FORUM

Report on Improvement of Quality of SDS

WG "Joint initiative ECHA Forum – ECHA ASOs on Improvement of the quality of SDS"

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This report presents the results of assessments of safety data sheets made by participating Member States under the Forum action on improvement of the quality of Safety Data Sheets. The results presented in the report are not necessarily representative of the situation in the EU-EEA market as a whole.

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1. Executive summary

National enforcement authorities (NEAs) controlling compliance with REACH requirements and ECHA's Forum for the Exchange of Information on Enforcement (Forum) are aware that there are issues with the quality of information provided in safety data sheets (SDSs). This was evident from the results reported from the Forum's coordinated REACH-EN-FORCE (REF) 2 project[1] on the Obligation of downstream users - formulators of mixtures. 29 Member States undertook inspections in 2011/2012 addressing *inter alia* the quality and management of the downstream users' own SDSs. The results from the evaluation of 4,500 SDSs during this project showed that about 50% of the checked SDSs had defects in the information provided. Specifically the content of sections 1, 2, 3, 8 and 15 had deficiencies rates ranging from between 10% and 20%.

Inspectors also recorded issues with the quality of information provided in extended SDSs during the Forum's REF-5 project on extended safety data sheets, exposure scenarios, risk management measures and operational conditions[2]. Significant quality deficits were observed in chemical safety reports assessed by the ECHA support team including a lack of clear and specific risk management measures. It was noted that in the majority of cases, such deficits are copied into the extended SDSs indicating that information transferred through the supply chain via extended SDSs is not of satisfactory quality in terms of accuracy, clarity, and usefulness. This was also confirmed by the inspectors' observations during the inspections undertaken during REF-5.

Taking account of this information, the Forum members proposed to undertake a joint action with ECHA's accredited stakeholder organisations (ASOs) to improve the quality of SDSs. The Forum set up a working group (WG) composed of Forum members/alternates and invited experts as well as representatives from ECHA ASOs with a mandate to:

- define the detailed scope of the joint action
- collect data on deficient SDSs
- analyse the data and identify the issues requiring priority actions
- report on the findings and recommendations
- implement solutions arising from the recommendations (task to be carried out by ECHA ASOs)
- monitor the progress and oversee the follow-up actions identified by the ASOs during the Forum's open session meetings from 2019 onwards.

[1] https://echa.europa.eu/documents/10162/13577/forum_report_ref2_en.pdf/6ae12cf0-a24d-4263-a30f-3dabf9928aed

[2] https://echa.europa.eu/documents/10162/13577/ref-5_report_en.pdf/1bee1c5c-2ed6-da94-91e4-eede3ce1ac37

The WG was set up in the second half of 2017 with scoping of the work plan completed in December of that year. Work on data collection and reporting of the findings was carried out throughout 2018 by the Forum members/alternates and invited experts. The WG collated data from the assessment of 197 SDSs which was carried out by 12 participating countries and then analysed the findings which are detailed in this report.

In parallel to this work, the WG asked the ECHA ASOs to share examples of initiatives taken by stakeholder organisations or industry groups to improve the quality of SDS and also invited stakeholder organisations to share data on deficient SDSs.

The findings from the SDS sections which were identified as those being the most relevant to this project, i.e. Sections 1, 2, 3, 7, 8, 9, 10, 11, 12 and 15 are set out in section 2 of this report. The numbers of SDSs analysed for each section and subsection, as well as the numbers of SDSs which were found to have issues, are set out in the tables for each section below. The numbers of sections with information missing, and those with information which is present but not adequate or appropriate to comply with the requirements of Annex II of REACH are recorded separately. The overall percentage of issues identified for each section and subsection are provided as well as brief descriptions of the main problems identified by the assessing inspectors.

The main issues noted relate to:

- no reporting on uses advised against, unclear identified uses and the absence of the required emergency telephone number in Section 1
- incorrect classification in SDS Section 2 and in correlation with this issue, incorrect reporting of concentration ranges of ingredients in mixtures in Section 3
- not providing national occupational exposure limits and an inadequacy of the information provided on control measures, including engineering controls and specific details on personal protective equipment (PPE) in Section 8
- lack of information on the physical/chemical, toxicological and eco-toxicological properties in Sections 9, 11 and 12, with no explanation as to the reason for the absence of the information as required to be stated.

Where information is not provided at all or where there are inadequacies in the information in the SDS, there are consequences for users and actors down the supply chain. For example, in this initiative, it can be seen that classification of mixtures appears to have been incorrectly assigned in Section 2 as it is often inconsistent with the concentration ranges in Section 3, or that the harmonised classification of ingredient substances was not provided in Section 3.2, or that pH was not taken account of. Incorrect classification results in inaccurate labelling and potentially the provision of inaccurate information on safe handling and risk management measures.

To address the issues noted, the WG has set out recommendations for improving the quality of each section and indicated to whom they are addressed. There are recommendations for ECHA ASOs to implement, for national enforcement authorities to

consider, and for the Commission and ECHA to take into account when addressing REACH Review Actions 3 and 12.

Overall, the recommendations advocate better consistency checks by compilers across all sections of the SDS, advise those responsible for SDSs to put pressure on software providers to ensure that the templates are compliant with Annex II requirements, provision of specific and more detailed guidance on issues which have shown the highest rates of problems and in some areas the need to consider closer cooperation with authorities responsible for enforcing occupational safety and health (OSH) regulations.

Following the publication of this report, ECHA ASOs will be requested to focus on implementing solutions based on the findings and the recommendations of the WG, and during the annual open sessions of the Forum meetings they will be requested to report back to Forum on the actions taken.

This initiative is a new and innovative method of working within Forum: a joint action by Forum, NEAs and ECHA ASOs with the aim to improve the quality of SDSs through identifying solutions that can be implemented by the responsible actors within industry. The project's success may set precedence for future methods of working more closely with ECHA ASOs on issues of interest.

Throughout the project, the WG has communicated and coordinated with ECHA staff involved in the Exchange Network on Exposure Scenarios (ENES) programme and has received feedback and advice on the report and way forward.

Additionally, the Commission are tackling a number of issues identified under the REACH Review Action 3 related to the workability and quality of (information in) extended SDSs. Therefore, this WG will follow the outcomes of the first COM-ECHA REACH Review Action 3 workshop. The working group has already identified that some of the issues and recommendations would best be handled under this Action.

2. Detailed results of the action

2.1. General overview

Objective and scope of the Joint Initiative

Background

The Forum has noted the persistent problem of deficiencies in quality of the SDSs that remains a concern despite the numerous enforcement projects of the Forum, enforcement activities in the Member States and diverse actions undertaken to promote the compliance with the SDS requirements.

Therefore the Forum decided on a possible way to improve the quality of SDS via means other than only enforcement of the REACH Regulation by working together with stakeholder organisations to jointly find solutions for this issue.

Objective

The objectives are for the Forum WG to identify the common deficiencies found in the SDSs and propose recommendations to relevant stakeholders for improvement, in order for those responsible including ECHA ASOs to propose and implement solutions to the issues noted. The WG will also monitor the progress of the implementation of the recommendations. The WG anticipates an improvement in the quality of the SDS by the means of pro-active measures taken by industrial stakeholder organisations both at a European and national level.

Scope

The scope of the initiative is to analyse the deficiencies in a specific sample of SDSs checked by participating inspectors in Member States and seek to understand, together with stakeholders, what the main issues are for SDS authors and what potential problems prevent authors from compiling compliant SDSs. The findings could be used by stakeholder organisations for training purposes – to highlight and explain the most common issues found in SDS. This would help the companies to avoid such quality problems in their SDSs.

Information from inspected SDSs of substances or mixtures classified as hazardous was collected using the SDS checklist developed by ECHA[3]. The reporting could be from both on-site and desktop checks. The focus was on the quality of information in Sections 1, 2, 3, 8, 9, 11, 12 and 15 of the SDSs. Inspectors also chose to report checks on Sections 7 and 10 and the findings from those are also in the report. In order to carry out a qualitative analysis the inspectors were asked to provide additional information on issues noted with

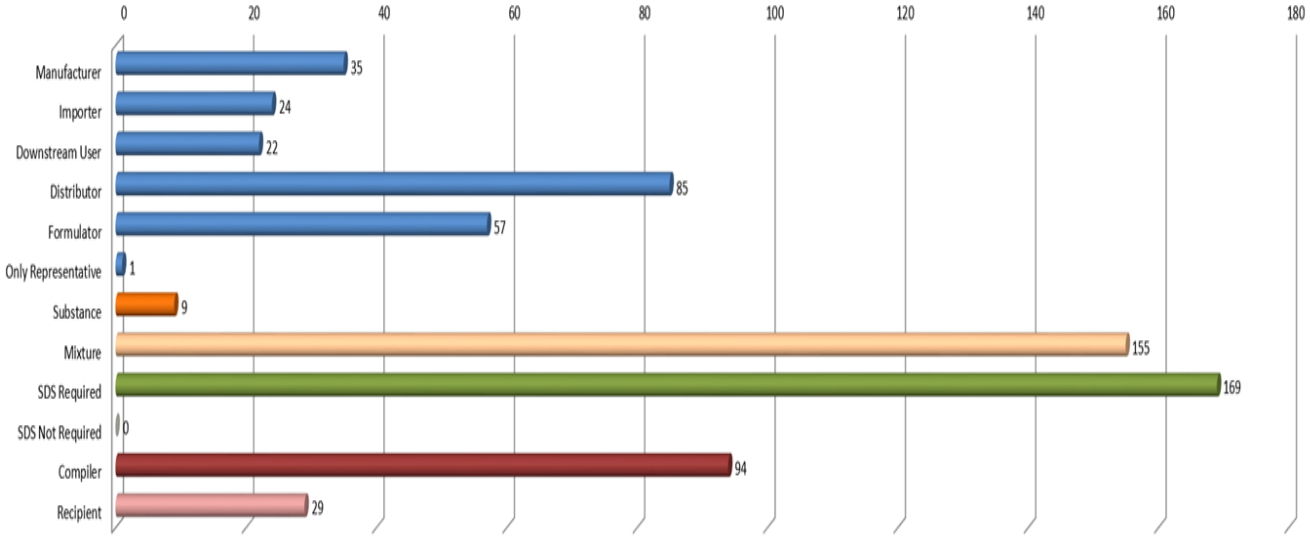
[3] https://echa.europa.eu/sv/regulations/reach/safety-data-sheets/checklist

quality in the free text fields in the checklist. The project did not focus on exposure scenarios, although certain related aspects were touched upon in Section 8.

2.2. Participation and number of checked SDS

The WG collected the data from 12 participating countries[4] that provided information on 197 checked SDSs. Not all sections in the SDS where controlled for all of the samples, which is why the number of controlled SDSs can vary from section to section in the analyses in chapter 2.3.

The graph below shows a summary of the role of the company where the SDS was checked, whether the SDS checked related to a substance or a mixture and if the company where the SDS was checked compiled or received the SDS.



[4] CY,CZ,DE,DK, EE,FI,IE,LT,NL,PT,SE,UK

2.3. Main findings, main problems and recommendations from the WG

2.3.1. Section 1 - Identification of the substance/mixture and of the company/undertaking

Main findings

Section of the SDS	Sum of sections: info not adequate/not present	No. of sections: info is present but not adequate/not appropriate	No. of sections: info is not present	Total no. checked for this section	% of SDSs checked with issues in this section
1.1: Product identifier	16	10	6	194	8%
1.1: Registration number (RN) (is required for registered substances = ¼ of the investigated SDS)	28	4	24	51	55%
1.2: Relevant identified uses	37	21	16	195	19%
1.2: Uses advised against	129	4	125	194	66%
1.3: Details of the supplier of the SDS	25	17	8	193	13%

1.3: e-mail address of competent person for the SDS	25	1	24	195	13%
1.3: responsible person in MS if supplier not located in MS (is relevant for about 1/3 of investigated SDSs)	34	0	34	65	52%
1.4: emergency telephone number	84	56	28	195	43%

In Section 1 of the SDS, there are 4 subsections (1.1) to (1.4). Most of the 197 SDSs identified issues related to this Section.

The information in Section 1.1 (Product identifier) usually was present and adequate. In 5 % of the cases the name contained in the product label was different from the name on the SDS. Also, in the case of SDSs of registered substances, the registration number is often absent. This may be due to the timing of collecting SDS for this project (before or shortly after the 2018 registration deadline).

The information in Section 1.2 (Uses) needs to be improved. In almost 20 % of the cases, there is a non-compliance of the important information on identified uses (information is absent or non-adequate). Information on uses advised against is absent in 2/3 of the SDS. This is regrettable, but it may be due to some ambiguity in the legal requirement to list 'uses advised against'.

Section 1.3 (Details of the supplier) most often provides the required information, in contrast with Section 1.4 (Emergency telephone number), where potential issues were noted in more than 40 % of the SDSs collected.

Main problems

- It is of concern that the information on 'relevant identified uses' is not adequate and that 'uses advised against' are absent. It should be clear that where as a result of a REACH chemical safety assessment the supplier considers certain uses unsafe, this should be communicated in the SDS. Downstream user obligations are also reliant on being able to identify their uses in the SDS, so it is a problem if they are not able to do so. The observations indicate that some clarifications may be needed.

- The absence of the appropriate emergency telephone number is also of concern in Section 1. With the current efforts towards the implementation of Annex VIII to CLP (on emergency response), it is expected that this situation will improve over the next few years, if at least the necessary SDS updates are made.

Recommendations from the WG:

Recommendations for ECHA ASOs

1. The WG recommends that sector organisations (including downstream user sector organisations) assist their members with the identification of relevant uses and uses advised against, for example by providing 'sector use maps' (lists of typical uses in a specific (sub-)sector).
2. More generally speaking, stakeholders could engage in motivating the companies they represent to update their SDSs regularly, or after specific events (e.g. after an update of REACH Annex II on safety data sheets, after the entry into application of CLP Annex VIII on Poison Centres, …).
3. Promote quality criteria for SDS software. One of the criteria could be: the software must offer the option to select in a database the relevant national poison centre in the EU, including its telephone number and hours of operation (if an official advisory body exists in the Member State where the substance or mixture is placed on the market).

Recommendations for REACH Review Action 3

4. Develop a guide on Section 1.2 of the SDS, clarifying what is expected in terms of the description of the identified use and addressing the issue of uses advised against.

Recommendation for All concerned parties

5. The concept of emergency telephone number is not well understood. It may be worthwhile making a promotion campaign to improve this situation, certainly because of the upcoming changes in this area after the application of CLP Annex VIII on Poison centres.

2.3.2. Section 2 – Hazards identification

Main findings

Section 2.1 Classification of the substance or mixture:

Section of the SDS	Sum of sections: info not adequate/ not present	No. of sections: info is present but not adequate/not appropriate	No. of sections: info is not present	Total no. checked for this section	% of SDSs checked with issues in this section
2.1. Classification of the substance or mixture	43	36	7	127	34%
- Substance - Regulation 1272/2008 (CLP)	21	5	16	36	58%
- Mixture - Regulation 1272/2008 (CLP)	71	48	23	181	39%

Main problems:

- Assessments of Section 2.1 in 127 SDSs showed that:
  - classification was incorrectly assigned in some cases due to the fact that the information provided in Section 3.2 was not correct for example, provision of incorrect concentration ranges (percentage range too wide) or the harmonised classification of ingredient substances was not provided in section 3.2
  - information was inconsistent with labelling information
  - hazard statements were omitted
  - classification was not present although required.

- Additionally, information from other sections in the SDS was not taken into account resulting in incorrect classification provided in section 2.1. Examples of this are not taking the extreme pH provided in section 9 into consideration, or information from sections 11 and 12 not correlating with the classification.

- Specifically, assessments of the information provided for substances (36 SDSs checked) recorded that issues related to:
  - harmonised classification not being used
  - missing hazard statements.

- Assessments of the information provided for mixtures (181 SDSs checked) recorded that issues related to:
  - Incorrect classification (43 cases) (including conflicting information with that provided in section 3)
  - missing hazard statements.

- Assessments also showed that information on hazard identification was in section 3 rather than in section 2 which indicates that the SDSs were not in compliance with REACH.

- In seven assessments of SDSs for mixtures, classification was provided according to the revoked Dangerous Preparations Directive (DPD) only (no CLP classification was provided).

Section 2.2 Label elements:

Section of the SDS	Sum of sections: info not adequate/ not present	No. of sections: info is present but not adequate/not appropriate	No. of sections: info is not present	Total no. checked for this section	% of SDSs checked with issues in this section
2.2. Label elements	31	22	9	79	39%
- Substance - Regulation 1272/2008 (CLP)	8	8	0	18	44%
- Hazard pictogram(s)	4	4	0	15	27%
- Signal word(s)	6	5	1	15	40%
- Hazard statements	4	4	0	14	29%
- Precautionary statements	3	2	1	12	25%
If only Hazard/Risk codes are given is there a reference to Section 16?	5	0	5	7	71%
Supplemental information (Arts 25& 32(6) of CLP)	7	0	7	9	78%
- Mixture - Regulation 1272/2008 (CLP)	60	42	18	178	34%
- Hazard pictogram(s)	54	32	22	183	30%
- Signal word(s)	50	30	20	183	27%

- Hazard statements	58	38	20	183	32%
- Precautionary statements	58	38	20	182	32%
Supplemental information (Arts 25& 32(6) of CLP)	66	5	61	113	58%

Main problems:

Overall the main issues recorded related to:

- missing or incorrect hazard statements or pictograms
- incorrect classifications including classification for endpoints missing
- the classification differing from that provided in section 2.1
- the harmonised classification was not provided

For substances the issues noted in section 2.2 were:

- the harmonised classification was not provided and
- incorrect hazard statements were provided.

For mixtures, of the 183 SDSs checked, the issues noted in section 2.2 were:

- inadequate classification of mixtures resulting in incorrect labelling
- incorrect or missing hazard pictograms
- the signal word was not provided at all or was incorrect
- hazard statements were not provided or were incorrect due to the incorrect classification being assigned – in some cases due to lack of consideration of extreme pH
- regarding precautionary statements non-compliances were similar to those above with statements not provided or were provided incorrectly, for example, they were not worded according to CLP or did not reflect the classification
- supplemental information was not provided at all or not provided correctly, e.g. EUH statements were not provided or the name of the allergenic substance was not provided correctly for EUH208
- there were cases (4) where labelling according to the revoked DPD only was provided with no CLP labelling information given.

Section 2.3 Other hazards:

Section of the SDS	**Sum of sections: info not adequate/**	**No. of sections: info is present but not**	**No. of sections: info is not present**	**Total no. checked for this section**	**% of SDSs checked with issues in**

	not present	adequate/not appropriate			this section
2.3. Other hazards	58	2	56	163	36%

Main problems:

- Inadequate information was provided in 2 cases in section 2.3 - information on freezing properties not provided as ”other hazard” although required in two SDSs.
- Information was not present, e.g. indication of whether the substance or mixture meets the criteria for persistent bio accumulative and toxic (PBT) or very persistent and very bio accumulative (vPvB).

Recommendations from the WG:

Based on the non-compliances noted, recommendations for improving the quality of section 2 of the SDS include:

Recommendations for ECHA ASOs:

1. As it was noted that information required in section 2 was provided in section 3 and vice versa showing that there are SDSs which have not been updated in line with the latest update to Annex II of REACH (Reg. EU No. 2015/830), companies must be made aware of the need to provide updated SDSs and recipients must request SDS compiled in accordance with Annex II from their EU supplier.
2. It should be highlighted to formulators/importers of mixtures that there is a need to check consistency between sections 2 and 3 of the SDS, especially with regard to the provision of the correct concentration ranges in section 3.2.
3. Additional consistency checks are required with information in other sections of the SDS such as section 9 for information on flammability, pH, sections 11 and 12 for consistency with toxicological and eco-toxicological test results.
4. Advise companies to check if a substance or the ingredients of a mixture have harmonized classification in accordance to Article 4(3) of the CLP Regulation.
5. Advise companies to use the Guidance on the compilation of safety data sheets provided by ECHA.
6. Guidance is needed on labelling compliance.
7. Advise companies to request that non-EU suppliers provide the recipient of the substance or mixture with a safety data sheet compiled in accordance with Annex II, or information that will allow the importer to conclude whether the substance/mixture is hazardous and compile a compliant SDS when required.

Recommendations for national enforcement authorities:

8. Allocate resources to guide and help companies and inform them about the importance of the correct labeling and hazard information for the workers e.g. by using checklists developed by industry or authorities

2.3.3. Section 3 – Composition / information on ingredients

Main findings

Section of the SDS	Sum of sections: info not adequate/not present	No. of sections: info is present but not adequate/no	No. of sections : info is not present	Total no. checked for this section	% of SDSs checked with issues in
3.1. Substances	15	14	1	31	48
3.2. Mixtures					
- Concentration % (ranges)	38	10	28	180	21
- Classification according to Regulation 1272/2008	42	25	17	180	23
- Classification according to Directive 67/548/EEC	25	17	8	64	39
- Constituent substance identifier (name, EC/CAS No.)	25	11	15	175	14
- Constituent substance registration number	96	79	17	169	57

From the comments provided, the main issues were related to range of percentages of concentrations, to substances in a mixture that were not provided, classification for individual substances were incorrect or missing or according to DPD. Also, there were

issues with the product identification of the substances (article 18.2) and in some cases, information on ingredients was in section 2 rather than in section 3. Furthermore, the registration numbers of the ingredient substances was missing, when required.

Main problems

The main issues reported were:

- Classification was still according to DPD (this type of classification is not permitted after June 2017, according to Commission Regulation (EU) 2015/830 of 28 May 2015);
- The concentration was provided in the range of percentages. Basing the classification on the highest percentage, the classification in section 2 was incorrect. However, in reality the classification was based on real concentration(s) which highlights the issue about incorrect use of concentration ranges.
- The identity or classification of substances was incorrect.

Recommendations from the WG:

Recommendations for the ECHA ASOS:

1. Provide a short guide with examples on how to assign concentration ranges;
2. State that is no longer possible to classify mixtures according to DPD (Directive 1999/45/EC);
3. When using concentration ranges, the maxima of the given ranges should result in the same classification as the actual concentrations that were used for classification;
4. When using a range of percentages, the health and environmental hazards must describe the effects of the highest concentration of each ingredient;
5. Information on the consequences of not paying full attention to the details in section 3, i.e. higher classification of the overall product (section 2) may be required due to incorrect application of concentrations/incorrect identifiers etc;
6. Attention should be given to sections 2, 8, 11 and 12 to confirm that the information is consistent with section 3;
7. The formulator of mixtures has to consider the SDS of the suppliers of the components when classifying mixtures and just not relying on the information provided by software.

2.3.4. Section 7 – Handling and Storage

Main findings

Section of the SDS	Sum of sections: info not adequate/not present	No. of sections: info is present but not adequate/not appropriate	No. of sections: info is not present	Total no. checked for this section	% of SDSs checked with issues in this section
7.1. Precautions for safe handling	30	28	2	81	37%
7.2. Conditions for safe storage, including any incompatibilities	26	22	4	76	34%
7.3. Specific end use(s)	24	5	19	70	34%

- Section 7 was not a section with a high priority at the start of the project, so the response rate is possibly not as high as it could have been.

- Section 7.1: Of the 81 sections reported on, 30 (37%) were non-compliant in that 2 SDSs had no information present in the section and 28 provided inadequate information for the user. The remarks (17/28) indicated that the information was not specific enough. Although the remarks don't go into detail to explain the inadequacy of the information, the term "use sufficient/good ventilation" was highlighted a number of times.

- Section 7.2: Inspectors reported on 76 sections and found 34% non-compliance with the requirements for providing information on safe storage and incompatibilities. Inspectors reported that the information was too generic or not specific enough to be useful for the user; they also noted that in some cases not all of the required information was present. The legal text could be an issue here as it states "If relevant", so it is possible the SDS supplier does not consider certain information to be relevant, but does not indicate this and simply leaves the section empty.

- Section 7.3: 70 SDSs were reported on and 24 (34%) were found to be non-compliant. No information was present in 19 cases, and in the 5 where the information was present it was deemed to be inadequate. Inspectors noted that the information was vague or referred only to Section 1.2 of the SDS. Advice in the SDS tends to be generic and rarely addresses the specific uses identified in Section 1.2, while the uses are addressed in the exposure scenarios for a substance SDS. However when there is a mixture SDS (as the majority in this project were) without ES attached, then this section would be a good option to incorporate any relevant

advice from component substance exposure scenarios that apply to the mixture as a whole.

Main problems

- The main issues in Section 7 related to generic or missing information for safe handling and storage. This could result in insufficient information for workers to handle the substance/mixture safely and for workplaces to carry out their risk assessments (under the Chemical Agents Directive).
- For Section 7.3 there seems to be a lack of understanding of what kind of information is expected. The legal text and the ECHA Guidance point to this section being potentially useful for mixture safety data sheets, but without any detail about which information should be provided or how it should look.

Recommendations from the WG:

Recommendations for ECHA ASOs / REACH Review Action 3:

1. Promote/pressure software providers to leave provision for amending this section to enable SDS suppliers to add more use specific information, in particular when compiling a mixture SDS.
2. Encourage users to check and feedback to their supplier when information in this section is missing or not helpful.

Recommendation for national enforcement authorities:

3. More emphasis is needed on providing information specific to the uses of the mixture/substance and relevant to the workplace risk assessment. This could be a point of cooperation under REACH Review Action 12, where issues with this section could be identified by OSH inspectors when inspecting workplaces and evaluating workplace risk assessments, and enforced/referred by REACH inspectors with regards to the SDS content.

Recommendations for REACH Review Action 3

4. Related to the recommendation in Section 8, to develop (more) guidance/examples on how to transfer information from several substance SDSs to a mixture SDS and consider if that advice could be provided in Section 7.3.

2.3.5. Section 8 – Exposure controls / personal protection

Main findings

Section of the SDS	Sum of sections: info not adequate/ not present	No. of sections: info is present but not adequate/ not appropriate	No. of sections: info is not present	Total no. checked for this section	% of SDSs checked with issues in this section
8.1. Control parameters	59	45	14	157	38%
- 8.1.1 National limit values	67	18	49	148	45%
- 8.1.2 Information on currently recommended monitoring procedures	115	3	112	133	86%
- 8.1.3 If air contaminants are formed when using the substance or mixture as intended	99	0	99	120	83%
- 8.1.4 The relevant DNELs and PNECs for the substance/s for the exposure scenarios	89	6	83	139	64%
- 8.1.5 Details of any control banding approach used	102	0	102	109	94%
8.2. Exposure controls	73	66	7	151	48%
- 8.2.1 Appropriate engineering controls	83	43	40	155	54%
- 8.2.2 Individual protection measures, such as personal protective equipment	85	66	19	169	50%
- 8.2.3 Environmental exposure controls	105	14	91	150	70%

8.1: A general comment about this section is that information is mostly provided (only in 9% of cases was no information provided), but in many cases the information is not adequate.

- 8.1.1: 45% indicate a problem in this subsection. From the "Remarks" field the main problem is that the national limit value is not given, so either it is missing or another country's values is included instead (e.g. US, UK or Germany) – this seems

to be a "translation error" in that during translation certain sections such as this one and Section 15 that refer to national legislation cannot be simply translated.

- 8.1.2: 86% indicate an issue, with the vast majority due to the information simply being missing. In the majority of cases monitoring would not be required as there are a limited number of OELs. However the question is whether it should be indicated that monitoring is not required or whether it can be assumed that when the section is blank that it is not required. For an OEL monitoring may be required, but there can be different national limits and different monitoring methods accepted nationally. Question is for which other limits would monitoring be required. This could be cross-linked with subsection 8.1.1. so when e.g. an OEL is indicated but there are no monitoring procedures in subsection 8.1.2 then this is a problem that a DU could ask their supplier about. It is also noticeable that there are very few standard phrases in the EUPhrac catalogue for this section, which might be an indication that what is expected is not clear.

- 8.1.3: 83% indicate an issue, all of them due to missing information. This could be because air contaminants are not formed during the foreseen uses, in which case should this be indicated rather than left blank. Leaving this section blank may indicate that the supplier doesn't know what contaminants are formed, which is not in line with having assessed the foreseen uses.

- 8.1.4: 64% indicate an issue, with the vast majority due to missing information. It is noted that about three quarters of SDS checked during this project were for mixtures, and several of the remarks indicate that the DNEL/PNEC was not provided for all components of the mixture or not in line with the composition (Section 3.2). It is legitimately possible for this to be the case as some of the substances in the mixture that lead to classification may not have been registered above 10 tonnes/year.

- 8.1.5: 94% indicate an issue, all of them due to missing information. It is suspected that control banding is not used in the majority of cases, but the registrant has not indicated anything.

8.2: Similar to section 8.1 information is mostly provided (only in 5% of cases was no information was provided), but in this case the information is not sufficiently detailed.

- 8.2.1: 54% indicate an issue, with about half indicating missing information and the other half indicating inadequate information. The "Remarks" mostly point to the information being too general or vague, in particular with regard to ventilation. Several comments on "use sufficient/adequate ventilation" not being helpful or the number of air changes being missing. Question is whether it should refer to exposure scenarios where there are some.

- 8.2.2: 50% indicate a problem, with the majority pointing to inadequate information. More Remarks were made for this that any of the other subsections of Section 8, and a clear issue is observed. The PPE specification is missing, mainly for gloves but also respiratory protection (most comments refer to EN standards, glove material, thickness etc. not being provided). Seems a clear case where the DU can communicate with the supplier that the information is not sufficient (e.g. via the Dutch SDS check tool).
- 8.2.3: 74% indicate a problem, with the majority pointing to missing information. The Remarks don't provide anything further. In the legal text there is a reference to exposure scenarios so the registrant may be relying on that but then doesn't

indicate it (however the majority are mixtures, so most likely there are no ES). Perhaps there is no environmental hazard but again this should be indicated.

Main problems

There are two main problems with Section 8, information is either missing or not detailed or specific enough to be useful.

1. It is suspected that as many of the checks were for mixture SDS the information from the component SDS including exposure scenarios, has not been incorporated properly (either as attachments/annexes or within the main SDS body). This includes the DNEL/PNEC and the exposure controls.
2. In some cases where there is missing information there may be a good reason (e.g. no environmental hazard) but it is not indicated, or the information is elsewhere in the SDS (e.g. in the exposure scenario) but there is no reference made.
3. Lastly, for substance SDS, the information has simply been omitted by the supplier and feedback from the downstream user could improve the situation.

Recommendations from the WG:

Recommendations for ECHA ASOs:

1. Sector organisations could encourage their members (e.g. through an information/awareness campaign) to feedback to their suppliers when this information is missing (e.g. OELs/DNELs for substances in the mixture), not specific enough to be helpful (especially in Section 8.2, when, for example, glove specifications are not provided), or there are translation errors (e.g. OEL not applicable to the MS).
2. Promote/pressure SDS suppliers to indicate "not relevant" for any section that is not relevant rather than leaving empty (e.g. have this as a default in their software)
3. Develop/promote a database of national limit values that SDS authors can be referred to.
4. Provide and promote examples where SDS Section 8 has been done well (or at least where certain subsections have been done well), so that these can be used as examples of what is expected.

Recommendations for national enforcement authorities:

5. Promote checking of indication of "strictly controlled conditions" (SCC) for intermediate registrations in Section 8.2. This relates to the Forum's REF-7 harmonised enforcement project where there is an issue with downstream users providing a confirmation to their supplier that they will comply with SCC, then not doing it. SCC being specifically indicated in the SDS Section 8.2 supports certain MS inspectors to take action.
6. Contribute to standard phrase development, for the type of information that inspectors would look for, e.g. in the monitoring section.

Recommendations for REACH Review Action 3

7. Develop (more) guidance/examples on how to transfer information from several substance SDS to a mixture SDS. Investigate if there are any existing software/tools that can already do this.
8. Promote the good examples provided by ASOs/Inspectors (see recommendations for ASOs above).

2.3.6. Section 9 – Physical and chemical properties

Main findings

Section of the SDS	Sum of sections: info not adequate/not present	No. of sections: info is present but not adequate/not appropriate	No. of sections: info is not present	Total no. checked for this section	% of SDSs checked with issues in this section
9.1. Information on basic physical and chemical properties	54	47	7	182	30%
9.2. Other information	72	8	64	160	45%

30 % of reported SDS indicated issues with information requirements in section 9.1. From the remarks from inspectors, it is derived that the qualification 'not adequate' is most often because one or multiple properties are missing or if indicated that the property is not applicable or available there is no information given as to the reason why.

In 3 (out of 182) cases it was reported that the missing properties were needed for classification or risk management at the workplace.

In 6 (out of 182) cases there was an extreme pH but the product was not classified according to this.

For section 9.2 ('Other information') 45 % of the SDSs checked were reported to have issues. In most of these cases the answer from inspectors was that the information wasn´t provided but with no additional information if this was required. If you only take the ´not adequate answers´ into account the number of cases with issues drops to 5%. Data is

frequently absent in Section 9.2. This may be because there is no list of properties, which one has to report in this section. The producer of the SDS has to judge which properties are relevant and the legislation doesn´t specify that a "not applicable" answer should be stated.

Main problems

- Data on clearly specified mandatory properties is missing in 9.1 or if it is stated that a particular property does not apply or if information on a particular property is not available, the reasons are not given.

Recommendations from the WG:

Recommendations to ECHA ASOs:

1. In the revision of Annex II to REACH there is a major change suggested in section 9 of the SDS, to comply with the revised UN GHS text. This also means that there will be a more detailed description when a property is relevant. It is a good assumption that the revision will enter into force. Since there are, legislative changes ongoing the WG suggests not to further elaborate on this issue with the ASOs at the moment. WG would however encourage the ASOs to implement and inform their members of the new information requirements when the legislation has been adopted.
2. A general recommendation is still that all sections should be completed, including where they are not relevant this should be indicated. A way forward is to facilitate the checking of Section 9 properties and request an update from their supplier if they are missing and not indicated as not relevant. In particular those that are relevant for the workplace risk assessment should be a focus e.g. vapour pressure, flash point etc.

Recommendation for REACH Review Action 3:

3. Further clarification to be provided on how to communicate Section 9 properties for a mixture SDS, making clear those properties that apply to the mixture as a whole, and those that remain substance specific and need to be communicated per ingredient.

Recommendations for All concerned parties:

4. Concerning the cases with extreme pH and classification based on this according to point 3.3.2.3 in Annex II to CLP the Forum has elaborated a recommendation to launch an information campaign to highlight the issue.

Section 10 – Stability and reactivity

Main findings

Section of the SDS	Sum of sections: info not adequate/not present	No. of sections: info is present but not adequate/not appropriate	No. of sections : info is not present	Total no. checked for this section	% of SDSs checked with issues in this section
10.1. Reactivity	19	5	14	83	23%
10.2. Chemical stability	12	5	7	80	15%
10.3. Possibility of hazardous reactions	13	6	7	78	17%
10.4. Conditions to avoid	12	6	6	79	15%
10.5. Incompatible materials	16	4	12	78	21%
10.6. Hazardous decomposition products	9	7	2	80	11%

- There are 6 subsections 10.1 to 10.6. The findings are quite similar across most of the sections so they will be described collectively in the main, with some reference to particular sections when relevant. Around 80 SDS (78-83 responses received across the subsections) were specifically reported on out of the total (197).

- Section 10.1 indicated the highest amount of issues with 23%, while 10.6 indicated the lowest amount of issues with 11%, with an average of 17% across all subsections. For 2 of the subsections (10.1 and 10.5) the issues were mainly related to missing information. For the remaining subsections there was an equal split between missing information and information not being adequate, but in neither case were the numbers particularly high.

The remarks for each of the subsections does not reveal anything interesting. The highest number of remarks was 4 for section 10.1 where 19 issues were identified. 3 of the 4 remarks indicated simply that information was missing, the 4th remark indicated that the possibility of chlorine gas being generated was not indicated.

This was not a section that was of particular concern for this WG and the results support that.

Main problems

- Checks of subsections 10.1 Reactivity and 10.5 Incompatible materials both indicate missing data, and are related in the type of information that is expected.

Recommendations from the WG:

Recommendations for ECHA ASOs:

1. Raise awareness for their members who are downstream users to feedback to the supplier if the subsections are empty and seek clarification, or indicate any incompatibilities if known.
2. Raise awareness for their members who are downstream users to check the information in Section 10 against the handling information in Section 7.

Recommendations for national enforcement authorities:

3. Pay particular attention to the 2 subsections 10.1 and 10.5 during the check of the SDS. If there are no known incompatibilities this should also be indicated rather than the section being left blank.
4. Inspectors to check the information in Section 10 against the handling information in Section 7 (consistency check).

2.3.7. Section 11 – Toxicological information

Main findings

Section of the SDS	Sum of sections: info not adequate/not present	No. of sections: info is present but not adequate/not appropriate	No. of sections: info is not present	Total no. checked for this section	% of SDSs checked with issues in this section
11.1. Information on toxicological effects	63	55	8	166	38%
- 11.1.1 Substances: relevant hazard classes as listed in REACH	44	18	26	83	53%

- 11.1.2 Mixtures: relevant effects as listed in REACH	68	27	41	153	44%

From 166 checks on information on toxicological effects - 63 were not adequate / not appropriate or not were present (38 %). In 53 % of cases information on relevant hazard classes was not adequate / not appropriate or not was present. In 44 % of cases information on relevant effects was not adequate / not appropriate or not was present. In many cases toxicological data was incorrect or missing and / or in contradiction with classification without further explanation. Also relevant hazard classes and / or effects including those which were used for classification were not covered. That creates uncertainties and lack of clarity for the hazard identification and risk assessment.

Especially for mixtures, problems seem to be even higher than for substances. Instead of data for the mixture, just data for the single ingredients were specified. The data about the ingredients doesn't fit with the classification of the mixture.

Main problems

- Incorrect or missing available toxicology data.
- Contradiction between the toxicology data and classification.
- No further indication which data have been used for classification.
- Relevant hazard classes not covered.
- Relevant effects not covered.
- The standard phrase 'based on available data, the classification criteria are not met' for non-classification is not used.
- Wrong toxicity data of single ingredients led to mistakes in mixture classification.

Recommendations from the WG:

Recommendations for ECHA ASOs:

1. To ensure that toxicology data are provided separately for substances and for mixtures with clear indication which belong to which and how it is relevant for the end classification.
2. To decrease the contradiction between section 11 and sections 2 and 3 a plausibility check should be integrated in already existing software tools. As a solution it could be a tool that will be direct linked between section 11(12) and section 3 or 2.

Recommendations for REACH Review Action 3

3. Develop an online software tool to check the plausibility of toxicity data for substances. For example a comparison with the registration and/or C&L database is possible when using this tool. Due to the differences between the toxicity data of single ingredients and mixtures, also a small software tool could help to decrease mistakes due to wrong calculations

2.3.8. Section 12 – Ecological information

Main findings

Section of the SDS	Sum of sections: info not adequate/not present	No. of sections: info is present but not adequate/not appropriate	No. of sections : info is not present	Total no. checked for this section	% of SDSs checked with issues in this section
12.1. Toxicity	53	29	24	164	32%
12.2. Persistence and degradability	53	23	30	161	33%
12.3. Bioaccumulative potential	57	20	37	157	36%
12.4. Mobility in soil	69	24	45	159	43%
12.5. Results of PBT and vPvB assessment	47	17	30	155	30%
12.6. Other adverse effects	62	22	40	157	39%

147 remarks on 65 SDSs regarding Section 12 were found. Remarks like "The content/quality was not validated" were removed from the analysis. Remarks not pointing to the SDS deficiency were omitted. Remarks on individual SDSs were often repetitive for all subsections and some subsections were not sufficiently commented on. For those reasons the analysis was performed for the whole section 12 and numbers of identified deficiencies cannot be directly compared to data in the table above. Percentage of deficiencies in all subsections varied from 30 to 43 %.

Main problems

- *„Insufficient data*" - 19 SDSs were marked as providing insufficient data. The description varies from (in most cases) general information like „poor data" or „some info not provided as required" to more specific „provided data only on one species (fish) and only for Aquatic Acute". In other cases only very brief information was given like „ecotoxic to fish" or „mixture is biodegradable" without further details. Such SDSs are clearly non-compliant – receivers of such documents cannot get useful information on ecological properties of substance/mixture.
- *„No data*" - Most remarks (on 30 SDSs) stated that subsections contained only „No data" or similar expression without further explanation (or the subsection was left blank entirely). This is in contradiction to the REACH provision „If it is stated that a particular property does not apply (because the available data shows that the substance or mixture does not meet the criteria for classification) or if information on a particular property is not available, the reasons shall be indicated." In 7 cases there were no data in subsections even if some

of the substances in composition of the mixture were classified as hazardous to the aquatic environment. 2 SDSs only stated that „Product is not dangerous to the environment" in all subsections. Such explanation is not really different from „No data" SDSs without further explanation. On one case the SDS obviously contained no data but only a misleading reference to section 11.

- *Formal deficiencies* - Three SDSs were non-compliant because of formal mistakes – 2 SDSs had no subsections (or those cannot be identified) and one SDSs had incorrect headlines of subsections.
- *Misleading information* - Interestingly, only one SDS for a mixture showed a relatively common mistake: it is not clear whether information in individual subsections relates to the mixture or to its ingredients.
- *Only for substance not for mixture itself* - In two cases inspectors concludes that the SDS contains only information on substances (ingredients of mixture) but not on the mixture itself. However frequent, such a phenomenon cannot be simply described as a non-compliance.

Recommendations from the WG:

Recommendations for ECHA ASOs:

1. A general recommendation is to encourage the compilers of SDS to check that all of the properties have been indicated or justification provided why the property is not relevant. For example all subsections should have correct headlines.
2. Subsections should not be left blank. Subsections should not contain only "No data"/"Not available"/"NA" or similar without any reasoning.
3. It should be clear to the reader whether the information in subsections relates to the whole mixture or only to its ingredient.
4. Data in a SDS must be sufficient for the reader. Be sure that s/he can use the information for the proper handling of a substance/mixture. Also be it shall be ensured that information in this section is consistent with the information provided in the registration and/or in the chemical safety report.
5. Encourage their members to provide the correct form of reasoning in a SDS when a particular property does not apply or information on a particular property is not available (i.e. how to justify using e.g. "No data"/"Not available"/"NA" in SDS).

Recommendations for All concerned parties

6. Compile and supply a list of good examples of correct SDSs.
7. Launch an information campaign on the consistency of data in SDS and classification of mixtures. Alternatively, this topic can be included in future Forum enforcement projects.

2.3.9. Section 15 – Regulatory information

Main findings

Section of the SDS	Sum of sections: info not adequate/not present	No. of sections: info is present but not adequate/not appropriate	No. of sections: info is not present	Total no. checked for this section	% of SDSs checked with issues in this section
15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture	65	37	28	170	38%
- Other EU legislation, e.g. Seveso, EQS, Detergents etc.	67	13	54	167	40%
- National legislation	86	8	78	161	53%
- Authorisation (Annex XIV REACH)	61	0	61	106	58%
- Restriction (Annex XVII REACH)	60	1	59	115	52%
15.2. Chemical safety assessment	87	7	80	127	69%

Main problems

15.1:

- In many cases (about 40%) no information or incomplete information was given on other relevant EU legislation. Especially information on the regulations on detergents, OSH and Seveso was often missing;
- In many cases (about 50%) no information or incomplete information was given on relevant national legislation. Sometimes information was given about national legislation in other member states than the receiving country;
- In some cases the substance or mixture was the subject of special provisions in relation to the protection of human health or the environment at Union level (such

as Authorisation or Restriction), without mentioning this[5]. In some cases this information was given in section 2.3 (instead of 15.1);

15.2:

1. In many cases (about 70%) no information was given whether a chemical safety assessment was made for the substance or the mixture;

Recommendations from the WG:

Recommendations for ECHA ASOs:

1. Discuss the importance and options to improve the quality of the SDS software with major suppliers of SDS software in the EU. In many cases the missing data in section 15.1 and 15.2 are available in databases (national, international or in the registration dossier) which can be identified and used. Especially the next options in SDS software are of interest:
   - an option in SDS software to select relevant national legislation and EU legislation (like Seveso, OSH, Biocidal Products Regulation, regulation on detergents etc.) on certain chemicals
   - an option in SDS software to select information on Authorisation and Restriction on certain chemicals

2. Encourage their members to indicate whether a chemical safety assessment was carried out

Recommendations for ECHA

3. Further clarification to be provided on what is meant by "supplier" and "chemical safety assessment" in this Section i.e. who should indicate and when.

[5] The data in the questionnaire on this item (52-58% of the SDS checked had issues on this aspect) seems to indicate in a lot of cases the absence of information on Authorisation or Restriction. However, if the substance/mixture isn´t subjected to authorisation or restrictions it doesn´t have to be mentioned. So the non-compliance on this item probably will be lower than 52-58%.

3. Conclusions and Recommendations

3.1. Conclusions

The WG collated data from the assessment of 197 SDSs which was carried out by 12 participating countries. The findings from the sections which were identified as those being of the most significance, i.e. sections *1, 2, 3, 7, 8, 9, 10, 11, 12 and 15* are set out in chapter 2 of this report.

There were a number of issues in all the sections checked, with the main ones being:

- no reporting on uses advised against, unclear identified uses and an absence of a required emergency telephone number in Section 1
- incorrect classification in SDS Section 2 and in correlation with this issue, incorrect reporting of concentration ranges of ingredients in mixtures in Section 3
- non provision of national occupational exposure limits and an inadequacy of information provided on control measures, including engineering controls, environmental emission controls and specific details on personal protective equipment (PPE) in Section 8
- lack of information on the physical/chemical, toxicological and eco-toxicological properties in Sections 9, 11 and 12, with no explanation as to the reason for the absence of the information as required to be stated.

The issues are mainly related to:

1. It not being clear what is expected for certain Sections: e.g. 1, 3, 7 and 8
2. Missing information in Sections 1, 2, 7, 8, 9, 10, 11, 12 and 15
3. Information not specific enough, or too generic to be helpful in Sections 7, 8, 11 and 12
4. Consistency between sections: such as 2 (classification) and 3 (mixture composition), and even subsections 8.1.1 (national OELs) and 8.1.3 (monitoring)
5. Inconsistent or missing information related to ingredient(s) classification in Sections 3, 11 and 12.

Where information is not provided at all or where there are inadequacies in the information in the SDS, there are consequences for users and actors down the supply chain. For example, in this initiative, it can be seen that classification of mixtures appears to have been incorrectly assigned in Section 2 as it is often inconsistent with the concentration ranges in Section 3, or that the harmonised classification of ingredient substances was not provided in Section 3.2, or that pH was not taken into account. Incorrect classification results in inaccurate labelling and potentially the provision of inaccurate information on safe handling and risk management measures.

3.2. Recommendations

The recommendations in the main part of the report are mainly related to resolving the issues (missing/inconsistent/inadequately detailed information). It is the responsibility of the suppliers to review and correct their safety data sheets, however within this project and in collaboration with the ASOs, it is foreseen that the recipients take an active role in checking the SDS and informing their suppliers of the issues.

Overall the recipients of the SDS should check and feedback the following:

- That all sections, that are required, to be completed with sufficiently specific information. When the information is not relevant or available, the reason for this should be indicated as required by the legal text.

- That the safety data sheets are up-to-date with the current chemical legislation i.e. development of harmonised classification

- That there is consistency between the different sections of the safety data sheet

This could be achieved by developing guidance to clarify what is expected, supporting the development of IT-tools in discussion with service providers, publishing good examples, raising awareness through promotion campaigns etc. There are a number of recommendations on ASOs, authorities and ECHA to facilitate these actions and individual recommendations can be found in chapter 2.