



Report no. 9/22

Guidance on the compilation of Safety Data Sheets for Petroleum Products





Guidance on the compilation of Safety Data Sheets for Petroleum Products

Helena Niemelä (Concawe Science Executive)

This report was prepared by:

Jennifer Brown, Elisabetta Di Caprio, Francoise Douce, Paul Durie, Jenny Eklund, Christina-Lito Kotsiki, Inkeri Majander, Alberto Martin Aparicio, Mirela Mavrinac, Cristina Mertl, Helena Niemelä, Susanne Schunder-Tatzber, Lionel Sylvestre, Marilena Trantallidi, Ahmed Turay, Jan Urbanus, Iwona Weselak, Manos Zogopoulos

Under the supervision of:

Helena Niemelä (Concawe Science Executive) Marilena Trantallidi (Concawe Science Associate)

At the request of:

Concawe ad-hoc Safety Data Sheet (SDS) group, a subgroup of the Product Stewardship Management Group (PSMG)

We thank for their contribution:

• Members of ad-hoc SDS group:

Jennifer Brown, Javier Candeal Duro, Elisabetta Di Caprio, Francoise Douce, Jenny Eklund, Marcel Heinz, Christina-Lito Kotsiki, Joanna Kruszewska, Dan Maier, Inkeri Majander, Arianna Malpicci, Cristina Mertl, Helena Niemelä, Lionel Sylvestre, Jan Urbanus (Chair of the group), Angela Viglianti, Manos Zogopoulos

• Other member of Secretariat: Anja Mannaerts

Reproduction permitted with due acknowledgement

© Concawe Brussels June 2022



ABSTRACT

This Guidance addresses the specific Concawe recommendations for authoring of (extended) Safety Data Sheets for <u>Unknown or Variable composition</u>, <u>Complex</u> reaction products or of <u>B</u>iological materials (UVCB) petroleum substances, and mixtures containing one or several of these substances, in the Member States of the European Union. The present document provides guidance for the application of Regulation (EU) 2020/878 amending the requirements for the Safety Data Sheets (SDS) in revised Annex II of the REACH Regulation (EC) No 1907/2006, enforced in January 2021 and transition ending in December 2022.

Since the previous legal changes of REACH Annex II in 2015, more stringent requirements are now introduced to several SDS sections (most notably to 1.1, 1.3, 2.3, 3.1/3.2, 9.1, 9.2, 11.1, 11.2, 12.6, 14.1 and 14.7). There are also new mandatory sub-headings potentially requiring changes in the template format of SDS authoring software in companies.

KEYWORDS

Safety Data Sheets, SDS, UVCB, petroleum substance, mixture, REACH Regulation, EU, Guidance

INTERNET

This report is available as an Adobe pdf file on the Concawe website (www.concawe.eu).

NOTE

Considerable efforts have been made to assure the accuracy and reliability of the information contained in this publication. However, neither Concawe nor any company participating in Concawe can accept liability for any loss, damage or injury whatsoever resulting from the use of this information.

This CONCAWE Guidance reflects the legislation in force at the time of publication. It is the responsibility of the reader to ascertain the evolution of the legislative framework.

This report does not necessarily represent the views of any company participating in Concawe.



CONTENT	S	Page
SUMMARY		VI
INTRODUCT	ION	1
1.	SDS SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OFTHE COMPANY/UNDERTAKING1.1.PRODUCT IDENTIFIER1.2.RELEVANT IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE	4 4
	AND USES ADVISED AGAINST 1.3. DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET 1.4. EMERGENCY TELEPHONE NUMBER	6 7 7
2.	SDS SECTION 2: HAZARDS IDENTIFICATION2.1.CLASSIFICATION OF THE SUBSTANCE OR MIXTURE2.2.LABEL ELEMENTS2.3.OTHER HAZARDS	8 9 10
3.	SDS SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS3.1.SUBSTANCES (ALTERNATIVE TO 3.2)3.2.MIXTURES (ALTERNATIVE TO 3.1)	11 12 12
4.	SDS SECTION 4: FIRST AID MEASURES4.1.DESCRIPTION OF FIRST AID MEASURES4.2.MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED4.3.INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED	13 13 13 14
5.	SDS SECTION 5: FIREFIGHTING MEASURES5.1.EXTINGUISHING MEDIA5.2.SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE5.3.ADVICE FOR FIREFIGHTERS	15 15 15 16
6.	SDS SECTION 6: ACCIDENTAL RELEASE MEASURES6.1.PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES6.2.ENVIRONMENTAL PRECAUTIONS6.3.METHODS AND MATERIALS FOR CONTAINMENT AND CLEANING UP6.4.REFERENCE TO OTHER SECTIONS	17 17 18 19 20
7.		21 22 22 23
8.	8.1. CONTROL PARAMETERS	24 24 25
9.		27 29 39



10.	10.1. 10.2. 10.3. 10.4. 10.5.	N 10: STABILITY AND REACTIVITY REACTIVITY CHEMICAL STABILITY POSSIBILITY OF HAZARDOUS REACTIONS CONDITIONS TO AVOID INCOMPATIBLE MATERIALS HAZARDOUS DECOMPOSITION PRODUCTS	43 44 44 44 44 44		
11.	SDS SECTION	N 11: TOXICOLOGICAL INFORMATION INFORMATION ON HAZARD CLASSES AS DEFINED IN	45		
	11.2.	REGULATION (EC) NO 1272/2008 INFORMATION ON OTHER HAZARDS	46 47		
12.	12.1. 12.2. 12.3. 12.4. 12.5. 12.6.	N 12: ECOLOGICAL INFORMATION TOXICITY PERSISTENCE AND DEGRADABILITY BIOACCUMULATIVE POTENTIAL MOBILITY IN SOIL RESULTS OF PBT AND VPVB ASSESSMENT ENDOCRINE DISRUPTING PROPERTIES OTHER ADVERSE EFFECTS	49 50 51 52 52 52 53 53		
13.	SDS SECTION 13.1.	N 13: DISPOSAL CONSIDERATIONS WASTE TREATMENT METHODS	54 54		
14.	14.1. 14.2. 14.3. 14.4. 14.5. 14.6.	N 14: TRANSPORT INFORMATION UN NUMBER OR ID NUMBER UN PROPER SHIPPING NAME TRANSPORT HAZARD CLASS(ES) PACKING GROUP ENVIRONMENTAL HAZARDS SPECIAL PRECAUTIONS FOR USER MARITIME TRANSPORT IN BULK ACCORDING TO IMO INSTRUMENTS	55 55 56 56 56 56 56		
15.	SDS SECTIO 15.1. 15.2.	N 15: REGULATORY INFORMATION SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE CHEMICAL SAFETY ASSESSMENT	57 57 58		
16.	SDS SECTION 16: OTHER INFORMATION 59				
17.	EXTENDED SDSS (ANNEXES) 60				
18.	APPROACHES TO SAFE USE COMMUNICATION FOR CLASSIFIED MIXTURES				
19.	GLOSSARY				
20.	REFERENCE	S	65		
APPENDIX 1	: LINK OF H- ESCOM PHR	STATEMENTS AND ASSOCIATED P-STATEMENTS WITH ASES	69		



APPENDIX 2: NON-EXHAUSTIVE LIST OF EU SAFETY, HEALTH AND ENVIRONMENTAL		
REGULATIONS/LEGISLATION SPECIFIC FOR PETROLEUM SUBSTANCESS OR MIXTURES	77	
APPENDIX 3: EXAMPLES OF SDS SECTIONS	78	
SDS SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF		
THE COMPANY/UNDERTAKING	78	
SDS SECTION 2: HAZARDS IDENTIFICATION	80	
SDS SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS	82	
SDS SECTION 4: FIRST AID MEASURES	85	
SDS SECTION 5: FIREFIGHTING MEASURES	87	
SDS SECTION 6: ACCIDENTAL RELEASE MEASURES	88	
SDS SECTION 7: HANDLING AND STORAGE	89	
SDS SECTION 8: EXPOSURE CONTROL/PERSONAL PROTECTION	92	
SDS SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES	97	
SDS SECTION 10: STABILITY AND REACTIVITY	99	
SDS SECTION 11: TOXICOLOGICAL INFORMATION	100	
SDS SECTION 12: ECOLOGICAL INFORMATION	102	
SDS SECTION 13: DISPOSAL CONSIDERATIONS	103	
SDS SECTION 14: TRANSPORT INFORMATION	104	
SDS SECTION 15: REGULATORY INFORMATION	107	
SDS SECTION 16: OTHER INFORMATION	109	
EXTENDED SDS (ANNEX)	112	
APPENDIX 4: EXAMPLE OF CONCAWE SUMI		
APPENDIX 5: DERIVED NO-EFFECT LEVELS (DNELS) IN CONCAWE REGISTRATION DOSSIERS	116	



SUMMARY

This Guidance addresses the specific Concawe recommendations for authoring of (extended) Safety Data Sheets for <u>U</u>nknown or <u>V</u>ariable composition, <u>C</u>omplex reaction products or of <u>B</u>iological materials (UVCB) petroleum substances, and mixtures containing one or several of these substances, in the Member States of the European Union.

The present document provides guidance for the application of Regulation (EU) 2020/878 amending the requirements for the Safety Data Sheets (SDS) in Annex II of the REACH Regulation (EC) No 1907/2006.

This guidance is primarily intended to be used by the REACH registrants (manufacturers or importers) of UVCB Petroleum substances together with the Concawe Report on Classification and labelling of UVCB Petroleum substances (Concawe report 1/22, 2022). Of course, the report can be used by other actors down the supply chain, such as formulators of petroleum product mixtures containing these specific UVCB petroleum substances and their mixtures.

This report explains the key requirements and recommendations for UVCB petroleum substances and mixtures containing them from section 1 to section 16 and possible annexes. Several practical recommendations are made on how to implement the new requirements for petroleum products. The report annexes contain best practices and other useful information as member companies' examples which could be helpful for continuous improvement of the quality of the safety data sheets.

Up-to-date safety data sheets enable safe management of UVCB petroleum products in various operations in their supply chains. High quality information also ensures protection of the health and safety of workers and the environment from the risks related to chemical agents at work, in line with the overall aims of the REACH Regulation.



INTRODUCTION

This Guidance addresses the specific Concawe recommendations for authoring of (extended) Safety Data Sheets for <u>Unknown or Variable composition</u>, <u>Complex reaction products or of</u> <u>Biological materials (UVCB) petroleum substances</u>, and mixtures containing one or several of these substances, in the Member States of the European Union.

The present document provides refining sector specific guidance for the application of the Commission Regulation (EU) 2020/878 amending the requirements for the Safety Data Sheets (SDS) in Annex II of the REACH Regulation (EC) No 1907/2006. This Regulation applies from 1 January 2021 with a transition until 31 December 2022. The associated revised ECHA Guidance on Safety Data Sheets (ECHA, 2020) does not specifically address UVCB substances and mixtures containing them. By providing guidance to its members Concawe envisages that consistent information is communicated in supply chains for petroleum products (substances and mixtures) ensuring that Downstream Users receive adequate advice for the implementation of safe handling.

This Guidance aims to complement the ECHA Guidance by highlighting and exemplifying the basic principles of the creation of (extended) Safety Data Sheets (SDSs) for UVCB Petroleum substances and mixtures containing them. It is applicable in the EU/EEA, where REACH and CLP regulations are legally enforced, and will be updated accordingly if this regulatory framework undergo significant changes.

Since the previous legal changes of REACH Annex II in 2015, the key changes to the SDS introduced by the Regulation (EU) 2020/878 include:

- More stringent content related requirements, of which the most important ones are:
 - Section 1.1: the unique formula identifier (UFI) required for certain hazardous mixtures and nanoforms, where applicable
 - Section 1.3 SDS supplier details
 - Section 2.3: Information on endocrine disrupting properties, where applicable
 - Sections 3.1 or 3.2: new identifiers, such as the specific concentration limit (SCL), the M-factor and the acute toxicity estimate ATE and additional information on nanoforms, where applicable
 - Section 9: additional physical and chemical properties, in line with GHS (versions 6 and 7) and additional information on nanoforms, where applicable
 - Section 11.1: Changed name of the sub-heading
 - Section 11.2: Information on other hazards (new sub-heading): Information on endocrine disrupting properties, where available
 - Section 12.6: Endocrine disrupting properties (new sub-heading), where available
 - Section 14.1 and 14.7: Changes in names of sub-headings
- New sub-headings to certain sections requiring potentially a change in the template format of SDS authoring software in companies.

In addition to the supply chain communication function of REACH, the important role of SDS for workplace risk management under the occupational health and safety legislation is now emphasised. According to Annex II legal text, SDS is primarily intended for the <u>users at the workplace</u> "- - to take the necessary measures relating to protection of human health and safety at the workplace, and protection of the environment". SDS also <u>communicates chemical information for various users in the supply chain</u> to "- - inform its audience of the hazards of a substance or a mixture and provide information on the safe storage, handling and disposal of the substance or the mixture." A specific link is made to the Directive 98/24/EC <u>on protection of the health and safety of workers from the risks related to chemical agents at work:</u> "In particular, the safety data sheet shall enable employers to determine whether any hazardous



chemical agents are present in the workplace and to assess any risk to the health and safety of workers arising from their use".

The SDS provision requirements now also specifically mention loading of ships carrying oil or fuel (MARPOL Annex I; Marpol, 2022). A requirement for clear and concise, precise and consistent information is also given in the legal text.

For Concawe's <u>UVCB petroleum substances</u>, it is critical that the SDS information is maintained consistent and up to date with the information in the Concawe portfolio of active registration dossiers. Concawe has introduced a review process, and the proper management of dossier changes is important for keeping SDSs consistent with their substance registrations. It is also extremely important to keep in mind that UVCB Petroleum substances are registered and identified as <u>substances</u> in SDS sections 1 and 3.1. An example of a UVCB substance gasoline (EC 289-220-8) is available as **Appendix 3, section 1**. During formulation to commercial products additional components and additives are blended, converting them to <u>mixtures</u>. For mixtures containing a petroleum substance, the same mixing rules as in Annex II part 3.2 apply. An example of blended gasoline mixture is available as **Appendix 3, section 3.2**.

This Guidance is primarily intended to be used by the REACH registrants (manufacturers or importers) of UVCB Petroleum substances together with the Concawe Report on Classification and labelling of UVCB Petroleum substances (Concawe report 1/22, 2022). Of course, the report can be used by other actors down the supply chain, such as formulators of petroleum product mixtures containing these specific UVCB petroleum substances and their mixtures. Suppliers have an important role in providing the relevant information to enable the correct identification, classification and labelling and safe use of the mixture.

It is recommended that SDS sections are not drafted in numerical order. A proposed and logical sequencing would be: start with 1 and 3, then 9, 11-12, 2, 4-5-6, 7-8-10, 13-14-15, 16, as shown in Figure 1. If Exposure Scenarios are placed in an Annex, then their contents should be aligned with the main body of the SDS and in particular sections 7 and 8. The order may vary case by case, and is strongly influenced on the process of the authors.

A consistency check among the various sections is required by the ECHA Guidance; if the recommended order is followed, errors can be minimised.



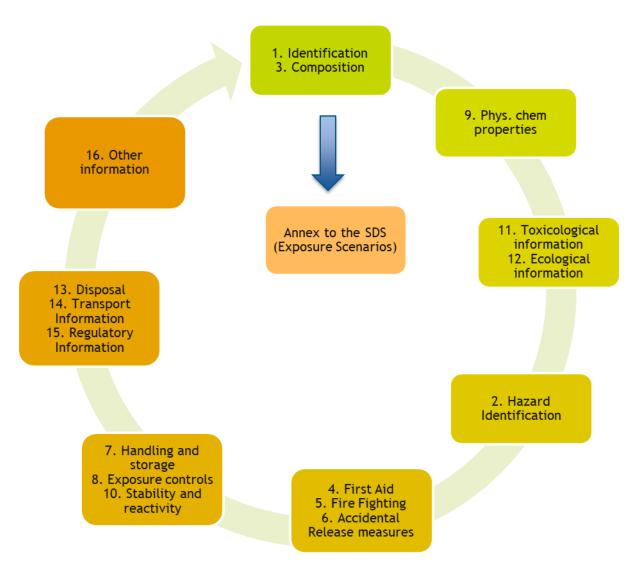


Figure 1: Recommended order for SDS authoring for petroleum substances - Modified from ECHA Guidance on Safety Data Sheets (December 2020, Table 1).



1. SDS SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Direct citation from the legal text of the Regulation (EU) 2020/878:

This section of the safety data sheet shall prescribe how the substance or mixture shall be identified and how the identified relevant uses, the name of the supplier of the substance or mixture and the contact detail information of the supplier of the substance or mixture, including an emergency contact, shall be provided in the safety data sheet.

The main new requirement for this section is the addition of product identifiers for UFI code and nanoforms in section 1.1. where applicable, more detailed description of identified uses in section 1.2. and details of SDS supplier information in section 1.3.

1.1. **PRODUCT IDENTIFIER**

There are different information requirements for substances and mixtures in Section 1.1, as identified in Annex II of the REACH Regulation (EC) No 1907/2006 and exemplified by the ECHA Guidance on Safety Data Sheets (ECHA, 2020).

To determine whether a safety data sheet covers a substance or a mixture, use the definitions in Article 2 of the CLP Regulation (EC) No 1272/2008, recital 45 of the REACH Regulation (UVCBs), and Annex VI of the CLP Regulation (UVCB substances with partially harmonised classification entries).

In line with these definitions, <u>an example of UVCB substance gasoline (EC 289-220-8) is given in Appendix 3 section 1, and an example of blended gasoline mixture in Appendix 3, section 3.2.</u> It needs to be emphasised that the current CLP rules may not fully fit for UVCB substances.

Substances

<u>Petroleum substances are REACH registered as UVCB substances</u>, to be declared in section 3.1, and have a partially harmonised classification in CLP Annex VI with specific Notes J, K, L, M, N, P.

Please note that for substances subject to registration under the REACH Regulation (EC) No 1907/2006, the product identifier must be consistent with that provided in the registration.

Assigning product identifiers for <u>substances</u> should be done in accordance with Article 18(2) of the CLP Regulation (EC) No 1272/2008).

Please note that product identifiers in Section 1.1 should align to Section 3.1; check for consistency.

Where the substance is included in Part 3 of Annex VI and / or the Classification and Labelling Inventory:



- a) Substance name (as given)
 - i. If using a name from Part 3 of Annex VI (Harmonised classification and labelling for certain hazardous substances), note that this name is subject to the same translation requirements as apply to the rest of the SDS.
- b) Index number (as given) and;
- c) EC number (as given).

Where the substance is not listed in Part 3 of Annex VI and / or the Classification and Labelling Inventory, provide:

- a) Chemical Abstract number (CAS) number and;
- b) Name set out in the IUPAC nomenclature or;
- c) Another international chemical name(s).

Where the name in the IUPAC nomenclature exceeds 100 characters, one of the other names (usual name, trade name, abbreviation) referred to in Section 2.1.2 of Annex VI to REACH may be used provided that the notification in accordance with Article 40 of CLP includes both the name set out in the IUPAC Nomenclature and the other name used.

- d) REACH registration number as assigned under Article 20(3) of the REACH Regulation(EC) No 1907/2006;
 - i. The registration number may be presented in full (e.g. 01-1234567890-11-1213) or the last four digits may be omitted as long as the supplier assumes the responsibility to provide the full registration number upon request according to point 1.1 of REACH Annex II.
 - ii. Where no REACH registration number is given, it is optional for the SDS author to explain why this is the case, e.g. This substance is exempted from Registration according to the provisions of Article 2(7) (a) and Annex IV of REACH.
- e) Other means of identification: these can be other names or synonyms by which the substance or mixture is labelled or commonly known, such as alternative names, numbers, company product codes or other unique identifiers may be provided.

Mixtures

Assigning product identifiers for <u>mixtures</u> should be done in accordance with Article 18(3) of the CLP Regulation (EC) No 1272/2008).

For mixtures, product identifiers in Section 1.1 should align with Section 3.2; check for consistency.

- a) Trade name or designation of the mixture;
- b) The identity of all substances in the mixture that contribute to the classification of the mixture as regards acute toxicity, skin corrosion or serious eye damage, germ cell mutagenicity, carcinogenicity, reproductive toxicity, respiratory or skin sensitization, specific target organ toxicity (STOT) or aspiration hazard, and;
- c) The Unique Formula Identifier (UFI) code (where applicable)



- i. An additional element which facilitates the identification of the product and the mixture contained in it. This is part of the information to be submitted, by a company according, to Article 45 and Annex VIII to CLP for emergency response reasons: it applies to mixtures classified for physical and/or health hazards and placed on the EU market.
- ii. A UFI normally corresponds to one mixture composition only; however, a single UFI can also cover mixtures whose compositions vary within certain limits.
- iii. The UFI is normally to be included on the packaging label, with voluntary inclusion in the SDS. In the case of mixtures which are not packaged, the UFI shall be indicated in the SDS or be included in the copy of the label elements referred to in Article 29(3), as applicable.
- iv. For packaged mixtures to be used at industrial sites the supplier has the possibility to include the UFI on the SDS instead of the label (or both).

For item b), where multiple hazardous chemical names are required to be listed in Section 1.1 for a mixture, a maximum of 4 chemical names should be considered, unless more than four names are needed to reflect the nature and the severity of the hazards.

The chemical names selected shall identify the substances primarily responsible for the major health hazards which have given rise to the classification and the choice of the corresponding hazard statements.

For UVCB petroleum substances, short names as used in the REACH registrations and CLP Annex VI are recommended for consistency and transparency.

As an important case for the refining sector, *fuels can be notified to poison centres based on the composition in their SDS*, see specific ECHA guidance on Annex VIII notification (ECHA, 2021a and 2021b).

1.2. RELEVANT IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED AGAINST

This subsection covers at least a brief description of the identified uses and uses advised against of the substance or mixture relevant for the recipient(s) insofar as these are known. Information can be extracted from the substance-specific and category chemical safety reports.

For registered substances, this must be consistent with the uses identified in the CSR and exposure scenarios in the Annex (extended SDS). If the substance has been registered as an intermediate under strictly controlled conditions as per REACH Article 17 or 18, this has to be indicated in this section (as well as in sections 7.3, 8.2 and 16).

A description of the uses advised against and why the use is advised against should be consistent with information given in Section 3.6 of the IUCLID dossier for substances which are registered.

Where applicable, this subsection should contain reference to information provided in the SDS Annex as exposure scenarios, SUMIs (safe use of mixtures information) or SWEDs (specific worker exposure determinants).



A consistency check (potential overlap) should be made with Section 7.3 and Section 16 (use descriptors only) and annex to the SDS, where applicable.

1.3. DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

This subsection contains company specific information from the supplier and is unique to the location where the product is placed on the market and where the product is intended to be used.

The full address and telephone number of the SDS supplier (whether it is the manufacturer, importer, only representative, downstream user or distributor) plus the functional e-mail address for a competent person responsible for the safety data sheet, must be identified.

Additionally, if the supplier is not located in the Member State where the product is placed on the market and the supplier has nominated a responsible person for the Member State, the full contact details for the responsible person shall be given.

Where an only representative has been appointed, details of the non-Union manufacturer or formulator may also be provided.

For REACH registrants placing a product on the market, the SDS supplier details must be consistent with the identity of the manufacturer, importer or only representative provided in the registration dossier.

1.4. EMERGENCY TELEPHONE NUMBER

This subsection contains company specific information from the SDS supplier and is unique to the location where the product is placed on the market and where the product is intended to be used.

References to emergency information services shall be provided.

If an official advisory body exists in the Member State where the substance or mixture is placed on the market (this may be the body responsible for receiving information relating to health referred to in Article 45 of the CLP Regulation (EC) No 1272/2008), its telephone number shall be given and can suffice.

Operational times and languages must also be stated.

An example for Section 1 of SDS for petroleum products is presented in Appendix 3.



2. SDS SECTION 2: HAZARDS IDENTIFICATION

Direct citation from the legal text of the Regulation (EU) 2020/878:

This section of the safety data sheet shall describe the hazards of the substance or mixture and the appropriate warning information associated with those hazards.

The main new requirement for this section is provisioning additional information on other hazards, especially on PBT/vPvB and endocrine disrupting properties in section 2.3., where applicable.

There is a legal requirement to list the classification of the product (substance or mixture) that arises from application of the classification rules in the CLP Regulation. The hazard(s) that the product presents to human health or the environment need to be indicated by means of:

- classification: hazard class and category, including associated hazard statements, and
- label elements: hazard pictogram(s), signal word, hazard statement(s) and precautionary statement(s).

2.1. CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

Substances

For <u>a substance</u> that already has a harmonised classification (an entry in Annex VI to CLP), this is legally binding for the hazard classes and differentiations covered in the entry. Those hazard classes and differentiations not covered in the entry must be evaluated and self-classified, as appropriate.

Petroleum substances are REACH registered as UVCB substances, and most of them have entries in CLP Annex VI, many subject to specific Notes J - P.

In this line, the Concawe report "*Hazard classification and labelling of petroleum substances in the European Economic Area - 2021*" (Concawe report 1/22, Concawe, 2022) contains an assessment of the hazardous properties of petroleum substances against the criteria of the CLP Regulation up to and including the 17th ATP and corrections to Annex VI.

Substances of similar chemical composition and/or similar hazard profiles can be collected together in categories. With the exception of petroleum coke and sulphur, most petroleum substances are UVCBs. A category approach allows data on individual category members to be applied (read-across) to other members of the category for which complete data may not be available or are impractical to obtain. The Concawe report 1/22 includes recommended classification and labelling for 21 categories and 4 stand-alone substances.

In those cases where EU harmonised classification exists for certain endpoints, it is supplemented with self-classification for all other endpoints as required by the CLP regulation.

For each category, the most severe hazard classification and labelling recommendation is presented as the default case in the body of the report.



However, based on the application of regulatory or oil industry notes, concentration limits for certain constituents of concern (e.g. for Naphtha category, these are benzene, toluene and n-hexane) and physical-chemical properties (e.g., flashpoint, viscosity), several classification and labelling permutations may be possible within a category. These permutations are presented in the **Appendix 6** of the C&L report.

These recommendations apply to petroleum substances produced in the refinery but do not cover formulated petroleum products placed on the market that are deemed to be mixtures. Guidance on the application of CLP in the context of REACH has been developed by ECHA (ECHA, 2017).

Mixtures

For <u>mixtures</u>, the rules set in Annex I of CLP Regulation apply on the classified component substances. If the mixture does not meet any criteria for classification in accordance with CLP Regulation this has to be clearly stated in this Section.

A statement is also required to distinguish clearly between mixtures that are classified as hazardous on the basis of their health, physical or environmental effects and those mixtures which are not classified but for which a SDS is required because they contain at least one classified component

- above a set limit (but below mixture classification threshold), or
- with an occupational exposure limit set <u>at Community level</u> (Art 31 of REACH Regulation), that is under the Chemical Agents Directive (98/24/EC) or the Carcinogens and Mutagens Directive (2004/37/EC) and their updates.

2.2. LABEL ELEMENTS

The label elements are directly associated with each specific classification listed in sub-section 2.1., as per the Annex I of the CLP Regulation, indicating the label elements required for each hazard class and category: hazard pictograms, signal word, hazard statements (H-statements) and associated precautionary statements (P-statements), selected based on the criteria set in Annex IV - Part 1 of the CLP Regulation.

CLP Regulation also lists the correct wording of both the H- and P-statements (Annex III and Annex IV - Part 2, respectively).

Normally, no more than six P-statements should be selected to appear on the label, unless necessary to adequately reflect the nature and the severity of the hazards. Guidance on the selection of P-statements has been developed by ECHA (ECHA, 2021b). For each hazard class and category, this guidance identifies P-statements as either: highly recommended, recommended or optional, and indicates that suppliers need to allocate statements based on knowledge of substance use and hazard profile.

For petroleum substances, the category specific recommendations for labelling in the Concawe report 1/22 include the P-statements selected and recommended by Concawe. Additionally, the full list of P-statements associated to respective hazard classes and categories is shown for completeness.



2.3. OTHER HAZARDS

The applicable supplemental information appearing on the label as per Article 25(1) to (6) and Article 32(6) of CLP Regulation are also to be provided in this sub-section.

Information on other hazards should be provided, on whether the substance or mixture components:

- meets the PBT/vPvB criteria;
- was included in the SVHC list for having endocrine disrupting properties;
- is identified as having endocrine disrupting properties in accordance with existing criteria¹.

For a mixture, this has to be mentioned for each such substance that is present in the mixture at a concentration equal to or greater than 0.1 % by weight.

Reference to other hazards which do not result in classification but which may contribute to the overall hazard of the material should be considered for listing. Examples could include:

- cold burns from contact with LPG
- hydrogen sulphide (H₂S) that can accumulate in the headspace of storage tanks and reach potentially hazardous concentrations
- thermal burns from handling at elevated temperatures of heavy fuels, bitumen, etc.
- carcinogenicity of used motor oils
- static electricity concerns associated with fuels
- dust explosion hazards (e.g. petroleum coke)
- respiratory irritation associated with overexposure to oil mist
- slipping hazard from oil mist deposited on surfaces.

A consistency check (potential overlap) of Section 2 should be made with Sections 7, 8, 9, 11, 12, 15, 16 and annex to the SDS, where applicable.

<u>An example for Section 2 of SDS Sheet for petroleum products is presented in</u> <u>Appendix 3.</u>

¹ Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council (OJ L 301, 17.11.2017, p. 1), or Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties (OJ L 101, 20.4.2018, p. 33).



3. SDS SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Direct citation from the legal text of the Regulation (EU) 2020/878:

This section of the safety data sheet shall describe the chemical identity of the ingredient(s) of the substance or mixture, including impurities and stabilising additives as set out below. Appropriate and available safety information on surface chemistry shall be indicated.

The main new requirement for the section 3.1 or 3.2 is the addition of new identifiers, such as the specific concentration limit (SCL), the M-factor and the acute toxicity estimate ATE and additional information on nanoforms, where applicable.

Either section 3.1 or 3.2 must be included in the SDS, as appropriate, for only one of either a substance or mixture as applicable.

The composition of substances obtained from oil (petroleum substances) depends on the crude oil used for the manufacture (as the composition of the crude oil varies depending on the place of origin) and the subsequent refinery processes. Therefore, there is natural, process-dependent variation in composition of petroleum substances.

<u>Petroleum substances</u> fall into the category called UVCB substance (Substances of Unknown or Variable composition, Complex reaction products or Biological materials) and section 3 should reflect this special feature.

These substances cannot be sufficiently identified by their chemical composition, because:

- The number of constituents is relatively large and/or
- The composition is, to a significant part, unknown and/or
- The variability of composition is relatively large or poorly predictable.

Therefore, UVCB substances require other types of information for their identification, in addition to what is known about their chemical composition.

For the identification of petroleum substances, it is recommended to give the name according to an established nomenclature system, preferably EC / CAS number (see Concawe petroleum substances inventory). Terms and definitions for identification of petroleum substances generally include the stream's source, refinery process, general composition, carbon number, boiling range or other appropriate physical characteristics, and predominant hydrocarbon type.

Constituents that are relevant for the classification and/or PBT assessment of the substance shall always be identified by the same identifiers, independently from their concentration.

For *mixtures containing a petroleum substance*, the same mixing rules as in Annex II part 3.2 apply.



In summary, <u>petroleum substances are REACH registered as UVCB substances, to be</u> <u>declared in section 3.1 and classified based on CLP Annex VI and Concawe</u> <u>Classification and Labelling Recommendations</u> (Concawe, 2022). When blended with other components or additives, they become <u>mixtures, to be declared in</u> <u>section 3.2.</u>

3.1. SUBSTANCES (ALTERNATIVE TO 3.2)

The requirements for this section have not changed fundamentally, except for nanomaterials, which are not usually relevant for petroleum substances. Currently, <u>UVCB petroleum substances are registered as substances</u>, and should therefore be declared in this section as before. Further guidance on their classification and labelling principles is given in the Concawe C&L Report 1 / 22.

The chemical identity of the substance shall be provided by providing at least the product identifier or one of the other means of identification given in subsection 1.1.

In this section, the specific concentration limit (SCL) shall be indicated, as well as the multiplication factor (M-factor) and the acute toxicity estimate (ATE), if available. Annex II of the REACH Regulation specifies that this information should be provided in Section 3.1, rather than Section 2.1. Despite these values being an integral part of a classification, they can be considered as tools to determine the correct classification of a mixture containing the substance in question.

3.2. MIXTURES (ALTERNATIVE TO 3.1)

This part of the legal requirements is undergoing fundamental changes. We refer to the legal text and expect the implementation principles still to be further clarified in the coming years. The Concawe Guidance given below reflects our current understanding of the situation.

Current Concawe Guidance is given in the examples: A SDS for UVCB substance Gasoline (EC 289-220-8) is given in Appendix 3, section 1, for UVCB substance Fuel oil, residual in Appendix 3, section 3.1 and an example for blended gasoline mixture in Appendix 3, section 3.2.

Where a specific concentration limit (SCL), an M-factor, or an acute toxicity estimate (ATE) is available, these must be indicated together with the classification information on the relevant component in this subsection 3.2.



4. SDS SECTION 4: FIRST AID MEASURES

Direct citation from the legal text of the Regulation (EU) 2020/878:

This section of the safety data sheet shall describe the initial care in such a way that an untrained responder can understand and provide it without the use of sophisticated equipment and without the availability of a wide selection of medications. If medical attention is required, the instructions shall state this, including its urgency.

The existing Concawe guidance on this section has not been changed.

This section is expected to be mostly similar for UVCB petroleum substances and their mixtures. Guidance on Safe Use from registration dossiers can be used as references for this section. Only where necessary, the relevant hazardous components contributing to the risk management can be specifically mentioned.

Section 4 should be relevant for the whole product, i.e. in case of a mixture, all the mixture's hazards as resulted from the component substances should be addressed.

Intended readers for the three sections are untrained personnel. Advice for medical personnel could be labelled as "Notes for the doctor".

4.1. DESCRIPTION OF FIRST AID MEASURES

Information on first aid measures for petroleum substances can be found in the 2021 First Aid reference guide² (Concawe, 2021a). First Aid Statements are indicated for all petroleum product categories for which acute health effects have been documented, and per exposure route (inhalation, skin, eye and incidental oral).

It should be noted that the initial care has to be described in such a way that it can be provided by an untrained responder. If medical attention is required this must be clearly stated.

4.2. MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED

Information on most important symptoms and effects from acute occupational exposure and delayed from exposure to the main categories of petroleum substances is provided in the 2021 First Aid reference guide (Concawe, 2021a), per exposure route (inhalation, skin, eye and incidental oral).

Long-term occupational exposure is not included in this guide. It has to be taken care of appropriately and according to local legal requirements. Minimisation of acute exposure to products also prevents chronic exposure and related health effects.

² The 2021 update of the guide is based on an intensive evidence-based research on medical databases by the Centre for Evidence-Based Practice (CEBaP) of the Belgian Red Cross (<u>www.cebap.org</u>).



4.3. INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

Recommendation on medical advice has been developed by Concawe in Section 2 of Concawe report on "Petroleum products - first aid emergency and medical advice" (Concawe, 1997).

An example for Section 4 of SDS for petroleum products is presented in Appendix 3.



5. SDS SECTION 5: FIREFIGHTING MEASURES

Direct citation from the legal text of the Regulation (EU) 2020/878:

This section of the safety data sheet shall describe the requirements for fighting a fire caused by the substance or mixture, or arising in its vicinity.

The existing Concawe guidance on this section has not been changed.

This section is expected to be mostly similar for UVCB petroleum substances and their mixtures. (Only where necessary, the relevant hazardous components contributing to the risk management can be specifically mentioned.)

Section 5 should be relevant for the whole product, i.e. in case of a mixture all the mixture's hazards as resulted from the component substances should be addressed. Concawe Report 5/02 (Concawe, 2002a) and generic Guidance on Safe Use from registration dossiers have been used as references for this section.

5.1. EXTINGUISHING MEDIA

Suitable extinguishing media:

- Foam (Specifically trained personnel only)
- Water fog (Specifically trained personnel only)
- Dry chemical powder
- Carbon dioxide
- Other inert gases (subject to regulations)
- Sand or earth

Unsuitable Extinguishing Media:

- Do not use direct water jets on the burning product; they could cause splattering and spread the fire.
- Simultaneous use of foam and water on the same surface is to be avoided as water destroys the foam.

5.2. SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

- It should be pointed out that, in the event of fire, product fumes or vapours can spread quickly and may be ignited by remote ignition sources. Consider whether resulting vapours are heavier or lighter than air.
- Incomplete combustion is likely to give rise to a complex mixture of airborne solid and liquid particulates and gases, including carbon monoxide, H₂S, SOx



(sulphur oxides) or sulfuric acid and unidentified organic and inorganic compounds.

• This substance may float and can be reignited on surface water.

5.3. ADVICE FOR FIREFIGHTERS

- Containers at risk can be cooled with water spray jet.
- Any fire residues and contaminated fire-fighting water should be collected and disposed of in accordance with local regulations.

Depending upon the respective hazards of substances, levels of protection advised can be divided into three categories:

- Self-Contained Breathing Apparatus (SCBA) with chemical resistant gloves.
- SCBA with a chemical protection suit only where personal (close) contact is likely.
- SCBA with gas-tight suit when close proximity to the substance or its vapours is likely.

An example for Section 5 of SDS for petroleum products is presented in Appendix 3.



6. SDS SECTION 6: ACCIDENTAL RELEASE MEASURES

Direct citation from the legal text of the Regulation (EU) 2020/878:

This section of the safety data sheet shall recommend the appropriate response to spills, leaks, or releases, to prevent or minimise the adverse effects on persons, property and the environment. It shall distinguish between responses to large and small spills, in cases where the spill volume has a significant impact on the hazard. If the procedures for containment and recovery indicate that different practices are required, these shall be indicated in the safety data sheet.

The existing Concawe guidance on this section has not been changed.

This section is expected to be mostly similar for UVCB petroleum substances and their mixtures. (Only where necessary, the relevant hazardous components contributing to the risk management can be specifically mentioned.)

Section 6 should be relevant for the whole product, i.e. in case of a mixture all the mixture's hazards as resulted from the component substances should be addressed.

It may be useful to consider providing guidance on who (i.e., neighbourhoods, regulatory authorities) the employer / professional user may need to notify in the event of an accidental release. Concawe Report 5/02 (Concawe, 2002a) and generic Guidance on Safe Use from registration dossiers have been used as references for this section.

6.1. PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

General information:

- Stop or contain leak at the source if safe to do so. Avoid direct contact with released material. Stay upwind. In case of large spillages, alert occupants in downwind areas.
- Keep non-involved personnel away from the area of spillage. Alert emergency personnel. Except in case of small spillages, the feasibility of any actions should always be assessed and advised, if possible, by a trained, competent person in charge of managing the emergency.
- It is recommended to eliminate all ignition sources if safe to do so (e.g. electricity, sparks, fires, flares).
- When the presence of dangerous amounts of H₂S around the spilled product is suspected or proved, additional or special actions may be warranted, including access restrictions, use of special protection equipment, procedures and personnel training. If required, notify relevant authorities according to all applicable regulations.
- When inside buildings or confined spaces ensure adequate ventilation.



Personal protection equipment for emergency responders:

- Small spillages: normal antistatic working clothes are usually adequate.
- Large spillages: full body suit of chemically resistant and antistatic material, if necessary heat resistant and insulated work gloves providing adequate chemical resistance, specifically to aromatic hydrocarbons. Note: gloves made of PVA are not water-resistant, and are not suitable for emergency use. If contact with hot product is possible or anticipated, gloves should be heat-resistant and thermally insulated.
- Work helmet.
- Antistatic non-skid safety shoes or boots, if necessary heat-resistant.
- Goggles or face shield, if splashes or contact with eyes is possible or anticipated.
- Respiratory protection: A half or full-face respirator with filter(s) for organic vapours/H₂S or a Self Contained Breathing Apparatus (SCBA) can be used according to the extent of spill and predictable amount of exposure. If the situation cannot be completely assessed, or if an oxygen deficiency is possible, only SCBA's should be used

6.2. ENVIRONMENTAL PRECAUTIONS

Spillages on to land:

- Prevent product from entering sewers, rivers, waterways or other bodies of water.
- If necessary dike the product with dry earth, sand or similar non-combustible materials.
- Let hot product cool down naturally.
- Large spillages may be cautiously covered with foam, if available, to limit fire risk. Do not use direct jets. When inside buildings or confined spaces ensure adequate ventilation.

Spillages in water or at sea:

- Product less dense than water: In case of small spillages in closed waters (i.e. ports), contain product with floating barriers or other equipment. Collect spilled product by absorbing with specific floating absorbents.
- If possible, large spillages in open waters should be contained with floating barriers or other mechanical means. If this is not possible, control the spreading of the spillage, and collect the product by skimming or other suitable mechanical means.
- The use of dispersants should be advised by an expert, and, if required, approved by local authorities.



Additional information:

<u>Note</u>: recommended measures are based on the most likely spillage scenarios for this material; however, local conditions (wind, air temperature, wave/current direction and speed) may significantly influence the choice of appropriate actions. For this reason, local experts should be consulted when necessary. Local regulations may also prescribe or limit actions to be taken.

Concentration of H_2S in tank headspaces may reach hazardous values, especially in case of prolonged storage. This situation is especially relevant for those operations which involve direct exposure to the vapours in the tank.

Spillages of limited amounts of products, especially in the open air when vapours will be usually quickly dispersed, are dynamic situations, which are unlikely to entail exposure to dangerous concentrations. As H_2S has a density greater than ambient air, a possible exception may regard the build-up of dangerous concentrations in specific spots, like trenches, depressions or confined spaces. In all these circumstances, however, the correct actions should be assessed on a case-by-case basis.

6.3. METHODS AND MATERIALS FOR CONTAINMENT AND CLEANING UP

Spillages on to land:

- Absorb spilled product with suitable non-combustible materials.
- Collect free product with suitable means. Collect recovered product and other contaminated materials in suitable containers for recycle, recovery or safe disposal.
- In case of soil contamination, remove contaminated soil for remediation or disposal, in accordance with local regulations.

Spillages in water or at sea:

- Collect recovered product and other contaminated materials in suitable tanks or containers for recycle, recovery or to safe disposal.
- Product which is denser than water will sink to the bottom, and usually no intervention will be feasible. If possible, collect the product and contaminated materials with mechanical means, and store/dispose of according to relevant regulations. In special situations (to be assessed on case-by case basis, according to expert judgement and local conditions), excavations of trenches on the bottom to collect the product, or burying the product with sand may be a feasible option



6.4. **REFERENCE TO OTHER SECTIONS**

Please see section 5 for firefighting measures, section 8 for exposure controls / personal protection, section 4 for first aid measures and section 13 for waste handling advice.

An example for Section 6 of SDS for petroleum products is presented in Appendix 3.

7. SDS SECTION 7: HANDLING AND STORAGE

Direct citation from the legal text of the Regulation (EU) 2020/878:

This section of the safety data sheet shall provide advice on safe handling practices. It shall emphasise precautions that are appropriate to the identified uses referred to under subsection 1.2 and to the unique properties of the substance or mixture.

Information in this section of the safety data sheet shall relate to the protection of human health, safety and the environment. It shall assist the employer in devising suitable working procedures and organisational measures according to Article 5 of Directive 98/24/EC and Article 5 of Directive 2004/37/EC.

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.

In addition to information given in this section, relevant information may also be found in section 8.

The existing Concawe guidance on this section has not been changed.

This section is expected to be mostly similar for UVCB petroleum substances and their mixtures. Guidance on Safe Use from registration dossiers can be used as references for this section. (Only where necessary, the relevant hazardous components contributing to the risk management can be specifically mentioned.)

Section 7 should be relevant for the whole product, i.e. in case of a mixture all the mixture's hazards as resulted from the component substances should be addressed.

Information must be given on how to handle and store petroleum products safely, to avoid potentially dangerous incidents.

The information is appropriate for the uses identified in Section 1.2, and to the unique properties of the petroleum substance or mixture (as given in Sections 9 and 10). It should be consistent with any exposure scenario provided and related to the protection of human health, safety and the environment. Please see the examples in Annex 3.

Consistency with other Sections

Section 7 needs also to be checked for consistency with the following Sections of the SDS. Some examples are presented below:

- Section 2.2- Label elements: Include specific precautionary statements in addition to the six included in the label. For example, in 7.1 "Do not handle until all the safety precautions have been read and understood" (P202) and/or "Wash hands thoroughly after handling" (P264) can be added.
- Section 8.2 Exposure controls: Engineering controls described in section 8.2 should be in line with section 7.1



- Section 9 Physical and chemical properties: Advice provided in order to manage risks is associated with the phys/chem properties such as flammability, explosiveness, evaporation etc.
- Section 10 Stability and Reactivity: Section 7 specifies the conditions for safe handling & storage including the incompatible packaging materials while Section 10 focuses on the qualitative description of hazards and their consequences. Cross references may be used to avoid overlap.
- Section 11 Toxicological information: Protective measures for safe handling are based on the evaluation of the health effects as described in Section 11. For example, in case of CMR classification users are advised: "Obtain special instructions before use".
- Section 12 Ecological information: Technical measures to prevent the environmental release such as filters are based on the evaluated environmental hazards.
- Exposure Scenarios Annex: If the SDS has corresponding exposure scenarios attached, which give the necessary recommendations relating to safe handling and use, and reference is made to it there is no need to use this subsection for detailed recommendations for specific end uses.

7.1. PRECAUTIONS FOR SAFE HANDLING

This sub-section should provide information concerning protective measures for safe handling and recommended technical measures such as containment, measures to prevent aerosol and dust generation and fire, measures required to protect the environment (e.g. use of filters or scrubbers on exhaust ventilation, use in a bonded area, measures for collection and disposal of spillages, etc.) and any specific requirements or rules relating to the substance or mixture (e.g. procedures or equipment which are prohibited or recommended).

7.2. CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

This sub-section should, if relevant, specify the conditions for safe storage such as specific design for storage rooms or vessels, incompatible material, conditions of storage (humidity limit/range, light, inert gas), special electrical equipment and prevention of static electricity.

The subsection should also include advice - if relevant - on quantity limits under storage conditions or an indication of threshold quantities above which the Seveso III Directive (EU, 2012) applies to the substance or substance class.

Special requirements such as the type of material used in the packaging/containers of the substance or mixture and any incompatibilities with packaging materials should be also indicated.

Regarding incompatibilities, some information might also be given in Section 10 - Stability and Reactivity. In such cases, repetition may be avoided by cross-references, with the content of Section 10 focusing on description of hazards and their consequences.



Some suppliers may choose to indicate here information about national storage class systems derived from the classification of the petroleum substance or mixture.

It is not recommended to add quality-related storage information to this subsection.

Where a substance has been registered as an isolated intermediate (on-site or transported), indicate consistency with the specific conditions in accordance with REACH Article 17 and 18.

- Technical measures and storage conditions: please see <u>examples in Appendix</u> <u>3 Section 7</u>
- Packaging materials: please see examples in Appendix 3 Section 7
- **Requirements for storage rooms and vessels:** please see <u>examples in</u> <u>Appendix 3 Section 7</u>
- Storage class: please see examples in Appendix 3 Section 7
- Further information on storage conditions: please see <u>examples in Appendix</u> <u>3 Section 7.</u>

7.3. SPECIFIC END USE(S)

If the SDS has corresponding exposure scenarios attached which give the necessary recommendations relating to safe handling and use and reference is made to them, there is no need to give further detailed recommendations in this Section for specific end uses. However, if a registrant has available information on safe use of his substance in end products he can make a reference here.

If no exposure scenarios are required, this Section may additionally be used to include equivalent information which would otherwise be given in an exposure scenario.

- Recommendations: please see examples in Appendix 3 Section 7
- Industrial sector specific solutions: please see <u>examples in Appendix 3</u> <u>Section 7</u>

An example for Section 7 of Safety Data Sheet for petroleum products is presented in Appendix 3. It has to be further completed with information depending on product's specific properties.

Based on the P statements of classified mixtures and any other information resulting from the consolidation of exposure scenarios of mixture components, it is suggested to use ESCom phrases³ (Cefic, 2022) from the Chemical Safety Assessment as per **Appendix 1**.

If the substance has been registered as a transported intermediate under strictly controlled conditions, reference should be made here to REACH Article 18 subparagraphs 4(a) to (f). Additionally, reference may be included to the ECHA Practical Guide 16 of June 2014 (ECHA, 2014b).

³ <u>https://cefic.org/guidance/reach-implementation/escom-package-guidance/</u>



8. SDS SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Direct citation from the legal text of the Regulation (EU) 2020/878:

This section of the safety data sheet shall describe the applicable occupational exposure limits and necessary risk management measures. 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.

Concawe existing guidance on this section has not been significantly changed. Some additional recommendations have been added.

Section 8 should be relevant for the whole product, i.e. in case of a mixture all the mixture's hazards as resulted from the component substances should be addressed.

It is noted that REACH Annex II and the accompanying ECHA guidance require consistency between this section and annexed Exposure Scenarios (ES's). Therefore, if ES's are annexed, a phrase can be included at the beginning of Section 8: "*Refer to the Exposure Scenario for your specific use contained in the Annex of the e-SDS*."

Recommendations for the specific subsections of Section 8 are given below:

8.1. CONTROL PARAMETERS

National Occupational Exposure Limits (OELs) and Biological Limit Values (BLVs): to be listed

- Some EU Member States have adopted whole substance OELs for gasoline, kerosine, oil mist, and/or bitumen fumes; these should be listed if applicable to the Member State where the product is placed on the market.
- Constituent OELs and BLVs should be aligned with the constituents mentioned in Section 3, also to avoid mentioning a multitude of substance (constituent) OELs with no practical meaning for UVCB exposure control. In any event, the values given must be those applicable for the EU Member State where the product is placed on the market.

Monitoring procedures:

- Workplace and personal exposure air monitoring, biological monitoring according to national or agreed standards (such as EN, NIOSH) at least for the most relevant substances mentioned in Section 8.1.1.
- Where there is a difference in methods for different countries, the monitoring methods of the country for which the SDS is being provided, takes precedence.
- Concawe has published reports with sampling and analytical methods for the assessment of inhalation exposure to LPG (12/04), gasoline (8/02), gas oils (8/15) and HFO (1/15R); (Concawe, 2002 b, 2004, 2015a, 2015b), which may be referenced in this section for those substances.



Air contaminants formed during intended use:

- For fuels, applicable national exposure OELs and BLVs for the air contaminants can be listed, e.g., for SO₂, NO₂.
- For fuels used in diesel engines, the applicable national OEL value for diesel engine exhaust emissions should be listed.

Derived No-Effect Levels (DNELs), Predicted No-Effect Concentrations (PNECs):

• Where a Chemical Safety Report is annexed or where DNELs or PNECs are available for the specific substances of the product as addressed in section 3, these shall be listed or tabled separately.

<u>Current DNEL values by category as used in REACH registration dossiers are listed</u> <u>in Appendix 5.</u> PNECs are not calculated for whole substances as these are UVCBs, but for representative constituents. Information can be found in IUCLID Section 13 of registration dossiers: PETRORISK file.

8.2. EXPOSURE CONTROLS

If one or more ES(s) for identified use(s) is/are annexed, text in this section may be limited

• For substances registered as isolated intermediates under Strictly Controlled Conditions (SCC) (Art. 17 or 18 registrations): SDS authors may refer to ECHA Practical Guide 16 of 2014 (ECHA, 2014b).

Appropriate engineering controls:

• Concise text applicable to all identified uses may be included and, in any event, needs to complement section 7

Personal protective equipment:

- **Gloves:** material, thickness and typical and minimum breakthrough time are required, for example:
 - "Check minimum breakthrough time and thickness before use, with consideration to the working conditions and time for which the gloves will be used."
- In addition to the information elements indicated in the legal text and the ECHA guidance, SDS authors may include some or all of the following generic statements which will improve the quality of the hand protection achieved with gloves in the workplace:
 - "Where hand contact with the product may occur the use of gloves approved to relevant standards (Europe: EN374) made from suitable materials may provide adequate chemical protection."
 - "Suitability and durability of a glove is dependent on usage, e.g. frequency and duration of contact, chemical resistance of glove material, dexterity requirement and other circumstances such as high temperature of product or process equipment. Always seek advice from glove suppliers."
 - "Contaminated gloves should be replaced."
 - "For continuous contact we recommend gloves with breakthrough time of more than 240 minutes with preference for > 480 minutes where suitable gloves can be identified. For short-term/splash protection we recommend the same, but recognize that suitable gloves offering this level of protection may not be available and in



this case a lower breakthrough time maybe acceptable so long as appropriate glove maintenance and replacement regimes are followed."

- "Personal hygiene is a key element of effective hand care. Gloves must only be worn on clean hands. After using gloves hands should be washed and dried thoroughly. Application of a non-perfumed moisturizer is recommended.
- "In general, glove thickness should be typically greater than 0.35 mm depending on the glove make and model but glove thickness is not a good predictor of glove resistance to a chemical as it is dependent on the exact composition of the glove material."
- Other parts of the body (skin): chemical protective clothing
- **Respiratory protective equipment:** Note that the ECHA guidance refers to Assigned Protection Factors but these are not EU-harmonised (see EN 529, Appendix C)
- Thermal hazard protection: important for substances handled at elevated temperatures (HFO, bitumen, molten sulphur, molten waxes)
- **Eye protection:** basic for petroleum substances or specific if the product carries a relevant H-phrase

Environmental exposure controls:

- Refer to section 6 of the eSDS and the ES
- Otherwise, include measures related to the specific product to prevent exposure or some generic statements such as:
 - "Do not dispose of via drains"
 - "Collect spilled product"
 - "Keep containers closed"

<u>An example for Section 8 of Safety Data Sheet for petroleum products is presented</u> <u>in Appendix 3.</u>

Based on the P statements of classified mixtures and any other information resulting from the consolidation of exposure scenarios of mixture components, *it is suggested to use ESCom phrases from the Chemical Safety Assessment as per Appendix 1.*



9. SDS SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Direct citation from the legal text of the Regulation (EU) 2020/878:

This section of the safety data sheet shall describe the empirical data relating to the substance or mixture, if relevant. Article 8(2) of Regulation (EC) No 1272/2008 shall apply.

To enable proper control measures to be taken, all relevant information on the substance or mixture shall be provided. The information in this section shall be consistent with the information provided in the registration or in the chemical safety report, where required, and with the classification of the substance or mixture.

In the case of a mixture, where information does not apply to the mixture as a whole, the entries shall clearly indicate to which substance in the mixture the data apply.

Reported properties shall be clearly identified and reported in the appropriate measurement units. The method of determination shall be provided, including measurement and reference conditions, if relevant for the interpretation of the numerical value. Unless specified otherwise, standard conditions of temperature and pressure are 20 °C and 101,3 kPa, respectively.

The properties listed in subsections 9.1 and 9.2 may be presented in a form of a list. Within the subsections, the order of listing the properties may be different if deemed appropriate.

The main new requirement for this section are the additional physical and chemical properties originating from GHS (versions 6 and 7 recently implemented into CLP) and additional information on nanoforms, where applicable. Therefore, this Concawe Guidance has been extensively updated to give applicable recommendations and test methods for petroleum substances and their mixtures.

The information provided in this section has to reflect the properties of the whole product (independently if it is a substance or mixture).

Not all the required information may be available in the registration dossier(s) of substance(s). In some cases the information should be experimentally determined for the whole product.

For UVCB substances, consistency check with process description in section 1.2 of the registration dossier is not needed (but recommended for flash point, initial boiling point).

Substances

The information in this section should be consistent with the information provided in the registration and/or in the chemical safety report where required, and with the classification of the substance.

Preferably, the data should have been obtained by applying the test methods referred to in the REACH or CLP Regulations, transport provisions or international principles or procedures for the validation of information, so as to ensure quality



and comparability of the results and consistency with other regulatory requirements.

REACH registration endpoint data should be available for registered substances, depending on their tonnage band. Concawe's UVCB petroleum substances have typically full registrations and thus endpoint data determined for all their relevant endpoints. Petroleum substances and their mixtures also have their own specific test methods, which have been collected in Concawe Report no. 7/12 (Concawe, 2012). Summaries are presented in sections 9.1 and 9.2 below.

Where no data can be reported for a particular property, the reason should be stated, e.g.:

- "does not apply" in case of lack of relevance, for a given reason (also to be stated, if not obvious) and not because of absence of information;
- *"no information is available"* in case the measurement on that property is not practical, i.e.
 - scientifically not necessary (other information available), or
 - technically not feasible, or
- actual *negative test results* are available.

The information should be consistent with the information provided in the registration dossiers and in the CSRs.

Mixtures

Where the information presented was not obtained on the mixture as a whole, the entries should clearly indicate to which substance in the mixture the data apply.

There can be significant differences for the availability of endpoint test data for components of a mixture. The Article 8 (2) of the CLP Regulation states the following: "For the purposes of determining whether a substance or a mixture entails any of the physical hazards referred to in Part 2 of Annex I, the manufacturer, importer or downstream user shall perform the tests required in that Part, unless there is adequate and reliable information already available." However, it is still recommended by the ECHA SDS Guidance (2020), Section 2.27, that additional testing should <u>not</u> be initiated on the basis of a need to "fill-in empty fields" in an SDS.

Properties relevant for mixture classification would have to be measured on the mixture itself; if measurement is technically not possible, this should be stated and relevant information on component substances should be indicated (e.g. lowest boiling point, flash point or viscosity, or highest water solubility, vapour pressure or log K_{ow}).

Also, relevant properties of the mixture components may be additionally indicated along with data on the mixture itself, if deemed as contributing to the safe use and classification of the mixture.

Traded blendstocks

For traded blendstocks, there may be significantly less data available than the SDS requirements of REACH Annex II, due to the nature of the operations.



Registration endpoint data for the substances should however be available and communicated to the recipient.

Suppliers should provide the relevant information to enable the correct identification, classification and labelling and safe use of the mixture.

9.1. INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

All basic properties below (yet not necessarily in this order) should be considered. Reported values should be clearly identified and given in the appropriate measurement units, along with the method of determination and reference conditions, if relevant. Unless specified otherwise, standard conditions of temperature and pressure are 20 $^{\circ}$ C and 101,3 kPa, respectively.



Property	REACH Annex II text	Recommended statement and test methods	Motivation / Justification	
(a) Physical state	The physical state (gas, liquid or solid) shall generally be indicated at standard conditions of temperature and pressure. The definitions of the terms gas, liquid and solid, as provided in Section 1.0 of Annex I to Regulation (EC) No 1272/2008, shall apply.	To be stated as observed	To be indicated typically at 20 °C and 101 kPa or their use temperature (e.g. heavy fuel oils or bitumens).	
(b) Colour	The colour of the substance or mixture as supplied shall be indicated. In cases where one safety data sheet is used to cover variants of a mixture which may have different colours, Also the term 'various' can be used to describe the colour.	To be stated as observed	Colour may vary depending on the UVCB petroleum substance type from clear or yellowish to brown or black.	
(c) Odour	A qualitative description of the odour shall be given if it is well-known or described in the literature. If available, the odour threshold shall be indicated (qualitatively or quantitatively) for additional mixture components.	To be stated as observed	Odour may vary depending on the UVCB petroleum substance from almost odourless to typical petroleum until pungent.	
(d) Melting point / freezing point	Does not apply to gases. Melting point and freezing point shall be indicated at standard pressure.	Statement: "does not apply / not required / technically not possible / most relevant test result with justification"	Melting point is not relevant for naphtha & kerosenes as these will have pour points below -20°C.	
	In case the melting point is above the measuring range of the method, it shall be indicated up to which temperature no melting point was observed.	(Naphthas) "Data not required as freezing point is less than -20°C (REACH Annex VII)".	For complex mixtures like petroleum products, melting point may be characterised by a range of temperatures reflecting the melting points of the individual components.	

report no. 9/22



Property	REACH Annex II text	Recommended statement and test methods	Motivation / Justification
	If decomposition or sublimation occur prior to or during melting, it shall be indicated. As regards waxes and pastes, the softening point/range may be indicated instead of the melting point and freezing point. As regards mixtures, if it is technically not possible to determine the melting point/freezing point, this shall be indicated.	 (Kerosines) "For UVCB, the melting point is not an adequate parameter. Instead a pour point range should be used." Test methods for pour point: IP15 EN ISO 3016- ASTM D97 Other cold flow properties of petroleum products, besides the pour point, are: cloud point (EN 23015, ISO 22995, ISO 3015, ASTM D5773, ASTM D2500), freezing point (ASTM D7153, IP529) and cold filter plugging point (EN 116, ASTM D6371-05). 	To better describe the physical phase or flow characteristics of petroleum products, the pour point is routinely used. These measurements basically define the lowest temperature that the product can be used in the intended application. Only relevant melting/freezing/ softening points/ranges for additional mixture components may be indicated.
(e) Boiling point or initial boiling point and boiling range	These properties shall be indicated at standard pressure. A boiling point at lower pressure might however be indicated, in case the boiling point is very high or in case decomposition occurs before boiling at standard press If the boiling point is above the measuring range of the method, the temperature up to which no boiling point was observed shall be indicated. If decomposition occurs prior to or during boiling, this shall be indicated.	Test methods: - EN ISO 3405 - ASTM D86 - IP123	This is a key property for UVCB petroleum substances and mixtures. Along with the flash point, the initial boiling point is a classification criterion for liquids flammability. Due to the definition of the boiling point given in the guidance, this relates ONLY to physical distillation. Therefore the Simdis methods EN 15199 & ASTM D3710 (currently, ASTM D3710 is withdrawn and replaced by ASTM D7096) cannot be



Property	REACH Annex II text	Recommended statement and test methods	Motivation / Justification
	As regards mixtures, if it is technically not possible to determine their boiling point or range, this shall be indicated; in that case, the boiling point of the lowest boiling ingredient shall also be indicated.		used - for gases; - for solids which either melt above 300°C or decompose before boiling; - for substances which decompose before boiling. Only relevant lowest boiling points for mixture components may be indicated.
(f) Flammability	Applies to gases, liquids and solids. It shall be indicated whether the substance or mixture is ignitable, i.e. capable of catching fire or being set on fire, even if not classified for flammability. If available and appropriate, further information may be indicated, such as whether the effect of ignition is other than a normal combustion (e.g. an explosion) and the ignitability under non-standard conditions. More specific information on the flammability may be indicated based on the respective hazard classification. The information provided in subsection 9.2.1 shall not be provided in this point.	Statement: "Petroleum gases, vapours from volatile petroleum liquid products and coke dusts may form explosive / flammable mixtures with air". Test methods for gases: - ISO 10156 - EN 1839 Test methods for liquids: - IP34 - EN ISO 2719 - ASTM D93 - EN ISO 13736 (ABEL CLOSED CUP METHOD)	 UVCB petroleum substances are typically flammable gases, liquids or solids. For liquids, flash point data are required to characterise flammability, as specified in Technical Guidance on Information Requirements/ CSA, section 7.1.10. Any of the industry standard closed- cup methods are acceptable, Abel, Pensky-Martens etc.
(g) Lower and upper explosion limit	Do not apply to solids. As regards flammable liquids, at least the lower explosion limit shall be indicated. If	Statement: "Petroleum gases and (vapours from) volatile petroleum liquid products may	



Property	REACH Annex II text	Recommended statement and test methods	Motivation / Justification
	the flash point is approximately -25 °C or higher, it may not be possible to determine the upper explosion limit at standard temperature; in that case, it is recommended to indicate the upper explosion limit at a higher temperature. If the flash point is higher than 20 °C, it may not be possible to determine the lower or the upper explosion limit at standard temperature; in that case, it is recommended to indicate both the lower and the upper explosion limits at a higher temperature.	form explosive / flammable mixtures with air". - Shake Flask method (OECD Test Guideline 107) - HPLC Method (EU A.8, OECD TG 117) - Slow-Stirring Method (OECD TG 123) - ASTM E681 - 09	
(h) Flash point	Does not apply to gases, aerosols and solids. For mixtures, a value for the mixture shall be indicated, if available. Otherwise, the flash point(s) of the substance(s) with the lowest flash point(s) shall be indicated.	Test methods: - ASTM D93 - IP34 - EN ISO 2719 - EN ISO 13736 - EN ISO 1516	This is a key property for UVCB petroleum substances. Along with the initial boiling point, the flash point is a CLP classification criterion for liquids flammability. This property is also important for classification in transport dangerous goods for flammable liquids.
(i) Auto- ignition temperature	Only applies to gases and liquids. As regards mixtures the auto-ignition temperature for the mixture shall be indicated, if available. If the value for the mixture is not available, the auto-ignition temperature(s) of the ingredients with the	Statement: "The relevant value range for UVCB petroleum substances may be found in the substance CSR / It is not possible to define	The auto-ignition temperature does not have to be determined for liquids having no flash point up to 200°C. In practice, liquids with a boiling point above 350°C will not have a flash point below 200°C.



Property	REACH Annex II text	Recommended statement and test methods	Motivation / Justification
	lowest auto-ignition temperature(s) shall be indicated.	a single self-ignition temperature for petroleum UVCB substances". Test methods: - ASTM-E 659 - DIN 51794	Therefore, determination of the auto-ignition temperature is not necessary in such cases if the flash point is not known
(j) Decomposition temperature	Only applies to self-reactive substances and mixtures, organic peroxides, and other substances and mixtures that may decompose. The self-accelerating decomposition temperature (SADT) and the volume to which it applies, or the decomposition onset temperature shall be indicated. It shall be indicated whether the temperature given is the SADT or the decomposition onset temperature. If no decomposition was observed, it shall be indicated up to which temperature no decomposition was observed, e.g. 'no decomposition observed up to x °C'.	Statement: "not applicable"	Does not apply for UVCB petroleum substances, as they are not self- reactive nor decomposing.
(k) pH	Does not apply to gases. The pH of the substance or mixture as supplied, or where the product is a solid,	Statement: "not applicable"	Does not apply to UVCB petroleum substances, as they do not dissolve and dissociate in water



Property	REACH Annex II text	Recommended statement and test methods	Motivation / Justification
	the pH of an aqueous liquid or solution at a given concentration, shall be indicated.		
(l) Kinematic viscosity	Only applies to liquids. The measurement unit shall be mm2/s. For non-Newtonian liquids, the thixotropic or rheopexic behaviour shall be indicated.	Test methods - ASTM D445 - ISO 3104 - ASTM D7042	Kinematic viscosity (if <=20.5 mm ² /s at 40 °C) is the classification criterion for aspiration toxicity of liquid hydrocarbons. Additional mixture components mentioned only if relevant.
(m) Solubility	Solubility shall generally be indicated at standard temperature. The solubility in water shall be indicated. The solubility in other polar and non-polar solvents may also be included. As regards mixtures, it shall be indicated if the mixture is fully or only partially soluble in or miscible with water or other solvent. As regards nanoforms, the dissolution rate in water or in other relevant biological or environmental media shall be indicated in addition to the water solubility.	Statement: "petroleum UVCB substances are insoluble / sparingly soluble in water".	Standard water solubility studies are not applicable to petroleum UVCB substances. UVCB petroleum substances are typically insoluble or sparingly soluble in water, but soluble in organic solvents. They can be experimentally determined or modelled. Standard tests for water solubility property are intended for single substances and are not appropriate for complex substance. However, for petroleum UVCB substances it may be characterised using quantitative structure property relationships (QSAR) for representative hydrocarbon structures that comprise the hydrocarbon blocks used to assess the environmental risk of this



Property	REACH Annex II text	Recommended statement and test methods	Motivation / Justification
			substance with the PETRORISK model. Water solubility of additional mixture components may differ significantly, and therefore relevant
			information can be added.
(n) Partition coefficient n- octanol/water (log value)	Does not apply to inorganic and ionic liquids and does not generally apply to mixtures. It shall be indicated whether the reported value is based on testing or on calculation. As regards nanoforms of a substance for which the n-octanol/water partition coefficient does not apply, the dispersion stability in different media shall be indicated.	Statement: "log Kow ranges are modelled for UVCB petroleum substances".	Standard tests for this property are intended for single substances and are not appropriate for a UVCB substance. However, for petroleum UVCB substances it may be characterised using quantitative structure property relationships (QSAR) for representative hydrocarbon structures that comprise the hydrocarbon blocks used to assess the environmental risk of this substance with the PETRORISK model. The relevant (differing) values for additional mixture components may be indicated.
(o) Vapour pressure	Vapour pressure shall generally be indicated at standard temperature. As regards volatile fluids, the vapour pressure at 50 °C shall also be indicated. In cases where one safety data sheet is used to cover variants of a liquid mixture or liquefied gas mixture, a range for the	Test methods: - The isothermal thermogravimetrical effusion method (RAE) - ASTM D5191 (7kPa - 130kPa for naphtha & gasolines) - ASTM D6378 (0kPa - 130kPa for naphtha,	Vapour pressure is a key determined property for UVCB petroleum gases and liquids. The relevant (lowest) values for additional mixture components may be indicated. The vapour pressure is important for
		•	be indicated.



Property	REACH Annex II text	Recommended statement and test methods	Motivation / Justification
	As regards liquid mixtures or liquefied gas mixtures, a range for the vapour pressure or at least the vapour pressure of the most volatile ingredient(s), where the vapour pressure of the mixture is predominantly determined by that or those ingredient(s), shall be indicated. The saturated vapour concentration may also be indicated.	gasoline & kerosines- ISO 13016-1 & 3(15.5 kPa - 103kPa for gasolines etc)	dangerous goods for liquified hydrocarbon gas mixtures (at 70 °C) and flammable liquids (at 50 °C).
(p) Density and/or relative density	 Only apply to liquids and solids. Density and relative density shall generally be indicated at standard conditions of temperature and pressure. The absolute density and/or the relative density based on water at 4 °C as reference (also referred to as the specific gravity) shall be indicated. In cases where variations in density are possible, e.g. due to batch manufacture, or where one safety data sheet is used to cover several variants of a substance or mixture, a range may be indicated. The safety data sheet shall indicate whether the absolute density (units e.g. g/cm3 or kg/m3) and/or the relative density (dimensionless) is being reported. 	Test methods: - ASTM D4052 - EN ISO 3675 - EN ISO 12185 - IP 365.	Density is a key determined property for UVCB petroleum substances. Gases are to covered under 'q' below The relevant (differing) values for additional mixture components may be indicated.



Property	REACH Annex II text	Recommended statement and test methods	Motivation / Justification
(q) Relative vapour density	Only applies to gases and liquids. As regards gases, the relative density of the gas based on air at 20 °C as reference shall be indicated. As regards liquids, the relative vapour density based on air at 20 °C as reference shall be indicated. As regards liquids, the relative density Dm of the vapour/air-mixture at 20 °C may also be indicated.	Statement: "not relevant" (except for gases and liquids).	Relative vapour density is not relevant for petroleum substances (except for gases and liquids).
(r) Particle characteristics	Only apply to solids. The particle size (median equivalent diameter, method of calculation of the diameter (number-, surface- or volume- based) and the range in which this median value varies), shall be indicated. Other properties may also be indicated, such as size distribution (e.g. as a range), shape and aspect ratio, aggregation and agglomeration state, specific surface area and dustiness. If the substance is in nanoform or if the mixture supplied contains a nanoform, those characteristics shall be indicated in this subsection, or referred to if already specified elsewhere in the safety data sheet.	Statement: "not applicable for petroleum substances", except for sulphur and coke. Test method: - UOP333-07 (for sulfur). - ISO 728:2021 (for coke)	Not applicable for heavy petroleum substances that may be solid at ambient temperatures yet are handled at elevated temperatures (such as bitumen). Also relevant for petroleum coke if delivered in a granular form



9.2. OTHER INFORMATION

While all properties listed in sub-section 9.1. should be included with adequate information in the safety data sheet (or with a clear indication on whether data not relevant or not available), additional properties listed in sub-section 9.2. are to be included only if relevant for the safe use of the substance or mixture.

Information with regard to physical hazard classes

For UVCB petroleum substances, the other relevant properties may include: (please deselect non-relevant)

Property	REACH Annex II text	Recommended statement and test method	Motivation / Justification
(b) Flammable gases	As regards pure flammable gas, the following information may be provided in addition to data on the explosion limits referred to in point (g) of subsection 9.1.: (i) the TCi (maximum content of flammable gas which, when mixed with nitrogen, is not flammable in air, in mol. %); (ii) the fundamental burning velocity if the gas is classified as Category 1B based on fundamental burning velocity. As regards a flammable gas mixture, the following information may be provided in addition to data on the	To be stated only if relevant	ISO 10156 as amended and, if using fundamental burning velocity for Category 1B, see ISO 817 as amended 'Refrigerants-Designation and safety classification, Annex C:- Method of test for burning velocity measurement of flammable gases'). Instead of the test apparatus according to ISO 10156 as amended, the test apparatus for the tube method according to clause 4.2 of EN 1839 as amended (Determination of explosion limits of gases and vapours) may be used



Property	REACH Annex II text	Recommended statement and test method	Motivation / Justification
	 explosion limits referred to in point (g) of subsection 9.1.: (i) explosion limits, if tested, or an indication of whether the classification and category assignment is based on calculation; (ii) fundamental burning velocity if the 		
	gas mixture is classified as Category 1B based on fundamental burning velocity		
(c) Aerosols	The following total percentage (by mass) of flammable components may be provided, unless the aerosol is classified as Aerosol category 1 because it contains more than 1 % (by mass) flammable components or has a heat of combustion of at least 20 kJ/g and is not submitted to the flammability classification procedures (see the Note in Paragraph 2.3.2.2 of Annex I to Regulation (EC) No 1272/2008)	To be stated only if relevant	No aerosols among petroleum products
(e) Gases under pressure	As regards pure gas, critical temperature may be provided. As regards gas mixture, pseudo-critical temperature may be provided.	To be stated only if relevant	Data can be found in the literature, calculated or determined by testing. Most pure gases are already classified in the UN RTDG, Model Regulations (UN, 2019 b)
(f) Flammable liquids	When the substance or mixture is classified as flammable liquid, data on the boiling point and flash point do not	To be stated only if relevant	Liquid products with a flash point of more than 35 °C and not more than 60 °C need not be classified in Category 3 if negative results have been obtained in the sustained



Property	REACH Annex II text	Recommended statement and test method	Motivation / Justification
	need to be provided under this point as that data are to be indicated in accordance with the subsection 9.1. Information on sustained combustibility may be provided.		 combustibility test L.2, Part III, section 32 of the UN RTDG, Manual of Tests and Criteria(UN, 2019a). Other methods: ISO 9038:2002 Test for sustained combustibility of liquids ISO/TR 29662:2020(en) Petroleum products and other liquids – Guidance for flash point and combustibility testing
(g) Flammable solids	The following information may be provided: (i) burning rate, or burning time as regards metal powders, (ii) statement on whether the wetted zone has been passed;	To be stated only if relevant	No flammable solids among petroleum products
(p) Corrosive to metals	The following information may be provided: (i) metals that are corroded by the substance or mixture, (ii.) corrosion rate and statement on whether it refers to steel or aluminium,	To be stated only if relevant	Reference to section 7



Property	REACH Annex II text	Recommended statement and test method	Motivation / Justification
	(iii.) reference to other sections of the safety data sheet with regard to compatible or incompatible materials.		

Other safety characteristics

Properties, safety characteristics and test results listed below may be useful to indicate as regards a substance or a mixture, to be stated only if relevant and if data are available.

- Formation of exposable dust/air mixtures (relevant for petroleum coke)
- Evaporation rate
- Miscibility
- Conductivity
- Corrosiveness
- Gas group

An example for Section 9 of SDS for petroleum products is presented in Appendix 3.



10. SDS SECTION 10: STABILITY AND REACTIVITY

Direct citation from the legal text of the Regulation (EU) 2020/878:

This section of the safety data sheet shall describe the stability of the substance or mixture and the possibility of hazardous reactions occurring under certain conditions of use and also if released into the environment, including, where appropriate, a reference to the test methods used. If it is stated that a particular property does not apply or if information on a particular property is not available, the reasons shall be given.

The existing Concawe guidance on this section has not been changed.

The aim of Section 10 should provide the reader with a simple and concise overview on the chemical's reactivity and possible physicochemical hazards, as well as their consequences.

This section is expected to be mostly similar for UVCB petroleum substances and their mixtures. (Only where necessary, the relevant hazardous components contributing to the risk management can be specifically mentioned.)

Section 10 should be relevant for the whole product, i.e. in case of a mixture all the mixture's hazards as resulted from the component substances should be addressed.

In the sense of typical chemical reactivity, petroleum products are stable. Neither hydrocarbons nor typical fuel additives or oxygenate components are reactive under normal ambient conditions.

The major physicochemical risks associated with hydrocarbons relate to their flammability. Contact with strong oxidizing chemicals may also lead to violent reactions. These issues need to be addressed in Sections 10.4 'Conditions to avoid' and 10.5 'Incompatible materials'. Detailed advice on safe conditions of use and storage is to be provided in Section 7.

In addition, as pointed out in the ECHA Guidance (2020), a particular feature of Section 10 is the high degree of potential overlap with other SDS Sections, as well as between the subsections of Section 10 itself. It is recommended to review Section 10 against the relevant other Sections (Sections 7, 8.2 and 9) to avoid giving conflicting information. Unnecessary repetition between Sections should also be avoided and the information must be given in a clear and concise manner.

10.1. REACTIVITY

This subsection focuses on the qualitative description of the intrinsic reactive properties of the product. In general, **there are no known reactivity hazards associated with hydrocarbons**. A consistency check (potential overlap) should be made with Sections 7 and/or 9. Possible hazard class information should be given in these Sections instead of Section 10.



10.2. CHEMICAL STABILITY

Information on stability under normal ambient and/or anticipated conditions should be given. **Hydrocarbons are stable**. No specific consistency check is needed.

10.3. POSSIBILITY OF HAZARDOUS REACTIONS

This subsection focuses on the outcomes of possible hazardous reactions. Under normal conditions of storage and use hazardous reactions will not occur. A consistency check (potential overlap) should be made with Sections 2 and 9. Possible dust or vapour/air explosion hazards should be discussed in these Sections instead of Section 10.

10.4. CONDITIONS TO AVOID

As petroleum products are typically flammable or combustible substances, **avoiding high temperatures, sparks, flames or other ignition sources is recommended.** Static electricity hazards may also need to be pointed out. If appropriate, a very brief description of risk management measures may be given.

A consistency check (potential overlap) should be made with Sections 7.1 and 7.2.

10.5. INCOMPATIBLE MATERIALS

Typically, strong oxidizing agents, acids, alkalis or halogens may be considered incompatible with petroleum products. A consistency check (potential overlap) should be made with Sections 7.1 and 7.2.

10.6. HAZARDOUS DECOMPOSITION PRODUCTS

Hazardous decomposition products formed by other means than combustion are typically not known. A consistency check (potential overlap) should be made with Section 5. Possible hazardous combustion products should be given in this Section instead of Section 10.

<u>An example for Section 10 of SDS for petroleum products is presented in</u> <u>Appendix 3.</u>

11. SDS SECTION 11: TOXICOLOGICAL INFORMATION

Direct citation from the legal text of the Regulation (EU) 2020/878:

This section of the safety data sheet is meant for use primarily by medical professionals, occupational health and safety professionals and toxicologists. A concise but complete and comprehensible description of the various toxicological (health) effects and the available data used to identify those effects shall be provided, including where appropriate information on toxicokinetics, metabolism and distribution. The information in this section shall be consistent with the information provided in the registration and/or in the chemical safety report where required, and with the classification of the substance or mixture.

The main new requirement for this section is to provide information on any endocrine disruptive properties of the substance or substances in the mixture, where available. Also the names of sub-headings have been changed. Some more detailed recommendations on CLP hazard classes are also given.

Petroleum substances are usually tested and REACH registered as "whole" UVCB substances, and classified based on CLP Annex VI, supported by the Concawe Classification and Labelling (C&L) Recommendations (Concawe, 2022). When blended with other components or additives, the petroleum substances become mixtures.

The substance information in this section on their hazards to human health should be based on the content of the lead registration dossier, and be consistent with the C&L of the specific member dossier. The application principles of CMR marker substances (like benzene, n-hexane, toluene for naphthas) are described in the Concawe C&L report (Concawe, 2022).

For mixtures, all components contribute to the C&L based on the CLP mixture rules.

Consistency with the sections 2, 4, 6, 7, 8, 9, 13, 14, 15 of the SDS to be checked.

As recommended by the ECHA SDS Guidance 2020, Section 2.27, additional testing should <u>not</u> be initiated on the basis of a need to "fill-in empty fields" in an SDS. This applies especially to animal testing.

Substances

The information in this section should be consistent with the information provided in the substance registration dossiers and in the CSRs from the application of REACH Annexes VII to XI. Amount of data available depends on the registered tonnage band. Concawe's UVCB petroleum substances have typically full registrations and thus endpoint data determined for all their relevant endpoints.

Mixtures

There can be significant differences in availability of endpoint test data for UVCB petroleum substances and other components of a mixture. Registration endpoint data for the substances should, however, be available depending on the registered tonnage band.



For a given endpoint, if a mixture has not been tested as a whole, <u>relevant</u> information on the substances listed under section 3 shall be provided; the entries should clearly indicate to which substance in the mixture the data apply.

Only <u>relevant</u> data for hazardous mixture components are recommended to be mentioned (in line with section 2 and 3, to ensure clarity and consistency). For example, the components contributing to the classification of the mixture for a particular endpoint.

Moreover, for CMR endpoints, according to Art 6(3) of CLP Regulation, the <u>relevant</u> available information for the substances in the mixture have to be used and listed.

11.1. INFORMATION ON HAZARD CLASSES AS DEFINED IN REGULATION (EC) NO 1272/2008

The following information on hazard classes as defined in the CLP Regulation (EC) No 1272/2008 (yet not necessarily in this order) should be considered:

Property	Recommended statement ¹	Motivation / Justification ²
(a) acute toxicity	The classification conclusion of the substance or mixture (including ATEs, if applied)	If not classified, the reasoning should be stated: lack of data / technical impossibility to obtain the data / inconclusive data / "based on available data, the classification criteria are not met"
(b) skin corrosion/irritation	The classification conclusion of the substance or mixture	If not classified, the reasoning should be stated: lack of data / technical impossibility to obtain the data / inconclusive data / "based on available data, the classification criteria are not met"
(c) serious eye damage/ irritation	The classification conclusion of the substance or mixture	If not classified, the reasoning should be stated: lack of data / technical impossibility to obtain the data / inconclusive data / "based on available data, the classification criteria are not met"
(d) respiratory or skin sensitisation	The classification conclusion of the substance or mixture	If not classified, the reasoning should be stated: lack of data / technical impossibility to obtain the data / inconclusive data / "based on available data, the classification criteria are not met"
(e) germ cell mutagenicity	The classification conclusion of the substance or mixture	If not classified, the reasoning should be stated: lack of data / technical impossibility to obtain the data / inconclusive data /



Property	Recommended statement ¹	Motivation / Justification ²
		"based on available data, the classification criteria are not met"
(f) carcinogenicity	The classification conclusion of the substance or mixture	If not classified, the reasoning should be stated: lack of data / technical impossibility to obtain the data / inconclusive data / "based on available data, the classification criteria are not met"
(g) reproductive toxicity	The classification conclusion of the substance or mixture	If not classified, the reasoning should be stated: lack of data / technical impossibility to obtain the data / inconclusive data / "based on available data, the classification criteria are not met"
(h) STOT-single exposure	The classification conclusion of the substance or mixture	If not classified, the reasoning should be stated: lack of data / technical impossibility to obtain the data / inconclusive data / "based on available data, the classification criteria are not met"
(i) STOT-repeated exposure	The classification conclusion of the substance or mixture	If not classified, the reasoning should be stated: lack of data / technical impossibility to obtain the data / inconclusive data / "based on available data, the classification criteria are not met"
(j) aspiration hazard	The classification conclusion of the substance or mixture	If not classified, the reasoning should be stated: lack of data / technical impossibility to obtain the data / inconclusive data / "based on available data, the classification criteria are not met"

¹ <u>Substances</u>: as in the registration dossier or Concawe C&L report (Concawe, 2022). Mixtures: as available and communicated e.g. by the supplier. In minimum the name of the component(s) causing the classification. Also ATEs applied for mixtures are to be provided.

² ECHA, 2020

11.2. **INFORMATION ON OTHER HAZARDS**

In this sub-section, it is requested to provide information on adverse health effects caused by endocrine disrupting properties, where available, for the substances identified as having endocrine disrupting properties in Subsection 2.3 "other hazards".



Since these properties have not been documented for UVCB petroleum substances, it is advised to use the phrase: "The currently available information does not indicate that this substance has endocrine disrupting properties as defined by the criteria set out in Section B of Regulation (EU) No 2017/2100."

Additionally, other <u>relevant</u> information on adverse health effects can be included even when not required by the classification criteria.

<u>An example for Section 11 of Safety Data Sheet for petroleum products is presented</u> <u>in Appendix 3.</u>



12. SDS SECTION 12: ECOLOGICAL INFORMATION

Direct citation from the legal text of the Regulation (EU) 2020/878:

This section of the safety data sheet shall provide information to enable evaluation of the environmental impact of the substance or mixture where it is released to the environment. Subsections 12.1 to 12.7 of the safety data sheet shall provide a short summary of the data including, where available, relevant test data and clearly indicating species, media, units, test duration and test conditions. This information may assist in handling spills, and evaluating waste treatment practices, control of release, accidental release measures and transport. 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. Additionally, if a substance or mixture is not classified for other reasons (for example, due to the technical impossibility of obtaining the data or to inconclusive data) this should be clearly stated on the safety data sheet.

Some properties are substance specific, i.e. bioaccumulation, persistence and degradability, and that information shall be given, where available and appropriate, for each relevant substance in the mixture (i.e. those which are required to be listed in section 3 of the safety data sheet and are hazardous to the environment or PBT/vPvB - substances). Information shall also be provided for hazardous transformation products arising from the degradation of substances and mixtures.

The information in this section shall be consistent with the information provided in the registration and/or in the chemical safety report where required, and with the classification of the substance or mixture.

Where reliable and relevant experimental data are available, that data shall be provided and take precedence over information obtained from models.

This section provides information for the evaluation of the environmental effects of the product when released to the environment. The main new requirement is to provide information on any endocrine disruptive properties of the substance or substances in the mixture, where available. Also a new sub-heading for endocrine disrupting properties have been added. Some more detailed recommendations on environmental hazards are also given.

The information in this section should apply to the substance or mixture as placed on the market and be consistent with the information provided in the registration and/or in the chemical safety report where required, and with the classification of the substance or mixture. Check consistency with sections 2, 3, 6, 7, 9, 13, 14, 15 of the SDS.

There can be significant differences in availability of endpoint test data for UVCB petroleum substances and other components of a mixture. Registration endpoint data for the substances should, however, be available depending on the registered tonnage band. As recommended by the ECHA SDS Guidance 2020, Section 2.27, additional testing should <u>not</u> be initiated on the basis of a need to "fill-in empty fields" in an SDS. This applies especially to animal testing.



Substances

The information in this section should be consistent with the information provided in the substance registration dossiers and in the CSRs from the application of REACH Annexes VII to XI. Amount of data available depends on the registered tonnage band. Concawe's UVCB petroleum substances have typically full registrations and thus endpoint data determined for all their relevant endpoints.

Given the complexity of petroleum substances which are UVCBs, the information communicated in this section of the SDS can be generated based on testing performed with the full substance, only part of its constituents, data generated on analogues or using modelling results based on known composition of the substance. Different approaches can be used for different properties (e.g. it is possible to have full substance information for persistence, and use constituent-based results for bioaccumulation). In general, it is advisable to use experimental results when available. Unless indicated otherwise, the data presented in a SDS is representative of the product as a whole, rather than for individual components.

Both experimental results and predicted toxicity values can be found in the registration dossier of the substance.

Mixtures

For a given endpoint, if a mixture has not been tested as a whole, <u>relevant</u> information on the substances listed under section 3 shall be provided; the entries should clearly indicate to which substance in the mixture the data apply.

Only data for <u>relevant</u> hazardous mixture components are recommended to be mentioned (in line with section 2 and 3, to ensure clarity and consistency). For example, the ones contributing to the classification of the mixture for a particular endpoint.

Some properties are substance specific (subsections 12.2 - 12.6), and information should be given where available and appropriate, for each individual substance in the mixture which is required to be listed in Section 3 and is hazardous to the environment or has PBT/vPvB properties.

12.1. TOXICITY

Despite the complexity of UVCB petroleum substances, experimental aquatic toxicity results can be generated at whole substance level, and are available from the work performed by Concawe and its Member Companies. This testing is performed using Water Accommodated Fractions (WAF) and therefore the results are expressed as LL50 for the case of acute toxicity, and NOELR for chronic toxicity, as opposed to the typical LC50 and NOEC (which are used for aquatic testing of discrete substances).

When experimental values are not available, it is possible to use compositional data to generate aquatic toxicity estimations using the QSAR tool Petrotox. These values provide a reliable and conservative assessment that can be used for the purpose of the SDS, both for acute and chronic toxicity at three trophic levels. Petrotox can be downloaded from the Concawe website and needs the installation of the open source tool KNIME to run.



Ideally, experimental information on acute and chronic aquatic toxicity for three trophic levels should be available for a toxicity risk assessment. However, since this would rarely be the case for any petroleum substance, it is recommended to use experimental results when available, and Petrotox predictions to provide estimations for the missing values.

When several different values are available for the same species and duration, it is advisable to use the most reliable one (or the one flagged as "Key study"). In case several reliable studies are available, all of them can be reported (in case there are only 2 or 3 values) or simply the minimum and maximum effect values for those studies can be indicated (for the few cases were many reliable values may be available).

Species	Acute (LL50)	Chronic (NOELR)
Fish		mg/L (data source, e.g OECD 203 or Petrotox prediction)
Invertebrates	mg/L	mg/L
Algae	mg/L	mg/L

These effect values could be provided in a Table like the one shown below:

It is also possible to provide qualitative statements in addition to the toxicity values, which can make the SDS easier to use. For instance, the GHS classification cut-offs can be used to indicate "*The substance is harmful to aquatic organisms*" or "*The substance is very toxic to aquatic organisms*".

12.2. PERSISTENCE AND DEGRADABILITY

Information covering the biodegradability of the full UVCB substance is more rarely available, but it can sometimes be generated. This is normally in the form of ready biodegradability tests. As happens for the assessment of toxicity, it is recommended to use these experimental values if available. In this case a generic sentence indicating the result of the test such as *"this substance degrades quickly in the environment"* or *"the substance is not readily biodegradable"* can be used.

More frequently, experimental information at UVCB substance level will not be available. In this case, caution should be advised. According to Concawe's evaluation of the Persistence, Bioaccumulation, and Toxicity of Petroleum Hydrocarbons documented in the "PBT report" (Concawe, 2019), some of the constituents in petroleum substances can potentially fulfil the criteria for being considered persistent. For instance, any constituent with a carbon number of 13 or less is considered as biodegradable. Conversely, every constituent with a carbon number of 21 or more (except n-paraffins) is potentially persistent.

In the absence of ready biodegradability data, it is therefore advised to use the generic sentence: "This UVCB substance may contain constituents which do not degrade rapidly in the environment".

Photodegradation can also be an important route of biodegradation for PAHs, therefore, in case a specific petroleum substance contains PAH, it is also suggested to account for this phenomenon by using the sentence: "This substance contains up to X % of constituents which degrade quickly under direct light" or "This substance contains constituents which degrade quickly under direct light".



12.3. BIOACCUMULATIVE POTENTIAL

Experimental information at UVCB substance level will not be available. In this case, caution should be advised. According to Concawe's PBT report (Concawe, 2019) some of the constituent in petroleum substances can potentially fulfil the criteria for being considered bioaccumulative. However, trophic magnification factors available indicate that petroleum constituent do not have the potential to biomagnify through the food chain. It is therefore advised to use the generic sentence: "This substance may contain constituents that bioaccumulate, but do not biomagnify in biota".

12.4. MOBILITY IN SOIL

Based on the physicochemical properties of **petroleum UVCB constituents**, there are extremely few cases of structures present in them that could present any mobility in soil. It is therefore suggested to add the following sentence: "*This substance is not mobile in soil*".

However, for the case of mixtures, petroleum substances are sometimes mixed with components (such as alcohols or ethers) showing greater mobility. When it is known that those components are significantly more mobile than the petroleum substance, it is recommended to use instead the statement "*This product contains additives which, if released into the environment, present moderate mobility in soil*".

It is also common to use this section to add information on other environmental compartments, by adding statements such as "*This product floats on water*" or "*Expected to migrate from water to soil*".

12.5. RESULTS OF PBT AND VPVB ASSESSMENT

For most petroleum UVCB substances, reference can be made to the PBT assessment contained in the internal Concawe PBT report which is subject to regular review (Concawe, 2019). The current conclusion is that some of the constituents existing in UVCB petroleum substances may fulfil either the criteria for P or B or T, but there are no structures that fulfil all the criteria for PBT or vPvB. However, regulatory decisions in recent years disagree with this conclusion, and as a result a number of hydrocarbons present in petroleum substances have been listed as PBT/vPvB.

Where a chemical safety report is required for the UVCB substance, the information in this section of the safety data sheet shall be consistent with the results of the PBT and vPvB assessment as set out in the chemical safety report.

The conclusion of the PBT and vPvB assessment of the registered substance should be reflected accordingly in this section:

"This substance is a UVCB and may contain constituents identified as SVHC. No other representative hydrocarbon structures were found to meet the PBT / vPvB criteria."

Otherwise, the following generic sentence proposed by ECHA guidance <u>may</u> be used:

"According to the results of its assessment, this substance is not a PBT or a vPvB".



For the products that are **mixtures**, the following generic sentence proposed by ECHA guidance is recommended: *"This mixture does not contain any substances that are assessed to be a PBT or a vPvB"*.

12.6. ENDOCRINE DISRUPTING PROPERTIES

Since these properties have not been documented for UVCB petroleum substances, it is advised to use the phrase: "The currently available information does not indicate that this substance has endocrine disrupting properties as defined by the criteria set out in Section B of Regulation (EU) No 2017/2100."

12.7. OTHER ADVERSE EFFECTS

Available information - if any - such as environmental fate (exposure), photochemical ozone creation potential, ozone depletion potential, or global warming potential shall be addressed here.

An example for Section 12 of Safety Data Sheet for petroleum products is presented in Appendix 3.



13. SDS SECTION 13: DISPOSAL CONSIDERATIONS

Direct citation from the legal text of the Regulation (EU) 2020/878:

This section of the safety data sheet shall provide information for proper waste management of the substance or mixture and/or its container to assist in the determination of safe and environmentally preferred waste management options, consistent with the requirements of Directive 2008/98/EC of the European Parliament and of the Council by the Member State in which the safety data sheet is being supplied. Information relevant for the safety of persons conducting waste management activities shall complement the information given in section 8.

Where a chemical safety report is required and where a waste stage analysis has been performed, the information on the waste management measures shall be consistent with the identified uses in the chemical safety report and the exposure scenarios from the chemical safety report set out in the annex to the safety data sheet.

No changes were introduced with the revised REACH Annex II (EU, 2020).

This section is expected to be mostly similar for UVCB petroleum substances and their mixtures. (Only where necessary, the relevant hazardous components contributing to the risk management can be specifically mentioned).

Section 13 should be relevant for the whole product, i.e. in case of a mixture all the mixture's hazards as resulted from the component substances should be addressed.

13.1. WASTE TREATMENT METHODS

In this section, information shall be provided for the proper waste management of the petroleum products and the appropriate waste treatment methods.

In case the waste is likely to include any contaminated packaging waste, advice on treatment methods for contaminated packaging should also be provided.

Ensure consistency of this section with the classification in Section 2 and with the exposure controls in Section 8 as well as the annexed exposure scenarios. Where possible, specify the relevant List of Wastes (LoW) codes according to the European Waste Catalogue Code (Decisions 2000/532/EC, 2001/118/EC).

As the legal responsibility for disposal rests with the disposer, it is recommended to use the following generic sentence "Dispose of in accordance with all applicable local, national and European regulations".

An example for Section 13 of Safety Data Sheet for petroleum products is presented in Appendix 3.

Based on the P statements of classified mixtures and any other information resulting from the consolidation of exposure scenarios of mixture components, it is suggested to use ESCom phrases from the Chemical Safety Assessment as per **Appendix 1**.



14. SDS SECTION 14: TRANSPORT INFORMATION

Direct citation from the legal text of the Regulation (EU) 2020/878:

This section of the safety data sheet shall provide basic classification information for the transport/shipment of substances or mixtures mentioned in section 1 by road, rail, sea, inland waterways or air. Where such information is not available or relevant this shall be stated.

Where relevant, this section shall provide information on the transport classification for each of the following international agreements which are transposing the UN Model Regulations for specific transport modes: the Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), the Regulations concerning the International Carriage of Dangerous Goods by Rail (RID) and the European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN), all three of which have been implemented by Directive 2008/68/EC of the European Parliament and of the Council, as well as the International Maritime Dangerous Goods (IMDG) Code for the transport of packaged goods and the relevant IMO codes for the transport of bulk cargo by sea and the Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO TI).

The existing Concawe guidance on this section has not been changed.

This section is expected to be mostly similar for UVCB petroleum substances and their mixtures. Minor changes in the names of sub-headings have been made. Guidance on Safe Use from registration dossiers can be used as references for this section. (Only where necessary, the relevant hazardous components contributing to the risk management can be specifically mentioned.)

Section 7 should be relevant for the whole product, i.e. in case of a mixture all the mixture's hazards as resulted from the component substances should be addressed.

This section of the safety data sheet shall provide basic Dangerous Goods classification information for the transport/shipment of substances or mixtures by road, rail, sea, inland waterways or air.

14.1. UN NUMBER OR ID NUMBER

The UN number or the ID number determined under ADR, RID, ADN, IMDG or ICAO / IATA shall be provided.

The ID number is only applicable for carriage by inland waterways in tank-vessels.

14.2. UN PROPER SHIPPING NAME

The proper shipping name / name and description as provided in Table A of Chapter 3.2 of ADR, RID, Tables A and Table C of Chapter 3.2 of ADN, Chapter 3.2 of IMDG and the list of Dangerous Goods in Section 4.2 of ICAO / IATA, supplemented, when applicable, for generic or "not otherwise specified" (N.O.S.) names with the technical name(s) and or marine pollutant in brackets as required, shall be provided.



14.3. TRANSPORT HAZARD CLASS(ES)

The transport hazard class (and subsidiary risks) assigned to the substances or mixtures based on the predominant hazard that they present according to ADR, RID, ADN, IMDG and ICAO / IATA regulations shall be provided.

14.4. PACKING GROUP

The packing group number (I, II, III) shall be provided, if applicable, as required by the ADR, RID, ADN, IMDG and ICAO / IATA regulations. The packing group number is assigned to certain substances / mixtures in accordance with the degree of danger they represent.

For the purpose of carriage by inland waterways in tank-vessels some substances or mixtures may be further subdivided.

14.5. ENVIRONMENTAL HAZARDS

It shall be indicated whether the substance or mixture is environmentally hazardous according to the criteria reflected in ADR, RID, ADN, and whether it is a marine pollutant according to the IMDG Code.

For the purpose of carriage by inland waterways in tank-vessels these criteria may be further subdivided.

14.6. SPECIAL PRECAUTIONS FOR USER

Information shall be provided on any special precautions which a user should or must take or be aware of in connection with transport or conveyance for all relevant modes of transport.

14.7. MARITIME TRANSPORT IN BULK ACCORDING TO IMO INSTRUMENTS

This subsection only applies when cargoes are intended to be carried in bulk according to IMO instruments and is applicable to liquid, solid and liquefied gas cargoes in bulk.

Where applicable the following information, Bulk cargo /Product name, Ship type, Pollution category, whether the cargo is considered hazardous to the marine environment or the material is hazardous in bulk should be provided

If it is not intended that the substance/mixture be transported in bulk a statement to this effect should be made, for example: *"Product is not transported in bulk."*

An example for Section 14 of SDS for petroleum products is presented in Appendix 3.



15. SDS SECTION 15: REGULATORY INFORMATION

Direct citation from the legal text of the Regulation (EU) 2020/878:

This section of the safety data sheet shall describe the other regulatory information on the substance or mixture that is not already provided in the safety data sheet (such as whether the substance or mixture is subject to Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer, Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC or Regulation (EC) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of dangerous chemicals.

The existing Concawe guidance on this section has not been changed.

This Section of the safety data sheet is to describe the other regulatory information that is not already provided elsewhere in the document, i.e. whether the substance or mixture is subject to other regulatory acts, either at EU or national level, such as:

- REACH authorisations
- REACH restrictions
- Exposure to chemical agents and chemical safety legislations
- Ozone depleting substances
- Persistent organic pollutants
- Export and import of dangerous chemicals
- Seveso (major accident hazards) category

15.1. SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE

Sub-section 15.1 should include confirmation of applicability of indicated legislation with substance identity information in Section 3.

Appendix 2 includes a non-exhaustive list of EU regulatory acts that may be relevant to petroleum substances and mixtures.

One reliable resource is ECHA's EU Chemicals Legislation Finder (EUCLEF) (via ECHA, 2022), which gives an overview of the EU's legislation on chemicals and where information is available on petroleum substances: applicable laws and associated obligations. For each piece of legislation, a summary of all the relevant information is given, including the scope, obligations, exemptions, regulatory activities and lists of impacted substances, together with links to the full legal texts in all EU languages.



Obviously, in the case of EU Directives, relevant are the national transposing legislation in the respective Member State, as well as any other national measures that may be applicable.

In case the substance as such or in the mixture is subject of specific provisions such as authorisations given under Title VII or restrictions under Title VIII of REACH Regulation, these provisions have to be mentioned in this sub-section. In case an authorisation imposes conditions or monitoring arrangements to a downstream user they have to be provided as well.

15.2. CHEMICAL SAFETY ASSESSMENT

Sub-section 15.2 indicates whether chemical safety assessment for the substance or the mixture has been carried out. If a chemical safety assessment is indicated, it also has to be confirmed that exposure scenario(s) (ESs) for the relevant hazardous petroleum substance, or safe use information for hazardous mixture, is/are attached (in the Annex), as relevant for the identified uses listed in Section 1 of the SDS.

If a classified substance has been registered as a transported intermediate under strictly controlled conditions as per REACH Article 18, no chemical safety assessment is required and this should be indicated.

In case of mixtures, where no ESs Annex is attached and the preferred option is to integrate content-consolidated extract of the relevant information on Operational Conditions and Risk Management Measures (RMMs) from the received ESs in the relevant sections of the SDS for the mixture, this should be specified as appropriate.

An example for Section 15 of Safety Data Sheet for petroleum products is presented in Appendix 3.



16. SDS SECTION 16: OTHER INFORMATION

Direct citation from the legal text of the Regulation (EU) 2020/878:

This section of the safety data sheet shall contain other information that is not included in sections 1 to 15, including information on the revision of the safety data sheet such as: (a) in the case of a revised safety data sheet, a clear indication of where changes have been made to the previous version of the safety data sheet, unless such indication is given elsewhere in the safety data sheet, with an explanation of the changes, if appropriate. A supplier of a substance or mixture shall be able to provide an explanation of the changes upon request; (b) a key or legend to abbreviations and acronyms used in the safety data sheet; (c) key literature references and sources for data; (d) in the case of mixtures, an indication of which of the methods of evaluating information referred to in Article 9 of Regulation (EC) No 1272/2008 was used for the purpose of classification; (e) a list of relevant hazard statements and/or precautionary statements. Write out the full text of any statements, which are not written out in full under sections 2 to 15; (f) advice on any training appropriate for workers to ensure protection of human health and the environment.

The existing Concawe guidance on this section has not been changed.

This Section is meant to include information that is not included in previous Sections relevant to the SDS compilation of the SDS itself, such as:

- information on the revision of the SDS: changes to previous version, with brief explanation of the changes, if appropriate;
- key to abbreviations and acronyms used in the document;
- key literature references and sources for data (e.g. the supplier's documentation and CSR, the ECHA substance database (ECHA 2022), GESTIS (IFA, 2022), etc.);
- full text of Hazard or Precautionary statements mentioned in Sections 2.1 and 3.2;
- advice on health and environment training appropriate to workers related to the respective substance or mixture they use or may be exposed to in the course of their work.

In the case of mixtures (e.g. motor fuels), details must be provided regarding the method used to determine the classification for the hazard classes where the classification criteria are met. However, it is not necessary to list the basis for determining that a mixture does not meet the classification criteria for a particular hazard class.

If disclaimers (e.g. *"the information herein is based upon the present state of our knowledge")* are to be included in the SDS, they may be placed in this Section, or placed outside any of the defined sections. This is to make clear that such disclaimers are not part of the regulated format and content as defined in Annex II of REACH Regulation. <u>An example for Section 16 of SDS for petroleum products is presented in Appendix 3.</u>



17. EXTENDED SDSs (ANNEXES)

The REACH regulation requires that Exposure Scenarios (ESs), detailing operational conditions and risk management measures needed for safe use, for all identified uses are developed via the chemical safety assessment as part of the substance registration if the substance meets the criteria for hazard classification. The ESs should be annexed to the SDS of the substance. CONCAWE has made use of a series of standardised use titles, as documented in the Handbook (Concawe 2021b).

To date, there is no mandatory or harmonised format for the ES to be annexed to the substance SDS. Systems such as CHESAR can produce as an output the ES for communication in a particular format that can be used for SDS authoring. SDS authors can only annex ESs to a SDS if these have been included in the substance registration dossier but are not obliged to include the ESs for all registered uses for a substance.

If a classified substance has been registered as a transported intermediate under strictly controlled conditions as per REACH Article 18, no Exposure Scenarios are required to be annexed to the SDS.

If a substance carries only very limited hazard classification (for example, skin irritant), then Exposure Scenarios for identified uses may be (nearly) identical and appear repetitive. In such an event, it may be conceivable to consolidate the Exposure Scenarios into a single one for documentation efficiency reasons.

<u>A CONCAWE recommendation for eSDS for petroleum products is presented in</u> <u>Appendix 3.</u>



18. APPROACHES TO SAFE USE COMMUNICATION FOR CLASSIFIED MIXTURES

Based on ECHA guidance on the compilation of safety data sheets (ECHA, 2020) and guidance for downstream users (ECHA, 2014a), the three (3) options for including information to communicate to downstream users are the following:

- **Option 1:** Attach relevant ES(s) for the substances in the mixture in an annex to SDS;
- **Option 2:** Append safe use information for the mixture-as an annex to the SDS;
- **Option 3:** Integrate the relevant information of the ES(s) into the main body of the SDS of the product (mixture) SDS.

The formulator can select the most effective method or provide information in different ways to different customer groups as appropriate. The process should be as efficient as possible, proportionate to the risk, and relevant and understandable to the recipients.

Option 1 is the most suitable approach when communicating to customers who are also formulators. It may also be suitable for end users of the mixture when the appropriate RMMs for an identified use are clearly specified in one ES for each identified use¹. This is an easy option for SDS authors and is clear for inspectors. However, it may not be straight-forward to understand by the recipient.

Option 2 is the most suitable approach when useful information cannot be readily integrated into the main body of the SDS, when there is a wide range of uses with different conditions of use and when the ESs are more complex.

Two approaches have been developed by industry to identify the information to communicate.

The first approach, namely the "Safe Use of Mixtures Information" (SUMI), is where sector organisations identify the RMMs for typical products and uses within their sector. They generate SUMIs giving this advice in a user-friendly way in a suitable template². The formulators select the appropriate SUMI for their product, and check that it is consistent with the ES received from their suppliers. An explanatory document³ has been published by the Downstream Users of Chemicals Coordination group (DUCC, 2017). SUMIs are a means to communicate information on the safe use of mixtures to end-users, i.e. professional and industrial workers. Concawe intends to publish SUMIs for professional use for some of the main product groups (Concawe, 2021b). <u>An example of a SUMI on professional diesel fuel use is included in</u> **Appendix 4**.

The second approach, namely the "Lead Component Identification" (LCID), is intended for situations when a suitable SUMI is not available. The formulator identifies the lead components in a mixture and derives safe use information for the mixture from the RMMs for the lead components. Cefic, the European Chemical

² A harmonised format to be agreed among sector organisations

³ <u>https://static.ducc.eu/media/file/2021-</u>

¹ Identified uses of petroleum substances are documented in the Concawe Handbook which is updated annually; available at: <u>https://www.concawe.eu/reach/documents-to-download/</u>

^{08/}How%20to%20use%20SUMIs_operational%20framework_18%2007%202017.pdf



Industry Council, has published a practical guide on the LCID methodology⁴ with German VCI (Cefic and VCI, 2018). For Concawe products, the LCID methodology can be used for Naphthas as lead component.

<u>Option 3</u> is the recommended approach when communicating to end users in the case where there is a relatively small number of identified uses and/or conditions of use. It is not suitable if diverse advice on the operational conditions (OCs) and RMMs for various uses is necessary.

It is recommended that the OCs and RMMs from an ES are clearly identified <u>as such</u> in the SDS of the mixture. Therefore, the use of the harmonised catalogue of standard phrases for communication of risk management advice (ESCom), improves the level of communication in the supply chain. The Concawe specific EUPHRAC phrases are included in the ESCom package.

To facilitate option 3, the relationship between ES and SDS sections is shown in the Table below:

ES section	SDS Section(s)
ES name	1.2
Operational conditions and risk management measures	7, 8
Control of workers exposure	
Product (article) characteristics	7, 8, 9
• Amount used (or contained in articles)	7, 8
• Frequency and duration of use/exposure	7, 8
• Technical ⁵ and organisational ⁶ conditions and measures	(5, 6), 7, 8
• Conditions and measures related to personal protection, hygiene and health evaluation	(5, 6), 7, 8
Other conditions affecting workers exposure	7, 8
Control of consumer exposure	
Product (article) characteristics	7, 8, 9
• Amount used (or contained in articles)	7, 8
• Frequency and duration of use/exposure	7, 8
• Information and behavioral advice for consumers ⁷	1, 2

⁴ <u>https://cefic.org/app/uploads/2016/03/Practical-Guide-Safe-Use-Information-for-Mixtures-under-</u> <u>REACH_v6-1-1.pdf</u>

 $[\]overline{}^{5}$ To prevent release at process level (source) (7, 8) and control dispersion from source to worker (7, 8)

⁶ To prevent/limit releases, dispersion and exposure (5, 6, 7, 8)

⁷ Adult/child, indoors/outdoors



ES section		SDS Section(s)
٠	Other conditions affecting consumers exposure	7, 8
Contro	of environmental exposure	
•	Product (article) characteristics	7, 8, 9
•	Amount used	7, 8
•	Frequency and duration of use (or from service life)	7, 8
•	Technical ⁸ and organisational ⁹ conditions and measures	6, 7, 8
•	Conditions and measures related to biological sewage treatment plant ¹⁰	12
•	Conditions and measures related to municipal sewage treatment plant	8, 12, 13
•	Conditions and measures related to external treatment of waste (including article waste)	13
•	Other conditions affecting environmental exposure	7, 8, 12

 ⁸ To prevent release at process level (source) (7), to reduce or limit discharges, air emissions and releases to soil (7, 8)
 ⁹ To prevent/limit release from site (6, 7, 8)
 ¹⁰ Incl. discharge rate of STP, application of the STP sludge on soil



19. GLOSSARY

ATE	Acute Toxicity Estimate
BLV	Biological Limit Values
BOEL	Bionding Occupational Exposure Limit Value
C&L	Classification and Labelling
CLP	Regulation on Classification, Labelling and Packaging of substances and
	mixtures (Regulation (EC) No 1272/2008)
CAS	Chemical Abstract Service
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
DNEL	Derived No Effect Level
ECHA	European Chemicals Agency
EN	European Norm
ES	Exposure Scenario
ESCom	Exposure Scenario Communication
eSDS	Extended Safety Data Sheet (SDS with Annex containing ES)
GES	Generic Exposure Scenarios
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
H Statement	Hazard Statement
IOEL	Indicative Occupational Exposure Limit Value
LC50	Lethal Concentration 50 %
LL50	Lethal Loading 50 %
M Factor	Multiplication Factor
NOEC	No Observed Effect Concentration
NOELR	No Observable Effect Loading Rate
OC	Operational Condition
OEL	Occupational Exposure Limit Value
P Statement	Precautionary Statement
PBT/vPvB	Persistent, Bioaccumulative, Toxic / very Persistent, very Bioaccumulative
PNEC	Predicted No Effect Concentration
QSAR	Quantitative Structure-Activity Relationship
REACH	Regulation concerning the Registration, Evaluation, Authorisation and
	Restriction of Chemicals (Regulation (EC) No 1907/2006)
RMM	Risk Management Measure
SCBA	Self-Contained Breathing Apparatus
SCL	Specific Concentration Limit
SDS	Safety Data Sheet
UFI	Unique Formula Identifier
UVCB	Unknown or Variable composition, Complex reaction products or of Biological
	materials
WAF	Water Accomodated Fraction



20. **REFERENCES**

Cefic (2022) ESCom Package Guidance. Brussels: The European Chemical Industry Council <u>https://cefic.org/guidance/reach-implementation/escom-package-guidance/</u> (remark: the maintenance responsibility has recently been handed over from Cefic to BDI).

Cefic and VCI (2018) REACH Practical Guide on Safe Use Information for Mixtures under REACH. The Lead Component Identification (LCID) Methodology. Final version 6.1.1. 31.8.2018. Brussels: The European Chemical Industry Council

https://cefic.org/app/uploads/2016/03/Practical-Guide-Safe-Use-Information-for-Mixturesunder-REACH_v6-1-1.pdf

Concawe (1997) Petroleum products - first aid emergency and medical advice. Report No. 1/97. Brussels Concawe

Concawe (2002a) Amended safety data sheet directive (2001/58/EC). Report No. 5/02. Brussels: Concawe

https://www.concawe.eu/wp-content/uploads/2017/01/2002-00123-01-e.pdf

Concawe (2002b) Method for monitoring exposure to gasoline vapour in air - revision 2002. Report No. 8/02. Brussels: Concawe https://www.concawe.eu/wp-content/uploads/2017/01/rpt_02-8-2003-01127-01-e.pdf

Concawe (2004) Method for monitoring exposure to LPG containing small amounts of 1,3butadiene. Report No. 12/04. Brussels: Concawe https://www.concawe.eu/wp-content/uploads/2017/01/rpt0412-2004-02496-01-e.pdf

Concawe (2012) REACH - Analytical characterisation of petroleum UVCB substances. Report No. 7/12. Brussels: Concawe https://www.concawe.eu/wp-content/uploads/2017/01/rpt_12-7-2012-05443-01-e.pdf

Concawe (2015a) Risk assessment for emissions from hot heavy fuel oil during barge loading. Report No. 1/15R. Brussels: Concawe https://www.concawe.eu/wp-content/uploads/2017/01/2016-04-18_rpt_15-1r-withappendices-final-revised-apr2016.pdf

Concawe (2015b) Monitoring method for inhalation exposure to gas oil vapour and aerosol. Report No. 8/15. Brussels: Concawe https://www.concawe.eu/wp-content/uploads/2017/01/rpt_15-8.pdf

Concawe (2019 - internal document) An evaluation of the Persistence, Bioaccumulation, and Toxicity of Petroleum Hydrocarbons (revision 2). Concawe's Ecology Group, Brussels, July 2019.

Concawe (2021a) First Aid Reference Guide - 2021 update. Report No. 8/21. Brussels: Concawe https://www.concawe.eu/wp-content/uploads/Rpt_21-8.pdf

Concawe (2021b) Identified Uses of Petroleum Substances - 2021 Dossier Update. Concawe Handbook No. 2021/01. Brussels: Concawe https://www.concawe.eu/wp-content/uploads/Handbook-of-Identified-Uses-of-PS_2021-dossier-update.pdf

Concawe (2022) Hazard classification and labelling of petroleum substances in the European Economic Area - 2021. Report No. 1/22. Brussels: Concawe https://www.concawe.eu/wp-content/uploads/Rpt_22-1.pdf



DUCC (2017): How to use SUMIs: operational framework. Brussels: Downstream Users' Coordination Group <u>https://static.ducc.eu/media/file/2021-</u>

08/How%20to%20use%20SUMIs_operational%20framework_18%2007%202017.pdf

ECHA (2014a) Guidance for downstream users. Version 2.1 - October 2014 <u>https://echa.europa.eu/documents/10162/2324906/du_en.pdf/9ac65ab5-e86c-405f-a44a-190ff4c36489</u>

ECHA (2014b) How to assess whether a substance is used as an intermediate under strictly controlled conditions and how to report the information for the intermediate registration in IUCLID Practical Guide 16.

https://echa.europa.eu/documents/10162/2324906/pg16_intermediate_registration_en.pdf/2 91b6e50-5598-42d3-8a2b-d63d50a68104

ECHA (2016) Guidance on information requirements and chemical safety assessment. Part E: Risk characterisation. Version 3.0 - May 2016.

https://echa.europa.eu/documents/10162/17224/information_requirements_part_e_en.pdf/1 da6cadd-895a-46f0-884b-00307c0438fd

ECHA (2017) Guidance on the Application of the CLP Criteria. Version 5.0 - July 2017. https://echa.europa.eu/documents/10162/2324906/clp_en.pdf/58b5dc6d-ac2a-4910-9702e9e1f5051cc5

ECHA (2018) Guide on Safety Data Sheets and Exposure Scenarios. <u>https://echa.europa.eu/safety-data-sheets-and-exposure-scenarios-guide</u>

ECHA (2020) Guidance on the compilation of safety data sheets. Version 4.0 - December 2020 <u>https://echa.europa.eu/documents/10162/2324906/sds_en.pdf/01c29e23-2cbe-49c0-aca7-72f22e101e20</u>

ECHA (2021a) Guidance on harmonised information relating to emergency health response -Annex VIII to CLP Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures Version 4.0 March 2021 https://echa.europa.eu/documents/10162/17235/guidance_on_annex_viii_to_clp_en.pdf/412 c5874-f8ec-cf52-fe1e-2fbe08fe2d11?t=1614687077313

ECHA (2021b) Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008. Version 4.2 - March 2021

https://echa.europa.eu/documents/10162/2324906/clp_labelling_en.pdf/89628d94-573a-4024-86cc-0b4052a74d65

ECHA (2022): Substance database. <u>https://echa.europa.eu/</u>

EU (1998) Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC). Official Journal of the European Communities No. L 131, 05.05.1998

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31998L0024.

EU (2000) Commission Decision (2000/532/EC) of 3 May 2000 replacing Decision 94/3/EC establishing a list of wastes pursuant to Article 1(a) of Council Directive 75/442/EEC on waste and Council Decision 94/904/EC establishing a list of hazardous waste pursuant to Article 1(4) of Council Directive 91/689/EEC on hazardous waste. Official Journal of the European Communities No. L226, 6.9.2000

https://op.europa.eu/en/publication-detail/-/publication/239a2785-9115-4e06-adae-66c8e08a5a42

EU (2001) Commission Decision (2001/118/EC) of 16 January 2001 amending Decision 2000/532/EC as regards the list of wastes. Official Journal of the European Communities No. L47, 16.2.2001

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32001D0118

EU (2004a) Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC). Official Journal of the European Communities No. L 158, 30.4.2004, p. 50-76. https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A02004L0037-20140325 (Remark: recently amended by Directive (EU) 2022/431 of 9 March 2022 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work. OJ 16.3.2022 L 88/1.)

EU (2004b) Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC. Official Journal of the European Communities No. L 158, 30.4.2004 (repealed by Regulation (EU) 2019/1021). https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32004L0037

EU (2006) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. Official Journal of the European Union No. L396, 30.12.2006, as corrected by Official Journal of the European Union No. L136, 29.05.2007 and as further amended

http://data.europa.eu/eli/reg/2006/1907/2014-04-10 Consolidated version of 1.3.2022: https://eur-lex.europa.eu/legalcontent/en/TXT/HTML/?uri=CELEX:02006R1907-20220301

EU (2008a) Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods. Official Journal of the European Union No. L 260, 30.9.2008.

https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32008L0068

EU (2008b) Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives. Official Journal of the European Union No. EU (2008) L 312, 22.11.2008 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02008L0098-20180705

EU (2008c) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (CLP), amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. Official Journal of the European Union No. L 353, 31.12.2008 http://data.europa.eu/eli/reg/2008/1272/ojhttp://data.europa.eu/eli/reg/2008/1272/oj Consolidated version of 10.5.2021: http://publications.europa.eu/resource/cellar/e3f31046b274-11eb-8aca-01aa75ed71a1.0013.02/DOC_1

EU (2009) Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer. Official Journal of the European Union No. L 286, 31.10.2009

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32009R1005



EU (2012a) Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC. Official Journal of the European Union No. L197, 24.7.2012 (Seveso III) .

https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32012L0018

EU (2012b) Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals. Official Journal of the European Union No. L 201, 27.7.2012

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32012R0649

EU (2017) Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council. http://data.europa.eu/eli/reg_del/2017/2100/oj

EU (2018) Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. Official Journal of the European Union No. L 101, 20.4.2018 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32018R0605

EU (2019) Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants. Official Journal of the European Union No. L 169, 25.6.2019

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32019R1021

EU (2020) Commission Regulation (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Official Journal of the European Union No. L 203, 26.6.2020

https://eur-lex.europa.eu/legal-

<u>content/EN/TXT/?toc=OJ%3AL%3A2020%3A203%3ATOC&uri=uriserv%3AOJ.L_.2020.203.01.0028.</u> 01.ENG

IFA (2022) GESTIS Substance Database. Sankt Augustin: Institut fur Arbeitsschutz der Deutchen Gessetzlichen Unfallversicherung https://gestis-database.dguv.de/

Marpol (2022): International Convention for the Prevention of Pollution from Ships. <u>https://www.lr.org/en/marpol-international-convention-for-the-prevention-of-pollution/</u>

UN (2019a) UN RTDG, Manual of Tests and Criteria. 7th revised edition. At https://unece.org/fileadmin/DAM/trans/danger/publi/manual/Rev7_E.pdf

UN (2019b) RTDG, Model Regulations at https://unece.org/rev-21-2019

UNE (2006) Respiratory protective devices - Recommendations for selection, use, care and maintenance - Guidance document. UNE EN 529:2006.



APPENDIX 1: LINK OF H-STATEMENTS AND ASSOCIATED P-STATEMENTS WITH ESCOM PHRASES

H224/H225/H226 (Flammable/highly flammable/extremely flammable/extremely vapour) N/A Prevention: •P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. For measures to control risks from physicochemical properties, refer to main body of the SDS, section 7 and/or 8. •P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. •P233: Keep container tightly closed. •P240: Ground and bond container and receiving equipment. •P241: Use explosion-proof equipment. •P242: Use non-sparking tools. •P242: Use non-sparking tools. •P242: Use non-sparking tools. •P280: Wear protective gloves/protection/face protection/face protection/hearing protection/face protection/hearing •P280: Wear protective clothing/eye	H statement	Concentration limit (%) according to CLP Regulation	Low (L), moderate (M) or high (H) hazard according to REACH Guidance E ¹	Associated P-Statement (prevention, response, storage) ²	Selection of ESCom phrase by SDS author (Sections 7, 8, 13)
	(Flammable/highly flammable/extremely flammable liquid and	N/A	N/A	 •P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. •P233: Keep container tightly closed. •P240: Ground and bond container and receiving equipment. •P241: Use explosion-proof equipment. •P242: Use non-sparking tools. •P243: Take action to prevent static discharges. •P280: Wear protective gloves/protective clothing/eye protection/face protection/hearing 	properties, refer to main body of the SDS, section 7

¹ REACH Guidance E, Table E.3-1 (ECHA, 2016). ² These appear in the SDS in section 2.2.



H statement	Concentration limit (%) according to CLP Regulation	Low (L), moderate (M) or high (H) hazard according to REACH Guidance E ¹	Associated P-Statement (prevention, response, storage) ²	Selection of ESCom phrase by SDS author (Sections 7, 8, 13)
			•P303 + P361 + P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].	
			•P370 + P378: In case of fire: Use [define media] to extinguish.	
			Storage: •P403 + P235: Store in a well- ventilated area.	
H300/301/302 (fatal/toxic/harmful if swallowed)	0.1 (Cat. 1-3); 1 (Cat. 4)	H/M	P264 - Wash (³) thoroughly after use P270 - Do not eat, drink or smoke when using this product	These classifications do not appear in the Concawe C&L guide for petroleum substances
H304 (May be fatal if swallowed and enters airways - aspiration hazard) ⁴	10	Not listed	Prevention: No P-statement ⁵ Response: •P301 + P310: IF SWALLOWED: Immediately call a POISON CENTER/doctor/	Do not ingest. If swallowed then seek immediate medical assistance
			 •P331: Do NOT induce vomiting Storage: •P405: Store locked up 	

³ Need to specify body parts. This could be Process Category (PROC)-driven, though quite generic.

⁴ This is usually considered relevant to liquids with viscosity below a cut-off, but note that this hazard is also relevant in case of excessive exposure to aerosol and mist where product enters the airways also in liquid form.

⁵ For prevention focus, add e.g. 'Never syphon by mouth' (not ESCom phrase).



H statement	Concentration limit (%) according to CLP Regulation	Low (L), moderate (M) or high (H) hazard according to REACH Guidance E ¹	Associated P-Statement (prevention, response, storage) ²	Selection of ESCom phrase by SDS author (Sections 7, 8, 13)
H310 (fatal if in contact with the skin)		Н	P262 - Do not get in eyes, on skin, or on clothing P264 P270 P280	This classification does not appear in the Concawe C&L guide
H311/312 (toxic/harmful if in contact with the skin)		M	P280	This classification does not appear in the Concawe C&L guide
H314 (Causes severe skin burns and eye damage)	1	Н	P260 P264 P280	This classification does not appear in the Concawe C&L guide
H315 (causes skin irritation)	10	L	 Prevention: P264: Wash thoroughly after handling P280: Wear protective gloves/protective clothing/eye protection/face protection Response: P302 + P352: IF ON SKIN: Wash with plenty of water/ P321: Specific treatment (see on label with reference) P332 + P313: If skin irritation occurs: Get medical advice/attention P362 + P364: Take off contaminated clothing and wash it 	Ensure that direct skin contact is avoided. Identify potential areas for indirect skin contact. Wear suitable gloves tested to EN374. Clear spills immediately. Wash off any skin contamination immediately. For further specification, refer to section 8 of the SDS.



H statement	Concentration limit (%) according to CLP Regulation	Low (L), moderate (M) or high (H) hazard according to REACH Guidance E ¹	Associated P-Statement (prevention, response, storage) ²	Selection of ESCom phrase by SDS author (Sections 7, 8, 13)
			before reuse	
H317 (May cause an allergic skin reaction)		Н	P261 P272 - Contaminated work clothing should not be allowed out of the workplace P280	This classification does not appear in the Concawe C&L guide
H318 (causes serious eye damage)	1	Not listed	P280	This classification does not appear in the Concawe C&L guide
H319 (causes serious eye irritation) ⁶	10	L	 Prevention: P264: Wash thoroughly after handling P280: Wear protective gloves/protective clothing/eye protection/face protection Response: P302 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313: If eye irritation persists: Get medical advice/attention. 	Use suitable eye protection. Avoid direct eye contact with product, also via contamination on hands.

⁶ Not directly applicable to any petroleum substance registered under REACH. However, neat benzene is classified for this endpoint.



H statement	Concentration limit (%) according to CLP Regulation	Low (L), moderate (M) or high (H) hazard according to REACH Guidance E ¹	Associated P-Statement (prevention, response, storage) ²	Selection of ESCom phrase by SDS author (Sections 7, 8, 13)
H330 (fatal if inhaled)		Н	P260 P271 P284 - In case of inadequate ventilation, wear respiratory protection	This classification does not appear in the Concawe C&L guide
H331/332 (toxic/harmful if inhaled)		M (H331)	P261 P271 P403 (H331) P233 (H331) P405 (H332)	H331 does not appear in the Concawe C&L guide. H332 is covered by DNEL-driven controls, in particular ventilation (general or local).
H334 (May cause allergy or asthma symptoms or breathing difficulties if inhaled)	0.1 or 1	Н	P261 P284	H334 does not appear in the Concawe C&L guide
H335 (May cause respiratory irritation); H336 (May cause drowsiness or dizziness) (specific target organ toxicity after single exposure)	N/A	M/L	For H336: Prevention: •P261: Avoid breathing dust/fume/ gas/mist/vapours/spray. •P271: Use only outdoors or in a well-ventilated area. Response: •P304 + P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. •P312: Call a POISON CENTER/doctor/if you feel unwell.	H335 does not appear in the Concawe C&L guide. For H336 products: Covers indoor and outdoor use. Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour). Store substance within a closed system.



H statement	Concentration limit (%) according to CLP Regulation	Low (L), moderate (M) or high (H) hazard according to REACH Guidance E ¹	Associated P-Statement (prevention, response, storage) ²	Selection of ESCom phrase by SDS author (Sections 7, 8, 13)
			 Storage: P403+P233: Store in a well-ventilated place. Keep container tightly closed. P405: Store locked up. 	
H340/341 (may cause or is suspected of causing mutagenicity - categories 1A, 1B and 2); H350/351 (may cause or is suspected of causing carcinogenicity - categories 1A, 1B and 2); H360/361 (may damage/is suspected of damaging fertility or the unborn child - categories 1A, 1B and 2);		Н	For H350 & H351 & H340: Prevention: •P201: Obtain special instructions before use. •P202: Do not handle until all safety precautions have been read and understood. •P280: Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/) Response: •P308 + P313: IF exposed or concerned: Get medical advice/attention. Storage: •P405: Store locked up.	For H350 & H340: Consider technical advances and process upgrades (including automation) for the elimination of releases. Minimise exposure using measures such as closed systems, dedicated facilities and suitable general/local exhaust ventilation. Drain down and flush system prior to equipment break-in or maintenance. Access to work area only for authorised persons. Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training. Wear suitable coveralls to prevent exposure to the skin. Wear respiratory protection when its use is identified for certain contributing scenarios. For further specification, refer to section 8 of the SDS. Clear spills immediately. Dispose of this material and its container at hazardous or special waste collection point. Ensure safe systems of work or equivalent arrangements are in place to manage risks. Ensure control measures are regularly inspected and maintained. Consider the need for risk based health surveillance. For H351: Minimise exposure using measures such as contained and enclosed systems, properly designed and



H statement	Concentration limit (%) according to CLP Regulation	Low (L), moderate (M) or high (H) hazard according to REACH Guidance E ¹	Associated P-Statement (prevention, response, storage) ²	Selection of ESCom phrase by SDS author (Sections 7, 8, 13)
				maintained dedicated facilities and suitable general/local exhaust ventilation. Drain down and flush system prior to equipment break-in or maintenance. Ensure staff are informed of and trained on the nature of exposure and basic actions to minimise exposure. Wear suitable coveralls to prevent exposure to the skin. Wear suitable gloves tested to EN374. Wear respiratory protection when its use is identified for certain contributing scenarios. Clear spills immediately. Dispose of this material and its container at hazardous or special waste collection point. Ensure control measures are regularly inspected and maintained. Consider the need for risk based health surveillance.
H362 (may cause harm to breastfed children - additional category for effects on or via lactation)		Not listed	P201 P260 - Do not breathe dust/fume/gas/mist/ vapours/spray P263 - Avoid contact during pregnancy and while nursing P264 - P270 - Do not eat, drink or smoke when using this product	H362 does not appear in the Concawe C&L guide
H370 and H371 (specific target organ toxicity after single exposure (SE))	10 20?	H (H370) M (H371)	P260 P264 P270	These classifications do not appear in the Concawe C&L guide
H372 (specific target organ toxicity after repeated exposure (RE))	1; 10?	Not listed	P260 P264 P270	According to the Concawe C&L guide this classification is always linked to a carcinogenicity classification, hence protective measures are already defined.



H statement	Concentration limit (%) according to CLP Regulation	Low (L), moderate (M) or high (H) hazard according to REACH Guidance E ¹	Associated P-Statement (prevention, response, storage) ²	Selection of ESCom phrase by SDS author (Sections 7, 8, 13)
H373 (specific target organ toxicity after repeated exposure)		Not listed	P260	According to the Concawe C&L guide this classification is always linked to a carcinogenicity classification, hence protective measures are already defined.
EUH066 (Repeated exposure may cause skin dryness or cracking) ⁷	None	Not listed ⁸	No P statement	If repeated and/or prolonged skin exposure to the substance is likely, then wear suitable gloves tested to EN374 and provide employee skin care programmes. <u>Note</u> : in case that the substance is also classified as H315, H340 and/or H350, the phrase may be limited to: 'Provide employee skin care programmes'.

 ⁷ Skin defatting hazard does not relate to a classifiable endpoint. Supplemental hazard statement, not included in the UN GHS.
 ⁸ Rated lower than the skin irritation hazard in that it is linked only to repeated and/or prolonged exposure.



APPENDIX 2: NON-EXHAUSTIVE LIST OF EU SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR PETROLEUM SUBSTANCESS OR MIXTURES

Citations of original legislation listed below implicitly refer to amendments to-date by subsequent acts, as applicable. Acts repealed by the listed legislation can be seen in the respective record on the European Union law portal, EUR-Lex, at http://eur-lex.europa.eu.

- Registration, evaluation, authorisation and restriction of chemicals (REACH): Regulation (EC) No. 1907/2006 of 18 December 2006;
- Major accidents hazards involving dangerous substances (SEVESO III): Council Directive 2012/18/EU of 4 July 2012;
- Chemical agents at work: Council Directive 98/24/EC of 7 April 1998;
- Carcinogens and mutagens at work: Directive 2004/37/EC of the European • Parliament and of the Council of 29 April 2004; or Directive (EU) 2019/130 of the European Parliament and of the Council of 16 January 2019 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens work. at Remark: recently amended by Directive (EU) 2022/431 of 9 March 2022 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work. OJ 16.3.2022 L 88/1.
- Young people at work: Council Directive 94/33/EC of 22 June 1994;
- *Pregnant and breastfeeding workers*: Council Directive 92/85/EEC of 19 October 1992;
- *Health and safety signs at work*: Council Directive 92/58/EEC of 24 June 1992;
- *Eco-label award scheme*: Regulation (EC) No 1980/2000 of 17 July 2000;
- Aerosol dispensers: Council Directive 75/324/EEC of 20 May 1975;
- Ambient air quality and cleaner air for Europe: Directive 2008/50/EC of the European Parliament and Council of 21 May 2008;
- Import and export of hazardous substances: Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012;
- *Hazardous waste*: Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 (Waste Framework Directive);
- *Transport of Dangerous Goods*: Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008;
- Limitation of emissions of volatile organic compounds from use of organic solvents:
- Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) use of organic solvents in certain activities and installations;
- Directive 2004/42/EC of the European Parliament and of the Council of use of organic solvents in certain paints and varnishes and vehicle refinishing products.



APPENDIX 3: EXAMPLES OF SDS SECTIONS

SDS SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

"Gasoline - Base Grade" (used as example)

	substance/mixture	and of the company/undertaking			
1.1. Product identifier					
	Substance (UVCB)				
	: Gasoline - Base Grade				
	: 649-378-00-4				
	289-220-8				
	86290-81-5				
REACH registration No	XX-XXXXXXXXXXXX	-XXXX			
Product code	YYYYYYYY				
Type of product	Fuel				
Synonyms	: SU10				
Product group	Trade product				
Other means of identification	Conforms to EN 228				
1.2. Relevant identified uses of the s	ubstance or mixture	and uses advised against			
1.2.1. Relevant identified uses					
Main use category :	Industrial use, Professio	nal use			
Industrial/Professional use spec	For professional use on Used in closed systems				
Use of the substance/mixture	Fuel				
Function or use category :	Fuels				
Title	Life cycle stage	Use descriptors (optional example)			
Manufacture of substance (classified; including H340 and/or H350 and/or H361; (containing 0% to 1% benzene))x	Industrial, Manufacture	PROC1, PROC2, PROC3, PROC8a, PROC8b, PROC15, PROC28, ERC1, ESVOC SPERC 1.1.v1			
Formulation & (re)packing of substances and mixtures (classified; including H340 and/or H350 and/or H361; (containing 0% to 1% benzene))×	Industrial, Formulation	PROC1, PROC2, PROC3, PROC8a, PROC8b, PROC15, PROC28, ERC2, ESVOC SPERC 2.2.v1			
Use of substance as an intermediate (classified; including H340 and/or H350 and/or H361; (containing 0% to 1% benzene))x	Industrial	PROC1, PROC2, PROC3, PROC8a, PROC8b, PROC15, PROC28, ERC6a, ESVOC SPERC 6.1a.v1			
Use of substance as a fuel (classified; including H340 and/or H350 and/or H361;	Industrial	PROC1, PROC2, PROC8a, PROC8b, PROC15, PROC28, ERC7, ESVOC SPERC 7.12a.v1			
(containing 0% to 1% benzene))x					
	Professional	PROC1, PROC2, PROC8a, PROC8b, PROC16, PROC28, ERC9a, ERC9b, ESVOC SPERC 9.12b.v1			

Full text of use descriptors: see section 16



1.2.2. Uses advised against

Title	Use descriptors (optional)	Reason
Use in Cleaning Agents: Professional (not classified as H340, H350 or H361; (containing less than 0.1% benzene))×	PROC1, PROC2, PROC3, PROC4, PROC8a, PROC8b, PROC10, PROC11, PROC13, ERC8a, ERC8d	For reasons of protection of human health, this use is no longer supported in the registration dossier.

Full text of use descriptors: see section 16

1.3. Details of the supplier of the safety data sheet [The full address and telephone number of the supplier]

[An email address for a competent person responsible for the safety data sheet] [(Responsible person for the Member State, a full address and telephone number)]

[(Details of the non-Union manufacturer or formulator)]

1.4. Emergency telephone number

Emergency number

: For Chemical Emergency Call (Telephone number including country code, spoken language and times available) 24hr/day 7days/week



SDS SECTION 2: HAZARDS IDENTIFICATION

"Jet A1" (used as example)

2.1 Classification of the substance or mixture

Classification (EC Regulation No 1272/2008):

Flam. Liq. 3 H226, Skin Irrit. 2 H315, Asp. Tox. 1 H304, STOT SE 3 H336, Aquatic Chronic 2 H411

For the full text of classifications referred to in this section and H-phrases and classification methods, see Section 16.

2.2 Label elements

Labelling (EC Regulation No 1272/2008):

Hazard pictograms



Signal word : Danger

Hazard statements:

H226 Flammable liquid and vapour.
H304 May be fatal if swallowed and enters airways.
H315 Causes skin irritation.
H336 May cause drowsiness or dizziness.
H411 Toxic to aquatic life with long lasting effects.

Precautionary statements:

Prevention:

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P273 Avoid release to the environment.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

Response:

P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. P331 Do NOT induce vomiting.

Disposal:

P501 Dispose of contents/container according to the disposal routes specified by law.

2.3 Other hazards

Other hazards not contributing to the classification : The product is heavier than air and in the event of a leak, vapour may accumulate in confined spaces and low lying areas where it may easily be accidentally ignited. The product may charge electrostatically: use earthing leads when transferring from one container to another. Any substance, in case of accidents involving pressurized circuits and the like, may be accidentally injected under the skin, even without external damage. In such a case, the victim should be brought to an hospital as soon as possible, to get specialized medical treatment. Do not wait for symptoms to develop. In exceptional cases (i.e prolunged storage in tanks contaminated with water, and presence of anaerobic sulfate-



reducing microbial colonies), the product may undergo a degradation and generate small amounts of sulfur compounds, including H2S.

According to the results of current assessment(s), This substance/any component substance in the mixture does not meet the PBT criteria of REACH regulation, annex XIII

According to the results of current assessment(s), This substance/any component substance in the mixture does not meet the vPvB criteria of REACH regulation, annex XIII



SDS SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

"Fuel oil, residual" (used as example)

3.1. Substance

Chemical nature: A complex and variable combination of paraffinic, cyclic and aromatic hydrocarbons having a carbon number range predominantly of C15 to C50 and boiling in the range of approximately 150°C to 750°C. They may contain sulphurated derivatives and organic acids. This product contains polycyclic aromatic hydrocarbons (PAH), some of which are considered carcinogens.

Substance type : UVCB

Chemical Name	EC-No	REACH registration No	CAS-No	Weight %	Classification (Reg. 1272/2008)
Fuel oil, residual	270-675-6	01-2119474894-XX	68476-33-5	>99	Carc. 1B (H350) Repr. 2 (H361d) Acute Tox. 4 (H332) STOT RE 2 (H373) Aquatic Acute 1 (H400) Aquatic chronic 1 (H410) (SCL) (M-factor) (ATE)

For the full text of the H-Statements mentioned in this Section, see Section 16.

3.2. Mixture

"GASOLINE, UNLEADED" (used as example)

Chemical characterisation:

Composition/ Information on ingredients: Mixture of hydrocarbons with carbon numbers predominantly in the range C4-C12

The substances identified as "constituents" are chemical compounds that are typically present in the UVCB substance.

Their presence may be relevant for hazard classification, or other health / environmental reasons (i.e. OELs)

All these chemical compounds are not added deliberately as such. Quantities are variable and not predetermined.



Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [EU-GHS / CLP]
Gasoline (Low boiling point naphtha - unspecified) Main component	(CAS-No.) 86290-81-5 (EC-No.) 289-220-8 (EC Index-No.) 649-378-00-4 (REACH Registration-No) : 01- 2119471335-39-xxxx	>= 80 < 90	Flam. Liq. 1, H224 Skin Irrit. 2, H315 Muta. 1B, H340 Carc. 1B, H350 Repr. 2, H361 STOT SE 3, H336 Asp. Tox. 1, H304 Aquatic Chronic 2, H411 (SCL) (M-factor) (ATE)
tert-Butyl methyl ether (MTBE) (Additive)	(CAS-No.) 1634-04-4 (EC-No.) 216-653-1 (EC Index-No.) 603-181-00-X (REACH Registration-No) 01- 2119452786-27-xxxx	>= 0,1 < 10	Flam. Liq. 2, H225 Skin Irrit. 2, H315 (SCL) (M-factor) (ATE)
tert-Butyl ethyl ether (ETBE) (Additive)	(CAS-No.) 637-92-3 (EC-No.) 211-309-7 (EC Index-No.) N/A (REACH-Reg. No) 01- 2119452785-29-xxxx	>= 0,1 < 10	STOT SE 3, H336 Flam. Liq. 2, H225 (SCL) (M-factor) (ATE)
tert-Amyl methyl ether (TAME) (Additive)	(CAS-No.) 994-05-8 (EC-No.) 213-611-4 (EC Index-No.) 603-213-00-2 (REACH Reg. No) 01- 2119453236-41-xxxx	>= 0,1 < 10	Flam. Liq. 2, H225 Acute Tox. 4 (Oral), H302 STOT SE 3, H336 (SCL) (M-factor) (ATE)
Ethanol (Additive)	(CAS-No.) 64-17-5 (EC-No.) 200-578-6 (EC Index-No.) 603-002-00-5 (REACH Reg. No) 01- 2119457610-XXXX	>= 0,1 < 5	Flam. Liq. 2, H225 Eye irrit. 2, H319 (SCL) (M-factor) (ATE)
n-Hexane (CONSTITUENT)	(CAS-No.) 110-54-3 (EC-No.) 203-777-6 (EC Index-No.) 601-037-00-0	>= 3 < 5	Flam. Liq.2, H225 Skin Irrit.2, H315 Repr.2, H361f STOT SE3, H336 STOT RE2, H373 Asp. Tox.1, H304 Aquatic Chronic2, H411 (SCL) (M-factor) (ATE)
Benzene (CONSTITUENT)	(CAS-No.) 71-43-2 (EC-No.) 200-753-7 (EC Index-No.) 601-020-00-8	>= 0,1 < 1	Flam. Liq.2, H225 Skin Irrit.2, H315 Eye Irrit.2, H319 Muta.1B, H340 Carc.1A, H350 STOT RE1, H372 Asp. Tox.1, H304 (SCL) (M-factor) (ATE)



Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [EU-GHS / CLP]
Toluene (CONSTITUENT)	(CAS-No.) 108-88-3 (EC-No.) 203-625-9 (EC Index-No.) 601-021-00-3	>= 3 < 10	Flam. Liq. 2, H225 Repr. 2, H361d Asp. Tox. 1, H304 STOT RE 2, H373 Skin Irrit. 2, H315 STOT SE 3, H336 (SCL) (M-factor) (ATE)

Full text of H-statements: see section 16



SDS SECTION 4: FIRST AID MEASURES

"DIESEL FUEL" (used as example)

4.1. Description of first aid measures

First-aid measures general:

Before starting first aid: If there is any suspicion of inhalation of H2S (hydrogen sulphide), Rescuers must wear breathing apparatus, belt and safety rope, and follow rescue procedures. In case of spontaneous vomiting, transport the victim to a hospital, to verify the possibility that the product has been aspired into the lungs. IF exposed or concerned: Get medical advice/attention.

First-aid measures after inhalation: Inhalation is unlikely because of the low vapour pressure of the substance at ambient temperature. Exposure to vapours may however occur when the substance is handled at high temperatures with poor ventilation. Remove to fresh air, keep the casualty warm and at rest. Check if casualty is conscious and breathing normally. If casualty is breathing and unconscious place in recovery position and check breathing regularly. If casualty is not breathing - start with CPR (cardio-pulmonary resuscitation).

First-aid measures after skin contact: Remove contaminated clothing, contaminated footwear and dispose of safely. Wash skin with soap and water. Seek medical attention if skin irritation, swelling or redness develops and persists. Do not use salves or ointments, unless directed by doctor. When using high pressure equipment, injection of product can occur. Send the casualty immediately to hospital. Do not wait for symptoms to develop.

First-aid measures after eye contact: Remove contact lenses, if present and easy to do so. Rinse eyes thoroughly for at least 15 minutes. Keep eyelids well apart. If irritation, blurred vision or swelling occurs and persists, obtain medical advice from a specialist. First-aid measures after ingestion: Do not induce vomiting as there is high risk of aspiration. Do not give anything by mouth to an unconscious person. In case of ingestion, always assume that aspiration has occurred. Send the casualty immediately to hospital. Do not wait for symptoms to develop. In case of spontaneous vomiting, keep head low, to avoid the risk of aspiration into the lungs.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms / injuries (general indications): There are potential chronic health effects to consider.

Symptoms/effects after inhalation: Harmful if inhaled. Inhalation of vapours may cause headache, nausea, vomiting and an altered state of consciousness.

Symptoms/effects after skin contact: Causes skin irritation. Prolonged and repeated skin contact may cause reddening, irritation and dermatitis, due to a defatting effect.

Symptoms/effects after eye contact: Contact with eyes may cause a light transient irritation. Symptoms/effects after ingestion: Swallowing the liquid may cause aspiration into the lungs with the risk of chemical pneumonitis. May be fatal if swallowed and enters airways. Symptoms/effects upon intravenous administration: No information available.

Chronic symptoms: Suspected of causing cancer in contact with skin. May cause damage to organs (thymus, liver, blood) through prolonged or repeated exposure.



4.3. Indication of any immediate medical attention and special treatment needed

Notes for the doctor: Obtain medical attention if casualty has an altered state of consciousness or if symptoms do not resolve. In case of ingestion, always assume that aspiration has occurred. Send the casualty immediately to hospital. If necessary, drain stomach by gastric lavage ONLY under qualified medical supervision. Send patient to hospital. Immediately begin artificial respiration if breathing has ceased. Administer oxygen if necessary.



SDS SECTION 5: FIREFIGHTING MEASURES

"FUEL OIL, RESIDUAL; LOW SULFUR FUEL OIL (HFO)" (used as example)

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media: Carbon dioxide. Dry powder. Foam.

Unsuitable extinguishing media: Do not use a solid water stream as it may scatter and spread fire.

5.2. Special hazards arising from the substance or mixture

Explosion hazard: Heavier than air, vapours may travel long distances along ground, ignite and flash back to source. Heat may build pressure, rupturing closed containers, spreading fire and increasing risk of burns and injuries.

Hazardous decomposition products in case of fire: Toxic fumes. Carbon oxides (CO, CO2). Aldehydes. Polycyclic-aromatic hydrocarbons (PAH). Carbon (C). Ketones.

5.3. Advice for firefighters

Protection during firefighting: Complete protective clothing. Do not enter fire area without proper protective equipment, including respiratory protection.

Other information: Notify fire brigade and environmental authorities. Evacuate unnecessary personnel. Use water spray or fog for cooling exposed containers.



SDS SECTION 6: ACCIDENTAL RELEASE MEASURES

"FUEL OIL, RESIDUAL; LOW SULFUR FUEL OIL (HFO)" (used as example)

6.1. Personal precautions, protective equipment and emergency procedures

General measures: No flames, no sparks. Eliminate all sources of ignition. Do not smoke. Use special care to avoid static electric charges. Prevent any contact with hot surfaces.

6.1.1. For non-emergency personnel

Protective equipment: Do not attempt to take action without suitable protective equipment. Gloves. Safety glasses.

Emergency procedures: Avoid contact with skin and eyes.

6.1.2. For emergency responders

Protective equipment: Do not attempt to take action without suitable protective equipment. Breathing apparatus.

Emergency procedures: Evacuate unnecessary personnel. Eliminate all ignition sources if safe to do so.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

For containment: If spilled, may cause the floor to be slippery. Sweep up or vacuum up the product. Dike for recovery or absorb with appropriate material. Take up liquid spill into absorbent material, e.g: sand, saw dust. On water, recover/skim from surface and pour out in disposal container.

For cleaning up:

Other information: Dispose of contaminated material at an authorized site. Notify authorities if product enters sewers or public waters.

6.4. Reference to other sections

For further information refer to section 8 (personal protection) and 13 (waste handling).



SDS SECTION 7: HANDLING AND STORAGE

An example for Section 7 of SDS for petroleum products is presented. It has to be further completed with information depending on product's specific properties.

7.1. Precautions for safe handling

7.1.1 Protective measures

- (Subject to applicability if classified as CMR). Obtain special instructions before use.
- (Subject to applicability). A specific assessment of inhalation risks from the presence of H2S in tank headspaces, confined spaces, product residue, tank waste and wastewater, and unintentional releases must be made to help determine controls appropriate to local circumstances.
- (Subject to applicability). Risk of explosive mixtures of vapour and air. Ensure that all relevant regulations regarding explosive atmospheres and handling and storage facilities of flammable products, are followed.
- (Subject to applicability). Do not handle until all safety precautions have been read and understood.
- (Subject to applicability). Do not breathe fume/ mist/ vapours.
- Avoid contact of the product with skin and eyes. Do not ingest. Do not breathe vapours.
- Use personal protective equipment as required.
- For more information regarding protective equipment, see Section 8.2.2. and exposure scenarios Annex.

Measures to prevent fire

- Keep away from sources of heat/sparks/open flames/hot surfaces. No smoking.
- Ground/bond container and receiving equipment.
- Take precautionary measures against static electricity. Use only non-sparking tools.
- Ground/bond containers, tanks and transfer/receiving equipment.
- The vapour is heavier than air. Beware of accumulation in pits and confined spaces.
- (Subject to applicability). Do not use compressed air for filling, discharging, or handling operations.
- (Subject to applicability). Use only bottom loading of tankers, in compliance with European legislation.
- (Subject to applicability). Use explosion-proof electrical/ventilating/lighting equipment.

Measures to prevent aerosol and dust generation

- Use and store only outdoors or in a well-ventilated area.
- (Subject to applicability). During filling, metering and sampling splash proof grounded devices should be used.
- (Subject to applicability). Use only predominantly enclosed filling lines.

Measures to protect the environment

- Avoid release to the environment.
- Storage facilities should be designed with adequate bunds to prevent ground and water pollution in case of leaks and spills.



7.1.2 Advice on general occupational hygiene

- Ensure that proper housekeeping measures are in place.
- Contaminated materials should not be allowed to accumulate in the workplace and should never be kept inside the pockets.
- Keep away from food and beverages.
- Do not eat, drink or smoke when using this product.
- Wash the hands thoroughly after handling.
- Change contaminated clothes at the end of working shift.

7.2 Conditions for safe storage, including any incompatibilities

7.2.1 Technical measures and storage conditions:

- Cleaning, inspection and maintenance of the storage tanks must be done only by properly equipped and qualified personnel.
- Before entering storage tanks and commencing any operation in a confined area, check the atmosphere for oxygen content and flammability.
- Store separately from oxidizing materials.
- (Subject to applicability). If sulphur compounds are suspected to be present in the product, check the atmosphere for H2S content.
- (Subject to applicability). Where a substance has been registered as an isolated intermediate (on-site or transported), ensure technical measures are in place for rigorously containment and use under strictly controlled conditions in accordance with REACH Article 17 & 18.

Packaging materials:

- Recommended materials: For containers, or container linings use mild steel, stainless steel.
- Unsuitable materials: Some synthetic materials may be unsuitable for containers or container linings depending on the material specification and intended use. Compatibility should be checked with the manufacturer.
- Always keep in packaging which complies with transport requirements (see Section 14).

Requirements for storage rooms and vessels:

- Storage facilities design, equipment and operating procedures must comply with the relevant European, national or local regulatory requirements.
- (Subject to applicability). Storage area layout, tank design, equipment and operating procedures must comply with the relevant European, national or local legislation.

Storage class: 3

Further information on storage conditions:

- If the product is supplied in containers:
- Keep only in the original container, or in an approved container for this kind of product. Keep containers tightly closed and properly labelled. Protect from the sunlight.



- Empty containers may contain flammable product residues. Do not weld, solder, drill, cut or incinerate empty containers, unless they have been properly cleaned.
- (Subject to applicability). Light hydrocarbon vapours can build up in the headspace of containers. These can cause flammability / explosion hazards. Open slowly in order to control possible pressure release.

7.3.Specific end uses(s)

Recommendations: Observe instructions for safe handling and use.

Industrial sector specific solutions: Refer to Exposure Scenarios, attached as Annex.



SDS SECTION 8: EXPOSURE CONTROL/PERSONAL PROTECTION

"GASOLINE, UNLEADED" (used as example; to be based on the composition as declared in section 3.2)

8.1. Control parameters

Occupational Exposure Limits (national values)

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis					
Toluene 108-88-3		MAK-TMW	50 ppm 190 mg/m3	AT OEL					
	Further info	rmation: Risk of skin	absorption						
Toluene		MAK-KZW	100 ppm 380 mg/m3	AT OEL					
Ethanol	64-17-5	MAK-TMW	1.000 ppm 1.900 mg/m3	AT OEL					
Ethanol		MAK-KZW	2.000 ppm 3.800 mg/m3	AT OEL					
Cyclohexane	110-82-7	MAK-TMW	200 ppm 700 mg/m3	AT OEL					
Cyclohexane		MAK-KZW	800 ppm 2.800 mg/m3	AT OEL					
	Further info	mation: Indicative							
tert-butyl methyl ether	1634-04-4	MAK-TMW	50 ppm 180 mg/m3	AT OEL					
tert-butyl methyl ether		MAK-KZW	100 ppm 360 mg/m3	AT OEL					
	Further information: Risk of skin absorption								
	Further info	mation: Risk of skin	absorption						
n-Hexane	110-54-3	MAK-TMW	20 ppm 72 mg/m3	AT OEL					
n-Hexane		MAK-KZW	80 ppm 288 mg/m3	AT OEL					
methanol	67-56-1	MAK-TMW	200 ppm	AT OEL					
			260 mg/m3						
	Further info	rmation: Risk of skin							
methanol	MAK-KZW		800 ppm AT OEL 1.040 mg/m3						
	Further info	rmation: Risk of skin	absorption						
Dammana	74 42 2		4						
Benzene	71-43-2	TRK-TMW	1 ppm 3,2 mg/m3	AT OEL					
	Further info		II A 1, Risk of skin absorpt						
Benzene		TRK-KZW	4 ppm 12,8 mg/m3	AT OEL					
	Further info	rmation: See Annex I	II A 1, Risk of skin absorpt	ion					



	Further inform	Further information: Risk of skin absorption					
Naphthalene	91-20-3	91-20-3 MAK-TMW 10 ppm AT OEL					
		50 mg/m3					
	Further inform	Further information: Risk of skin absorption					

Biological occupational exposure limits

Substance name	CAS-No.	Control parameters	Sampling time	Basis
Toluene	108-88-3	o-cresol: 0,8 mg/l (Urine)	At the end of a work week / at the end of a work day / at the end of a shift	VGÜ2014
		toluene: 250 µg/l (Blood)	End of workday	VGÜ2014
Benzene	71-43-2	t,t-muconic acid: 1,6 mg/l (Urine)	At the end of a work week / at the end of a work day / at the end of a shift	VGÜ2014

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Substance name	End Use	Exposure routes	Potential health effects	Value		
Gasoline; Low boiling point naphtha - unspecified		Inhalation		840 mg/m3/ 8h		
Remarks:	long term, local	effects				
Gasoline; Low boiling point naphtha - unspecified	Consumers	Inhalation		180 mg/m3/ 24h		
Remarks:	long term, local			-		
Ethanol	Workers	Inhalation		950 mg/m3		
Remarks:	long term, syste					
Ethanol		Dermal		343 mg/kg		
Remarks:	long term, syste	emic effects				
Ethanol	Consumers	Inhalation		114 mg/m3		
Remarks:	long term, syste	emic effects				
Ethanol	Consumers	Dermal		206 mg/kg/day		
Remarks:	long term, syste	emic effects				
Ethanol	Consumers	Oral		87 mg/kg/day		
Remarks:	long term, syste	emic effects				
tert-butyl methyl ether	Workers	Inhalation	Acute local effects	357 mg/m3		
tert-butyl methyl ether	Workers	Dermal	Long-term systemic effects	bw/day		
tert-butyl methyl ether	Workers	Inhalation	Long-term systemic effects			
tert-butyl methyl ether	Consumers	Inhalation	Acute local effects	214 mg/m3		
tert-butyl methyl ether	Consumers	Oral	Long-term systemic effects	7,1 mg/kg bw/day		
tert-butyl methyl ether	Consumers	Dermal	Long-term systemic effects	bw/day		
tert-butyl methyl ether	Consumers	Inhalation	Long-term systemic effects	53,6 mg/m3		



Substance name	End Use	Exposure routes	Potential effects	health	Value
2-methoxy-2- methylbutane	Workers	Inhalation	Long-term effects	systemic	88 mg/m3
2-methoxy-2- methylbutane	Workers	Inhalation	Acute effects	systemic	353,3 mg/m3
2-methoxy-2- methylbutane	Workers	Dermal	Long-term effects	systemic	1601 mg/kg bw/day
2-methoxy-2- methylbutane	Consumers	Inhalation	Long-term effects	systemic	26,5 mg/m3
2-methoxy-2- methylbutane	Consumers	Inhalation	Acute effects	systemic	212 mg/m3
2-methoxy-2- methylbutane	Consumers	Dermal	Long-term effects	systemic	961 mg/kg bw/day
2-methoxy-2- methylbutane	Consumers	Oral	Long-term effects	systemic	1 mg/kg bw/day
methanol	Workers	Inhalation	Acute effects	systemic	260 mg/kg
methanol	Workers	Dermal	Long-term effects	systemic	40 mg/kg/day
methanol	Workers	Inhalation	Long-term effects	systemic	260 mg/kg
methanol	Consumers	Inhalation	Acute effects	systemic	50 mg/kg
methanol	Consumers	Dermal	Long-term effects	systemic	8 mg/kg/day
methanol	Consumers	Inhalation	Long-term effects	systemic	50 mg/kg
methanol	Consumers	Oral	Long-term effects	systemic	8 mg/kg/day
Benzene	Workers	Inhalation	Long-term effects	systemic	3,25 mg/m3/ 8h
Benzene	Workers	Dermal	Long-term effects	systemic	0,234 mg/kg/day

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

Substance name GASOL	INE	Envir	onmental Com	partment		Value	
Remarks:	compositi	on. Co not po	nventional met	hods of a	complex, unk deriving PNECs a gle representat	are not app	oropriate

8.2. Exposure controls

Appropriate engineering controls:

- Read in conjunction with the Exposure Scenario for your specific use contained in the Annex.
- The level of protection and types of controls necessary will vary depending upon potential exposure conditions. Select controls based on a risk assessment of local circumstances. Appropriate measures include:
- Use sealed systems as far as possible.
- Firewater monitors and deluge systems are recommended.
- Adequate explosion-proof ventilation to control airborne concentrations below the exposure guidelines/limits.
- Local exhaust ventilation is recommended.



- Eye washes and showers for emergency use.
- Consider technical advances and process upgrades (including automation) for the elimination of releases. Minimise exposure using measures such as closed systems, dedicated facilities and suitable general/local exhaust ventilation. Drain down systems and clear transfer lines prior to breaking containment. Clean/flush equipment, where possible, prior to maintenance.
- Where there is potential for exposure: restrict access to authorised persons; provide specific activity training to operators to minimise exposures; wear suitable gloves and coveralls to prevent skin contamination; wear respiratory protection when there is potential for inhalation; clear up spills immediately and dispose of wastes safely.
- Ensure safe systems of work or equivalent arrangements are in place to manage risks. Regularly inspect, test and maintain all control measures. Consider the need for risk based health surveillance.
- Prevent unauthorised persons entering the zone.

General Information:

- Consider technical advances and process upgrades (including automation) for the elimination of releases.
- Minimise exposure using measures such as closed systems, dedicated facilities and suitable general/local exhaust ventilation. Drain down systems and clear transfer lines prior to breaking containment.
- Clean/flush equipment, where possible, prior to maintenance. Where there is potential for exposure: restrict access to authorised persons; provide specific activity training to operators to minimise exposures; wear suitable gloves and coveralls to prevent skin contamination; wear respiratory protection when there is potential for inhalation; clear up spills immediately and dispose of wastes safely.
- Ensure safe systems of work or equivalent arrangements are in place to manage risks. Regularly inspect, test and maintain all control measures. Consider the need for risk based health surveillance.

Personal protective equipment:

- Read in conjunction with the Exposure Scenario for your specific use contained in the Annex.
- Personal protective equipment (PPE) should meet recommended national standards. Check with PPE suppliers.
- The provided information is made in consideration of the PPE directive (Council Directive 89/686/EEC) and the CEN European Committee for Standardisation (CEN) standards.

Eye protection	:	Wear goggles for use against liquids and gas. If a local risk assessment deems it so then chemical splash goggles may not be required and safety glasses may provide adequate eye protection. Approved to EU Standard EN166.
Hand protection		· · · · · · · · · · · · · · · · · · ·
	:	Personal hygiene is a key element of effective hand care. Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of

a non-perfumed moisturizer is recommended. Suitability and durability of a glove is dependent on usage, e.g. frequency



		and duration of contact, chemical resistance of glove material, dexterity. Always seek advice from glove suppliers. Contaminated gloves should be replaced. For continuous contact we recommend gloves with breakthrough time of more than 240 minutes with preference for > 480 minutes where suitable gloves can be identified. For short- term/splash protection we recommend the same but recognize that suitable gloves offering this level of protection may not be available and in this case a lower breakthrough time maybe acceptable so long as appropriate maintenance and replacement regimes are followed. Glove thickness is not a good predictor of glove resistance to a chemical as it is dependent on the exact composition of the glove material. Select gloves tested to a relevant standard (e.g. Europe EN374, US F739). When prolonged or frequent repeated contact occurs, Nitrile gloves may be suitable. (Breakthrough time of > 240 minutes.) For incidental contact/splash protection Neoprene, PVC gloves may be suitable. Glove thickness should be typically greater than 0.35 mm depending on the glove make and model.
Skin and body protection	:	Wear chemical resistant gloves/gauntlets and boots. Where risk of splashing, also wear an apron. Protective clothing approved to EU Standard EN14605.
Respiratory protection	:	If engineering controls do not maintain airborne concentrations to a level which is adequate to protect worker health, select respiratory protection equipment suitable for the specific conditions of use. Check with respiratory protective equipment suppliers. Where air-filtering respirators are suitable, select an appropriate combination of mask and filter. Where air-filtering respirators are unsuitable (e.g. airborne concentrations are high, risk of oxygen deficiency, confined space) use appropriate positive pressure breathing apparatus. All respiratory protection equipment and its use, must be in accordance with national and local regulations and national and EU standards. Select a filter suitable for combined particulate/organic gases and vapours [Type A/Type P boiling point > 65°C (149°F)] meeting EN14387 and EN143.

Environmental exposure controls:

- Read in conjunction with the section 6 and the Exposure Scenario for your specific use contained in the Annex.
- Keep containers closed
- Do not dispose of via drains
- Collect spilled product.



SDS SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

"JET A1" (used as example)

9.1. Information on basic physical and chemical properties

Physical state	Liquid at 20 °C and 101 kPa
Colour	light yellowish; clear, bright liquid, free from solid matter and decanted water at ambient temperature
Odour	typical petroleum
Odour threshold	Odour clearly perceptible

Characteristics	Values	Method	Note
Melting point/Freezing point	<= -47 °C	ASTM D2386	
Initial boiling point	ca. 150 °C	ASTM D 86	
Final boiling point	<= 300 °C	ASTM D 86	
Flammability			Flammable liquid; vapours may form explosive/flammable mixtures with air
Lower explosion limit	0,6 %(V)		GESTIS Substance Database (*)
Upper explosion limit	6,5 %(V)		GESTIS Substance Database (*)
Flash point	> 38 °C	ASTM D 3828	
Auto-ignition temperature	220 - 250°C		CSR Concawe
Decomposition temperature	-		not applicable
рН	-		not applicable
Kinematic viscosity	ca. 0,6 mm2/s at 20 °C	EN ISO 3104	
Solubility	< 0,02 g/l in water at 20 °C		GESTIS Substance Database (*)
Partition coefficient n- octanol/water (log value)	1.99 - 18.02		Modelled range of log Pow for constituents of kerosine substances (CSR Concawe)
Vapour pressure	<= 2 kPa at 37,8 °C	ASTM D 6378	
Density	775 - 840 kg/m3 at 15 °C	ASTM D 4052	
Relative density	-		not relevant
Relative vapour density	-		no data available
Particle characteristics	-		not relevant, product is liquid

(*) GESTIS Substance Database: <u>https://gestis-database.dguv.de/</u>



9.2. Other information

9.2.1. Information with regard to physical hazard classes

(Selected as relevant for a petroleum product)

Characteristics	Result	Method	Note
Explosives	not explosive	Derivation from chemical structure	no chemical groups associated with explosive properties in the molecule (CSR Concawe)
Oxidising liquids	not oxidising	Derivation from chemical structure	not able of reacting exothermically with combustible materials (CSR Concawe)

9.2.2. Other safety characteristics

(Selected as relevant for JET A1 product)

Characteristics	Result	Method	Note
Conductivity	50-600 pS/m	ASTM D2624	Electrical conductivity



SDS SECTION 10: STABILITY AND REACTIVITY

A generic product (used as example)

10.1 REACTIVITY There are no known reactivity hazards associated with this product.

10.2 CHEMICAL STABILITY Stable at normal ambient temperatures.

10.3 POSSIBILITY OF HAZARDOUS REACTIONS No potentially hazardous reactions known.

10.4 CONDITIONS TO AVOID Avoid heat, flames and other sources of ignition. Static electricity and formation of sparks must be prevented.

10.5 INCOMPATIBLE MATERIALS Strong oxidizing agents, acids, alkalis and halogens.

10.6 HAZARDOUS DECOMPOSITION PRODUCTS No known hazardous decomposition products.



SDS SECTION 11: TOXICOLOGICAL INFORMATION

"Fuel diesel" (used as example)

11.1. Information on toxicological effects

Acute toxicity (oral): Not classified (Based on available data, the classification criteria are not met)

Acute toxicity (dermal): Not classified (Based on available data, the classification criteria are not met)

Acute toxicity (inhalation): Harmful if inhaled.

Additional information: (according to composition)

Fuels, Diesel - Gasoil, unspecified (68334-30-5)		
LD50 oral rat	ca 7600 mg/kg bodyweight (OECD 420; API, 1980; ARCO 1992)	
LD50 dermal rabbit	> 2000 mg/kg (OECD 402; ARCO, 1992)	
LC50 inhalation - Rat	> 4.81 mg/l/4h (OECD 403; ARCO 1991)	

Skin corrosion/irritation: Causes skin irritation. pH: Lack of data (on mixture / components of the mixture) - Data not available

Additional information: (according to composition)

Serious eye damage/irritation: Not classified (Based on available data, the classification criteria are not met) pH: Lack of data (on mixture / components of the mixture) - Data not available Additional information: (according to composition)

Respiratory or skin sensitisation: Not classified (Based on available data, the classification criteria are not met)

Additional information: (according to composition)

Germ cell mutagenicity: Not classified (Based on available data, the classification criteria are not met) Additional information: (according to composition)

Carcinogenicity: Suspected of causing cancer (Dermal). Additional information: (according to composition)

Reproductive toxicity: Not classified (Based on available data, the classification criteria are not met) Additional information: (according to composition)

STOT-single exposure: Not classified (Based on available data, the classification criteria are not met) Additional information: (according to composition)

STOT-repeated exposure: May cause damage to organs (thymus, liver, blood) through prolonged or repeated exposure (Dermal). Additional information: (according to composition)



Fuels, Diesel - Gasoil, unspecified (68334-30-5)		
NOAEL (dermal, rat/rabbit, 90 days)	0.1 ml/kg (OECD 411, ARCO, 1994)	
NOAEC (inhalation, rat, dust/mist/fume, 90 days)	$_{\geq}$ 1.71 mg/l air (OECD 413, systemic effects) (Lock, Dalbey, Schmoyer, Griesemer; 1984)	
NOAEL (subchronic, oral, animal/male, 90 days)	\geq 5 ml/kg (OECD 408, systemic effects) (McKee, R.H., Plutnick, R.T., Traul, K.A. 1987)	
STOT repeated exposure	May cause damage to organs (thymus, liver, bone marrow) through prolonged or repeated exposure (Dermal).	

Aspiration hazard: May be fatal if swallowed and enters airways.

Additional information: (according to composition) For all low-viscosity petroleum products (less than 20,5 mm2/s at 40 $^{\circ}$ C), there is the risk of aspiration into the lungs. This may occur directly after ingestion, or subsequently in case of vomiting (spontaneous or induced). In this case there is the possibility of an inflamation of the lung tissues (chemical pneumonia). This is a serious condition requiring medical treatment. Aspiration into lungs can cause a chemical pneumonia

Potential adverse human health effects and symptoms: Harmful if inhaled, May cause damage to organs through prolonged or repeated exposure, Aspiration into lungs can cause a chemical pneumonia, Suspected of causing cancer, Prolonged and repeated skin contact may cause reddening, irritation and dermatitis, due to a defatting effect.



SDS SECTION 12: ECOLOGICAL INFORMATION

"Distillates (petroleum), hydrotreated heavy paraffinic" (used as example)

12.1. TOXICITY

The substance is not considered toxic to the aquatic environment, as it does not meet the criteria for classification based on the available data.

Aquatic toxicity data

Species	Acute toxicity	Chronic Toxicity
Fish (Onchorynchus mykiss)	LL50 (96h) >100 mg/L	NOELR (28 d) > 1000 mg/L
	(OECD 203)	(Petrotox v4.0)
Invertebrates (Daphnia	EL50 (48h) >1000 mg/L	NOELR (21 d) > 10 mg/L
magna)	(OECD 202)	(Petrotox v4.0)
Algae (Pseudokirchnerella	EL50 (48 h) >100 mg/L	NOELR (28 d) > 1000 mg/L
subcapitata)	(OECD 201)	(Petrotox v4.0)

12.2. PERSISTENCE AND DEGRADABILITY

This UVCB substance is not readily biodegradable and may contain constituents which do not degrade rapidly in the environment.

12.3. BIOACCUMULATIVE POTENTIAL

This substance may contain constituents that bioaccumulate, but do not biomagnify in biota.

12.4. MOBILITY IN SOIL

This substance is not mobile in soil.

This substance is insoluble and floats on water.

12.5. RESULTS OF PBT AND VPVB ASSESSMENT

According to the results of its assessment, this substance is not PBT or vPvB.

12.6. ENDOCRINE DISRUPTING PROPERTIES

The currently available information does not indicate that this substance has endocrine disrupting properties as defined by the criteria set out in Section B of Regulation (EU) No 2017/2100.

12.7. OTHER ADVERSE EFFECTS



SDS SECTION 13: DISPOSAL CONSIDERATIONS

"Lubricant Base Oil" (used as example)

13.1. Waste treatment methods

13.1.1.Product/Packaging disposal

Product: Recover or recycle if possible. It is the responsibility of the waste generator to specify the toxicity and physical properties of the material generated in order to determine the proper waste classification and disposal methods in compliance with applicable regulations. Do not dispose into the environment, in drains or in water courses.

Packaging disposal: Dispose in accordance with prevailing regulations, preferably to a recognized collector or contractor. The competence of the collector or contractor should be established beforehand.

European Waste Catalogue Number (EWC): 13 08 99

This code is given as a recommendation. The final user has the responsibility for the attribution of the most suitable code according to the actual use(s) of the material, contaminations or alterations.

13.1.2. Waste treatment-relevant information: Do not apply industrial sludge to natural soils.

13.1.3 Sewage disposal-relevant information: Should not be disposed of by release to sewers.

13.1.4 Other disposal recommendations: Disposal should be in accordance with applicable regional, national, and european legislation. Classification of waste is always the responsibility of the waste generator.



SDS SECTION 14: TRANSPORT INFORMATION

"High Benzene Naphtha" (used as example)

SECTION 14: Transport information

14.1 UN number

ADN: 1268

ADR: 1268

RID: 1268

IMDG: 1268

IATA: 1268

14.2 Proper shipping name

ADN: PETROLEUM DISTILLATES, N.O.S. WITH MORE THAN 10% BENZENE

ADR: PETROLEUM DISTILLATES, N.O.S.

RID: PETROLEUM DISTILLATES, N.O.S.

IMDG: PETROLEUM DISTILLATES, N.O.S. (NAPHTHA)

IATA: PETROLEUM DISTILLATES, N.O.S.

14.3 Transport hazard class

ADN: 3

ADR: 3

RID: 3

IMDG: 3

IATA: 3



14.4 Packing group

ADN

Packing group: I

Classification Code: F1

Labels: 3 (N2, CMR, F)

CDNI Inland Water Waste Agreement: NST 3212 Naphtha.

ADR

Packing group: I

Classification Code: F1

Hazard Identification Number: 33

Labels: 3

RID

Packing group: II

Classification Code: F1

Hazard Identification Number: 33

Labels: 3

IMDG

Packing group: I

Labels: 3

IATA

Packing group: I

Labels: 3



14.5 Environmental hazards

ADN

Environmentally hazardous: yes

ADR

Environmentally hazardous: yes

RID

Environmentally hazardous: yes

IMDG

Marine pollutant: yes

14.6 Special precautions for user

Remarks: Special Precautions: Refer to Section 7, Handling & Storage, for special precautions which a user needs to be aware of or needs to comply with in connection with transport.

14.7 MARITIME TRANSPORT IN BULK ACCORDING TO IMO INSTRUMENTS

Pollution category: Y

Ship type: 3

Product name: Benzene and mixtures having 10% benzene or more (i)



SDS SECTION 15: REGULATORY INFORMATION

"Diesel (placed in Germany)" (used as example)

<u>15.1</u> Safety, health and environmental regulations/legislation specific for the substance or mixture

Chemicals Ban Ordinance: Prohibitions and restrictions of placing on the market according to § 3 ChemVerbotsV

Food Contact Materials and Articles Directive, Annex 1 to § 3: No. 5

Maternity Protection Act and Young Persons Employment Act: The restrictions of employment as per the Articles 11 and 12 of the Administrative Order on the Protection of Mothers at the Workplace and Art. 22 of the Act on the Protection of Young People at the Workplace have to be observed.

Substance number / category as per the Major Accidents Ordinance:

2.3.3 Petroleum products and alternative fuels: Gas oils (including diesel fuels, home heating oils and gas oil blending streams)

1.2.5.3 P5c Flammable liquids

1.3.2 E2 Hazardous to the Aquatic Environment in Category Chronic 2

Water contaminating class: WGK 2 significantly water endangering; code no. 76, Announcement according to § 66 (1) AwSV from 10.08.2017

TA Luft: 5.2.5 I

Community provisions on the protection of the health and the environment

Directive 2010/75/EU on industrial emissions (integrated pollution prevention and control) -Chapter V - Special provisions for installations and activities using organic solvents:

When properly used, product is not subject to VOC-Guideline (see Section 1.2).

Regulation (EC) no. 1907/2006, Annex XVII (REACH-Regulation):

No. 3 - liquid substances or mixtures classified as dangerous by the definitions of the EEC Directive no. 67/548 and the Directive 1999/45/EC;

Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC (SEVESO III):

Annex I, Part 1:
P5c FLAMMABLE LIQUIDS
E2 Hazardous to the Aquatic Environment in Category Chronic 2.
Annex I Part 2:
34. Petroleum products and alternative fuels.
(c) gas oils (including diesel fuels, home heating oils and gas oil blending streams).

Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding (tenth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC):

This product is subject to the restrictions set by the national legislation transposing the Directive.

Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work:



This product is subject to the restrictions set by the national legislation transposing the Directive.

15.2 Chemical Safety Assessment

A chemical safety assessment was performed for the substance(s) in the product within the framework of the REACH registration. It was verified that control of the main constituent as a lead substance ensures appropriate control of all other constituents of the mixture. Therefore, the scenarios listed in the Annex are those developed for the main substance CAS-NR.: 68334-30-5



SDS SECTION 16: OTHER INFORMATION

"E10 Gasoline blend" (used as example)

Full text of hazard classes and H-Statements referred to under sections 2 and 3

Acute Tox. Aquatic Chronic Asp. Tox. Carc. Eye Irrit. Flam. Liq. Muta. Repr. Skin Irrit. STOT RE STOT SE	Acute toxicity Chronic aquatic toxicity Aspiration hazard Carcinogenicity Serious eye damage / Eye irritation Flammable liquids Germ cell mutagenicity Reproductive toxicity Skin corrosion/irritation Specific target organ toxicity - repeated exposure Specific target organ toxicity - single exposure
H224	Extremely flammable liquid and vapour.
H225	Highly flammable liquid and vapour.
H301	Toxic if swallowed.
H302	Harmful if swallowed.
H304	May be fatal if swallowed and enters airways.
H311	Toxic in contact with skin.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H331	Toxic if inhaled.
H336	May cause drowsiness or dizziness (Inhalation).
H340	May cause genetic defects.
H350	May cause cancer.
H361d	Suspected of damaging the unborn child.
H361f	Suspected of damaging fertility.
H361fd	Suspected of damaging fertility. Suspected of damaging the unborn child.
H370	Causes damage to organs (optic nerve (nervus opticus), central nervous system).
H372	Causes damage to organs (haematopoietic system) through prolonged or repeated exposure (oral, inhalation and dermal).
H373	May cause damage to organs (nervous system) through prolonged or repeated exposure (inhalation).
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

List of acronyms:

ADN = European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

- ADR = Agreement Concerning the International Carriage of Dangerous Goods by Road
- ATE = Acute Toxicity Estimate
- BCF = Bioconcentration factor
- BLV = Biological Limit Value

CAS-No = Chemical Abstracts Service number

CMR = Carcinogen, Mutagen, or toxic to Reproduction

- CSA = Chemical Safety Assessment
- CSR = Chemical Safety Report



DMEL = Derived Minimal Effect Level DNEL = Derived No Effect Level EC50 = The effective concentration of substance that causes 50% of the maximum response. ECHA = European Chemicals Agency EC-Number = EINECS and ELINCS Number (see also EINECS and ELINCS) EINECS = European Inventory of Existing Commercial Chemical Substances EL50 = effective load 50% ELINCS = European List of notified Chemical Substances EPA = Environmental Protection Agency(U.S.)GES = Generic Exposure Scenario IATA = International Air Transport Association IC50 = inhibition concentration 50%ICAO-TI = Technical Instructions for the Safe Transport of Dangerous Goods by Air IMDG = International Maritime Dangerous Goods Koc = soil organic carbon-water partitioning coefficient Kow = octanol-water partition coefficient LC50 = Lethal Concentration to 50 % of a test population LD50 = Lethal Dose to 50% of a test population (Median Lethal Dose) LGK = Storage class LL50 = Lethal Load 50% LOAEC = Lowest Observed Adverse Effect Concentration LOAEL = Lowest Observed Adverse Effect Level NOAEC = No Observed Adverse Effect Concentration NOAEL = No Observed Adverse Effect Level NOEC = No Observed Effect Concentration NOEL = No Observed Effect Level OECD = Organization for Economic Co-operation and Development **OEL = Occupational Exposure Limit** OSHA = European Agency for Safety and Health at Work PBT = Persistent, Bioaccumulative and Toxic substance PEC = Predicted Effect Concentration PNEC = Predicted No Effect Concentration (Q)SAR = Quantitative Structure Activity Relationship RID = Regulations concerning the International Carriage of Dangerous Goods by Rail RMM = Risk Management Measure STEL = Short term exposure limit SVHC = Substances of Very High Concern TLV = Threshold Limit Value TRA = Targeted Risk Assessment TRGS = Technical Rules for Hazardous Substances (Germany) TWA = Time-Weighted Average UVCB = substance of unknown or variable composition, complex reaction products or biological materials vPvB = very Persistent and very Bioaccumulative

Sources of information:

Chemical Safety Reports (CSR); Guidance of Safe Use (GSU), chemical databases and handbooks

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Flam. Liq. 1 H224 - On basis of test data Skin Irrit. 2 H315 - Calculation method Asp. Tox. 1 H304 - On basis of test data Repr. 2 H361fd - Calculation method Muta. 1B H340 - Calculation method Carc. 1B H350 - Calculation method STOT SE 3 H336 - Calculation method Aquatic Chronic 2 H411 - Calculation method

Markings (|) in the left border and/or text in red indicate changes in the previous main version.

Disclaimer: The above data are in accordance with our knowledge and experience at the given date of revision and exclusively refer to the product in its as-delivered condition as it is unambiguously identifiable by the product number. In the case of usages deviating from those given in section 1 or when the product is mixed with other materials or is altered in the course of a production process, the statements given in the extended Safety Data Sheet may not apply without restrictions or even not at all any more. The data are not applicable to other products of the same or a similar designation.



EXTENDED SDS (ANNEX)

The REACH Regulation requires in Article 31, paragraph 7 that Exposure Scenarios, describing operational conditions and risk management measures necessary for safe use of a classified substance, are placed in an Annex to the SDS, for all identified uses.

There are however no mandatory requirements for the presentation format of the Exposure Scenarios and level of detail provided in the various sections. Consequently, a variety of formats and approaches have emerged in extended Safety Data Sheets authored by member companies, each with their own merits, and CONCAWE cannot presently recommend a single preferred option. For example, table of uses and use descriptors can also be listed here (instead of section 1.2.1).

In addition, for classified mixtures there are several options to present the safe handling requirements, as described in Chapter 18 of this report, and therefore also for mixture SDS no recommendation is available at present.

Further practical examples of Exposure Scenarios from supplier's and recipient's point of view are available e.g. in the ECHA (2018) Guide on Safety data sheets and Exposure scenarios (ECHA, 2018).



APPENDIX 4: EXAMPLE OF CONCAWE SUMI

DISCLAIMER: THIS SUMI EXAMPLE IS ONLY DRAFT - NOT PUBLISHED BY CONCAWE

SUMI

Safe Use of Mixtures Information for end-users



Concawe SUMI - Professional Diesel Use

This document is intended to communicate the conditions of safe use for the product, based on the exposure assessments required under REACH, and should always be read in combination with the product's Safety Data Sheet and labels.

General description of the process covered

Covers the use as a fuel (or fuel additive) and includes activities associated with its transfer, use, equipment maintenance and handling of waste.

Operational conditions - applicable to all contributing scenarios

Covers use at ambient temperatures

Covers daily exposures up to 8 hours

Provide a good standard of general ventilation OR Ensure operation is undertaken outdoors Assumes a good basic standard of occupational hygiene is implemented.

Risk Management Measures (RMMs) - applicable to all contributing scenarios

General measures (flammability hazard, if classified as H224 or H225 or H226):

Use in contained systems. Avoid ignition sources – No Smoking. Handle in well ventilated area to prevent formation of explosive atmosphere. Use equipment and protective systems approved for flammable substances. Restrict line velocity during pumping to avoid generation of electrostatic discharge. Ground/bond container and receiving equipment. Use non-sparking tools.

General measures (aspiration hazard, if classified as H304):

Do not ingest. If swallowed then seek immediate medical assistance.

General measures (skin irritants):

Ensure that direct skin contact is avoided. Identify potential areas for indirect skin contact. Wear suitable gloves tested to EN374. Clear spills immediately. Wash off any skin contamination immediately.

General measures applicable to all activities:

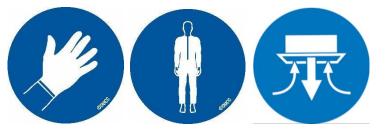
Minimise exposure using measures such as contained and enclosed systems, properly designed and maintained dedicated facilities and suitable general/local exhaust ventilation. Ensure staff are informed of and trained on the nature of exposure and basic actions to minimise exposure. Wear suitable coveralls to prevent exposure to the skin. Clear spills immediately. Ensure control measures are regularly inspected and maintained.



Consider the need for risk based health surveillance.

Risk Management Measures (RMMs) - applicable to specific contributing scenarios

Contributing	Specific RMM
scenario	
Bulk transfers Dedicated facility	Ensure material transfers are under containment or extract ventilation Wear chemically resistant gloves (tested to EN374) in combination
	with 'basic' employee training.
Drum/batch transfers Dedicated facility	Use drum pumps Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training.
Refuelling	Use drum pumps Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training.
General exposures Closed systems	Handle substance within a closed system
Use of fuels Closed systems	Handle substance within a closed system
Equipment cleaning and maintenance	Drain down and flush system prior to equipment break-in or maintenance Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training.
Storage	Store substance within a closed system



See also section 8 of the Safety Data Sheet (SDS) for specifications.

For the disposal of product residues and waste please refer to section 13 of the SDS.

Additional good practice advice

Follow the product instructions as specified on the label, or in the product's technical literature.

Do not empty the product into drains / surface water / ground water.

Disclaimer

In the case that this product contains ingredients classified as hazardous to the environment, the use has been assessed to be safe for the environment. The assessment is based on the exposure parameters that are described for the product use in the corresponding SPERCs. This document has been developed using the best knowledge currently available and the information is provided in good faith. The use of the compiled information remains the responsibility of the user, according to their role, as indicated below. Concawe is under no



condition liable for any damage of any nature whatsoever resulting from the use or reliance on this paper.

Regarding end-users

According to Occupational Health and Safety (OSH) legislation, the employer of workers that use products remains responsible for communicating any other relevant use or safety information to the employees. When developing workplace instructions for employees, the Safe Use of Mixtures Information (SUMI) should always be considered in combination with the SDS and the labelling (P-statements) of the product. The information provided in the present document should not be changed by the recipient (employer). If specific changes are needed, for example on the Operational Conditions or Risk Management Measures, the recipient should contact their supplier (formulator).



APPENDIX 5: DERIVED NO-EFFECT LEVELS (DNELS) IN CONCAWE REGISTRATION DOSSIERS¹

Concawe	Endpoint	DNEL
Category		
Bitumen	W-INH-LOC-LT	2.88 mg/m ³
bitumen	GP-DERM-LOC-LT	0.61 mg/kg/day
	W-INH-SYS-LT	27.34 mg/m ³
CrackedGO	W-INH-SYS-A	2229.76 mg/m ³
ClackedGO	W-DERM-SYS-LT	2.42 mg/kg/day
	GP-ORAL-SYS-LT	1.04 mg/kg/day
Footsoil	W-INH-LOC-LT	5.58 mg/m ³
FOOLSOII	GP-INH-LOC-LT	1.19 mg/m ³
	W-INH-SYS-LT	2.73 mg/m ³
Footsoil (carc)	W-INH-LOC-LT	5.58 mg/m ³
	W-DERM-SYS-LT	0.97 mg/kg/day
	GP-ORAL-SYS-LT	0.74 mg/kg/day
	W-INH-SYS-LT	0.18 mg/m ³
HFO	W-DERM-SYS-LT	0.065 mg/kg/day
пго	GP-ORAL-SYS-LT	0.015 mg/kg/day
	W-INH-SYS-A	4716.8 mg/m ³
	W-INH-SYS-LT	164.56 mg/m ³
	W-DERM-SYS-LT	217.05 mg/kg/day
HRBO	GP-INH-SYS-LT	34.78 mg/m ³
	GP-DERM-SYS-LT	93.02 mg/kg/day
	GP-ORAL-SYS-LT	25 mg/kg/day
Kerosine	GP-ORAL-SYS-LT	N/A
LBO	W-INH-LOC-LT	5.58 mg/m ³
LDU	GP-INH-LOC-LT	1.19 mg/m ³
	W-INH-SYS-LT	2.73 mg/m ³
	W-INH-LOC-LT	5.58 mg/m ³
LBO (carc)	W-DERM-SYS-LT	0.97 mg/kg/day
	GP-ORAL-SYS-LT	0.74 mg/kg/day
MK1	GP-ORAL-SYS-LT	N/A
	W-INH-SYS-A	1286.4 mg/m ³
Naphtha	W-INH-LOC-LT	837.5 mg/m ³
	W-INH-LOC-A	1066.67 mg/m ³
	GP-INH-SYS-A	1152 mg/m ³
	GP-INH-LOC-LT	178.57 mg/m ³

¹ As in 2021 Concawe registration dossiers



Concawe	Endpoint	DNEL
Category		
	GP-INH-LOC-A	640 mg/m ³
	W-INH-SYS-LT	1.9 mg/m ³
	W-INH-SYS-A	1286.4 mg/m ³
	W-INH-LOC-LT	837.5 mg/m ³
Naphtha (carc)	W-INH-LOC-A	1066.67 mg/m ³
Napittia (carc)	GP-INH-SYS-LT	0.41 mg/m ³
	GP-INH-SYS-A	1152 mg/m ³
	GP-INH-LOC-LT	178.57 mg/m ³
	GP-INH-LOC-A	640 mg/m ³
	W-INH-SYS-LT	16.4 mg/m ³
	W-INH-SYS-A	5002.7 mg/m ³
	W-DERM-SYS-LT	2.91 mg/kg/day
OtherGO	GP-INH-SYS-LT	4.85 mg/m ³
	GP-INH-SYS-A	3001.6 mg/m ³
	GP-DERM-SYS-LT	1.25 mg/kg/day
	GP-ORAL-SYS-LT	1.25 mg/kg/day
	W-INH-SYS-LT	16.4 mg/m ³
OtherGO (carc)	W-INH-SYS-A	5002.7 mg/m ³
	W-DERM-SYS-LT	2.91 mg/kg/day
	GP-ORAL-SYS-LT	1.25 mg/kg/day
OxiAsnh	W-INH-LOC-LT	2.88 mg/m ³
OxiAsph	GP-DERM-LOC-LT	0.61 mg/kg/day
Paraffinwax	N/A	N/A
Petrolatum	N/A	N/A
Petrolatum	W-INH-SYS-LT	2.73 mg/m ³
(carc)	W-DERM-SYS-LT	5.81 mg/kg/day
(care)	GP-ORAL-SYS-LT	0.74 mg/kg/day
	W-INH-SYS-LT	136.68 mg/m ³
	W-DERM-SYS-LT	48.45 mg/kg/day
RAE	GP-INH-SYS-LT	28.89 mg/m ³
	GP-DERM-SYS-LT	5.19 mg/kg/day
	GP-ORAL-SYS-LT	5.19 mg/kg/day
	W-INH-SYS-LT	136.68 mg/m ³
RAE (carc)	W-DERM-SYS-LT	48.45 mg/kg/day
	GP-ORAL-SYS-LT	5.19 mg/kg/day
Slackwax	N/A	N/A
	W-INH-SYS-LT	2.73 mg/m ³
Slackwax (carc)	W-DERM-SYS-LT	5.81 mg/kg/day
	GP-ORAL-SYS-LT	0.74 mg/kg/day



Concawe	Endpoint	DNEL
Category		
	W-INH-SYS-A	1500.8 mg/m ³
	W-DERM-SYS-LT	2.91 mg/kg/day
	GP-INH-SYS-LT	4.85 mg/m ³
SRGO	GP-INH-SYS-A	900.48 mg/m ³
	GP-DERM-SYS-LT	1.25 mg/kg/day
	GP-ORAL-SYS-LT	1.25 mg/kg/day
	W-INH-SYS-LT	16.4 mg/m ³
Sulfur	N/A	N/A
TDAE	W-INH-LOC-LT	5.58 mg/m ³
TDAL	GP-INH-LOC-LT	1.19 mg/m ³
	W-INH-SYS-LT	2.73 mg/m ³
TDAE (carc)	W-DERM-SYS-LT	0.97 mg/kg/day
	GP-ORAL-SYS-LT	0.74 mg/kg/day
	W-INH-SYS-LT	2.73 mg/m ³
UATO	W-INH-LOC-LT	5.58 mg/m ³
UATO	W-DERM-SYS-LT	32.3 mg/kg/day
	GP-ORAL-SYS-LT	0.74 mg/kg/day
	W-INH-SYS-LT	2.73 mg/m ³
UDAE	W-DERM-SYS-LT	0.97 mg/kg/day
	GP-ORAL-SYS-LT	0.74 mg/kg/day
	W-INH-SYS-LT	68.34 mg/m ³
	W-INH-SYS-A	4288 mg/m ³
	W-DERM-SYS-LT	2.91 mg/kg/day
VHGO	GP-INH-SYS-LT	20.22 mg/m ³
	GP-INH-SYS-A	2572.8 mg/m ³
	GP-DERM-SYS-LT	1.25 mg/kg/day
	GP-ORAL-SYS-LT	1.25 mg/kg/day



Concawe Boulevard du Souverain 165 B-1160 Brussels Belgium

Tel: +32-2-566 91 60 Fax: +32-2-566 91 81 e-mail: info@concawe.eu http://www.concawe.eu

