Recommendations for Best Practice in Safety Data Sheets Preparation for Components Supplied to Formulators

This document is a compilation of recommendations for best practice in the provision of information in Safety Data Sheets (SDS) for additives and components used for blending lubricant products. It has been prepared by the ATIEL Health, Safety and Environment Committee in collaboration with the ATC Health, Safety and Legislation (HSL) Group. Although some of the information may be over and above legal requirements, SDS which do not include this information, cause problems for downstream formulators, when they are preparing SDS for their own lubricant products, providing safe handling advice to blending plants and complying with other essential regulatory requirements.

Some typical examples of insufficient information are provided in blue italics text.

Recommendations are made in bold green text, which may reduce the need to revert back to suppliers and, therefore, make the SDS communication process more efficient and less time-consuming for all involved.

The advice included in this document, may also be relevant to companies wishing to supply good quality SDS to their customers, in other formulating industries, and to software companies who provide SDS writing programs to the chemical industry.

Safety Data Sheet

SECTION 1: Identification of the substance/mixture and of the company/undertaking

No particular issues

SECTION 2: Hazards Identification

A/ Product is not classified (and not expected to be classified based on Section 3 composition) however, H-statements appear in this section. *(Suppliers, particularly of non-EU origin, often assign H-statements as a precaution, but it's unclear if classification is really needed).*

Recommendation: If component is not classified, H-statements should not be used. If H-statements are assigned unnecessarily to non-hazardous materials, there is a risk that SDS users will ignore them when they are needed.

B/ Product is not classified (and not expected to be classified based on Section 3 composition), however, other warning statements appear which are not compatible with non-classification, or the information in Section 11. *(This frequently happens with base oils, which are not classified, but on repeated exposure can cause defatting of the skin, which, in turn, may lead to irritation or other skin problems).*

E.g. Section 2 says "MAY CAUSE EYE, SKIN AND RESPIRATORY TRACT IRRITATION. INGESTION MAY CAUSE GASTRIC DISTURBANCES" while Section 11 states "Skin (Rabbit) Non-irritant, Eye (Rabbit) Non-irritant".

Recommendation: Warning statements should be proportional to the classification and in line with Section 11 wording. For base oils, the possibility for defatting of the skin with repeated exposure could be mentioned by adding

a statement such as "*Prolonged or repeated skin contact without proper cleaning can clod the pores of the skin resulting in disorders such as oil acne/folliculitis.***" In cases where the product may cause irritation on repeated exposure, but the effect is insufficient to classify based on EU CLP criteria, it would be helpful to add a statement to say so. For SDS covering countries outside the EU, certain statements are needed to comply with other legislation e.g. ANSI (defatting irritant) or HNOC (defatting irritant). For SDS prepared according to REACH Regulation (EU) 1907/2006 and subsequent amendments, these phrases could be placed in Section 2.3 (Other hazards).**

SECTION 3: Composition/information on ingredients

A/ Chemical reference numbers, such as REACH, EC or CAS numbers, are often missing or deemed as proprietary. *(Sometimes, even for EU CLP Annex VI substances).*

Recommendation: For non-hazardous substances with an occupational exposure limit present at 1% or more, and hazardous substances present at, or above, 1% (or 0.1% depending on substance classification), these reference numbers should be provided in the EU. Formulators need these numbers to comply with national product registration laws, check against prohibited/restricted substance rules and other national or customer specific requirements. In the EU, where companies wish to keep component identity confidential by the use of generic chemical names, these names should be registered with ECHA before use.

B/ One or more hazardous substances are listed in Section 3, but it is not possible to tell if there are other substances present or not. *(If formulators know that there are no other substances present, then this helps them comply with national inventory and product registration laws, and also to check against prohibited/restricted substance lists).*

Recommendation: There is no need to disclose unclassified substances (unless they have an occupational exposure limit). However, if other substances are present, a statement to say that the remainder of the formulation is composed of only non-classified substances, or hazardous substances below their SDS declaration limit, would be very helpful. If no other substances are present, a statement could be added to say that the substances listed in Section 3 cover 100% of the component.

C/ Concentration ranges chosen for substances are either on, or straddle the classification cut off levels for the assigned H-statements.

E.g. Zinc dialkyldithiophosphate classified Skin Irrit.2 H315, Eye Dam.1 H318, Aquatic Chronic 2 H411 present at 1 to 3%. (Classification limit for Eye Irrit.2 H319 is 1%, for Aquatic Chronic 3 H412 is 2.5% and for Eye Dam.1 H318 is 3%. Therefore component could be classified H319 alone, H319-412 or H318-412 depending on actual amount of ZDTP present.)

Recommendation: The figure used for top of range should be *less than* the cut off value (e.g. 2.99 or <3%) and should not straddle classification levels (e.g. 1-<2.5%, 2.5-<3%, 3-<10%), leading to classification uncertainty. It is appreciated that some of these problems result from SDS software not providing sufficient flexibility, but perhaps this is something that SDS software providers could be asked to consider.

D/ Individual or total concentrations of substances with similar H-statements, exceed the classification cut off levels for those H-statements. Therefore, the information on ingredients provided does not support the classification given in Section 2.

***E.g. 1** - Zinc dialkyldithiophosphate classified Skin Irrit.2 H315, Eye Dam.1 H318, Aquatic Chronic 2 H411 present at 5%, but component is not classified for eye irritancy.*

***E.g. 2** - Ingredient name*	*CAS no.*	*Conc. (% w/w)*	*EU Classification*
Acid phosphate	*Proprietary*	*30 - 60*	*Skin Corr.1C H314*
Amine	*Proprietary*	*20 - 30*	*Acute Tox.3 H301* *Skin Corr.1C H314* *Aquatic Acute 1 H400, Aquatic Chronic 1 H410*

(No identifiers and additive is only classified Skin Corr.1C H314, Aquatic Acute 1 H400, Aquatic Chronic 1 H410. The hazard highlighted in red, is above the limit for labelling, so why does this not apply?)

Recommendation: The data in Section 3 should support the component classification. However, ensuring that substance ranges set in Section 3 do not exceed classification limits when combined can be difficult where mixtures contain many substances with multiple hazards. If there is a valid justification why a lower or no classification is needed, this should be stated elsewhere in the SDS. Either test data or a statement saying the total amount of ingredients with a certain hazard is less than the cut off for classification in Section 3, 11 or 12 would be helpful.

E/ The composition declared in Section 3 does not match the mixture being supplied.
E.g. Strong acids or bases (usually corrosive) are listed at levels which would exceed classification limits, but component is not classified in Section 2. When asked, suppliers state that these substances are fully reacted. However, this raises further questions as to why these substances are still declared in Section 3 and have the hazards of the reaction products themselves been considered?
Recommendation: The reaction product (if hazardous) should be given in Section 3 and not the original substances. An exception may occur in aqueous solutions (e.g. certain metal working fluids or coolants) where reactions may be reversible. If the reaction is incidental, the calculation rules may apply, unless there is overriding data on the product as a whole, which should be given in Section 11 or 12.

F/ No clear statement saying if component is a substance or mixture. *(This would assist with decisions on inventory status, downstream product composition enquiries and restricted substance checks).*
Recommendation: The information could be inserted in Section 1, 2 or 3, e.g. *"Product type/definition: UVCB"*. **However, Regulation (EU) 453/2010 (amendment to REACH Annex II) stipulates that sub-headings of "3.1 Substances" or "3.2 Mixtures" (not both) should be used in Section 3. If it is a substance, then the supplier is obliged to mention the REACH registration number in section 1.1. For certain single substances, it would be helpful if the presence of preservatives or antioxidants was indicated, e.g. bisphenol A or alkylated phenols used as preservative at low levels in synthetic base fluids, as these substances may be restricted, or of concern in certain markets or applications.**

G/ A substance declared in Section3 is listed in EU CLP Annex VI, but the official classification is dependent upon a Nota. The classification in Section 3 is provided without the data needed to show whether the Nota should apply or not.
E.g. Mineral base oils are declared as present, but with no statement to say if DMSO extract by IP 346 is <3% or not.
Or, a mixture contains more than 0.1% gas oil for which the supplier provides the Annex VI classification of Carc.1B H350. However, they do not classify the mixture as carcinogenic. No information is provided to support the use of the Nota that allows for non-classification.
Recommendation: The information could be inserted as a footnote in Section 3 or other sections of the SDS e.g.

Product/Ingredient name	*Identifiers*	*%*	*Hazard Classification Regulation (EC) No. 1272/2008 [CLP]*
Distillates (petroleum), solvent-dewaxed heavy paraffinic	*REACH#: 01-2119471299-27* *EC: 265-169-7* *CAS: 64742-65-0* *Index: 649-474-00-6*	*100*	*Not classified*

The mineral oils in this product contain < 3% DMSO extract (IP 346).

Non-classified substances (as above) should be listed if an occupational exposure limit applies. IP346 results could be mentioned in Section 9 or 11.

H/ Substances of Very High Concern (SVHCs) are not declared in Section 3.
Recommendation: The identity and amount of these substances should be declared on the SDS, if they are present at 0.1% or more.

I/ Skin sensitizing substances are present at 1% or more, but the component is not classified as a skin sensitizer.
Recommendation: If the component does not require classification based on skin sensitization test data, this should be explained in Section 11. Where data exists to establish a specific concentration limit (SCL) below which the substance does not cause sensitization, then it is also helpful to include this information, as it may be possible that downstream formulators would be using the substance below this level in their own products. Also, if data is available to establish if the sensitizer is classified as Skin Sensitizing Sub-category 1A (strong sensitizer) or 1B (weak/moderate sensitizer), it would useful to include this too. Otherwise, formulators who are supplying products to the USA, which contain 0.1 to <1% of a sensitizer, would have to classify their products as sensitizing, unless the sensitizer was Category 1B (in which case a 1% limit applies).

SECTION 4: First aid measures

No particular issues

SECTION 5: Fire-fighting measures

No particular issues

SECTION 6: Accidental release measures

No particular issues

SECTION 7: Handling and storage

No particular issues

SECTION 8: Exposure controls/personal protection

Insufficient detail is provided on the type of gloves and respiratory masks to be used. *(Questions are received regularly from customers about this).*
Recommendation: Specific details on appropriate PPE (e.g. glove materials, thickness and typical or minimum breakthrough time) should be provided for general handling, based on intended use of product. It is appreciated that this is a difficult area, as choice of PPE will depend on manner of use of the product. However, independent expert advice should be sought (e.g. from PPE suppliers) where needed. For practical advice from Cefic go to:
http://www.cefic.org/Documents/IndustrySupport/REACH-Implementation/Guidance-and-Tools/Practical-consideration-on-Gloves-Thickness.pdf

SECTION 9: Physical and chemical properties

A/ Data points which help determine classification (on non-classification) are missing.
E.g. Kinematic viscosity at 40°C (for hydrocarbon fluids), % DMSO extract by IP346 (for mineral base oils), VOC content.
Recommendation: The ECHA guidance on SDS compilation recommends that Kinematic viscosity at 40°C should be provided if more than 10% hydrocarbons are present. Other data that helps determine classification, such as DMSO extract by IP 346, or VOC content, could be provided here or in other sections of the SDS.

B/ Numerical data without units are provided.
Recommendation: All units should be clearly indicated.

SECTION 10: Stability and reactivity

No particular issues

SECTION 11: Toxicological information

Statements do not match with classification in Section 2, or classification expected from Section 3 ingredients.

E.g.1 - "Moderately irritating to skin", however there is no classification in Section 2 or irritating substances declared in Section 3.

E.g.2 - For an additive which is not classified as hazardous.

Target organs: *Contains material which may cause damage to the following organs: eyes*

Acute effects - Eye contact: *Non-irritating to the eyes*

Recommendation: All statements should be in line with the overall classification of the component. In this example the supplier has double counted eye damage effects to also be a target organ effect. For specific target organ (STOT) and chronic (CMR) effects, GHS requires information in the SDS at certain trigger points (e.g. 0.1%) even though classification and labelling may only be required at higher concentrations (e.g. 0.3% or 1%). This information could be placed in this Section 11, although it should be clear on whether the effect only concerns the ingredient and if it is expected to contribute to the hazards of the overall product or not.

SECTION 12: Ecological information

A/ Section 3 shows substances classified as Aquatic Acute 1 H400 or Aquatic Chronic 1 H410, but no M factor (or EC/LC 50 data from which M factor can be determined) is provided. *(This data has been required since the 2nd ATP in 2012).*

Recommendation: Where components contain substances with Aquatic Acute 1 H400 or Aquatic Chronic 1 H410 classification, M factor, or data from which it can be derived, should be provided here or in Section 3.

B/ Incomplete sets of eco-toxicological test data are provided which can be misleading. *(In principle, these discrepancies should disappear when the substances are registered under REACH, unless the supplier opts out).*

E.g. test data for fish and/or daphnia are provided, but not for algae. By read across from other suppliers' data, it is the algae result that causes a more severe classification. However, the supplier only classifies to the level indicated by the fish/daphnia data.

Recommendation: Missing data may be available for the ECHA website which should be checked. This issue should be resolved by 2018, by which time all substances should have been registered. It has been noted that classifications in ECHA registration dossiers can sometimes be questionable in respect to selection and interpretation of data. However, where data is publically available, e.g. via the REACH process, and is relevant, then, it should be taken into account by suppliers. The supplier should be able to justify their classification and labelling position.

SECTION 13: Disposal considerations

No particular issues

SECTION 14: Transport information

No particular issues

SECTION 15: Regulatory information

A/ There are statements claiming that all the substances in the component are listed on various national chemical inventories. However, one or more of the CAS numbers provided in Section 3 (or CAS numbers that correspond to the EC numbers provided), cannot be found on those inventory listings. No further information is provided to explain the basis for the listing.

Recommendation: Where substance identifiers used in Section 3, are not listed on the inventories claimed as compliant, extra information on the basis for compliance, would be helpful to formulators when carrying out their own national product registrations. The overall inventory status of the component should include all substances present in the mixture (not just the main components or those declared on the SDS).

B/ Very general statements are used to provide the status information for each chemical inventory, such as "listed or exempt".

Recommendation: It would be much more helpful to indicate which case applies, especially when preparing data for product registrations or importation. This can be difficult where mixtures contain substances with a different status on each inventory, but additional information would help, e.g. *"One component polymer exempt, all other substances listed"*, **or** *"One substance NDSL listed, all others DSL listed"*.

C/ There are statements which say "Polymer exempt". It is not possible to tell if the supplier has considered the differing requirements for polymer exemption between different regulatory systems.

Recommendation: Where polymer exemption applies under REACH, a statement to say if all monomers have been pre-registered or registered would be helpful.

D/ A general statement of "Restrictions apply" appears alongside the name of a chemical inventory.

Recommendation: If restrictions apply to import or use of the component in that country, a small amount of extra detail will reduce the need for the user to make further enquiries.

E.g. "This additive package can only be imported into (country name) by (name of supplier)"

E/ Hazardous substances not declared in Section 3, but which are present on various regulatory lists (US State RTK lists in particular) are listed as present. However, there is no indication of amount present in component.

E.g. US regulations

SARA 313 toxic chemical : notification and release reporting	*Lead 0 - 0.0001*
(w/w%) RQ (Reportable quantity) :	*CERCLA: Hazardous substances.: Cadmium: 10 lbs. (4.54 kg); Arsenic: 1 lb. (0.454 kg); Lead: 1 lb. (0.454 kg);*

Recommendation: The amount of hazardous substance present should be indicated (e.g. *"max 1ppm Cadmium, Arsenic"*), **as these substances are always of concern and often restricted. Formulators will need to know how much could be in their final products.**

F/ There is no information on national regulations.

Recommendation: Information about listing on various national inventories like Norway, Sweden, Finland, Denmark, Italy and Switzerland would be helpful.

G/ References to "REACH" currently refer to EU REACH regulations. However, going forward, other countries are introducing similar legislation and also referring to it as "REACH", e.g. K-REACH in Korea. It may become necessary to distinguish clearly between those systems.

SECTION 16: Other information

Exposure scenarios attached to SDS are often only provided in English language.

Recommendation: These should be provided in the local language of the SDS. For advice on exposure scenarios go to: http://www.atiel.org/reach/introduction

Priority of SDS Improvements

It is appreciated that the implementation of all these improvements to SDS could take considerable effort. Therefore, it is suggested that applying the following prioritisation would produce the most benefit for the time and effort taken.

Higher priority	*Sections 2 and 3*
↓	*Sections 11 and 12*
	Sections 8 and 9
Lower priority	*Section 15*

Key to Hazard Classifications

Hazard Category		**H-Statement**	
Acute Tox.3	*Acute toxicity (oral) 3*	*H301*	Toxic if swallowed
Skin Corr.1C	*Skin corrosion/irritation 1C*	*H314*	Causes severe skin burns and eye damage
Skin Irrit.2	*Skin corrosion/irritation 2*	*H315*	Causes skin irritation
Eye Dam.1	*Serious eye damage/irritation 1*	*H318*	Causes serious eye damage
Eye Irrit.2	*Serious eye damage/irritation 2*	*H319*	Causes serious eye irritation
Carc.1B	*Carcinogenicity 1B*	*H350*	May cause cancer
Aquatic Acute 1	*Hazardous to the aquatic environment–Acute Category 1*	*H400*	Very toxic to aquatic life
Aquatic Chronic 1	*Hazardous to the aquatic environment–Chronic Category 1*	*H410*	Very toxic to aquatic life with long lasting effects
Aquatic Chronic 2	*Hazardous to the aquatic environment–Chronic Category 2*	*H411*	Toxic to aquatic life with long lasting effects
Aquatic Chronic 3	*Hazardous to the aquatic environment–Chronic Category 3*	*H412*	Harmful to aquatic life with long lasting effects

Boulevard du Souverain 165 ● B–1160 Brussels ● Belgium ● **Tel:** +32 2 566 91 37 ● **Fax:** +32 2 566 91 36 ● **E-mail:** info@atiel.org