingen voor de werkgevers c.q. DU over hoe ze zelfstandig de kwaliteit en bruikbaarheid van een (e)SDS kunnen controleren. Herkent de werkgever dat de verkregen (e)SDS van onvoldoende kwaliteit is dan moet hij zich alsnog inspannen om de nodig informatie te genereren (al dan niet door bij zijn leverancier navraag te doen om betere informatie). Hierdoor kunnen werkgevers invloed uitoefenen in de supply chain om de kwaliteit van de (e)SDS te verbeteren. Een dergelijke invloed kan voornamelijk via upstream communicatie met de leverancier en bij voorkeur als een gecoördineerde actie binnen een branche organisatie of sector.

2 Background

The Safety Data Sheet (SDS) is the main tool for providing information on safe use of substances and chemical mixtures to users. The REACH legislation (EC/1907/2006 and amendments) is the present legal basis for SDS in Europe. For substances registered in volumes of 10 tonnes or more per year per registrant an SDS is required. An exposure scenario (ES) is required if the substance fulfils the criteria for any of the hazard classes or categories set out in Article 14(4) of the REACH Regulation or are assessed to be a PBT or vPvB. An ES needs to include all uses leading to exposure that are covered by the registration.
Short but clear descriptions of these exposure scenarios need to be appended to the SDS, which is then called an extended SDS (eSDS). These exposure scenarios should describe the relevant operational conditions (OC) and risk management measures (RMM) that are required for safe use of the substance in the relevant use(s).
For mixtures, no specific exposure scenarios are required to be supplied with the SDS. However, the information from the exposure scenarios from the components of the mixture should be presented in some form in or with the SDS, either via incorporation in the body of the SDS (section 8) or via appending all relevant exposure scenarios, or via creation of a specific mixture exposure scenario.

A proper (e)SDS should indicate in reasonable detail how the substance or mixture should be handled safely. In that way, the (e)SDS would be an invaluable tool for the risk assessment that is necessary according to the 'Chemical Agents Directive' (CAD, Directive 98/24/EC). However, there are signals that the quality and usefulness of the (e)SDS presently are not (always) sufficient for proper use in the risk assessment under CAD.
In the past, before the implementation of the REACH regulation, the SDS in The Netherlands were not used very often as a source of information on safe use of substances, neither by employers, nor by workers. The large size and the complexity of the SDS were seen as an important barrier to their successful use (Van Niftrik and Krop, 2003). It can be hypothesized that the addition of exposure scenarios to the SDS since the start of REACH, has improved this situation, as exposure scenarios aimed at specific uses can provide information on the specific conditions for safe use. A study undertaken in 2012 by the Finish authorities, however, reports that 49% of around 90 eSDS had inconsistencies in the RMM between the main text of the SDS and the exposure scenario(s). Furthermore, the added value of the exposure scenario(s) was considered to be doubtful, because end users often had difficulties of recognizing their own use, or due to the fact that the terminology in the exposure scenario(s) was unclear. Finally, understanding the exposure scenario(s) by end users is reported to be a problem (Forsman-Katainen *et al.*, 2012).

Because of these signals of insufficient quality and usefulness of (e)SDS, and because (e)SDS are considered as a primary source of information for employers to meet their Occupational Safety and Health (OSH) obligations, the Dutch Inspectorate SZW (Social Affairs and Employment) has requested a systematic evaluation of (e)SDS that they have gathered in the scope of their REACH inspections. The goal of this evaluation was to enable decisions on further actions for improvement of the quality and the use of the (e)SDS.

This report is the result of that evaluation, that was performed by TNO Triskelion bv on behalf of the Bureau REACH, that acts as the sponsor for this study and as intermediate between I-SZW and the contractor.

2.1 The (e)SDS considered in this study

A specific subsample of 50 (e)SDS was randomly included in this study by Bureau REACH and I-SZW for further evaluation by TNO Trsikelion. These were for the most part (e)SDS showing certain shortcomings according to a quick scan undertaken by the labour inspectors gathering these (e)SDS. The REACH inspection project was carried out in 2012 among ca. 500 companies. The general impression based on the inspector's screening was that most (e)SDS were not up-to-date or failed to meet REACH obligations. However, the inspectors had not carried out a substantive evaluation of the information. It is notable that the inspectors had not encountered many (e)SDS including exposure scenarios. Such (e)SDS - with exposure scenarios - were all selected for further evaluation independent of whether they were screened as non-compliant.

All (e)SDS included in this study were evaluated in the same way without being biased by the original evaluation by the labour inspectors.

2.2 Methods

2.2.1 General

The aim of the project was to evaluate the current state of (e)SDS from the perspective of the DU's who need to use the information contained in the (e)SDS in order to fulfil their obligations for safe and healthy working environment that stem from the national implementation of the Chemical Agents Directive (CAD). The focus here is on the sections 7 and 8 of the (e)SDS in conjunction, where necessary with section 2. The evaluation also involved the exposure scenarios of the extended data sheets (e)SDS along with any other information that is indirectly relevant to health and safety.
The (e)SDS were evaluated against the following criteria:
1) formal compliance with legal requirements of REACH Art. 31 and Annex II,
2) quality of the data,
3) clarity of the information communicated, and
4) usability of this information.

To enable a systematic and consistent evaluation of the (e)SDS, a checklist was made that contained the relevant items of the (e)SDS to be checked. The REACH regulation (Art. 31, Requirements for safety data sheets) and Annex II of REACH, describing requirements for the compilation of safety data sheets in more detail, were studied to extract those elements that are relevant in the scope of 'usefulness for the risk assessment process at the workplace'. These elements were studied in detail and specific issues were put in the checklist. Because REACH in several cases refers to other legislation (e.g. the CLP Regulation) relevant parts of those pieces of legislation where also studied and in some cases resulted in specific items for evaluation. In many cases, additional explanation to guide the evaluation was added in the checklist too, e.g. information on where to find certain information for comparison with information in the (e)SDS.
Where possible, it was attempted to separate items for evaluation in three types:

1. Items that are directly relevant for evaluation of compliance with the legislation
2. Items that are mostly related to quality of the (e)SDS
3. Items that are mostly related to the usefulness of the (e)SDS for the risk assessment at the workplace

Compliance with the legislation is evaluated by an assessment of the (e)SDS against Art. 31 and Annex II of REACH and legislation referred therein. Examples of such items are the requirement that the (e)SDS should be in the official language of the Member State, which in our study is Dutch, and the requirement that there should be no empty sections in the (e)SDS.
Some items are clearly relevant for compliance with the legislation, but cannot easily be concluded upon on a straightforward manner, because they involve a form of value judgement. For example, the legislation states that: "The information in the safety data sheet shall be written in a clear and concise manner."(Annex II, 0.2.3.). Whether or not something is written in a 'clear and concise' manner will to a certain extent be a matter of subjective judgement. Nevertheless, these items were considered also in relation to compliance with the legislation.

Regarding the quality of the (e)SDS, it was specifically checked whether the content of the relevant items appeared to be correct. For example, for substances with a harmonized classification and labelling, it was checked whether that harmonized classification and labelling was correctly mentioned in the (e)SDS. It was also checked whether there were inconsistencies in the (e)SDS, e.g. between different sections of the body of the (e)SDS or between an appended exposure scenario and the body of the (e)SDS.

In order to conclude on the 'usefulness of the (e)SDS' we examined whether the (e)SDS is sufficiently aimed at the receiver of the substance or mixture and whether appropriate technical control measures are recommended in the (e)SDS. Most elements of 'usefulness of the (e)SDS' are the kind of items for which it is very difficult to draw a definitive conclusion only by a desk-analysis of the concerned (e)SDS. Whether or not recommended technical control measures are 'appropriate' will e.g. be a matter of judgement of the situation at the workplace.

In the course of our study, it was realized that here is not a clear-cut differentiation between items relevant for compliance, quality or usefulness. Many elements of the (e)SDS can be considered to be relevant for all three or at least two of those issues. Therefore, the conclusions on several specific items checked have been assigned to more than one of these issues.

Please note that where an evaluation was made of the compliance with the legislation, this was done by experts in risk assessment and not by legal experts.

The entire questionnaire consisted of a rather large number of items. For some of these items a specific indication of how they were evaluated is considered useful for the further reading. These are discussed below.

2.2.2 Evaluation of specific items

2.2.2.1 Are the (e)SDS up-to-date?

The (e)SDS were gathered in 2012. One of the important requirements regarding (e)SDS is that they should be up-to-date. When relevant new information has become available, the (e)SDS should be updated. The registration under REACH and the possible derivation of DNELs in that process should be regarded as relevant new information and should lead to an up-date of the (e)SDS. Therefore, (e)SDS of substance dated from before 2010 are most probable not up-to-date, with a few exceptions (if the volume of manufacture or import is too low to require registration before the deadline of 1-12-2010 or if the registration has taken place much before the deadline and not updated since). In this study, all (e)SDS of substance were for substances that were registered by a number of registrants (as we verified by checking the ECHA website with registered substances[1]). Publication before 2011 (accounting for the fact that after registration the update of the (e)SDS will take some time) and the absence of DNELs for substances for which derivation of DNELs was expected, were taken as strong indication for the conclusion that the (e)SDS was up-to-date. (e)SDS of mixtures that contained classified substances, as mentioned in the (e)SDS (*i.e.* those contributing to the classification of the mixture), should also contain the DNELs of these substances and should also be updated. Since this can only be done after receipt of the updated (e)SDS for the substances by the formulator, it is assumed that this will take more time than the update of substance (e)SDS. We have therefore checked whether the mixture (e)SDS were from before July 2011 or before 2012 as an indication of not being up-to-date. We have to stress here that abovementioned shortcomings are strong indications but not unambiguous evidence for (e)SDS not being up-to-date. To be able to conclude on this aspect a more investigative analysis of the supply chain is required. Such an analysis was however outside the scope of this study.

2.2.2.2 Consistency with the CSA

The information in the (e)SDS of a substance should be consistent with the results of the Chemical Safety Assessment (Art. 31(2)). Since the Chemical Safety Assessment was not available for the current research, this item was evaluated by comparing identified uses, physico-chemical data, DNELs (or DMELs) and classification and labelling for the substances, when registered under REACH, with the equivalent information disseminated for the substance on the ECHA website.

2.2.2.3 Are the relevant ES appended?

For hazardous substances that meet the criteria for classification as defined in article 14(4) of REACH or PBT and vPvB substances that need to be registered under REACH, the suppliers has as a rule to provide with an extended safety data sheet ((e)SDS) that includes all relevant exposure scenarios. However, if there is no exposure scenario appended for such an (e)SDS, this does not necessarily mean that the supplier is non-compliant, for the following reasons:

- There is no exposure expected to the substance. This may be valid as a general rule. In the case of working conditions this is however very unlikely. Sampling and maintenance will, for example, always result in "relevant exposure" even if closed systems are assumed in place.

[1] http://echa.europa.eu/nl/information-on-chemicals/registered-substances

- The substance is exempted from registration, for example because it is exclusively used in product and process orientated research and development and the risks to human health and the environment are adequately controlled, the so-called PPORDs.

Whether one of the reasons mentioned above applies, or whether an appended exposure scenario is indeed relevant for the user could not be evaluated within the scope of this study. Therefore, it was assumed that the absence of an exposure scenario in the (e)SDS of a hazardous substance is a strong indication for non-compliance, but also that the presence of any exposure scenario in a substance (e)SDS indicate compliance for this issue.

2.2.2.4 Classification of substances

A distinction needs to be made here between self-classification and harmonized classification and the classification of substances as such and of mixtures. Checking the correctness of the self-classification of substances or mixtures requires detailed analysis of the hazard data of the substances (as such or in the mixtures). This was outside the scope of this study. This item was evaluated by comparing the classification for substances provided in the (e)SDS with the harmonised or self-classification(s) available in the C&L inventory database of ECHA. A difference between the classification for a specific endpoint reported on the (e)SDS and the harmonised classification for the same end-point is a strong indication of non-compliance. If an (e)SDS contains additional classifications compared to the harmonised classification, this was also counted as 'inconsistent with the harmonised classification', but not as non-compliance, because not all endpoints may or even can be covered by the harmonised classification.

A difference between the most common self-classification on the C&L inventory and the classification reported in the (e)SDS was considered to be an indication of potential incorrect classification on the (e)SDS, specifically if a specific hazard class from the C&L inventory database was not reported in the (e)SDS.
The classification of the substances was also compared superficially with the information in sections 9 (Physical and chemical properties) and 11 (Toxicological information) of the (e)SDS to judge whether the classification appeared consistent with the information in those sections. If, e.g. the section 11 provided positive information on the occurrence of irritation of the skin, but no classification for skin irritation was present, this was considered to be an inconsistency.

2.2.2.5 Safe storage and use, appropriate handling

Methods for handling the substance of mixture should be "appropriate to the unique properties of the substance or mixture." (Annex II, 7). This was evaluated using expert judgement. For example, if a substance is classified as flammable or corrosive, one expects to find handling advice that takes account of these effects. Therefore if any precaution against fire was absent in Section 7 while the substance was flammable, this was considered to be an indication of lack of appropriate methods of handling. Similarly, the lack of recommendation on the use of protective gloves for a corrosive substance was also seen as such an indication of lack of appropriate methods of handling.

2.2.2.6 Incompatible products

Without specific knowledge on incompatibility of certain products with the substance or mixture, it is hardly possible to evaluate this item. Therefore, there would only be a remark on this item if it was expected, based on expert

judgement or on information elsewhere in the (e)SDS, that incompatible products would exist, while no incompatible products were mentioned.

2.2.2.7 Applicable national occupational exposure limits
The list[2] of legal occupational exposure limits in the Netherlands was checked to evaluate whether these limits were correctly reported in the (e)SDS.

2.2.2.8 Relevant DNELs (or DMELs)
The disseminated information on the registered substances at the ECHA website was checked to evaluate whether the DNELs (or DMELs) published in the (e)SDS were the same as those disseminated on the ECHA website.

2.2.2.9 Consistency between ES and sections 7 and 8
Annex II of REACH states for section 7: "Where a chemical safety report is required, the information in this section of the safety data sheet shall be consistent with the information given for the identified uses in the chemical safety report and the exposure scenarios showing control of risk from the chemical safety report set out in the annex to the safety data sheet." Therefore, it was checked whether the recommendations in section 7 (Handling and storage) were consistent with those in the exposure scenario(s) (if appended). For section 8, subsection 8.2 (Exposure controls), Annex II states: "The information required in the present subsection shall be provided, unless an exposure scenario containing that information is attached to the safety data sheet." Therefore, it is acceptable if subsection 8.2 refers to the exposure scenario(s). However, if section 8.2 contains recommendations, these were checked for consistency with both section 7 and the appended exposure scenario(s). For the appropriateness of the recommended personal protection equipment, a comparison of the reported effectiveness in the exposure scenario with assigned protection factors published in literature was made in case of doubt.

2.2.2.10 Clear description of uses
The uses of the substance or mixture should be sufficiently clearly described to be useful for the receiver in the scope of his risk assessment at the workplace. If the uses were only described in generic terms as e.g. "industrial uses", "professional uses" or by indicating only the Process Categories (PROCs) from the REACH use descriptor system, this was considered not sufficiently clear, because the generic terms "industrial use" and "professional use" provide too limited information on what the actual foreseen uses are, while the PROCs are too abstract for most receivers to be useful.

2.2.2.11 Useful descriptions of safe conditions and risk management measures
The usefulness of an (e)SDS as source of information for the risk assessment at the workplace is very much a function of the clarity in which the safe operational conditions and the necessary risk management measures are described and the extent to which these conditions for safe use are specific. For example, a recommendation of "prevent all skin contact" is in many cases not very useful if there is no indication how to do it. A recommendation to "use local exhaust ventilation if the concentration is above the occupational exposure limit" would also not qualify as useful, because there is generally no way for the user to know when or at what activities the concentration would be above the occupational exposure limit.

[2] http://wetten.overheid.nl/BWBR0008587/BijlageXIII/geldigheidsdatum_31-07-2013

2.2.2.12 Guidance for communication in the supply chain

For this item it was evaluated whether there was any useful guidance, e.g. in the form of a reference to a form on the internet that could be used to send information to the supplier.

3 Results

3.1.1 Description of the (e)SDS included in this study

In total 50 (extended) Safety Data Sheets were evaluated, 26 were (e)SDS of single substances and 24 were of mixtures. A total of 16 (e)SDS contained one or more ES; 15 were (e)SDS for single substances and 1 was an (e)SDS of a mixture. It should also be mentioned here that 20 out of the 26 (e)SDS of substances were published after December 1, 2010 – the first registration deadline - while only 12 of the 24 (e)SDS of mixtures were published after this date. Some information on these (e)SDS is summarized in Table 1.

Table 1. Information on evaluated (extended) Safety Data Sheets

Element	**Number of (e)SDS**	**Remark**
(e)SDS of substance	26	Number includes also substances dissolved in water
- Of which substances dissolved in water	8	
- Of which published after December 1, 2010	20	An appendix with one or more exposure scenarios is expected under specific conditions
○ Of which with one or more exposure scenarios	15	
(e)SDS of mixture	24	
- Of which published after December 1, 2010	12	
○ Of which with one or more exposure scenarios	1	

Note that also that five of the (e)SDS of substances published after December 1, 2010 did not contain exposure scenarios – while this would have been expected. One of these (e)SDS was published in the middle of September 2011 and the other four all more than a year after the first REACH deadline.

For three of the five substances a registration number was provided on the (e)SDS. Four of the five substances were also classified for human health hazards, the rest only classified for physico-chemical hazards.

3.1.2 Compliance with legal requirements

The number of (e)SDS that did not give ground for concern related to the compliance issues mentioned in Table 2 is zero. The number of (e)SDS that showed no 'critical' compliance issues mentioned in Table 2 is one.

In Table 2 the number of (e)SDS that were considered to be possibly not in compliance with the legislation is reported, together with the reason for (possible) non-compliance. It is also indicated whether the issue is considered to be of administrative nature or more 'critical'. A non-compliance of administrative

nature can lead to some difficulties in understanding or use, but does not necessarily lead to insufficient usefulness in the scope of a risk assessment for the workplace. Critical issues are those that may limit understanding and usefulness for risk assessment at the workplace, such as the lack of exposure scenario(s) when expected or inconsistencies within the (e)SDS and between the main part of the (e)SDS and ES.

Table 2. Number of (potentially) non-compliant (e)SDS by reason of possible non-compliance

Reason for potential non-compliance	**Number of (e)SDS**	**Remarks**	**Mostly adminis-trative (A) or critical (C)[3]**
(e)SDS not up-to-date[4] • Substances • Mixtures	 6 of 26 14 of 24	 Substance (e)SDS dated before 2011 Mixture (e)SDS dated before July 2011	 C C
(e)SDS not (fully) in Dutch	10	3 (e)SDS were fully not in Dutch, while 10 (e)SDS were partly not in Dutch [a)]	C
(e)SDS not dated on the first page	1	Date is presented on all other pages	A
Pages not numbered or total number of pages not mentioned	2		A
(e)SDS does not contain the sections as indicated in the REACH legislation	4	These were all old (e)SDS from far before the REACH deadline.	A
Information not in correct sections (as indicated in the REACH legislation)	8	This includes the four (e)SDS which were from far before REACH (see item here above). Still, the necessary information is reported in the body of the SDS, but in incorrect sections.	A
No exposure scenarios appended when expected	5 out of 20	In three cases a registration number is reported and four of the substances are hazardous for humans.	C
Not (fully) clear whether the encountered (e)SDS is the most recent version	14		A
Registration number not provided for a substance in a substance (e)SDS published after 1-1-2011	3 of 20	Checked only for (e)SDS of substances published after 1-1-2011.	A
Inconsistencies in the (e)SDS	11	Also counted as issues relevant to the 'Quality' of (e)SDS.	C

[3] Administrative non-compliancedoes not necessarily lead to insufficient usefulness in the scope of a risk assessment for the workplace. Critical issues are those that may limit understanding and usefulness for risk assessment at the workplace.

[4] Please note that the (e)SDS concerned here are the ones that are encountered at the DU's premisses. Not up-to-date (e)SDS may indicate either noncompliance of the (possible) registrant or a malfunctioning supply chain.

Reason for potential non-compliance	**Number of (e)SDS**	**Remarks**	**Mostly adminis-trative (A) or critical (C)[3]**
Empty (sub)sections	5	A subsection was also considered empty if the subsection contained a remark such as 'no information available', while such a subsection is required to contain information. No really 'empty' (sub)sections were found.	A
Required (ISO[5]) units not (completely) used	9	Usually this relates to the vapor pressure that was expressed in either mbar or mm Hg and in some cases without mentioning of the temperature. There was one (e)SDS in which hardly any unit was mentioned.	A
Substance identification not fully according to the present rules	5 of 26	In two cases only a trade name was given. CAS- or registration number missing in other cases[b)]	C
Relevant uses of the substance or mixture that one would expect based on other information on the (e)SDS, were not indicated	11	Seven of these were from (e)SDS that were published before 1-1-2011 for substance and before 1-7-2011 for mixture[c)]	C
Substances not classified according to CLP[6]	1 of 20	Only checked for the (e)SDS of substances published after the entry into force of this requirement in the CLP Regulation (1-12-2010)	C
Substances not classified according to DSD[7]	3 of 26		C
Mixtures not fully classified according to DPD[8]	7 of 24	In most cases the numbers of the R-phrases were not mentioned; all of these (e)SDS were published from before the first REACH deadline.	C

[5] International Standards Organization
[6] Classification, Labeling and Packaging of substances and mixtures Regulation (EC/1272/2008) and amendments
[7] Dangerous Substance Directive (67/548/EEC) and amendments
[8] Dangerous Preparations Directive (1999/45/EC) and amendments

Reason for potential non-compliance	**Number of (e)SDS**	**Remarks**	**Mostly adminis-trative (A) or critical (C)[3]**
The classification of the substance did not match with the *harmonized* classification in the C&L inventory database	6 of 26	This can in some cases be caused by specific contaminants, which lead to additional classifications or due to the fact that the (e)SDS contains also the classification for hazard classes that are not (yet) harmonized. In only two out of the six cases there were strong indications that the harmonized classification was not reported correctly in the (e)SDS (and, hence, only two cases of actual non-compliance as far as the classification is concerned). There were only two (e)SDS were we had strong indications of non-compliance.	C (A[9])
The classification of the substance is different from that of the most common self-classification	2 of 26	This can in some cases be caused by specific contaminants, which lead to divergent classifications.	C
The classification of one or more ingredients of a mixture that is mentioned in section 3 (Composition/information on ingredients) is either missing or not according to the present classification	7 of 24		C
Substance not identified in section 3 (Composition/information on ingredients) in accordance with the identification in section 1 (Identification of the substance/mixture and of the company/undertaking)	1 of 26	This (e)SDS is from far before the first REACH deadline	A
Substances in the mixture that are classified not (all) mentioned	2 of 24	Based on the descriptions it is expected that not all relevant substances have been mentioned with their classification in these cases	C
Not clearly indicated that eating, drinking and smoking at the workplace is not allowed	22	Twelve of these (e)SDS were from before the first REACH deadline	A

[9] If the inconsistency is due to extra hazard classes included in the (e)SDS that are not (yet) harmonized

Reason for potential non-compliance	**Number of (e)SDS**	**Remarks**	**Mostly adminis-trative (A) or critical (C)[3]**
Applicable occupational exposure limits not (completely or correctly) reported	15 of 31	Nine of these (e)SDS were published before 1-12-2010. In our sample there were 31 substances for which an OEL existed.	C
Relevant DNELs (or DMELs) not mentioned	11 of 32	Only evaluated for (e)SDS published after 31-12-2010.	C
When protective gloves are recommended, proper glove material and glove thickness are not both mentioned	44	In most of these cases the necessary thickness was not mentioned. In all (e)SDS, usually in section 8, the use of protective gloves is recommended, even if there is no clear and apparent reason (no human health classification).	C
When protective gloves are recommended, minimum breakthrough time is not mentioned	37	In all (e)SDS, usually in section 8, the use of protective gloves is recommended, even if there is no clear and apparent reason (no human health classification)	C
Type of adequate respiratory protection not mentioned (when relevant)	23	Thirteen of these (e)SDS were from after 31-12-2010. Eight were for substances, of which 6 from after 31-12-2010.	C
Conditions to avoid, in relation to e.g. temperature, pressure, are not mentioned	13	This relates to situations where no conditions are mentioned, but it is also not clear that there are no relevant conditions	C
Measures to prevent risks due to incompatible materials are not mentioned (if such materials are mentioned)	34 of 40	Only checked based on expert judgment for (e)SDS where incompatible materials were mentioned. If no issues with incompatible materials were mentioned this was not further scrutinized - although this may also be a case on noncompliance – because such an approach was technically not feasible within the scope of this study.	C
Incomplete information on toxicity of substance or mixture	26	This relates to lack of information on certain hazard classes of substances either single substances or in mixtures that are relevant for the classification of the mixture, where such information is required (e.g. carcinogenicity). Three of the cases relate to an (e)SDS of a substance published after 1-1-2011.	A[d)]

[a)] In several (e)SDS one or more phrases was in either German or English. It is probable that these have been incompletely translated from original (e)SDS in German or English. For example, "European Emergency Numbers -> Chapter 16"or "voor verdere vragen

gerelateerd aan Product Environment, Safety and Health" and in other cases part of the phrases are in German, e.g.: "Isomerengemisch" or "außerhalb der Geschäftszeiten: (Beratungsstelle für Vergiftungserscheinungen, Berlin)". It is worth mentioning here the case of (e)SDS that – technically speaking - was considered to be in Dutch, although it was apparently translated to Dutch from another language by either a computer translation tool or a person with a rather limited knowledge of the Dutch language. This (e)SDS contained phrases such as: "Raad van voorzichtigheidsbeginsel" (instead of "voorzorgsmaatregelen"; precautionary statements) and "Er bestaan geen conclusies over waardering van nadelig gevolg voor de ongeboren vrucht.".

[b)] In some cases the identification via a chemical name can still be sufficiently clear, even when a CAS-number or other identification number is lacking. In such a case the effect of not identifying the substance according to present rules is not critical for the risk assessment at the workplace.

[c)] The requirement to indicate the uses of the substance or mixture was however also in the legislation before REACH.

[d)] This is considered more administrative than critical, because for risk assessment at the workplace the responsible people tend not to be toxicologists that can interpret this kind of information in detail and therefore such risk assessment relies on classification, OELs and DNELs.

Toxicological information

Several (e)SDS do not mention all toxicological endpoints for which information or relevant conclusions are expected in the REACH dossier of the substance or of the ingredients in the mixture. The REACH requirements provide specific indication for what endpoints information is to be provided. While not all the endpoints will lead to a conclusion on hazards, the requirement is to present relevant information, which includes information indicating that in studies no effect was seen for a specific endpoints at the highest dose. Since all substances have been registered in the first 2010 registration deadline, we have assumed that this should lead to some relevant text on all the toxicological endpoints mentioned in the REACH text. For (e)SDS that have been made 'pre-REACH' the requirements were less stringent. However, 11 of the (e)SDS published after 1-1-2011 also did not mention information on all relevant endpoints.

In several cases only acute toxicity is mentioned. In eight (e)SDS no relevant information is provided on whether or not the substance or mixture is carcinogenic, mutagenic and/or reprotoxic. In one (e)SDS at "hazard for inhalation" it is stated "Not applicable for gasses and mixtures of gases.", which appears to be a very strange statement. One (e)SDS only refers to the IUCLID file of the substance for the information on toxicity of the substance, while users of substances generally will not have access to the IUCLID file. A few (e)SDS only present information for those endpoints for which the substance or mixture is classified, while Annex II of REACH does not indicate that information on endpoints for which no classification is needed can be omitted.

3.1.3 Quality of the (e)SDS

The quality of the (e)SDS is in this study considered to be related to whether the content of the different (sub)sections is correct and consistent. Several issues of non-compliance are also relevant in the scope of 'quality', but are already reported under the heading 'non-compliance'. Inconsistencies within the (e)SDS are however considered to be such an important indication of limited quality, that, while they are also reported above under 'non-compliance', they are also specifically mentioned here. Table 3 presents the items that were considered to be mostly related to quality of the (e)SDS and also the number of (e)SDS that, in the view of the researchers, did not have sufficient quality.

Table 3. Number of (e)SDS that were considered to be of insufficient quality by item of quality

Reason for lack of quality	**Number of (e)SDS**	**Remarks**
Inconsistencies between different sections of the (e)SDS	11	See a number of examples in the text below the table[a)].
The data on physico-chemical data and classification in the (e)SDS were not fully consistent with the disseminated data on the ECHA website.	8	In most cases this was concluded based on a possibly incorrect classification. It was checked for all (e)SDS, including those for mixtures and those published before the first REACH deadline.
Methods for safe handling in section 7 (Storage and handling) appear not in agreement with the hazards of the substance or the exposure scenario(s)	23	In several cases, the use of appropriate personal protection is recommended, while the substance is considered not to be hazardous to human health. In a case of a carcinogenic substance, the only recommendations are for 'avoid contact' and 'adequate ventilation', while more technical control measures related to closed handling would be expected.
No advice on safe handling and storage for specific uses	49	Only very general advice and/ or advice in contradiction with the physico-chemical and toxicological information provided in the (e)SDS. The contradictions encountered were in both directions. There were (e)SDS where methods for safe handling were missing while in other cases methods for safe handling were mentioned that were not justified by the physico-chemical and toxicological properties of the substance. [b)]
No reference to specific exposure scenario(s) for specific uses in section 7 (Storage and handling)	16 of 20	Only checked for (e)SDS of substances published after 1-1-2011
No proper appropriate engineering controls reported in section 8 (Exposure controls/ personal protection)[c)]	19	

Reason for lack of quality	Number of (e)SDS	Remarks
Control measures in section 8 (Exposure controls/ personal protection) are not in agreement with those in the exposure scenario(s)[c)]	7 of 20	Only checked for (e)SDS of substances published after 1-1-2011
Classification of the substance or mixture does not appear to be in accordance with the information in section 9 (Physical and chemical properties) or section 11 (Toxicological information)[d)]	5	This was only checked in relation to the physico-chemical and toxicological data that were provided in the sections 9 or 11. Expert judgment was used to evaluate whether a mentioned effect in one of these sections would be expected to lead to a classification.
Probable exposure routes are not mentioned in section 11.1.7 of the SDS	45	
List with explanation of relevant R- and S-phrases or H- and P-statements is missing	10	

a) There were several inconsistencies in (e)SDS mainly between section 7 (Handling and Storage) and section 8 (Exposure controls/ personal protection). Some illustrative examples:
   - section 7 states: "The work process should, in as far as technically possible, be organized in such a way that no dangerous substances are emitted or that contact with the skin can be excluded." and: "Local exhaust ventilation required", while section 8 states: "Suitable technical measures: no information available."
   - Or, section 7 states: "Precautions for safe handling of the substance or mixture: no special measures necessary.", while section 8 states, amongst others: "Avoid contact with the eyes and the skin" and: "Skin protection: safety gloves" and: "Eye protection: tight fitting safety glasses".
   - In section 15, three "Dangerous substances that should be indicated on the label" are mentioned that are not mentioned under "Dangerous components" in section 3. Furthermore, section 15 mentions: "Account should be taken of limitations for working of expecting mothers and breastfeeding mothers", while the mixture is not classified for such hazards and section 2 does not specify this hazard and the only substance mentioned in section 3 does not have a related R-phrase for this hazard.
   - Section 4.2 mentions, amongst other effects: causes serious burns. However, the substance as used in the concentrations provided and reported in section 3.1 as skin effect only causes irritation of the skin, as correctly stated in section 2.1 and section 2.2.
   - Section 1 reports a REACH registration number, which is for substances, while section 2.1 reports that the product is a "mixture".
   - Section 10.6 states: "Under normal circumstances of storage and use no dangerous breakdown products are expected.", but section 11 states: "Exposure to breakdown products can be hazardous to health. After exposure delayed serious effects can occur. Can cause irritation of the eyes, nose and throat due to exposure to vapor, mist or smoke that can occur during normal use."

b) Concerning safe handling, the (e)SDS very often provided either a too general en therefore not practical advice or advice which was in contradiction with the physico-chemical and toxicological information in the (e)SDS . Some illustrative examples:
   - No advice for safe handling in relation to skin exposure for irritating or sensitizing substances is given in section 7 (Handling and storage); this occurred for 11 (e)SDS), while in all (e)SDS the use of gloves is recommended in section 8 (Exposure controls/ personal protection)
   - No advice for prevention of fire in section 7 (Handling and storage) for two flammable substances

- In five (e)SDS, measures for skin or respiratory protection are mentioned or preventive measures for fire hazards are mentioned in section 7 (Handling and storage) while the substance does not appear to have effects on skin, respectively via inhalation or is not considered to be flammable
- For one carcinogenic, mutagenic and reprotoxic substance the only advice is to "prevent all personal contact" and to "use adequate ventilation", while no advice on use of closed systems or personal protection is given in section 7 (Handling and storage)
- In an exposure scenario of a substance the use of closed systems is prescribed, but this is not reported in section 7 (Handling and storage).

c) The subsection "appropriate engineering controls" (subsection 8.2.1 of the (e)SDS), is very often not adequately or correctly filled in. Sometimes some relevant information can be found under other sections. Most often the information is too generic and therefore not really useful in practice. Some further explanation and illustrative examples:
   - In nine cases where no appropriate engineering controls are mentioned in section 8 (Exposure controls/ personal protection) there is a reference to controls mentioned in section 7 (Handling and storage).
   - In four (e)SDS no engineering controls are mentioned under the appropriate heading (of section 8.2.1), but local exhaust ventilation or ventilation is mentioned under one of the headings of personal protective equipment.
   - Two (e)SDS contain no information at all on appropriate engineering controls
   - One (e)SDS only mentions the need for adequate ventilation without any further specification. In other (e)SDS we read "Use handling rooms, local exhaust ventilation or other technical control measures to keep concentrations in air below the recommended exposure limits."
   - For a corrosive substance the (e)SDS does not provide any advice on e.g. containment or screens to prevent exposure due to splashes
   - One (e)SDS mentions: "Use a closed system, local exhaust ventilation or other technical control measures to keep occupational exposure to contamination in air below the recommended or legal exposure limits.", however, this (e)SDS does not mention any occupational exposure limits.

d) Cases where we found inconsistencies between the that the classification and the toxicity or physico-chemical data:
   - In two (e)SDS (of the same classified substance) toxicity data are not reported, so it cannot be checked whether the classification could be correct
   - One (e)SDS mentions: "Can lead to irritation of the eyes" and "Can lead to irritation of the skin", while the mixture is, according to the (e)SDS, not classified for these effects
   - In one (e)SDS possible health effects are reported in sections 3 and 11, but the mixture is not classified accordingly.

3.1.4 Usefulness of the (e)SDS for the RI&E in the workplace

A general requirement of the legislation is that (e)SDS should be concise and clearly written. As regards the length of the (e)SDS, it was concluded that this could in most cases be considered 'concise'. Though users tend to think of (e)SDS as lengthy (see e.g. Van Niftrik and Krop (2003)), this is largely unavoidable, due to the large number of sections and subsections to report. As regards the language used, it was concluded that this was in most cases 'clear', based on the subjective but expert judgment of the researchers. Still, the (e)SDS are certainly not written in a laymen's language while full understanding of the (e)SDS will require at least a minimum level of knowledge of occupational hygiene. Moreover, shortcomings as discussed above may further impair the clarity of the (e)SDS. Most relevant in this respect are the following items:

- Items discussed under 'Compliance with legal requirements'
  - No exposure scenario, while this is expected
  - Inconsistencies in the (e)SDS
  - Relevant use of substance or mixture not indicated
  - Not (all) classified substances in a mixture that appear to influence the classification of the mixture appear to be mentioned

    - Applicable occupational exposure limits not (completely) mentioned
    - Relevant DNELs (or DMELs) not mentioned
    - Conditions to avoid, in relation to e.g. temperature, pressure, are not mentioned
- Items discussed under 'Quality of the (extended) Safety Data Sheets'
    - Methods for safe handling in section 7 (Handling and storage) appear not in agreement with the hazards of the substance or the exposure scenario(s)
    - No advice on safe handling and storage for specific uses
    - No proper appropriate engineering controls reported in section 8 (Exposure controls/ personal protection)
    - Control measures in section 8 (Exposure controls/ personal protection) not in agreement with those in the exposure scenario(s).

Some of the other items may be less relevant for the risk assessment at the workplace assuming that the DU has a high level of understanding of occupational health issues. For example, if a classification is not fully consistent with the toxicological data, the user can always account for the most conservative (severe) hazard given. If the probable exposure route is not mentioned, the user can assume that both inhalation and skin exposure are relevant. A DU with relative high level of expert knowledge is however not the rule. For this reason we think that inconsistencies in classification and toxicological data and the lack of reliable ES, will also result in limited usefulness of the (e)SDS.

There are, next to the already mentioned items, also several other issues that may limit the usefulness of the (e)SDS (see table 4).

Table 4. Number of (e)SDS that have insufficient usefulness because of specific issues[a)]

Reason for insufficient usefulness	**Number of (e)SDS**	**Remarks**
(e)SDS not written in a concise and clear manner	4	See the text for explanation.
(e)SDS not sufficiently aimed at the user	33	See the text for explanation.
Relevant operational conditions not presented in the exposure scenario(s)	3 of 16	Only (e)SDS with exposure scenario(s) were checked.
Relevant risk management measures not presented in the exposure scenario(s)	3 of 16	Only (e)SDS with exposure scenario(s) were checked.
No (estimated) exposure levels provided in the exposure scenario(s)	7 of 16	Only (e)SDS with exposure scenario(s) were checked.
Exposure scenario(s) are not specifically aimed at specific uses	10 of 16	Only (e)SDS with exposure scenario(s) were checked.
The body of the SDS does not provide useful descriptions of safe use conditions and risk management measures	48	See the text for explanation.

Reason for insufficient usefulness	Number of (e)SDS	Remarks
The exposure scenario(s) do not provide useful descriptions of safe use conditions and risk management measures	7 of 16	Only (e)SDS with exposure scenario(s) were checked.

a) Some illustrative examples of the issues reported above:

- In one case a lot of occupational exposure limits (from several countries) were reported, which makes it rather difficult to find the relevant information. Mentioning a list of OELs from different countries is suggested as a proper method by the ECHA Guidance on Safety Data Sheets, but in the view of the researchers this leads to confusion for users.
- One (e)SDS was a compilation of a set of three separate (e)SDS ; the first was for the full product of a two-component system, with reference in many cases to the separate (e)SDS of the components. The first (e)SDS was therefore not considered useful if provided as stand-alone.
- Some examples of ambiguous information that is of little practical help:
    - "An exposure assessment may be necessary"
    - "Prevent the forming of flammable or explosive concentrations in air and concentrations that are higher than allowed"
    - "Reduce the risks at handling of the substance to a minimum by means of protection and prevention measures"
    - "Because the product consists of multiple substances, the durability of glove material cannot be calculated in advance and should be tested before use"
    - "Stay upwind of the source", for a product probably used indoors
    - "Wear appropriate hand, body and head protection"
    - "Professional uses: PROC1, PROC10…." Without further explanation of what these PROCs are
    - "Prevent inhalation of vapor and spray mist"
    - "Use general rules for working with chemicals"
    - "The necessary effectiveness of the protective measures depends on the possible conditions of exposure" etc.

3.1.5 Observations concerning the encountered ES

- For about two-thirds of the (e)SDS with appended exposure scenarios, these exposure scenarios were considered to be of clear added value compared to the recommendations in the body of the (e)SDS.
- However, there have also been various quality issues as we illustrate here with some examples:
    - The sample under investigation included two different (e)SDS for the same substance (stemming from two different suppliers). Both (e)SDS mention an impressive list of (possible) industrial and professional uses (10 or 11 depending on the (e)SDS), but use only one overall exposure scenario without any differentiation in use, activity or Process Category. This approach leads to recommendations of rather stringent operational conditions and risk management measures that are aimed at the highest exposure situation and are toe our judgment far too stringent for many other uses.
    - The sample under investigation also included an (e)SDS for a substance that is used in many different types of mixtures (in different product categories). One of the uses is in cleaning agents, both industrial and professional. For industrial use (in a combination of various product categories) recommendations for industrial spraying are provided. However, no recommendations for professional spraying are provided. It is considered rather

likely that such a substance will also occur in cleaning agents that can be sprayed by professionals and therefore either recommendations for professional spraying or specific indication of 'use adviced against' for professional spraying would be expected.

- The previously mentioned (e)SDS also prescribes the use of safety glasses for consumer uses. However technically correct this advice may be it is not considered to be a very practical one as it is generally assumed that consumers will not have safety glasses and they do not tend to read, let alone follow the safety advice on product labels.
- The exposure scenarios of one (e)SDS do separately describe control measures for different concentrations for skin exposure, but not for inhalation exposure while this is toe all probability the case given the properties of the substance and the intended use.
- For one substance, that is used as a watery solution, the exposure scenario appears to be aimed at the use of the substance as gas.
- In one exposure scenarios for a product used by professionals the descriptions of activities was made solely by reference to Process Categories (PROCs) without any further explanation on what these PROC's are, which makes it very difficult for users to identify their own use.

3.1.6 Summary of the findings

Based on the combination of results on compliance, quality and usefulness of the evaluated (e)SDS the following conclusion can be drawn. It's important to realize, however, that the studied (e) SDS were the ones encountered at the DU's premises two years ago. It is therefore uncertain whether the conclusions presented here are still representative of the situation today. Relevant toe this discussion are the ECHA initiatives with a view to improve the quality of the (e) SDS which are already in deployed for some years. Relevant initiatives are the exchange network for exposure scenarios ENES (Exchange Network on Exposure Scenarios) and the CSR / ES Roadmap. These initiatives have been introduced by ECHA and implemented in collaboration with the industry and a number of interested countries. It is likely that these initiatives, the commitment of the industry and national actions like targeted inspections, have resulted in the improvement in the area of (e)SDS.

None of the studied (e)SDS was found to be in full compliance with all specific requirements of the legislation. For only one of the (e)SDS the non-compliance issues were considered not to seriously limit the use of the (e)SDS in the risk assessment for the workplace.

Twenty (40%) of the (e)SDS were considered not up-to-date, i.e. they were published before 2011 (for substances) or before July 2011 (mixtures). Ten (e)SDS (20%) were not completely in the Dutch language.

Other major elements that were found to be non-compliant were:

- the specification of details for skin protection were lacking (> 85% of the (e)SDS)

- lack of indication of measures to prevent risks due to incompatible materials (85% of those (e)SDS where incompatible materials were mentioned).

Inconsistencies, mostly between Section 7 (Handling and storage), Section 8 (Exposure controls / personal protection) and the exposure scenarios, were found for around 20% of the (e)SDS, while in around half of the (e)SDS there was doubt whether the methods for safe handling in Section 7 (Handling and storage) were in agreement with the hazards of the substance as provided in Section 9 (Physical and chemical properties) or Section 11 (Toxicological information). Both indications for 'overprotective' recommendations for safe handling as well as indications for insufficiently protective recommendations for safe handling occurred.

Advice for safe handling and storage was not aimed at specific uses in any of the (e)SDS, except one. Probable exposure routes were not specified in 90% of the (e)SDS.

Twenty (e)SDS contained one or more appended exposure scenarios; one of those (e)SDS was for a mixture. Five (e)SDS of classified substances published in 2011 or later did not have any appended exposure scenario; four of these were classified as hazardous for human health. Two of the five recent (e)SDS did not contain a registration number, which may indicate either that their suppliers did not yet have to register the substance, due to low volumes or that the chemicals were illegally on the market or that the SDS was not replaced by one that meets the REACH requirements.

Fifteen (e)SDS did not mention the presently valid relevant Occupational Exposure Limit for the substance or an ingredient in the mixture, which may, for nine of the (e)SDS, be due to the fact that they were not up-to-date. About a third of the (e)SDS published in 2011 or later did not mention the DNELs for the registered substances or ingredients of mixtures.

Appropriate engineering controls were not reported in around 40% of the (e)SDS in the relevant subsection of Section 8 (Exposure controls/personal protection). In some cases these engineering controls were mentioned in a the wrong place, namely in Section 7 (Handling and storage) or in another subsection of Section 8, but in several cases there was no mention of appropriate engineering controls.

More than 90% the (e)SDS were considered to be written in a concise and clear manner. The limited number of exceptions that were either not concise or not clearly written were due to different reasons, including one (e)SDS which technically was in Dutch, but with many errors in the language.

In our opinion, more than 95% of the (e)SDS did not provide sufficiently useful advice, aimed at the receiver, on safe handling and risk management measures in the body of the (e)SDS, i.e. Sections 7 (Handling and storage) and 8 (Exposure controls/personal protection). Almost invariably, the recommendations in these sections are in such general wording, that they are not considered to help the DU in deciding on proper conditions and risk management measures.

For about two-thirds of the (e)SDS with appended exposure scenarios, these exposure scenarios were considered to be of clear added value compared to the recommendations in the body of the (e)SDS. However, for the remaining about one-third of the (e)SDS with appended exposure scenarios, the exposure scenarios were of no added value than the information in the body of the (e)SDS. In these cases the recommendations in the exposure scenarios were not sufficiently concrete, specific and/or clear.

3.2 Comparison of the results with earlier studies

Van Niftrik and Krop (2003) concluded in an earlier study on SDS that the SDS was not used very often as a source of information, neither by employers, nor by workers, because of its large size and complexity.

In a recent Finnish study of almost 90 (e)SDS it was concluded that almost half of the risk management measures was inconsistent between the body of the (e)SDS and the exposure scenario(s). The Finnish study also concluded that the added value of the exposure scenarios was questionable, because of difficulties for users to identify their use and a lack of understandability of the exposure scenarios at the end of the supply chain (Forsman-Katainen *et al.*, 2012). Compared to these findings, our study shows some improvement. Only in about one-third of the (e)SDS with exposure scenarios there were apparent discrepancies between the body of the (e)SDS and the exposure scenarios. And in more than half of the cases the exposure scenarios were considered to provide more concrete, specific and clear advice for safe use and therefore they provided added value of the body of the SDS, which in more than 95% of the cases was not considered to provide useful advice on safe use.

A recent German study evaluated many issues in relation to REACH, including the opinion of registrants, formulators, distributors, sector groups, downstream users and authorities on the quality of the (e)SDS (Reihlen and Jepsen, 2013). The large majority respondents indicated that the quality of (e)SDS should be improved. Possible improvements included more standardization, best-practice examples, expert guidance for people who have to create an (e)SDS, national checks, better explanation of DNELs and better registration dossiers. There was often some disagreement between the registrants and downstream users. Exposure scenarios, according to the respondents, could be improved by more best-practice examples, more accounting for information from end users, better standard phrases and better IT-instruments. Evaluation of exposure scenarios by ECHA and sector specific solutions were amongst the most recommended measures. Again, there appeared to be some discrepancies in views on what is most important between registrants and downstream users.

4 How to improve the (e)SDS quality and usefulness

Quality shortcomings of the (e)SDS are infringements upon REACH and frustrate the implementation obligations related to workplace safety legislation. REACH authorities at national and EU level and national authorities for workplace safety along with the industry have an interest and obligation in promoting high-quality (e)SDS and are the main actor to do so.

All different actors are currently engaged in various activities aiming at improving (e)SDs quality at both EU and national level. Worth mentioning in this context are the Forum REACH-EN-FORCE projects[10] and the CSR/ES Roadmap[11]. (e)SDS are also addressed at national level by the Dutch project aimed at SME's which is jointly set up by the government and the industry.

The current study was not aimed at identifying additional or the best ways to accomplish the required (e)SDS quality enhancement but rather as a reality check that can be used as input for the current and future actions. All actors are encouraged to intensify their efforts along the recommendations formulated by the REACH-EN-FORCE 2 Project[12] .

One of the recommendations is addressed at the industry and the knowledge building within companies. We can strongly concur with this recommendation. Especially the users of (e)SDS (DU c.q. employers) have a key role to play. It is important for them to be able to independently control the quality of (e)SDS they receive from their suppliers and utilize upstream communication to enhance the quality. This is preferably organized at branch level. Based on our analysis we have formulated a general advice for users with which we conclude this report. Industry is invited to further elaborate on this general guidance and promote good practices in this direction.

4.1 Guidance for users

In the following we provide some guidance for DU's who want to check and possibly influence the quality of the (e)SDS as it is in their own advantage to receive high quality (e)SDS.

The supplier is mainly responsible for the quality and usefulness of the (e)SDS. However, the user does have some obligations in relation to the quality of the (e)SDS. One may consult on this the extensive ECHA guidance for DU[13]. We outline here the most important items.

If the user has new information on the hazard, use or exposure of a substance, which is not in line with the information on the (e)SDS, he is required to inform his supplier in order for this information to be taken into account in an update of the chemical safety assessment.

[10] http://echa.europa.eu/nl/about-us/who-we-are/enforcement-forum
[11] http://echa.europa.eu/nl/csr-es-roadmap
[12] http://echa.europa.eu/documents/10162/13577/forum_report_ref2_en.pdf
[13] http://echa.europa.eu/documents/10162/13634/du_en.pdf

Furthermore, the user can exert some influence on the quality and usefulness of the (e)SDS in the following way.

1. Check whether the quality of the (e)SDS appears to be OK
    a. Check whether all relevant information is available (see items above)
    b. Check for apparent inconsistencies in the information (see items above)
2. Check whether the recommendations in the body of the (e)SDS (specifically sections 7 (Handling and storage) and 8 (Exposure controls / personal protection)) and in the exposure scenarios that are appended (if any) are specific and clear:
    a. Is the information provided in understandable and proper Dutch language?
    b. Are the recommendations specified for specific uses and activities?
        i. One general set of recommendations for many and various uses or activities is usually not very useful
    c. Are the recommendations sufficiently informative?
        i. One may expect something more concrete than “Prevent all contact” or “Use appropriate personal protection” or “If the concentrations are high, use respiratory protection”
    d. Do the recommendations fit to the activities of the user?
        i. For example, “use in closed systems” usually does not fit to professional situations and recommendations for spray activities are not fitting if a product is not intended to be sprayed
3. If the quality of the (e)SDS appears not to be OK or if the recommendations in the body of the (e)SDS or in the appended exposure scenarios are not concrete, specific or clear, contact the supplier of the substance or mixture
    a. An e-mail address should be provided in section 1 (Identification of the substance/mixture and of the company/undertaking) of the (e)SDS
    b. Explain what appears to be wrong or insufficiently concrete, insufficiently specific or unclear
    c. Ask for an improved, more concrete, specific or clear (e)SDS
4. If an (e)SDS is provided for a substance and a REACH registration number is mentioned in section 1 (Identification of the substance/mixture and of the company/undertaking), but there is no exposure scenario appended or the appended exposure scenarios appear not to cover the use of the user: ask the supplier to account for the use of the user
    a. You have to do this within twelve months of the receipt of the (e)SDS
    b. Provide the supplier with relevant information on the use, the conditions of use and your risk management measures to allow him to account for your use in an updated exposure scenario
        - *There are some situations where no exposure scenario is needed, for example if the substance is only used for product*

and process oriented research, or if the substance is only used as a pesticide; however, if you are not sure about why an exposure scenario for your use is not provided: contact the supplier

- *Contacting the supplier is not necessarily the only option; however, this is the option that is related to improvement of the quality of the (e)SDS; for other options, see the Downstream User Guidance of ECHA (http://echa.europa.eu/documents/10162/13634/du_en.pdf)*

5. If a user is a member of a sector organization or branch organization, the common uses and activities in the sector or branch can be described in a combined effort and can be provided to the suppliers. This can help the suppliers to make concrete, specific and clear recommendations for safe use
    a. It can be very helpful to have the sector organization or branch organization make a translation of typical activities into Process Categories under REACH
6. If a supplier does not want to improve an (e)SDS that is considered to be clearly not useful by the user, the user can contact the Inspectorate SZW, who can check whether the (e)SDS is in compliance with all requirements and, if not, can take further action
    a. If a supplier is not willing to account for your use of the substance, you have the option to switch to a more willing supplier, to stop using the substance for this purpose or to make your own chemical safety assessment; for more information on the relevant options and related requirements, see the Downstream User Guidance of ECHA (http://echa.europa.eu/documents/10162/13634/du_en.pdf).

5 References

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