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Developing worker and consumer exposure scenarios for identified uses of petroleum substances under REACH - 2020 edition

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Developing worker and consumer exposure scenarios for identified uses of petroleum substances under REACH - 2020 edition

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ABSTRACT

Under REACH, Exposure Scenarios (ES) need to be developed for all identified uses of chemical substances that are manufactured or imported in quantities above 10 tonnes per year and classified as hazardous according to Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation). ES constitute an essential part of the REACH Chemical Safety Assessment (CSA) and are included in the Chemical Safety Report of the registration dossier. These scenarios describe the Risk Management Measures and Operational Conditions to be followed by supply chain actors to ensure that the substance can be used safely, i.e. without harm to humans or the environment, and which are required to be communicated to downstream users as an Annex to the extended Safety Data Sheet.

This report sets out the approaches that Concawe has adopted in developing worker and consumer ES for identified uses of petroleum substances under REACH. Exposure Scenarios had been initially developed by Concawe in view of the REACH 2010 registrations (Concawe report 11/12), and have been updated in 2020, as documented in the present report. Using the Generic Exposure Scenarios of the European Solvents Industry Group (ESIG) as reference point for consistency across other supply chains of complex substances, the 2020 updates for the Human Health (HH) part have been based on the most recent ECHA guidance documents on exposure and risk assessment and have considered further refinements needed for the Concawe CSAs, given the complex nature of petroleum substances. Concawe HH CSAs have been transcribed using the CHEmical Safety Assessment and Reporting (CHESAR) tool v3.3 developed by ECHA.

KEYWORDS

Exposure scenarios, chemical safety assessment, exposure and risk assessment, CHESAR, REACH

INTERNET

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

CONTENTS

Page

SUMMARY

Under REACH, manufacturers and importers of chemical substances (above 1 tonne/year) need to register to ECHA all identified uses as they occur throughout chemical life cycle. As per REACH Article 14.4, for those substances that are sold in quantities above 10 tonnes per year and classified as hazardous according to Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation), exposure scenarios (ES) are required to be developed for all the uses as part of the REACH Chemical Safety Assessment (CSA) and included in the Chemical Safety Report of the registration dossier. These scenarios describe the conditions to be followed by supply chain actors to ensure that the substance can be used safely, i.e. without harm to humans or the environment, and which are required to be communicated to downstream users as an Annex to the extended Safety Data Sheet (eSDS).

REACH ECHA Guidance D & E on Information Requirements and Chemical Safety Assessment define the basic principles for how to carry out an exposure assessment and risk assessment under REACH, respectively. This report sets out the approaches that Concawe has adopted in developing worker and consumer ES for identified uses of petroleum substances as part of REACH CSA. ES had been initially developed by Concawe in view of the REACH 2010 registrations (Concawe report 11/12), and have been updated in 2020, as documented in the present report. Updates for the Human Health (HH) part have been based on the most recent ECHA guidance documents and have considered further refinements needed for the Concawe CSAs, given the complex nature of petroleum substances. Concawe HH CSAs have been transcribed using the CHEmical Safety Assessment and Reporting (CHESAR) tool v3.3 developed by ECHA.

Concawe has made significant use of the European Solvents Industry Group (ESIG) Generic Exposure Scenarios (GES) for solvents as a reference point. ESIG GES represent a consensus between chemical manufacturers and downstream users of solvents on the form and content of ES and were already used by Concawe in the 2010 REACH registrations, as they cover petroleum substances well in terms of both typical uses and ranges of phys-chem properties. The GES-based ES are deemed sufficient in their scope to adequately address the range of representative activities associated with solvent uses and are written in a form that is understandable to downstream user sectors. Adopting the ESIG GES mapping has therefore enabled Concawe CSAs to remain consistent across other supply chains of complex substances, also known as UVCBs (Unknown or Variable composition, Complex reaction products or of Biological materials).

The process adopted by Concawe in developing the Human Health (HH) part (worker and consumer) of the CSA for petroleum substances consists of four elements/steps:

1. Mapping and describing uses of petroleum substances in accordance with ESIG GESs
2. Evaluation of human health risks associated with the uses
3. Providing additional good practice advice (if necessary)
4. Communication of safe use conditions

The structure of this report reflects and details the above four components of the HH CSA development process for petroleum substances as documented in ES in the Concawe REACH registration dossiers. These dossiers are annually updated and are available to Concawe member companies to construct the ES annexes of the SDS,

aiming to advise downstream users about the Risk Management Measures and Operational Conditions that should be in place. This report provides some additional help for downstream users to interpret ESs developed by Concawe.

1. INTRODUCTION

REACH Guidance D (ECHA, 2016a) and REACH Guidance E (ECHA, 2016b) on Information Requirements (IR) and Chemical Safety Assessment (CSA) define the basic principles for how to carry out an exposure assessment and risk assessment under REACH, respectively. This report sets out the approaches that Concawe has adopted in developing worker and consumer Exposure Scenarios (ES) for identified uses of petroleum substances as part of REACH Chemical Safety Assessments (CSA). ES had been initially developed by Concawe in view of the REACH 2010 registrations (Concawe report 11/12, 2012), and have been updated in 2020, as documented in the present report. Updates have been based on the most recent ECHA IR & CSA guidance documents and have considered further refinements needed for the Concawe CSAs, given the complex nature of petroleum substances.

The process adopted by Concawe in developing the worker and consumer ES for REACH CSAs of petroleum substances is described in ***Figure 1*** below and consists of four elements:

1.1. MAPPING AND DESCRIBING USES OF PETROLEUM SUBSTANCES

The uses of petroleum substances are mapped and described in a manner that aligns with the expectations of REACH Guidance D on exposure assessment (ECHA, 2016a) and REACH Guidance R12 on use description (ECHA, 2015). In this respect, Concawe has made significant use of the European Solvents Industry Group (ESIG) Generic Exposure Scenarios (GES) for solvents as a reference point. ESIG GES represent a consensus between chemical manufacturers and downstream users on the form and content of ES and were already used by Concawe in the 2010 REACH registrations, as they cover petroleum substances well in terms of both typical uses and ranges of phys-chem properties. The GES-based ES are deemed sufficient in their scope to adequately address the range of representative activities associated with solvent uses and are written in a form that is understandable to downstream user sectors. Adopting the ESIG GES mapping has therefore enabled Concawe CSAs to remain consistent across other supply chains of complex substances (aka UVCBs[1]).

1.2. EVALUATION OF HUMAN HEALTH RISKS ASSOCIATED WITH THE USES

Human health (worker and consumer) exposure and risks associated with the use of petroleum substances have been evaluated and progressed in a manner consistent with REACH Guidance R14 on occupational exposure assessment (ECHA, 2016c) and REACH Guidance R15 on consumer exposure assessment (ECHA, 2016d) for those uses identified under step 1 above. To this end, different approaches to exposure and risk evaluation and management have been followed depending on substance's hazard type:

a. Qualitative CSA

Qualitative hazards, as determined according to REACH endpoint specific Guidance R7a (ECHA, 2017a), have been addressed in alignment with REACH Guidance E on risk characterisation (ECHA, 2016b). The P (precautionary) statements (UN, 2019) associated with the qualitative hazards have been used as a basis to define the Risk Management Measures (RMMs) and Operational Conditions (OCs) required to control the risk associated with the use of petroleum substances.

[1] Unknown or Variable composition, Complex reaction products or of Biological materials

b. Quantitative CSA

For quantitative hazards, Concawe has used, as its basis, the exposure predictions contained within the ECETOC TRA v3.1 tool (ECETOC, 2004, 2009, 2012, 2014, 2018; hereinafter referred to as the TRA tool). The exposure predictions were compared with relevant Derived No-Effect Levels (DNELs) developed according to Boogaard *et al.* (2012) and the REACH Guidance R8 on characterisation of dose [concentration]-response for human health (ECHA, 2012). In addition, due to the nature of exposures arising from the use of petroleum substances, Concawe has addressed forms of exposure that are not within the scope of REACH but are necessary considerations for the effective management of health risks, *e.g.*, mists/fumes. Derivation of safe use advice (*i.e.* RMMs and OCs) to appear in the resulting ES, starts from input/default RMMs and OCs in ESIG GES. Alternative RMMs have been applied if these were considered more appropriate for petroleum substances, following the hierarchy of controls concept.

c. Semi-quantitative CSA

Petroleum substances associated with high hazards, *i.e.* carcinogenic, mutagenic and/or reprotoxic substances in accordance with REACH Guidance E, Table E.3-1 (ECHA, 2016b), have been addressed in a semi-quantitative manner. Concawe has used, as its basis, the exposure predictions contained within the TRA tool, but supplemented these frequently with actual exposure monitoring data from literature, exposure measured data shared by Concawe member companies, and/or higher tier exposure estimates. The exposure predictions were then compared with relevant Derived No-Effect Levels (DNELs) or were addressed qualitatively if it was not possible to derive a threshold value.

The RMMs and OCs determined based on the exposure and risk assessment have been used to develop the ES. However, alternative RMMs with greater exposure reduction effectiveness have been applied where appropriate (*e.g.* to reflect compliance with 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 (CMD)).

1.3. PROVIDING ADDITIONAL GOOD PRACTICE ADVICE

During the course of developing ES and CSAs for petroleum substances, additional information relevant for assessing and managing the associated health risks (e.g. skin defatting hazard) has been identified. This information, whilst not required to be part of the ES, is relevant for users of these substances and has been included in the ES for communication downstream.

1.4. COMMUNICATION OF SAFE USE

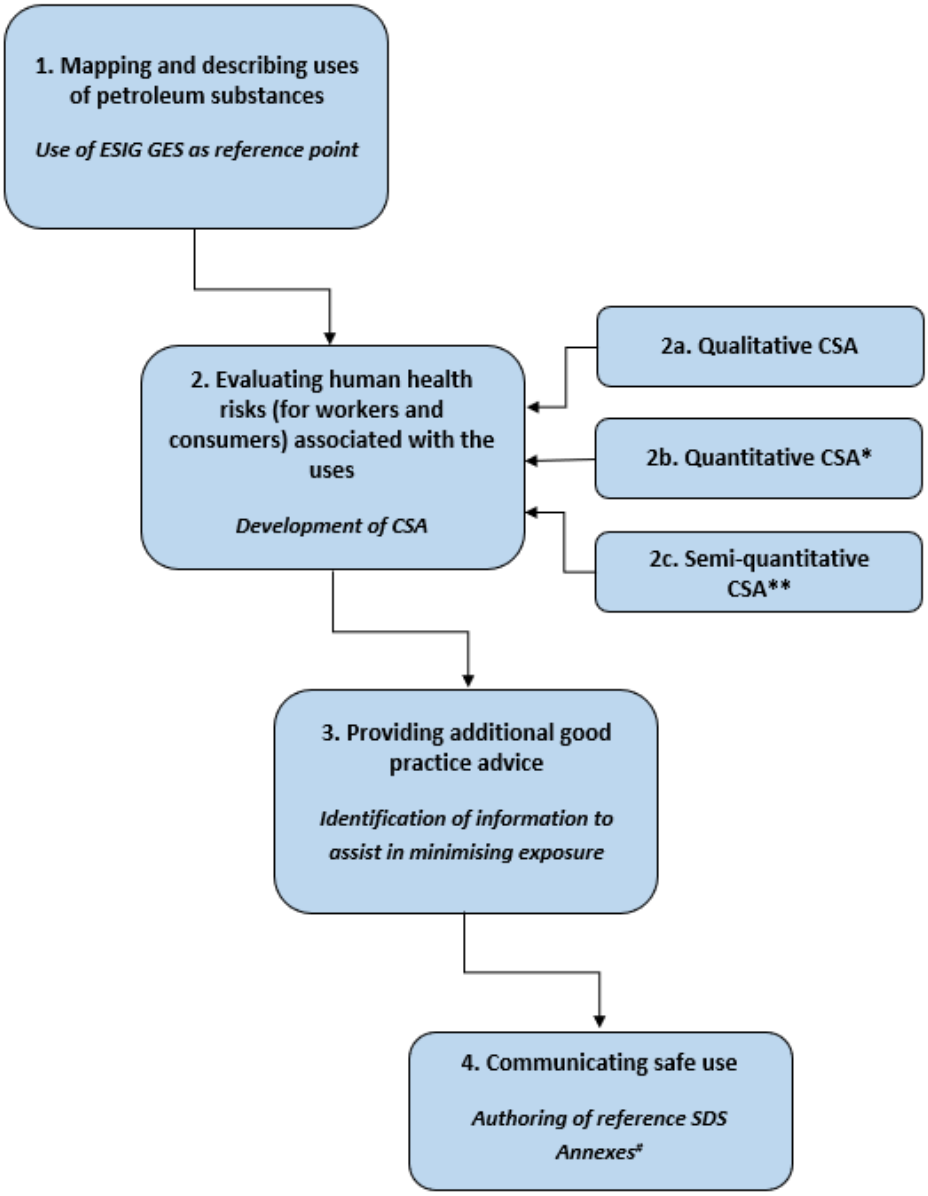
In the last step, the output of the qualitative, quantitative and/or semi-quantitative CSAs has been transformed into narrative ES where the choice of standard phrases reflected the RMMs and OCs required to manage associated risks. These phrases were sourced from the ESCom standard phrase library[2] or, where these were unavailable, Concawe developed (and substantiated) suitable phrases for subsequent review and potential incorporation within the library.

[2] https://cefic.org/app/uploads/2019/11/ESCOM-STANDARD-PHRASE-CATALOGUE-AND-XML-STANDARD-EXPLANATORY-NOTE.pdf

The structure of this report reflects and details the four components of the human health CSAs development process for petroleum substances.

The main purpose of the developed ES is linked to the development of REACH registration dossiers for petroleum substances prepared by Concawe. These dossiers are annually updated and are available to Concawe member companies to construct the ES annexes of the Safety Data Sheets (SDS), aiming to advise downstream users about the applicable RMMs and OCs. This report can also be used by downstream users to help interpret ESs developed by Concawe (see also **Chapter 3** and **Chapter 4**).

Figure 1. The process adopted by Concawe in developing the human health part of the Chemical Safety Assessment (CSA) for petroleum substances



* applicable if a DNEL is derived for the assessed substance

**applicable if the assessed substance is a carcinogen and/or mutagen

#Concawe is not responsible for SDS authoring; the responsibility of authoring eSDS lies with the registrants

2. DEFINING LIFE CYCLE STAGES FOR PETROLEUM SUBSTANCES

2.1. IDENTIFIED USES

REACH requires manufacturers and importers of chemical substances to register their uses[3] as they occur throughout their life cycle from manufacture, formulation, end use applications to waste disposal. For those substances that are sold in quantities above 10 tonnes per year and classified as hazardous (as per REACH Article 14.4), ES[4] are required to be developed for the identified uses as part of the REACH CSA (and included in Chemical Safety Report, CSR). These scenarios describe the conditions which, if followed, ensure that the substance can be used safely, *i.e.* without harm to humans or the environment, and which are required to be communicated to downstream users as an Annex to the eSDS[5].

Although the main end use for most petroleum substances is fuel use, there are additional end uses applicable to petroleum substances. Concawe has prepared a map[6] of identified uses based on input provided from all registrants. The mapping has been done by grouping applications into Concawe GES titles, which are based on the ESIG GES (see **Section 2.2.1**). Concawe has built on the work of ESIG in order to ensure a consistency of how safe use is determined and communicated through similar supply chains. The Concawe Handbook of Identified Uses of petroleum substances and the respective Use Descriptors is annually updated, along with the registration dossier update annual process, and is used to define the life cycle stages of all petroleum substances.

It is important to note that the primary method of communication of an 'identified use' under REACH is *via* the short title of the ES and its supporting explanatory scope statement, *i.e.* a brief general description of use. ECHA has introduced various Use Descriptors including Sectors of Use (SU), Product Categories (PCs), Process Categories (PROCs) and Environmental Release Categories (ERCs) to help further describe uses. However, it should be noted that these Use Descriptors fulfil a secondary role and are intended to assist in the process of use communication within supply chains; their role is described in greater detail in the REACH Guidance R12 (ECHA, 2015).

[3] Use as defined in REACH Article 3.24
[4] The full REACH definition for an ES (Article 3.37) is: 'ES' means the set of conditions, including RMMs and OCs, that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment.
[5] Extended Safety Data Sheet (SDS with Annex containing ES)
[6] The most recent Concawe "Handbook - Identified Uses of Petroleum Substances" can be downloaded *via*: www.concawe.eu/reach/documents-to-download; For 2020: "https://www.concawe.eu/wp-content/uploads/Handbook_Identified-Uses-of-PS_2020-dossier-update.pdf"

2.1.1. Classification and Labelling Permutations

It is important to note that composition of petroleum substances[7] can considerably vary as these are recognised, from a regulatory perspective, as substances of Unknown or Variable composition, Complex reaction products or of Biological materials (UVCBs). Under CLP and REACH, it is possible to group substances together into categories where their physical hazards, human and environmental toxicological properties and environmental fate properties are likely to be similar or follow a regular pattern as a result of structural similarities. Petroleum substances can be grouped together according to manufacturing processes which determine to a large degree their (similar) composition and physicochemical properties (Concawe report 22/20, 2020)

Within the Substance Identify Profile (SIP) of a petroleum substance, the physical-chemical properties (*e.g.* flashpoint, viscosity) can vary to such a degree that several classification and labelling (C&L) combinations, hereinafter denoted as 'C&L permutations', may apply for one petroleum substance. In ***Table 1***, the various C&L permutations per petroleum substance category are listed. The Table only includes qualitative and semi-quantitative hazards in accordance with Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation) and includes the 16 Concawe petroleum categories requiring a CSA. As can be seen, up to four permutations per petroleum category may apply. C&L permutations exist for the following hazard endpoints:

- *Flammability*: exact classification depending on flash point, initial boiling point and petroleum category;
- *Aspiration hazard*: classification applicable if the viscosity is ≤20.5 mm^2/s at 40°C;
- *Carcinogenicity*: classification applicable if the DMSO[8] extractables as measured by IP346 assay are ≥ 3.0% (IP, 1993)[9]

Detailed information on the C&L of petroleum substances can be found in Concawe C&L report in the European Economic Area (Concawe report 22/20, 2020).

2.1.2. Restricted Uses according to REACH Annex XVII

In line with REACH Annex XVII Entry 5, uses of petroleum substances with more than 0.1% by weight benzene are not supported in any application, except for:

- motor *fuels* which are covered by Directive 98/70/EC[10];
- substances and mixtures for use in industrial processes not allowing for the emission of benzene in quantities in excess of those laid down in existing legislation.

In line with REACH Annex XVII Entry 28 and Entry 29, uses of petroleum substances classified as carcinogen category 1 (A or B) and/or mutagen category 1 (A or B) are not supported in consumer products. Exempted from REACH Annex XVII Entry 28 and Entry 29 are, however, the following consumer uses:

[7] Within the scope of this report, a petroleum substance is defined by its unique EC number
[8] DiMethyl SulfOxide
[9] For OtherGO category the distinction was made in accordance with industry note N in Annex VI of CLP
[10] Directive 98/70/EC applies to (Article 2(1)) gasoline intended for the operation of internal combustion positive-ignition engines for the propulsion of vehicles and (Article 2(2)) diesel fuel used for self-propelling vehicles.

- motor fuels which are covered by Directive 98/70/EC[11];
- mineral oil products intended for use as fuel in mobile or fixed combustion plants;
- fuels sold in closed systems (*e.g.* liquid gas bottles).

[11] Directive 98/70/EC applies to (Article 2(1)) gasoline intended for the operation of internal combustion positive-ignition engines for the propulsion of vehicles and (Article 2(2)) diesel fuel used for self-propelling vehicles.

Table 1. Concawe petroleum substance categories and associated Hazard (H) Statements that require a qualitative and/or semi-quantitative Chemical Safety Assessment

Category	Permutation No.	Flammability	Aspiration	Skin irritation	Drowsiness / dizziness	Carcinogenicity	Mutagenicity	Skin cracking / defatting
CrackedGO	1	H226	H304	H315	-	H350	-	-
	2	-	H304	H315	-	H350	-	-
Footsoil	1*	-	-	-	-	-	-	-
	2	-	H304	-	-	-	-	-
HFO	1	-	-	-	-	H350	-	EUH066
	2	-	H304	-	-	H350	-	EUH066
HRBO	1*	-	-	-	-	-	-	-
	2	-	H304	-	-	-	-	-
Kerosine	1	H226	H304	H315	H336	-	-	-
	2	-	H304	H315	H336	-	-	-
LBO	1*	-	-	-	-	-	-	-
	2	-	H304	-	-	-	-	-
	3	-	-	-	-	H350	-	-
	4	-	H304	-	-	H350	-	-
Naphtha	1	H224/H225/H226	H304	H315	H336#	-	-	-
	2	H224/H225/H226	H304	H315	H336#	H350	H340	-
MK1	1	-	H304	H315	H336	-	-	-

OtherGO	1	H226	H304	H315	-	-	-	-
	2	-	H304	H315	-	-	-	-
	3	H226	H304	H315	-	H350	-	-
	4	-	H304	H315	-	H350	-	-
RAE	1	-	-	-	-	-	-	-
	2	-	-	-	-	H351	-	EUH066
SRGO	1	H226	-	-	-	-	-	EUH066
	2	-	-	-	-	-	-	EUH066
	3	H226	H304	-	-	-	-	EUH066
	4	-	H304	-	-	-	-	-
Sulfur	1	-	-	H315	-	-	-	-
TDAE	1*	-	-	-	-	-	-	EUH066
	2	-	H304	-	-	-	-	EUH066
	3	-	-	-	-	H350	-	EUH066
	4	-	H304	-	-	H350	-	EUH066
UATO	1	-	-	-	-	H350	-	EUH066
	2	-	H304	-	-	H350	-	EUH066
UDAE	1	-	-	-	-	H350	-	EUH066
	2	-	H304	-	-	H350	-	-
VHGO	1	H226	-	H315	-	H351	-	-
	2	-	-	H315	-	H351	-	-

	3	H226	H304	H315	-	H351	-	-
	4	-	H304	H315	-	H351	-	-

* Not classified permutations, *i.e.* no exposure and risk assessment and no ES for communication is required according to REACH Article 14

Hazard assessed only qualitatively.

2.1.3. Uses Advised Against by Concawe

In addition to uses restricted in accordance with REACH Annex XVII, Concawe also advises against using:

- Petroleum substances that predominantly consist of low molecular weight hydrocarbons (*i.e.* Naphtha, Kerosine, MK1 and SRGO) in widespread dispersive uses (*i.e.* professional and consumer), except for use in fuels;
- Petroleum substances in consumer lamp oils;
- Heavy Fuel Oils in professional applications that potentially lead to high exposures (*i.e.* use in coatings and use in road and construction applications)[12];
- Other gas oils, if classified as carcinogenic, in professional applications that potentially lead to high exposures (*i.e.* use in lubricants, use in functional fluids)[13].

Detailed explanation is provided in Section 2 of the Concawe Handbook of Identified Uses of Petroleum Substances[14].

2.2. DEFINING CONDITIONS OF USE

2.2.1. Generic Exposure Scenarios (GES)

The ESIG GES have been used as starting point for describing the life cycle and CSA of all petroleum substances. The ESIG GES approach recognises that although there are numerous applications, the handling associated with these applications could readily be consolidated into approximately 40 GES titles, covering workers (industrial and professional), consumers and the environment. Each GES title is supported by a list of Use Descriptors aligned with REACH Guidance R12 (ECHA, 2015), a scope statement that summarises the activities covered and typical RMMs and OCs in case these are needed for the demonstration of safe use. The development and continuous update of ESIG GES takes place in liaison/collaboration with relevant downstream user sector organisations to ensure the proposed OCs and RMMs reflect most current exposure and risk control practices applied downstream.

The ESIG GES comprise a starting point for CSAs of petroleum substances and aim to provide a consistent basis for developing substance-specific ES by Concawe in support of their substance registrations. Further refinement can be applied to reduce the risk characterization ratios if required with application of additional RMMs following the hierarchy of controls strategy. The ESIG GES files are available in both CHESAR and Excel formats. Further details are available on the ESIG website[15].

[12] Listed uses represent professional applications that have been previously supported by Concawe. Recommendation may be applicable to additional professional uses.
[13] Listed uses represent professional applications that have been previously supported by Concawe. Recommendation may be applicable to additional professional uses.
[14] https://www.concawe.eu/wp-content/uploads/Handbook_Identified-Uses-of-PS_2020-dossier-update.pdf. The most recent version can be downloaded *via*: www.concawe.eu/reach/documents-to-download.
[15] Available via: www.esig.org/regulatory/reach-ges

2.2.2. Carcinogenic and Mutagenic Substances

The ESIG GES have also been used as basis for the description of the life cycle of Carcinogenic and Mutagenic (CM) substances. However, in alignment with the CMD, only activities where exposure potential is limited (*i.e.* PROCs 1, 2, 3, 8a/28 (maintenance only), 8b, 9, 15, and 16) have been included in the CSA of CM substances. Furthermore, by default a specific set of Conditions of Use (CoU) has been applied in the CSA of CM classified substances – irrespective of the outcome of the quantitative assessment – to ensure that occupational exposure to these substances is minimised. More information on the semi-quantitative CSA is provided in **Section 3.5**.

2.2.3. Specific Consumer Exposure Determinants (SCEDs)

For consumer uses, Specific Consumer Exposure Determinants (SCEDs) have been used where available. A SCED, prepared by downstream user sector associations, contains reasonable worst-case use information for consumer products. The CoUs for a specific consumer use are summarised in a SCED document, which is available in written and typically also in electronic format. The latter can be imported directly into CHESAR. Most SCEDs are available in the ECHA Use Map Library[16]. Currently, Concawe SCEDs[17] have been applied for the consumer use of petroleum substances in fuels; SCEDs also exist for cleaning agents (developed by AISE), lubricants (developed by Concawe/ATIEL) and sealants and adhesives (developed by FEICA). A full list of all SCEDs used in Concawe CSAs and the applicable substance categories is provided in ***Table 2***.

For consumer uses for which no SCED was available, the CoU as specified in EGRET v2.0 (Zaleski *et al.*, 2014; ESIG, 2015) have been used.

[16] Available via: echa.europa.eu/csr-es-roadmap/use-maps/use-maps-library
[17]Available at: https://www.concawe.eu/wp-content/uploads/2017/12/Concawe_SCEDs_v2.1-supporting-explanation_2017.pdf

Table 2. List of Specific Consumer Exposure Determinants (SCEDs) used in Concawe CSAs per category of petroleum substances

Applicable sector	SCED code	SCED name	Applicable categories
Sealants and adhesives (FEICA)	FEICA_SCED_1_01_a_v1	Universal Glues	HRBO, OtherGO
	FEICA_SCED_1_02_a_v1	Glues DIY-use	HRBO, OtherGO
	FEICA_SCED_1_03_a_v1	Spray glues	HRBO, OtherGO
	FEICA_SCED_1_04_a_v1	Joint sealants	HRBO, OtherGO
Cleaning agents (AISE)	AISE_SCED_PC3_7_a_1	Air care products; Non aerosol	HRBO, LBO
	AISE_SCED_PC3_7_b_1	Air care products; Aerosol	HRBO, LBO
	AISE_SCED_PC31_6_a_1	Polishes and wax blends; Non-spray application	HRBO, LBO
	AISE_SCED_PC31_6_b_1	Polishes and wax blends; Spray application	HRBO, LBO
	AISE_SCED_PC35_1_a_1	Laundry products	HRBO, LBO
	AISE_SCED_PC35_3_a_1	Surface Cleaners; Non-spray application	HRBO, LBO
	AISE_SCED_PC35_3_b_1	Surface Cleaners; Spray application	HRBO, LBO
Lubricants (Concawe, ATIEL)	Concawe_SCED_24_1_a	Lubricants, Liquids, Filling vehicle engine	HRBO, LBO, OtherGO
Fuels (Concawe)	Concawe_SCED_13_1_a	Automotive refuelling (gasoline)	Naphtha
	Concawe_SCED_13_3_a	Automotive refuelling (diesel)	HRBO, SRGO, VHGO, LBO, OtherGO
	Concawe_SCED_13_4_a	Garden equipment refuelling	Naphtha, HRBO, SRGO, VHGO, LBO, OtherGO
	Concawe_SCED_13_5_a	Home space heater	HRBO, VHGO, LBO
	Concawe_SCED_13_7_a	Recreational vehicles (quad bikes or similar)	Naphtha, HRBO, SRGO, LBO, OtherGO

2.2.4. Non-Standard Conditions of Use

By default, the TRA tool has been used to estimate occupational exposure to petroleum substances. This is a simple Tier 1 tool and is built-in the CHESAR tool developed by ECHA. The TRA tool allows to modify the default predicted exposure based on percentage of substance in mixture, duration of activity, general ventilation, place of use, presence of local exhaust ventilation, respiratory protection and dermal protection. In the CHESAR tool, these modifiers are considered the "standard" or "default CoU".

In most instances, additional CoU have been applied in the CSA of petroleum substances, hereinafter referred to as "non-standard CoU". These non-standard CoU can be divided into four categories:

1) Non-standard CoU with an exposure reduction efficiency;
2) Additional good practice advice;
3) Higher Tier CoU (see **Section 2.2.5**);
4) Qualitative CoU (see **Section 3.3**).

Non-standard CoU with an exposure reduction efficiency have been applied to modify the inhalation and/or dermal exposure estimation in the CSA, either determined with the TRA tool or measured data. This has been performed only in a limited number of instances. The non-standard CoU with an exposure reduction efficiency together with their assigned exposure reduction factor and applicability domain are summarized in ***Table 3***.

Table 3. Non-standard CoU with an exposure reduction efficiency applied in the CSA of petroleum substances

Phrase Description	Assigned Exposure Reduction (%)	Applicable activities	Applicable categories	Reference
Use of drum pumps	90%#	Transfer activities (PROC 8a, 8b, 9)	All categories	Fraunhofer (2016)
Ensure material transfers are under containment or extract ventilation	90%#	Transfer activities (PROC 8a, 8b, 9)	All categories	Fraunhofer (2016)
Drain down and flush system prior to equipment break-in or maintenance	90%# (industrial) 80%# (professional)	Cleaning and maintenance (PROC 28)	All categories	Fraunhofer (2016)
Drain or remove substance from equipment prior to break-in or maintenance	80%#	Remanufacture of reject articles (PROC 9)	OtherGO, LBO, HRBO, VHGO, SRGO, UATO, Naphtha	Concawe (2012)
Specific operator training to reduce exposure	15%*	Manual spraying (PROC 11)	VHGO	Concawe (2012)
Vapour recovery system	80%#	Transfer activities (PROC 8b)	HFO	Fransman *et al.* (2011)
Complete segregation with ventilation and filtration of recirculated air	90%#	Transfer activities (PROC 8b)	HFO	Fransman *et al.* (2011)
Fume cupboard	99%#	Laboratory activities (PROC15)	HFO, Naphtha	Fransman et al. (2011)

Applies only to inhalation exposure estimates
* Applies to inhalation and dermal exposure estimates

For several activities, additional phrases have been identified that are considered good practice advice to minimise exposure but did not have an effect on quantitative exposure estimate, unless explicitly indicated. These phrases have been included in the CSA of all petroleum substances requiring a CSA. The CoU have not been considered neither in the qualitative nor in the quantitative CSA, except where otherwise indicated. The additional good practice CoU are summarised in ***Table 4***.

Table 4. Additional good practice advice

Task description	PROC	Additional good practice advice
Spraying activities (industrial)	7	• (if manual activity) Ensure operators are trained to minimise exposure • Segregate the activity away from other operations • Other skin protection measures such as impervious suits and face shields may be required during high dispersion activities which are likely to lead to substantial aerosol release, *e.g.* spraying
Transfer activities	8a/8b	• (if not a closed process) Ensure no splashing occurs during transfer • (for HFO transfers at manufacturing sites) Transfer via enclosed lines and clear transfer lines prior de-coupling • (for bottom loading of HFO without vapour recovery) Ensure displaced vapours are vented to a safe location
Roller, spreader, flow application	10	• (if manual activity) Use long handled brushes and rollers • Avoid contact with contaminated tools and objects
Spraying activities (professional)	11	• (if manual activity) Ensure operators are trained to minimise exposure • Segregate the activity away from other operations • Other skin protection measures such as impervious suits and face shields may be required during high dispersion activities which are likely to lead to substantial aerosol release, *e.g.* spraying
Dipping, immersion and pouring	13	• Allow time for product to drain from workpiece • Avoid contact with contaminated tools and objects • Clear spills immediately
Laboratory	15	• Put lids on containers immediately after use
Lubrication and greasing at high energy conditions	17/18	• Restrict area of openings to equipment • Segregate the activity away from other operations

		• Other skin protection measures such as impervious suits and face shields may be required during high dispersion activities which are likely to lead to substantial aerosol release, *e.g.* spraying
Cleaning and maintenance	28	• Wear suitable coveralls to prevent exposure to the skin • Clear spills immediately

2.2.5. Higher Tier Conditions of Use

The ART v1.5 tool (Schinkel *et al.*, 2013, 2014; McNally *et al.*, 2014; hereinafter referred to as ART tool) has been applied for the CSA of some occupational activities. The relevant CoU with an exposure reduction efficiency that require their communication down the supply chain are summarised in ***Table 5***. More information on how this tool has been applied in the CSA of petroleum substances is available in **Section 3.4**.

Table 5. Higher Tier assessment Conditions of Use with an impact on the emission potential and which are applied in the CSA of petroleum substances

Phrase Description	Higher Tier Tool	Applicable activities	Applicable categories
Transfer rate	ART	Transfer activities (PROC 8a, 8b, 9)	HFO
Application rate	ART	Spraying (PROC 7, 11)	TDAE, RAE, LBO, SRGO, Footsoil
Room size of the work area	ART	All activities	HFO, TDAE, RAE, LBO, SRGO, Footsoil

3. EVALUATING HUMAN HEALTH RISK FOR PETROLEUM SUBSTANCES FROM OCCUPATIONAL AND CONSUMER EXPOSURES

3.1. BACKGROUND

The format of the CSAs, including RMMs and OCs, follows the GES format, developed in accordance with REACH Guidance D (ECHA, 2016a) and REACH Guidance E (ECHA, 2016b). The approach is comprehensive, yet aims to be simple and transparent. It allows the documentation of key assumptions, such as adopted CoU and resulting risk management advice, in a consistent fashion.

A CSA for petroleum substances typically consists of a qualitative exposure and risk assessment for hazards for which no threshold value can be derived (*e.g.* phys-chem hazards, aspiration hazard or skin irritation) and a quantitative exposure and risk assessment for hazards for which a threshold value (*i.e.* a DNEL) can be derived. For CM classified substances, additionally a semi-quantitative exposure and risk assessment has been carried out. The detailed approach taken for each of these three types of hazards is described below.

The CSA of three petroleum substance categories, *i.e.* Kerosine, MK1 and Sulfur, only consists of a qualitative exposure and risk assessment as only qualitative hazards have been identified.

The CSA for human health has not been carried out for end uses in cosmetic products which is generally covered by the Directive 76/768/EEC[18]. This is in accordance with Article 14 (5b) of the REACH Regulation.

3.2. ASSESSMENT ENTITIES FOR UVCB SUBSTANCES

3.2.1. Volatile petroleum substances

When more than one exposure/hazard profile is relevant for a substance, Assessment Entities (AE) are defined. These aim to support a transparent organisation of assessment data for substances with a more complex chemistry. The assessment entity is a wrapper [container] for a set of substance property data used for chemical safety assessment purpose across all endpoints. It enables the assessor to define consistent datasets of properties that are relevant for specific compositions/forms (placed on the market or generated upon use) (ECHA, 2016a).

Petroleum substances are UVCBs containing constituents with a range of phys-chem properties. To fully model the potential toxicological hazards AE have been created to cover the varying phys-chem properties of the substance as they relate to dermal and inhalation exposure.

In the context of this report, petroleum substances are considered to be volatile if the **vast majority** of substance constituents have a vapour pressure (VP) above 500 Pa. This applies to the following petroleum substance categories: *Naphtha*, *Kerosine* and *MK1*.

As *Kerosines* and *MK1* are not classified for quantitative Human Health (HH) hazards, no quantitative exposure and risk assessment is necessary for those substances and hence no Assessment Entities (AE) have been defined.

[18] Environmental CSA of an end use in cosmetics fall under REACH scope, but not covered in this report.

For the *Naphtha* substance category, two AE have been considered for worker in the occupational and consumer (in fuel use) exposure and risk assessment:

I. "Registered substance as such" AE: The AE represents 100% of the substance itself. As a conservative assumption, the high volatility band (> 10kPa) was used in risk assessment when exposure was predicted using the TRA tool.

   The default toxicological endpoints for the substance itself have been applied for this AE.

II. "Benzene" AE: Due to its hazard profile (Carcinogen 1A), benzene was determined as the lead component constituent of the assessed substance and was considered separately in the risk assessment. As a conservative assumption, the high volatility band (> 10kPa) was used in risk assessment when exposure was predicted using the TRA tool.

   The toxicological endpoints for this AE have been taken from the benzene (EC number: 200-753-7) lead REACH registration dossier.

As the vapour pressure for both AE falls within the high(est) volatility band of the TRA tool, no specific considerations regarding the operating temperature are required.

Further, in CHESAR, five Assessment Entity Groups (AEG) based on these two AE have been created for the CSA of the Naphtha category. Those AEGs consist of 100% of the "Registered substance as such" and of five benzene concentration bands (*i.e.* <0.1%, <1%, <5%, <20% and <79%).

In the quantitative exposure and risk assessment, the Risk Characterisation Ratios (RCRs) for both AEs were determined separately. The highest of the two was used to determine if the assessed process is safe.

For substances with a benzene content below 0.1%, but with an n-hexane (EC number: 203-777-6) content of 3% or more and/or with a toluene (EC number: 203-625-9) content of 3% or more, the approach described above was adapted to account for the toxicological properties of these other two Naphtha constituents. Above the defined concentration limits, substances are considered reprotoxic (H361, *cf.* Concawe report 22/20). For such substances, the same RMMs and OCs have been applied in risk assessment as for a substance containing up to 1% benzene. Such an approach ensures protection of human health from exposure to n-hexane and toluene, since the risk assessment is based on benzene content, whose VP falls into the same (high) volatility band but its DNEL is much lower than the one of n-hexane and toluene.

The qualitative risk assessment was driven by the hazard profile of the benzene AE.

3.2.2. Low volatile petroleum substances

In the context of this report, petroleum substances are considered to be of low volatility if the vast **majority** of substance constituents have a VP below 500 Pa. This applies to the following categories: SRGO, CrackedGO, OtherGO, VHGO, LBO, HRBO, Footsoil, UDAE, RAE, TDAE, HFO, and UATO.

3.2.2.1. Occupational Use

For low volatile petroleum substance categories, up to five AE have been considered in the occupational exposure and risk assessment to account for the varying physico-chemical properties of these substances (see ***Table 6***):

I. "Aerosol" AE: GCxGC data of the worst-case substance within the petroleum substance category and EPI Suite™ v4.11 tool (US-EPA, 2017; hereinafter referred to as EPI Suite tool) have been used to estimate the molecular weight (MW) and VP to determine molecules (and their concentration in a substance at standard temperature) with a VP below 10 Pa. This cut-off was based on the aerosol definition within the ART tool (Fransman *et al.*, 2011). Additionally, the average MW of this AE was calculated using the same GCxGC data.

   A VP for this AE is not needed, because the TRA tool does not require a VP for estimating exposure to aerosols.

   The default short- and long-term inhalation DNELs of the substance have been applied for this AE.

II. "Vapour 10-500 Pa" AE: GCxGC data of the worst-case substance within the petroleum substance category and EPI Suite tool have been used to estimate the MW and VP to determine molecules (and their concentration in a substance at standard temperature) with a VP between 10 and 500 Pa. The lower cut-off was based on the aerosol AE (see above) and the upper cut-off was based on the TRA low volatility band. Additionally, the average MW of this AE was calculated using the same GCxGC data.

   When using the TRA tool, then a specific VP for this AE is not needed. The tool provides the same exposure estimates for any VP between 10 and 500 Pa. Thus, any VP between 10 and 500 Pa is applicable for this AE.

   The default short- and long-term inhalation DNELs of the substance have been applied for this AE.

III. "Vapour 500-10.000 Pa" AE: GCxGC data of a worst-case substance within the petroleum substance category and EPI Suite tool have been used to estimate the MW and VP to determine molecules (and their concentration in a substance at standard temperature) with a VP between 500 and 10.000 Pa. The lower and upper cut-offs were based on the TRA medium volatility band. Additionally, the average MW of this AE was calculated using the same GCxGC data.

   When using the TRA tool, then a specific VP for this AE is not needed. The tool provides the same exposure estimates for any VP between 500 and 10.000 Pa. Thus, any VP between 500 and 10.000 Pa is applicable for this AE.

   The default short- and long-term inhalation DNELs of the substance have been applied for this AE.

IV. "Vapour >10.000 Pa" AE: GCxGC data of a worst-case substance within the petroleum substance category and EPI Suite tool have been used to estimate the MW and VP to determine molecules (and their concentration in a substance at standard temperature) with a VP above 10.000 Pa. This cut-

off was based on the TRA high volatility band. Additionally, the average MW of this AE was calculated using the same GCxGC data.

When using the TRA tool, then a specific VP for this AE is not needed. The tool provides the same exposure estimates for any VP above 10.000 Pa. Thus, any VP between above 10.000 Pa is applicable for this AE.

The default short- and long-term inhalation DNELs of the substance have been applied for this AE.

V. "Dermal and oral" AE: 100% of the substance has been assessed in all instances for the dermal and oral route.

A specific VP for this AE is not needed, because TRA tool provides the same exposure estimates irrespective of the VP. However, for substances with a VP below 500 Pa, TRA tool no longer adjusts dermal exposure estimates based on the assessed duration and always assumes 8 hours of exposure (since the substance will no longer volatilise from the skin and may stay on the skin for the complete working shift). Thus, as a worst-case assumption, a VP below 500 Pa was assessed for the dermal AE in all instances.

The default long-term dermal DNEL and default long-term oral DNEL of the substance have been applied for this AE. Additionally, any applicable qualitative toxicological endpoint for the dermal route has been considered for this AE.

The concentrations of various AEs in AEGs for worker exposure assessment in CHESAR v.3.3 were set up in accordance with their actual concentrations in a substance (as described above) that resulted in linear adjustment of predicted exposure with TRA, i.e. the default concentration banding approach was not followed. Such a set-up is considered appropriate/reasonable and not leading to underestimating inhalation exposure, because the final estimate is obtained through summation across all AEs exposures (denoting fractions of different volatility) in the AEG[19].

[19] The newer version 3.5 of Chesar does not allow linear adjustment of worker TRA exposure with the concentration of AE, but automatically applies exposure modifying factors associated with TRA worker concentration bands. This set-up significantly impacts the RCR for petroleum substances when using the TRA tool in Chesar v.3.5 but raises the question if the concentration banding as applied for mixtures by the TRA tool is valid for AE of UVCBs that are all associated with the same toxicological endpoints and hazard benchmark values.

Table 6 Number and type of Assessment Entities (AE) per petroleum substance category (low vapour pressure substances only)

Petroleum substance	Dermal and oral AE <500 Pa	Aerosol AE <10 Pa	Low vapour pressure AE 10-500 Pa	Medium vapour pressure AE 500-10.000 Pa	High vapour pressure AE >10.000 Pa
SRGO	1	1	1	1	1
CrackedGO	1	1	1	1	1
OtherGO*	2	2	2	2	2
VHGO	1	1	1	1	1
LBO*	2	2	2	n.a.	
HRBO	1	1	1	n.a.	
Footsoil	1	1	1	n.a.	
UDAE	1	1	1	n.a.	
RAE	1	1	1	n.a.	
TDAE*	2	2	2	n.a.	
UATO	1	1	1	n.a.	
HFO	1	1	1#		

* separate AE have been used for the non-carcinogenic and carcinogenic permutation
# Only 1 AE has been used for molecules with VP above 10 Pa to allow comparison of modelled data with measured data for HFO fumes
n.a. – not applicable (combined quantity of molecules falling within this volatility band is below 0.5% of the total substance at 40°C)

The VPs of the substance constituents have been calculated based on the operating[20] temperature of the assessed processes. To this end, the operating temperatures according to ESIG GES have been followed for most petroleum substance categories. For those with high viscosity, *i.e.* UDAE, RAE, TDAE and HFO, elevated operating temperatures (60 - 120 °C) for some PROCs have been generally applied in the risk assessment. The respective operating temperatures have been taken from literature (Concawe 2015, 2021) and/or were defined in consultation with the Concawe members. For the manufacturing of petroleum substances in refineries in closed systems (PROC 1/2/3), high temperatures have been assumed for all substance categories by default; in those instances the assessment has been performed for the whole substance 100% ascribed to a high vapour pressure AE (>10,000Pa) in worker TRA.

Based on the operating temperatures (*e.g.* 20°C, 40°C, 50°C, 60°C, 80°C, 90°C, 120°C, Manufacturing), separate AEG have been created in CHESAR v3.3 for the CSA of low volatility petroleum substances. The rationale is that, at higher temperatures, certain fraction of low volatility molecules will transition into higher volatility TRA band and the composition of the whole substance will change (*i.e.* it

[20] The operating temperature used in this context is the temperature which prevails inside the equipment and piping during any intended operation/process and does not necessarily reflect temperature workers are exposed to. It is distinct from ambient temperature at the workplace that should be in the range of "thermal comfort". In worker TRA tool and ESIG GES files ambient temperature refers to 15-25°C (see section 2.2.5 of the ECETOC TR114). Subsequently, if substance is handled under different/elevated operating temperature, its VP should be recalculated accordingly.

will have more volatile constituents). An overview of the typical AEG compositions for each low volatile substance category can be found in **Annex I**.

In the quantitative exposure and risk assessment, the RCRs for all AE were determined separately and summed up to determine if the complete assessed process is safe.

AEG have been set up in a way to allow calculating the combined systemic, long-term RCR in the following way:

$$Combined systemic, long\text{-}term RCR = \\ dermal, systemic, long\text{-}term RCR of the "Dermal \wedge oral" AE + \\ inhalation, systemic, long\text{-}term RCR of the "Aerosol" AE + \\ inhalation, systemic, long\text{-}term RCR of the "Vapour 10\text{-}500 Pa" AE + \\ inhalation, systemic, long\text{-}term RCR of the "Vapour 500\text{-}10{,}000 Pa" AE + \\ inhalation, systemic, long\text{-}term RCR of the "Vapour > 10{,}000 Pa" AE$$

The same approach has been taken for the combined, systemic, short term RCR.

3.2.2.2. Consumer Use

For low volatile petroleum substance categories, the same AE as for occupational use have been considered in the consumer exposure and risk assessment. However, due to the limitations of the consumer TRA tool, the AE for the inhalation route have been manually combined into a single AE (see Annex II for details). Furthermore, since all consumer uses have been assessed at ambient temperature, only one AEG was created for each substance category in CHESAR 3.3. A detailed description on how the AEG composition was set up for low volatility substance categories marketed in consumer uses can be found in **Annex II**.

In the quantitative exposure and risk assessment the RCR for all AE were determined separately and summed up to determine if the assessed process is safe.

AEG has been set up in a way to allow calculating the combined systemic, long-term RCR in the following way:

$$Combined systemic, long\text{-}term RCR = \\ dermal, systemic, long\text{-}term RCR of the "Dermal \wedge oral" AE + \\ oral, systemic, long\text{-}term RCR of the "Dermal \wedge oral" AE + \\ inhalation, systemic, long\text{-}term RCR of the "Vapour" AE$$

The same approach has been taken for the combined, systemic, short term RCR.

3.3. QUALITATIVE EXPOSURE AND RISK ASSESSMENTS

3.3.1. Background

The qualitative exposure and risk assessment has largely been based on the prevention, response and storage P statements (UN, 2019) of the respective hazards (environmental considerations are not addressed in this report). In this way, it is ensured that the communicated safe use information in the Annex of the eSDS is in alignment with the main body of the SDS.

The qualitative assessment aims to reduce/avoid contact or incidents with the substance proportional to the degree of concern related to its health hazard. Exposures should be controlled to at least the levels that represent an acceptable

level of risk such that the implementation of the appropriate RMMs will ensure that the likelihood of an event occurring due to the substance hazard is negligible, and the risk is considered to be controlled to a level of no concern.

3.3.2. Occupational Use

3.3.2.1. Flammable Liquids and Vapours (H224/H225/H226)

For the hazard of “Flammable liquid and vapour” (H226), “Highly flammable liquid and vapour” (H225) and “Extremely flammable liquid and vapour” (H224) the qualitative risk characterisation conducted is consistent with the considerations and RMMs identified in ***Table 7*** below. ***Table 7*** also shows how many RMMs are already communicated in the SDS by virtue of the associated P Statements for the hazard.

Table 7. Elements of qualitative CSA and identified P Statements for flammability

Components of the qualitative CSA	Examples of relevant P Statements
• 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 • Comply with relevant EU/national regulations • Risk assessment of local workplace activities • Procedures supporting safe handling and maintenance of controls • Education and training of workers in understanding the hazards and control measures relevant to their activities • Provision of general ventilation • Good housekeeping and prompt clearance of spillages	Prevention: • 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 protection/... Response: • 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.

The outcome of the CSA is displayed within the relevant **ES of the CSR** by the inclusion of the general phrases:

- General measures (flammability): 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. Comply with relevant EU/national regulations.
- Assumes a good basic standard of occupational hygiene is implemented: Risk assessment of local workplace activities. Procedures supporting safe handling and maintenance of controls. Education and training of workers in understanding the hazards and control measures relevant to their activities. Provision of general ventilation. Good housekeeping and prompt clearance of spillages. [*Amongst other phrases*].

The outcome of the CSA is displayed within the relevant **ES for communication** by the inclusion of the general phrases:

- General measures (flammability): For measures to control risks from physicochemical properties, refer to main body of the SDS, section 7 and/or 8.
- Assumes a good basic standard of occupational hygiene is implemented.

The condensed statement for flammability in the ES for communication is in alignment with REACH Guidance E, Chapter E.2.6 (ECHA, 2016b).

No cut-off concentration triggering the classification of a mixture containing the assessed petroleum substance has been applied for these hazards.

3.3.2.2. Aspiration Hazard (H304)

"Aspiration" means the entry of a liquid substance directly into the trachea and lower respiratory tract. Aspiration of hydrocarbon substances can result in severe acute effects such as chemical pneumonitis, varying degrees of pulmonary injury or death. This property relates to the potential for low viscosity material to spread quickly into the deep lung and cause severe pulmonary tissue damage. Classification of a hydrocarbon substance for aspiration hazard is made on the basis of reliable human evidence or on the basis of physical properties.

The H Statement "May be fatal if swallowed and enters airways" (H304) relates to potential for aspiration, a non-quantifiable hazard determined by physico-chemical properties (*i.e.* viscosity) that can occur during ingestion or in case of vomiting following accidental ingestion. A DNEL for aspiration hazard cannot be derived.

There are no routine anticipated exposures by ingestion related to any supported uses of the substance. The risk arising from aspiration hazard is solely related to the physico-chemical properties of the substance and can therefore be controlled by implementing RMMs tailored to this specific risk.

For this hazard, a qualitative risk characterisation is consistent with the considerations and RMMs identified in ***Table 8*** below. ***Table 8*** also shows how many RMM are already communicated in the SDS by virtue of the associated P Statements for the hazard.

Table 8. Elements of qualitative CSA and identified P Statements for aspiration hazard

Components of the qualitative CSA	Examples of relevant P Statements
• Do not ingest. • If swallowed then seek immediate medical assistance. • Education and training of workers in understanding the hazards and control measures relevant to their activities.	Response: • P301 + P310: IF SWALLOWED: Immediately call a POISON CENTER/doctor/… • P331: Do NOT induce vomiting. Storage: • P405: Store locked up.

The outcome of the CSA is displayed within the relevant **ES of the CSR** by the inclusion of the general phrases:

- General measures (aspiration): Do not ingest. If swallowed then seek immediate medical assistance.
- Assumes a good basic standard of occupational hygiene is implemented: Education and training of workers in understanding the hazards and control measures relevant to their activities. [*Amongst other phrases*].

The outcome of the CSA is displayed within the relevant **ES for communication** by the inclusion of the general phrases:

- General measures (aspiration): Do not ingest. If swallowed then seek immediate medical assistance.
- Assumes a good basic standard of occupational hygiene is implemented.

A cut-off concentration triggering the classification of a mixture containing the assessed petroleum substance of ≥10% has been applied for this hazard (according to CLP Regulation, Section 3.10.3.3.1).

3.3.2.3. Skin Irritation (H315)

For the hazard of "Causes skin irritation" (H315) the qualitative risk characterisation conducted is consistent with the considerations and RMMs identified in ***Table 9*** below. This hazard is considered as "Low" according to REACH Guidance E, Table E.3-1 (ECHA, 2016b). ***Table 9*** also shows how many RMM are already communicated in the SDS by virtue of the associated P Statements for the hazard.

Table 9. Elements of qualitative CSA and identified P Statements for skin irritation

Components of the qualitative CSA	Examples of relevant P Statements
• Avoid direct skin contact with product. Identify potential areas for indirect skin contact • Identify potential areas for indirect skin contact • Wear gloves (tested to EN374) if hand contact with substance likely • Clean up contamination/spills as soon as they occur • Wash off any skin contamination immediately • Provide basic employee training to prevent / minimise exposures and to report any skin problems that may develop • Risk assessment of local workplace activities • Procedures supporting safe handling and maintenance of controls • Education and training of workers in understanding the hazards and control measures relevant to their activities • Good housekeeping and prompt clearance of spillages • Appropriate selection, testing and maintenance of equipment used to control exposure, e.g. (PPE) • Regular supply and laundering of work clothing; provision of washing and changing facilities	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 before reuse.

The outcome of the CSA is displayed within the relevant **ES of the CSR** by the inclusion of the general phrases:

- General Measures (skin irritants): Avoid direct skin contact with product. Identify potential areas for indirect skin contact. Wear gloves (tested to EN374) if hand contact with substance likely. Clean up contamination/spills as soon as they occur. Wash off any skin contamination immediately. Provide basic employee training to prevent / minimise exposures and to report any skin problems that may develop.
- Assumes a good basic standard of occupational hygiene is implemented: Risk assessment of local workplace activities. Procedures supporting safe handling and maintenance of controls. Education and training of workers in understanding the hazards and control measures relevant to their activities. Good housekeeping and prompt clearance of spillages. Appropriate selection, testing and maintenance of equipment used to control exposure, e.g. (PPE).

Regular supply and laundering of work clothing. Provision of washing and changing facilities. [*Amongst other phrases*].

The outcome of the CSA is displayed within the relevant **ES for communication** by the inclusion of the general phrases:

- 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. For further specification, refer to section 8 of the SDS.
- Assumes a good basic standard of occupational hygiene is implemented.

A cut-off concentration triggering the classification of a mixture containing the assessed petroleum substance of ≥10% has been applied for this hazard (according to CLP Regulation, Table 3.2.3).

3.3.2.4. Eye Irritation (H319)

The hazard "Causes serious eye irritation" (H319) is not directly applicable to any petroleum substance registered under REACH. However, neat benzene is classified for this endpoint. For any substance that contains more than 10% benzene (generic classification cut-off for reversible eye effects according CLP Regulation, Table 3.3.3) a qualitative risk assessment for eye irritation has been carried out.

The qualitative risk characterisation conducted is consistent with the considerations and RMMs identified in the ***Table 10*** below. This hazard is considered as "Low" according to REACH Guidance E, Table E.3-1 (ECHA, 2016b). ***Table 10*** also shows how many RMMs are already communicated in the SDS by virtue of the associated P Statements for the hazard.

Table 10. Elements of qualitative CSA and identified P Statements for eye irritation

Components of the qualitative CSA	Examples of relevant P Statements
• Use suitable eye protection • Avoid direct eye contact with product, also via contamination on hands • Risk assessment of local workplace activities • Education and training of workers in understanding the hazards and control measures relevant to their activities • Appropriate selection, testing and maintenance of equipment used to control exposure, e.g. PPE • Provision of washing and changing facilities	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.

The outcome of the CSA is displayed within the relevant **ES of the CSR** by the inclusion of the following general phrases:

- General measures (eye irritants): Use suitable eye protection. Avoid direct eye contact with product, also via contamination on hands.

- Assumes a good basic standard of occupational hygiene is implemented: Risk assessment of local workplace activities. Education and training of workers in understanding the hazards and control measures relevant to their activities. Appropriate selection, testing and maintenance of equipment used to control exposure, e.g. (PPE). Provision of washing and changing facilities. [*Amongst other phrases*].

The outcome of the CSA is displayed within the relevant **ES for communication** by the inclusion of the general phrases:

- General measures (eye irritants): Use suitable eye protection. Avoid direct eye contact with product, also via contamination on hands.
- Assumes a good basic standard of occupational hygiene is implemented.

A cut-off concentration triggering the classification of a mixture containing the assessed petroleum substance of ≥10% has been applied for this hazard (according to CLP Regulation, Table 3.3.3).

3.3.2.5. Drowsiness or Dizziness (H336)

The hazard of "May cause drowsiness or dizziness" (H336) applies to substances which may be toxic to the central nervous system. For substances for which an inhalation short-term and/or long-term DNEL has been derived for this endpoint, a quantitative risk assessment has been conducted. For substances without a DNEL, a qualitative risk assessment has been conducted, consistent with the considerations and RMMs identified in ***Table 11*** below. ***Table 11*** also shows how many RMMs are already communicated in the SDS by virtue of the associated P Statements for the hazard.

Table 11. Elements of qualitative CSA and identified P Statements for drowsiness or dizziness

Components of the qualitative CSA	Examples of relevant P Statements
• Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour) or handle the substance outdoors • Store substance within a closed system • Risk assessment of local workplace activities • Procedures supporting safe handling and maintenance of controls • Education and training of workers in understanding the hazards and control measures relevant to their activities • Good housekeeping and prompt clearance of spillages	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. Storage: • P403+P233: Store in a well-ventilated place. Keep container tightly closed. • P405: Store locked up.

The outcome of the CSA is displayed within the relevant **ES of the CSR** by the inclusion of the following CoU and general phrases:

- Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour) or handle the substance outdoors.
- Store substance within a closed system.
- Assumes a good basic standard of occupational hygiene is implemented: Risk assessment of local workplace activities. Procedures supporting safe handling and maintenance of controls. Education and training of workers in understanding the hazards and control measures relevant to their activities. Good housekeeping and prompt clearance of spillages. [*Amongst other phrases*].

The outcome of the CSA is displayed within the relevant **ES for communication** by the inclusion of the RMM and general phrases:

- 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.
- Assumes a good basic standard of occupational hygiene is implemented.

No cut-off concentration triggering the classification of a mixture containing the assessed petroleum substance has been applied for this hazard. It shall be noted that a cut-off concentration has been defined in CLP Regulation, but all petroleum substances with this hazard have been by default assessed at a concentration of 100%.

3.3.2.6. Carcinogenic Hazard (H350) and Mutagenic Hazard (H340)

The EU Directive 2004/37/EC (hereinafter CMD) exists for the control of exposure to carcinogens and mutagens (classified as category 1A or 1B according to CLP Regulation) in the workplace, which establishes a framework of expectations that can be used as the basis for applying a qualitative approach for any CSA. CMD sets out the minimum requirements for protecting workers who may be exposed to carcinogens and mutagens during work activities. Preventive measures must be taken for the protection of the health and safety of workers exposed to such substances. The risk phrase "may cause cancer" relates to the strength of evidence to indicate that the substance may cause cancer in humans. When a carcinogenic substance is considered a threshold carcinogen and/or if appropriate dose-response data from epidemiological and/or animal studies are available, it may be possible to derive a DNEL or DMEL which should then be used in quantitative risk characterisation to define the appropriate RMMs. However, when a carcinogenic substance is considered a non-threshold carcinogen and/or if appropriate dose-response data from epidemiological and/or animal studies are not available, it is not possible to derive a DMEL, and hence a qualitative approach to the CSA is required.

This general qualitative CSA approach aims to reduce/avoid exposure or incidents with the substance consistent with the expectations of CMD. The general rationale is two-fold:

1. That the uses of any such substance are limited to suitably equipped industrial or professional settings and will only be supported in circumstances where exposure potential is limited (PROCs 1, 2, 3, 8a/28 (maintenance only), 8b, 9, 15, and 16) and will not cover those situations where exposure to the substance might be expected to be significant (such as PROCs 7, 11, 17, 18, etc.). This limitation on use is consistent with the current expectations of CMD.

2. That a stringent set of RMMs is applied. Firstly, exposures should be controlled to at least the levels that represent an acceptable level of risk (*i.e.* represent a RCR of <1 for the DMEL or the otherwise critical non-carcinogenic adverse effect associated with exposure to the substance; the lowest DNEL is used for a quantitative CSA). Secondly, that rigorous systems of control are implemented to manage exposures in addition to and independent of the risk measures required to manage non-cancer endpoints (and which are described *via* the use of standard phrases linked to defined circumstances of use). The aim is that the net outcome is the description of the RMMs that when implemented will ensure that the likelihood of cancer occurring is minimised, and the risk is considered to be controlled.

For the hazard of "May cause cancer" (H350) and "May cause genetic defects" (H340) the qualitative risk characterisation conducted is consistent with the considerations and RMMs identified in ***Table 12*** below. These hazards are considered as "High" according to REACH Guidance E, Table E.3-1 (ECHA, 2016b). ***Table 12*** also shows how many RMMs are already communicated in the SDS by virtue of the associated P Statements for the hazard.

Table 12: Elements of qualitative CSA and identified P Statements for carcinogenicity and mutagenicity

Components of the qualitative CSA	Examples of relevant P Statements
• 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 its use is identified for certain contributing scenarios; 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. • Risk assessment of local workplace	<u>Prevention</u>: • 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/...) <u>Response</u>: • P308 + P313: IF exposed or concerned: Get medical advice/attention. <u>Storage</u>: • P405: Store locked up.

activities. • Procedures supporting safe handling and maintenance of controls. • Education and training of workers in understanding the hazards and control measures relevant to their activities. • Provision of general ventilation. • Good housekeeping and prompt clearance of spillages. • Appropriate selection, testing and maintenance of equipment used to control exposure, e.g. PPE, LEV. • Regular supply and laundering of work clothing. • Provision of washing and changing facilities. • Eating and smoking only in designated areas separate from the workplace.	

The outcome of the CSA is displayed within the relevant **ES of the CSR** by the inclusion of the following general phrases (for substance classified as carcinogenic (H350) and/or mutagenic (H340)):

- General measures (carcinogens): 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 its use is identified for certain contributing scenarios; 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.

- Assumes a good basic standard of occupational hygiene is implemented: Risk assessment of local workplace activities. Procedures supporting safe handling and maintenance of controls. Education and training of workers in understanding the hazards and control measures relevant to their activities. Provision of general ventilation. Good housekeeping and prompt clearance of spillages. Appropriate selection, testing and maintenance of equipment used to control exposure, e.g. PPE, LEV. Draining of equipment prior to maintenance; retention of drained material in sealed storage pending disposal or recycling. Regular supply and laundering of work clothing. Provision of washing and changing facilities. Eating and smoking only in designated areas separate from the workplace.

The outcome of the CSA is displayed within the relevant **ES for communication** by the inclusion of the general phrases (for substance classified as carcinogenic (H350) and/or mutagenic (H340)):

- General measures (carcinogens): 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.

- Assumes a good basic standard of occupational hygiene is implemented.

A cut-off concentration triggering the classification of a mixture containing the assessed petroleum substance of ≥0.1% has been applied for these hazards (according to CLP Regulation, Table 3.5.2 and Table 3.6.2).

3.3.2.7. Carcinogenic Hazard (H351)

For the hazard of "Suspected of causing cancer" (H351) the qualitative risk characterisation conducted is consistent with the considerations and RMMs identified in the ***Table 13*** below. This hazard is considered as "High" according to REACH Guidance E, Table E.3-1 (ECHA, 2016b). Substances classified as Carcinogenic category 2 are not within the scope of the CMD. The approach taken in the CSA therefore deviates from the CSA carried out for substances classified as Carcinogenic category 1, *i.e.* H350. ***Table 13*** also shows how many RMMs are already communicated in the SDS by virtue of the associated P Statements for the hazard.

Table 13. Elements of qualitative CSA and identified P Statements for Carcinogenicity category 2

Components of the qualitative CSA	Examples of relevant P Statements
• Control any potential exposure using measures such as contained systems, properly designed and maintained facilities and a good standard of general ventilation. • Drain down systems and transfer lines prior to breaking containment. • Drain down and flush equipment where possible prior to maintenance. • Where there is potential for exposure: Ensure relevant staff are informed of exposure potential and aware of basic actions to minimise exposures • Ensure suitable personal protective equipment is available • Clear up spills and dispose of waste in accordance with regulatory requirements	<u>Prevention:</u> • 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/...) <u>Response</u>: • P308 + P313: IF exposed or concerned: Get medical advice/attention. <u>Storage</u>: • P405: Store locked up.

• Monitor effectiveness of control measures • Provide regular health surveillance as appropriate • Identify and implement corrective actions. • Risk assessment of local workplace activities. • Procedures supporting safe handling and maintenance of controls. • Education and training of workers in understanding the hazards and control measures relevant to their activities. • Provision of general ventilation. • Good housekeeping and prompt clearance of spillages. • Appropriate selection, testing and maintenance of equipment used to control exposure, e.g. PPE, LEV. • Regular supply and laundering of work clothing. • Provision of washing and changing facilities. • Eating and smoking only in designated areas separate from the workplace.	

The outcome of the CSA is displayed within the relevant **ES of the CSR** by the inclusion of the following general phrases:

- General measures applicable to all activities: Control any potential exposure using measures such as contained systems, properly designed and maintained facilities and a good standard of general ventilation. Drain down systems and transfer lines prior to breaking containment. Drain down and flush equipment where possible prior to maintenance. Where there is potential for exposure: Ensure relevant staff are informed of exposure potential and aware of basic actions to minimise exposures; ensure suitable personal protective equipment is available; clear up spills and dispose of waste in accordance with regulatory requirements; monitor effectiveness of control measures; provide regular health surveillance as appropriate; identify and implement corrective actions.

- Assumes a good basic standard of occupational hygiene is implemented: Risk assessment of local workplace activities. Procedures supporting safe handling and maintenance of controls. Education and training of workers in understanding the hazards and control measures relevant to their activities. Provision of general ventilation. Good housekeeping and prompt clearance of spillages. Appropriate selection, testing and maintenance of equipment used to control exposure, e.g. PPE, LEV. Draining of equipment prior to maintenance; retention of drained material in sealed storage pending disposal or recycling. Regular supply and laundering of work clothing. Provision of washing and changing facilities. Eating and smoking only in designated areas separate from the workplace.

The outcome of the CSA is displayed within the relevant **ES for communication** by the inclusion of the general phrases:

- 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. 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.

- Assumes a good basic standard of occupational hygiene is implemented.

A cut-off concentration triggering the classification of a mixture containing the assessed petroleum substance of ≥1% has been applied for these hazards (according to CLP Regulation, Table 3.6.2).

3.3.2.8. Skin Defatting Hazard (EUH066)

The hazard "Repeated exposure may cause skin dryness or cracking" (EUH066) is generally applied to petroleum substances and solvents that have the capacity to extract lipids from the skin and that are not classified as skin irritants. This hazard does not relate to a classifiable endpoint, and there is no standardized test method to quantify the effect. Thus, a DNEL cannot be derived.

It should be noted that EUH066 is a supplemental hazard statement, which is not yet included in the UN GHS. Nevertheless, it is obligatory to assign the H Statement in accordance with Annex II to CLP Regulation, Part 1, section 1.2, when a substance or mixture has already been classified on the basis of the criteria in corresponding Annex I. The skin defatting hazard is rated lower than the skin irritation hazard in that it is linked only to repeated and/or prolonged exposure.

The qualitative risk characterisation conducted is consistent with the considerations and RMMs identified in the ***Table 14*** below. Table 14 also shows how many RMM are already communicated in the SDS by virtue of the associated P Statements for the hazard.

Table 14. Elements of qualitative CSA and identified P Statements for skin defatting hazard

Components of the qualitative CSA	Examples of relevant P Statements
• 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. • Risk assessment of local workplace activities • Education and training of workers in understanding the hazards and control measures relevant to their activities • Appropriate selection, testing and maintenance of equipment used to control exposure, e.g. PPE • Regular supply and laundering of work clothing • Provision of washing and changing facilities	No designated P Statements are assigned.

The outcome of the CSA is displayed within the relevant **ES of the CSR** by the inclusion of the following CoU and general phrases:

- 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.

- Assumes a good basic standard of occupational hygiene is implemented: Risk assessment of local workplace activities. Education and training of workers in understanding the hazards and control measures relevant to their activities. Appropriate selection, testing and maintenance of equipment used to control exposure, e.g. (PPE). Regular supply and laundering of work clothing. Provision of washing and changing facilities. [*Amongst other phrases*].

The outcome of the CSA is displayed within the relevant **ES for communication** by the inclusion of the additional good practice advice and general phrases:

- 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 (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).

- Assumes a good basic standard of occupational hygiene is implemented.

No cut-off concentration triggering the classification of a mixture containing the assessed petroleum substance has been applied for the skin defatting hazard.

The respective phrases have been added by default as additional good practice advice to all ES of the following petroleum substance categories: SRGO, HFO, UATO, UDAE and TDAE.

3.3.3. Consumer Use

3.3.3.1. Flammable liquids and vapours (H224/H225/H226)

For the hazard of "Flammable liquid and vapour" (H226), "Highly flammable liquid and vapour" (H225) and "Extremely flammable liquid and vapour" (H224) the qualitative risk characterisation conducted is consistent with the considerations and RMMs identified in the ***Table 15*** below. ***Table 15*** also shows how many RMM are already communicated in the SDS by virtue of the associated P Statements for the hazard.

Table 15. Elements of qualitative CSA and identified P Statements for flammability

Components of the qualitative CSA	Examples of relevant P Statements
• 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 • Comply with relevant EU/national regulations	Prevention: • 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 protection/... Response: • 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.

The outcome of the CSA is displayed within the relevant **ES of the CSR** by the inclusion of the general phrases:

- General measures (flammability): 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. Comply with relevant EU/national regulations.

The outcome of the CSA is displayed within the relevant **ES for communication** by the inclusion of the general phrase:

- General measures (flammability): For measures to control risks from physicochemical properties, refer to main body of the SDS, section 7 and/or 8.

The condensed statement for flammability in the ES for communication is in alignment with REACH Guidance E, Chapter E.2.6 (ECHA, 2016b).

No cut-off concentration triggering the classification of a mixture containing the assessed petroleum substance has been applied for the flammability hazard.

3.3.3.2. Aspiration Hazard (H304)

For the "Aspiration hazard" (H304) (**cf. 3.3.2.2** for definition and related H statement "May be fatal if swallowed and enters airways"), the qualitative risk characterisation conducted is consistent with the considerations and RMMs identified in the ***Table 16*** below. ***Table 16*** also shows how many RMMs are already communicated in the SDS by virtue of the associated P Statements for the hazard.

Table 16. Elements of qualitative CSA and identified P Statements for aspiration hazard

Components of the qualitative CSA	Examples of relevant P Statements
• Do not ingest • If swallowed then seek immediate medical assistance	General: • P102: Keep out of reach of children. Response: • P301 + P310: IF SWALLOWED: Immediately call a POISON CENTER/doctor/… • P331: Do NOT induce vomiting. Storage: • P405: Store locked up.

The outcome of the CSA is displayed within the relevant **ES of the CSR** by the inclusion of the general phrases:

- General measures (aspiration): Do not ingest. If swallowed then seek immediate medical assistance.

The outcome of the CSA is displayed within the relevant **ES for communication** by the inclusion of the general phrase:

- General measures (aspiration): Do not ingest. If swallowed then seek immediate medical assistance.

A cut-off concentration triggering the classification of a mixture containing the assessed petroleum substance of ≥10% has been applied for the aspiration hazard (according to CLP Regulation, Section 3.10.3.3.1).

3.3.3.3. Skin Irritation (H315)

For the hazard of "Causes skin irritation" (H315) the qualitative risk characterisation conducted is consistent with the considerations and RMMs identified in the ***Table 17*** below. This hazard is considered as "Low" according to REACH Guidance E, Table E.3-1 (ECHA, 2016b). ***Table 17*** also shows how many RMMs are already communicated in the SDS by virtue of the associated P Statements for the hazard.

Table 17. Elements of qualitative CSA and identified P Statements for skin irritation

Components of the qualitative CSA	Examples of relevant P Statements
• Ensure labelling complies with regulations • Provide clear instruction of use • Use child-resistant packaging • Minimise exposure by product design, such as encapsulation, pelletisation • Wear gloves if hand contact with substance likely • Wash off any skin contamination immediately	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 before reuse.

This qualitative assessment aims to reduce/avoid contact or incidents with the substance proportional to the degree of concern related to its health hazard. Exposures should be controlled to at least the levels that represent an acceptable level of risk such that the implementation of these RMMs will ensure that the likelihood of an event occurring due to the substance hazard is negligible, and the risk is considered to be controlled to a level of no concern.

The outcome of the CSA is displayed within the relevant **ES of the CSR** by the inclusion of the general phrases:

- General Measures (skin irritants): Ensure labelling complies with regulations. Provide clear instruction of use. Use child-resistant packaging. Minimise exposure by product design, such as encapsulation or pelletisation. Wash off any skin contamination immediately.

OR

- General measures (skin irritation): Dermal exposure during handling of consumer fuels is low and according to the Concawe SCEDs significantly less than 0.1% of the handled quantities are transferred to the skin. Exposure durations are very low and will typically not exceed one minute of dermal contact. The re-fuelling equipment is in general designed to minimise exposure (e.g. nozzle). Additionally, disposable gloves are usually provided at petrol stations.

The outcome of the CSA is displayed within the relevant **ES for communication** by the inclusion of the general phrase:

- General Measures (skin irritants): Ensure labelling complies with regulations. Provide clear instruction of use. Use child-resistant packaging. Minimise exposure by product design, such as encapsulation or pelletisation. Wash off any skin contamination immediately.

OR

- General measures (skin irritants): Ensure there is no direct skin contact with product. Remove accidental skin contamination.

A cut-off concentration triggering the classification of a mixture containing the assessed petroleum substance of ≥10% has been applied for the skin irritation hazard (according to CLP Regulation, Table 3.2.3).

3.3.3.4. Eye Irritation (H319)

The hazard "Causes serious eye irritation" (H319) is not applicable to any petroleum substance registered under REACH and substances with more than 1% benzene are not marketed for consumer uses. Thus, this H Statement is not applicable for any consumer use.

A cut-off concentration triggering the classification of a mixture containing the assessed petroleum substance of ≥10% has been applied for the eye irritation hazard (according to CLP Regulation, Table 3.3.3).

3.3.3.5. Drowsiness or Dizziness (H336)

For the hazard of "May cause drowsiness or dizziness" (H336) applies to substances which may be toxic to the central nervous system. Concawe advices that substances classified for this endpoint should not be marketed for consumer uses, except for consumer fuels (see also Chapter 2.1.3).

For substances for which an inhalation short-term and/or long-term DNEL has been derived for this endpoint, a quantitative risk assessment has been conducted. For substances without a DNEL, a qualitative risk assessment has been conducted consistent with the considerations and RMMs identified in the ***Table 18*** below. ***Table 18*** also shows how many RMMs are already communicated in the SDS by virtue of the associated P Statements for the hazard.

Table 18. Elements of qualitative CSA and identified P Statements for drowsiness or dizziness

Components of the qualitative CSA	Examples of relevant P Statements
• Handle substance outdoors or in a well-ventilated room with windows open • Store substance within a closed system	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. Storage: • P403+P233: Store in a well-ventilated place. Keep container tightly closed. • P405: Store locked up.

The outcome of the CSA is displayed within the relevant **ES of the CSR** by the inclusion of the following CoU:

- Handle substance outdoors or in a well-ventilated room with windows open.
- Store substance within a closed system.

The outcome of the CSA is displayed within the relevant **ES for communication** by the inclusion of the RMM:

- Covers indoor and outdoor use. Open windows during application to ensure natural ventilation.
- Store substance within a closed system.

No cut-off concentration triggering the classification of a mixture containing the assessed petroleum substance has been applied for this hazard. It shall be noted that a cut-off concentration has been defined in CLP Regulation, but all petroleum substances with this hazard have been by default assessed at a concentration of 100%.

3.3.3.6. Carcinogenic Hazard (H350) and Mutagenic Hazard (H340)

In alignment with REACH Annex XVII Entry 28 and Entry 29, petroleum substances classified for the hazard of "May cause cancer" (H350) and/or "May cause genetic defects" (H340) are not supported in consumer uses, except for:

- motor fuels which are covered by Directive 98/70/EC;
- mineral oil products intended for use as fuel in mobile or fixed combustion plants;
- fuels sold in closed systems (e.g. liquid gas bottles).

For the exempted uses, the qualitative risk characterisation conducted is consistent with the considerations and RMMs identified in the ***Table 19*** below. ***Table 19*** also shows how many RMMs are already communicated in the SDS by virtue of the associated P Statements for the hazard.

Table 19. Elements of qualitative CSA and identified P Statements for carcinogenicity and mutagenicity

Components of the qualitative CSA	Examples of relevant P Statements
• Minimise exposure by product design, such as encapsulation, pelletisation • Wear gloves if hand contact with substance likely • Wash off any skin contamination immediately	General: • P102: Keep out of reach of children. 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.

The outcome of the CSA is displayed within the relevant **ES of the CSR** by the inclusion of the following general phrase (for substances classified as carcinogenic (H350) and/or mutagenic (H340)):

- General measures (carcinogenicity, benzene): Dermal exposure during handling of consumer fuels is low and according to the Concawe SCEDs significantly less than 0.1% of the handled quantities are transferred to the skin. Inhalation exposure during handling of consumer fuels is low and according to the Concawe SCEDs significantly less than 1% of the handled quantities are released to the air. Additionally, the benzene concentration in the final product is below 1%. Exposure durations are very low and will typically not exceed a few minutes. The refuelling equipment is in general designed to minimise exposure (e.g. nozzle, vapour recovery systems at petrol stations, etc.). Additionally, disposable gloves are usually provided at petrol stations. The benzene concentration is further aligned with Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels.

The outcome of the CSA is displayed within the relevant **ES for communication** by the inclusion of the general phrase (for substances classified as carcinogenic (H350) and/or mutagenic (H340)):

- Covers percentage benzene in the final product up to <1%.

A cut-off concentration triggering the classification of a mixture containing the assessed petroleum substance of ≥0.1% has been applied for these hazards (according to CLP Regulation, Table 3.5.2 and Table 3.6.2).

3.3.3.7. Carcinogenic Hazard (H351)

Substances classified as Carcinogenic category 2 are not within the scope of REACH Annex XVII Entry 28 and Entry 29. Nevertheless, Concawe advices that substances classified for this endpoint should not be marketed for consumer uses, except for consumer diesel fuels (see also Chapter 2.1.3).

For the hazard of "Suspected of causing cancer" (H351) the qualitative risk characterisation conducted is consistent with the considerations and RMMs identified in the ***Table 20*** below. The approach taken aligns with the approach taken in the CSA for substances classified as carcinogenic category 1. ***Table 20*** also shows how many RMMs are already communicated in the SDS by virtue of the associated P Statements for the hazard.

Table 20. Elements of qualitative CSA and identified P Statements for carcinogenicity category 2

Components of the qualitative CSA	Examples of relevant P Statements
• Minimise exposure by product design, such as encapsulation, pelletisation • Wear gloves if hand contact with substance likely • Wash off any skin contamination immediately	General: • P102: Keep out of reach of children. 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.

The outcome of the CSA is displayed within the relevant **ES of the CSR** by the inclusion of the following general phrase:

- General measures applicable to all activities: Dermal exposure during handling of consumer fuels is low and according to the Concawe SCEDs significantly less than 0.1% of the handled quantities are transferred to the skin. Inhalation exposure during handling of consumer fuels is low and according to the Concawe SCEDs significantly less than 1% of the handled quantities are released to the air. Exposure durations are very low and will typically not exceed a few minutes. The refuelling equipment is in general designed to minimise exposure (e.g. nozzle). Additionally, disposable gloves are usually provided at petrol stations. The diesel composition is further aligned with Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels.

No relevant phrases are displayed within the relevant **ES for communication**.

A cut-off concentration triggering the classification of a mixture containing the assessed petroleum substance of ≥1% has been applied for these hazards (according to CLP Regulation, Table 3.6.2).

3.3.3.8. Skin Defatting Hazard (EUH066)

The hazard "Repeated exposure may cause skin dryness or cracking" (EUH066) is generally applied to petroleum substances and solvents that have the capacity to extract lipids from the skin and that are not classified as skin irritant. None of the (classified) petroleum substances registered under REACH are marketed for any consumer use with repeated and prolonged exposures. Solely, the use in consumer fuels may be applicable for some petroleum substances classified for this endpoint.

However, due to low, infrequent and short exposures during automotive refuelling, the qualitative CSA concluded that the risk is negligible for this hazard.

3.4. QUANTITATIVE EXPOSURE AND RISK ASSESSMENTS

3.4.1. Occupational Use

3.4.1.1. Inhalation Exposure

The inhalation exposure of the occupational use of petroleum substances was predicted using the TRA tool, the ART tool, and measured data from literature and/or available through Concawe members. Each of these methods to predict inhalation exposure is explained in detail below.

In most instances, the TRA tool (in CHESAR 3.3) has been used to predict occupational exposure to petroleum substances. As described in **Section 3.2**, a petroleum substance typically consists of countless number of molecules, all with varying vapour pressures. To account for this, each petroleum substance has been divided into AE that align with the volatility bands of the TRA tool. For AE covering molecules with a VP above 10 Pa, the default TRA tool exposure predictions for vapours have been used in risk assessment. For the AE covering molecules with a VP below 10 Pa, a more elaborated approach has been followed to account for aerosol formation during use. For molecules with a VP below 10 Pa, exposure *via* aerosols becomes more significant as compared to exposure *via* vapours (Schinkel *et al.*, 2013, 2014; McNally *et al.*, 2014). However, for most activities, the TRA tool does not account for aerosol formation, with the exception of spraying (PROC 7 and PROC 11), and greasing and lubrication at high energy conditions (PROC 17 and PROC 18). For these four PROCs, the default TRA tool predictions have been used for molecules with a VP below 10 Pa. For all other PROCs, the default TRA tool predictions have been used for molecules with a VP above 10 Pa and the following approach has been taken for the aerosol AE (the ESIG GES approach has been used to distinguish between activities with and without aerosol formation):

- Activities that may be associated with the formation of aerosols (PROC 4, 5, 6, 8a, 8b, 9, 10, 15) and which are carried out in **open systems**: The medium dustiness exposure predictions have been used in risk assessment for the aerosol AE as a substitute to estimate exposure to aerosols (*cf.* ECETOC, 2012). In a few limited instances where TRA failed to demonstrate acceptable exposure to aerosols, ART has been used to refine the exposure predictions (see below).

- Activities that may be associated with the formation of aerosols (PROC 1, 2, 3, 4, 5, 6, 8a, 8b, 9, 10, 15) and which are carried out in **closed systems**: The requirement to carry out the activity in closed systems was considered sufficiently protective to avoid the release of aerosols into the working environment. The requirement to carry out the operation under closed conditions was communicated *via* one of the following four CoU:

    - Handle substance within a closed system;
    - Store substance within a closed system;
    - Handle within a fume cupboard or implement suitable equivalent methods to minimise exposure;
    - Transfer under containment.

Additionally, typically the ESCom phrase "Closed systems" or "Use in contained systems" was included in the Contributing Scenario (CS) title of activities carried out in closed systems. To avoid over-application of RMMs, the use of Local Exhaust Ventilation (LEV) and general ventilation was not considered in the exposure prediction for activities in closed systems. In a few instances where a LEV and/or general ventilation was considered, exposure to aerosols was also assessed for the aerosol AE using the medium dustiness exposure predictions of the TRA tool.

- Activities that are not associated with the formation of aerosols (PROC 13, 14, 16, 19, 28): These activities are always carried out with low energy and the formation of aerosols has been considered negligible (see ESIG worker GES files).

Cleaning and maintenance activities have been assessed in a dedicated CS. Since the TRA tool currently does not provide exposure predictions for the associated PROC 28, PROC 8a exposure predictions have generally been used. PROC 28 has been mapped as an additional PROC relevant for the CS.

In case a non-standard CoU has been applied in risk assessment (see ***Table 3***), the exposure reduction factor has been applied manually in the CHESAR tool. Alternatively, if the exposure reduction efficiency aligned or was lower than the standard/default exposure reduction efficiency of the LEV in TRA, then the LEV (with TRA effectiveness) was used in the CHESAR tool. The non-standard CoU has been provided as free text in the CHESAR tool and has been communicated instead of the LEV in the reference SDS Annexes for petroleum substances.

In a few limited instances, the ART tool has been used to estimate occupational exposure to petroleum substances, in particular:

- Aerosol exposure for molecules with a VP below 10 Pa to refine TRA predictions based on medium dustiness assumption: For such assessments, the ART tool exposure estimate has solely been applied to the aerosol AE.

- Vapour exposure for substances at very high temperatures: For the manufacturing CS, it was assumed that the VP is 100.000 Pa. This is the upper VP limit of the ART tool, and can be considered a worst-case assumption. The ART tool exposure estimate has been applied to the complete substance.

- Exposure for substances with a very low volatility: For substances for which at least 95% of the molecules have a VP of less than 10 Pa (*e.g.* SRGO, TDAE, RAE, Footsoil, HRBO and LBO), the ART tool exposure predictions have been considered to represent exposure to the complete substance. It shall be noted that due to the conservative approach in determining the fraction of molecules below 10 Pa, realistically the fraction of molecules below 10 Pa is typically in the range or above 99% for these substances.

If the ART tool was used for risk assessment, then the 90th percentile exposure estimate has been used for the long-term exposure assessment. For the short-term exposure assessment, the 99th percentile exposure estimate of the ART tool has been used. This value was used for short-term exposure assessment as it is typically 2 to 4 times higher than the 90th percentile exposure estimate. These factors are in alignment with the considerations provided in the guidance document of the TRA tool (ECETOC, 2012).

Measured data was either directly taken from literature (*e.g.* Concawe, 2006, 2015, 2018, 2021) or were made available by Concawe member companies to facilitate

the REACH registrations of petroleum substances. Measured data were used for Naphtha with up to 1% benzene as laboratory agent (data from six Concawe member companies) and for HFO for (un)loading of marine vessels/barges and road tankers/rail cars (data from nine Concawe member companies). For the risk assessment, the 90th percentile exposure estimate based on an idealised log-normal distribution was used. Data points below the limit of quantification were substituted using the regression on order statistics and assuming a log-normal distribution. For the bottom (un)loading of road tankers/rail cars from HFOs only one data point was available. To obtain a reasonable worst-case exposure prediction in this instance, four times the measured value was used in the risk assessment of chronic effects (ECETOC, 2012) (*Note*: for the assessment of acute effects the TRA estimates were used).

In some instances, similar activities within one ES that are linked to different PROCs have been assessed in one CS. In such cases, the highest exposure predictions of all assessed PROCs according to the TRA tool have been used in the exposure and risk assessment. For example, for the storage of the substance usually PROC 1 and PROC 2 use conditions have been assessed in one ES. To avoid unnecessary repetitions, both PROCs have been assessed within one CS. To this end, the exposure predictions of PROC 2 have been used in the exposure and risk assessment and PROC 1 has been mapped as an additional PROC relevant for storage contributing activity.

3.4.1.2. Dermal Exposure

The dermal exposure of the occupational use of petroleum substances was typically predicted using the TRA tool. For HFO, for some CS dermal exposure predictions were based on measured data from literature.

For tasks involving the handling of petroleum substances with an operating temperature of more than 60˚C, dermal exposure was typically not assessed. This is in alignment with the ECETOC Technical Report 107 Appendix D-3 (ECETOC, 2009), which states that *"available evidence indicates that at operating temperatures above 60˚C, dermal exposures can be considered as unlikely to occur as any exposed individual will receive burns from (direct) skin contact"*. The ECETOC report also suggests that any quantitative estimate may be set at the level of PROC 1 and/or 3 to account for any indirect/incidental dermal exposure that may occur from touching contaminated surfaces or removing the gloves. The default dermal exposure estimate (without dermal Personal Protective Equipment, PPE) for PROC 1 in ECETOC TRA is 0.03 mg/kg/day, which is generally lower than the dermal DNELs for petroleum substances. PROC3 default estimate in TRA is considered overly conservative to represent indirect/incidental dermal exposure, as it is 2-fold higher than exposures predicted for more routine tasks involving direct dermal contact (e.g. PROC16).

Furthermore, for tasks where dermal exposure has been assessed, including tasks with significant direct dermal exposure at ambient temperature, the risk assessment is performed assuming typically 8h exposure. Any secondary indirect/incidental skin contact in tasks at temperatures >60oC should be considered negligible as no risk was already shown from 8h dermal exposure in tasks involving direct dermal contact.

In some instances, the dermal exposure predictions were corrected on the basis of the actual percentage in the mixture. As described in the ECETOC TR 107 Appendix D-3 (ECETOC, 2009), the TRA tool usually corrects the dermal exposure predictions for the presence of the substance in a mixture at level <100% based on concentration bands (>25%, 5-25%, 1-5%, <1%). However, for the dermal exposure

(contrary to the inhalation route) it is also justified to correct on the basis of the actual percentage in the mixture. This approach is further supported by validation study carried out by Marquart *et al.* (2017), who could show that the TRA tool dermal predictions tend to overestimate the actual dermal exposure by an order of magnitude at low concentrations of the substance in the mixture.

In alignment with REACH Guidance R14 (ECHA, 2016c), the exposure reduction efficiency of LEV was only considered justified for the dermal route in the two cases described below:

- For highly volatile substances, i.e. Naphtha, Kerosine and MK1 categories. However, for none of these three categories a quantitative CSA is required for the dermal route;

- For substances with a low VP where exposure is mainly *via* mists (*i.e.* PROC 7, PROC 11, PROC 17 and PROC 18).

3.4.1.3. Combined Exposure

A combined exposure assessment for workers from multiple tasks/CS was considered not necessary for the following reasons:

- Generally, the TRA tool has been used to predict occupational exposure to petroleum substances. The TRA tool is a Tier 1 tool, which generally provides conservative exposure estimates for the assessed CS. Summing up such Tier 1 exposure predictions would result in overly conservative outcome (REACH Guidance R15 (ECHA, 2016d)).

- Generally, 8h (full-shift) have been assessed in each CS of the ES. A combination of CS and further calculation of the time-weighted average for 8h would lead to a combined RCR lower than the highest RCR of the individual CS assessed.

- Dermal exposure estimates provided by the TRA tool for low volatile substances (<500 Pa) are not adjusted if the assessed time duration is below 8h (full-shift). Thus, for petroleum substances (with the exception of Naphtha), the dermal exposure predictions, irrespective of the assessed duration, can always be considered to represent full-shift worst-case exposure predictions. Further combining or summing up exposure estimates from different CS is scientifically not justified. If a worker is carrying out several tasks during a shift, the contributing scenarios with the highest dermal exposure estimates can be considered sufficiently conservative for all activities covered by an ES.

This justification is applicable to all petroleum substances requiring a quantitative CSA, with the exception of HFO. For HFO, most CS have been assessed for less than 8h. However, due to the hazard profile this substance, HFO is only used in closed systems and in a very low number of uses and processes. The tasks relevant for handling HFO are typically not carried out by the same personnel (*i.e.* plant operator, jetty operator, truck driver, laboratory technician, ship mechanic/technician, maintenance technician). A combined exposure assessment is therefore considered not necessary.

3.4.2. Consumer Use

3.4.2.1. Inhalation Exposure

The inhalation exposure of the consumer use to petroleum substances was predicted using the TRA tool together with SCEDs. The exposure predictions during car refuelling of gasoline were, however, supported by measured data from literature.

As the TRA tool does not provide short-term exposure predictions for consumers, an interim work around in CHESAR tool was developed to calculate short-term exposure as follows:

- Exposure duration ≤ 15 minutes: the default TRA tool exposure prediction was used as conservative assumption;
- Exposure duration >15 minutes but ≤ 1 hour: a 15 minutes time-weighted average was calculated based on the default TRA tool exposure prediction;
- Exposure duration >1 hour: 4 times the default TRA tool exposure prediction was used as conservative assumption. This approach is in line with the assumptions made for occupational exposure by the TRA tool.

The workaround was needed to enable reasonable comparison of the event exposure to acute systemic DNELs that characterize effects occurring after a single exposure event and comparison of short-term exposure to long-term systemic DNELs addressing repeated/continuous exposure over 24 hours In the latter case, modified Haber's law recommended by ECHA (ECHA, 2016d) was followed to adjust for shorter daily durations, *i.e.* for tasks that last significantly shorter than 24 hours (i.e. less than 8 hours). For the adjustment, a regression factor of 1 has been used (ECHA, 2016d – footnote 10). Since the short-term/acute inhalation DNEL addresses any acute toxic effects, this linear regression factor was considered sufficiently conservative.

In addition to the adjustment for shorter exposure duration (where applicable), further refinement of risk characterization was performed for those consumer products, for which SCEDs data indicate infrequent use, i.e. less than 15 times per year (ECHA, 2016d). For example, for the non-carcinogenic permutation of LBO, an **infrequent** long-term **systemic** DNEL for the inhalation route was derived and applied in the CSA of Lubricants consumer use. For **local** effects the adjustment of predicted exposure for infrequent use *was done manually* in CHESAR. Namely, the local long-term exposure estimate was decreased by a factor of 6, which corresponds to the ratio between the infrequent local inhalation DNEL (7.14 mg/m^3)[21] and the long-term local inhalation DNEL (1.19 mg/m^3).

For risk assessments based on measured data, the 90th percentile exposure estimate derived assuming an idealised log-normal distribution was used. Exposure measurements were linearly adjusted to align with the CoU specified in Concawe_SCED_13_1_a. That is if data in SCED states that the activity takes 5 minutes, then the e.g. 3 minutes exposure measurement value was linearly scaled to 5 minutes duration.

[21] Infrequent DNEL for consumer *inhalation* calculated as 7.14 mg/m^3: starting point NOEL of 500 mg/m^3 in a subacute rat inhalation study, modified by days/week [5/7] and hours/day of exposure [6/24] to give a modified starting point of 89.3 mg/m^3. Assessment factors then applied for Other Interspecies [2.5; ECHA default] and Intraspecies [5; ECETOC and Concawe value] uncertainties to give a final DNEL of 7.14 mg/m^3.

3.4.2.2. Dermal and Oral Exposure

The dermal and oral (where relevant) exposure from consumer use of petroleum substances was predicted in all cases using the TRA tool.

For the non-carcinogenic permutation of OtherGO, an infrequent long-term DNEL[22] for the dermal route was derived and as applied in the CSA of consumer uses that occur less than 15 times per year (ECHA, 2016d).

For HRBO, the dermal and oral absorption was considered in risk assessment. Molecules with a size above 500 Dalton are too large to penetrate the corneal layer (Bos and Meinardi, 2000). Thus, any dermal absorption of molecules above this size cut-off can be considered negligible. As a conservative approach and to be in line with REACH Guidance R.7c, Appendix R.7.12-4 (ECHA, 2017b), dermal absorption of 10% of molecules above 500 Dalton (conservatively assumed to be hydrocarbons with at least 35 carbon atoms) has been assumed. Similarly, for intestinal absorption of mineral oils it has been reported that there is no absorption of hydrocarbons above 30 carbon atoms if they are fed directly to rats (Barrowman *et al.*, 1989). Low absorption rates above 30 carbon atoms may be expected if hydrocarbons are fed as integral part of the diet (Barrowman *et al.*, 1989). Thus, as a worst-case consideration it has been assumed that the size cut-off above which hydrocarbons become too large to be intestinally absorbed is also 35 carbon atoms. Thus, as for the dermal route, an intestinal absorption of 10% of hydrocarbons with more than 35 carbon atoms has been assumed.

3.4.2.3. Combined Exposure

Most petroleum substances requiring a quantitative CSA are either not marketed in consumer products at all or used only in consumer fuels. Hence, for these substances, a combined exposure assessment (i.e. exposure from multiple products/uses) is not required.

Solely LBO and HRBO are marketed in a substantial number of consumer products. However, a combined exposure assessment for consumers was not considered required for the following reasons:

- Generally, the TRA tool has been used to predict consumer exposure for petroleum substances. The TRA tool is a Tier 1 tool, which is designed to provide conservative exposure estimates for the assessed contributing scenarios. Summing up such Tier 1 exposure predictions would result in overly conservative outcome (REACH Guidance R15 (ECHA, 2016d)).

- The permutations of HRBO and LBO that are marketed in consumer products are of very low toxicity (either non-classified according to CLP Regulation or only classified as aspiration hazard (H304)). No acute health effects have been reported.

- For HRBO, for most of the consumer uses the RCRs < 0.1 have been determined in the quantitative CSA (fuels, agrochemicals) or the risk is driven by exposure *via* the dermal route (cleaning products and lubricants), which by default

[22] Infrequent DNEL for consumer *dermal* calculated as 8.93 mg/kg: starting point NOAEL of 1000 mg/kg in a subacute rabbit dermal study, modified by days/week [3/7] and hours/day of exposure [6/24] to give a modified starting point of 107.14 mg/kg. Assessment factors then applied for Interspecies allometric [2.4; ECHA default] and Intraspecies [5; ECETOC and Concawe value] uncertainties to give a final DNEL of 8.93 mg/kg.

assumes exposure for 24h per product category. Thus, it is considered that the risk related to combined exposure is controlled.

3.4.3. Service Life

For Sulphur, the service Life Cycle Stage (LCS) for the use in matches, fireworks, and road and construction products has been included in the CSA. However, since for Sulfur only a qualitative CSA is necessary, the CSA of the service LCS was solely focused on the hazard of "Causes skin irritation" (see **Section 3.3.2.3**).

Service LCS for the use in road and construction products has been included in quantitative CSAs of LBO and OtherGO categories.

3.5. SEMI-QUANTITATIVE EXPOSURE AND RISK ASSESSMENTS

For semi-quantitative hazards, first an exposure and risk assessment as described for quantitative hazards has been carried out (see **Section 3.4**). The exposure predictions were benchmarked with the relevant DNELs of CM substance. The required RMMs resulting from this exposure and risk assessments were further supplemented with the RMMs summarised in ***Table 21***. The RMMs summarised in this Table have been applied irrespective of the outcome of the quantitative assessment to ensure that occupational exposure is minimised when CM substances are handled.

In instances where the RMMs determined in the quantitative exposure and risk assessment for a specific CS contradicted the RMMs listed in ***Table 21*** for the same CS, the more conservative RMM was applied. This was for example the case when the quantitative exposure and risk assessment concluded that the worker is required to "wear chemically resistant gloves (tested to EN374) in combination with specific activity training" (dermal exposure reduction factor of 95%) and the RMM listed in **Table 21** specified "wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training" (dermal exposure reduction factor of 90%). In such instances, the RMM "wear chemically resistant gloves (tested to EN374) in combination with specific activity training" was applied in risk assessment.

Table 21. Specific activities and associated RMMs for Carcinogenic & Mutagenic substances

Contributing Scenarios	PROC	Risk Management Measures
General exposures OR Bulk weighing	1/2	• Handle substance within a closed system. • Sample via a closed loop or other system to avoid exposure. • Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training. Wear suitable coveralls to prevent exposure to the skin.
General exposures Batch process OR Additive premixing Small scale	3	• Handle substance within a closed system. • Sample via a closed loop or other system to avoid exposure. • Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training. Wear suitable coveralls to prevent exposure to the skin.
Laboratory activities	15	• Handle within a fume cupboard or implement suitable equivalent methods to minimise exposure. • Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training. Wear suitable coveralls to prevent exposure to the skin.
Bulk transfers Loading and unloading OR Filling of equipment from drums or containers OR Refuelling	8a/8b	• Ensure material transfers are under containment or extract ventilation. • Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training. Wear suitable coveralls to prevent exposure to the skin.
Filling of articles/equipment OR Initial factory fill of equipment OR Material transfers OR Small scale weighing OR Transfer from/pouring from containers	9	• Ensure material transfers are under containment or extract ventilation. • Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training. Wear suitable coveralls to prevent exposure to the skin.
Use of fuels	16	• Handle substance within a closed system. • Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training. Wear suitable coveralls to prevent

		exposure to the skin.
Equipment cleaning and maintenance OR Maintenance and machine set up	8a/8b/28	• 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. Wear suitable coveralls to prevent exposure to the skin.
Remanufacture of reject articles	9	• Drain or remove substance from equipment prior to break-in or maintenance. • Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training. Wear suitable coveralls to prevent exposure to the skin.
Storage	1/2	• Store substance within a closed system. • Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training. Wear suitable coveralls to prevent exposure to the skin.

3.6. OTHER CONSIDERATIONS

3.6.1. Good occupational hygiene practice

In developing the exposure and risk assessments, Concawe has assumed that a good standard of occupational hygiene practice is implemented. Good occupational hygiene practice is considered by Concawe to constitute measures that are routinely encountered and applied to meet the requirements of relevant workplace legislation such as regulations supporting the EU Directive 89/391/EEC on Safety and Health at Work (OSH Framework Directive), in addition to specific RMM identified in the ES. These may include, but are not limited to:

- Risk assessment of local workplace activities;
- Procedures supporting safe handling and maintenance of controls;
- Education and training of workers in understanding the hazards and control measures relevant to their activities;
- Provision of general ventilation;
- Good housekeeping and prompt clearance of spillages;
- Appropriate selection, testing and maintenance of equipment used to control exposure, e.g. Personal Protective Equipment (PPE), Local Exhaust Ventilation (LEV);
- Draining of equipment prior to maintenance; retention of drained material in sealed storage pending disposal or recycling;
- Regular supply and laundering of work clothing; provision of washing and changing facilities; eating and smoking only in designated areas separate from the workplace.

This assumption is provided in each ES of the CSA and is communicated in the ES for communication *via* the phrase "Assumes a good basic standard of occupational hygiene is implemented".

3.6.2. Products which may release Hydrogen Sulphide or Sulfur Dioxide

For products that may release hydrogen sulphide (H_2S) and/or sulfur dioxide (SO_2) a qualitative risk assessment has been carried out. The qualitative risk characterisation is consistent with the considerations and RMMs identified in the ***Table 22*** below.

Table 22. Elements of qualitative CSA for hydrogen sulphide and sulfur dioxide release

Components of the qualitative CSA
• Segregation of areas • Access only to authorised persons • Permit to work systems • Confined space working procedures • Area H_2S and/or SO_2 alarms • Personal H_2S and/or SO_2 alarms • Personal escape sets • H_2S and SO_2 awareness training • Risk assessment of local workplace activities • Procedures supporting safe handling and maintenance of controls • Education and training of workers in understanding the hazards and control measures relevant to their activities • Provision of general ventilation • Appropriate selection, testing and maintenance of equipment used to control exposure, e.g. PPE, LEV

The outcome of the CSA is displayed within the relevant **ES of the CSR** by the inclusion of the general phrases:

- General measures (gas release): Use area and personal gas detectors to ensure that the worker is immediately alerted to gas hazards; Ensure segregation of worker from the source; Access to work area only for authorised persons; Ensure a permit to work system is in place; Follow confined space working procedures; Provide personal escape sets; Provide awareness training.

  OR

- General measures (gas release): Minimise exposure by product design, such as encapsulation or pelletisation. [Only for Use in Agrochemicals ES – Professional, Sulfur]

- Assumes a good basic standard of occupational hygiene is implemented: Risk assessment of local workplace activities. Procedures supporting safe handling and maintenance of controls. Education and training of workers in understanding the hazards and control measures relevant to their activities. Provision of general ventilation. Appropriate selection, testing and maintenance of equipment used to control exposure, e.g. PPE, LEV. [Amongst other phrases].

The outcome of the CSA is displayed within the relevant **ES for communication** by the inclusion of the general phrases:

- General measures (gas release): Use area and personal gas detectors to ensure that the worker is immediately alerted to gas hazards. Ensure segregation of worker from the source. Access to work area only for authorised persons. Ensure a permit to work system is in place. Follow confined space working procedures. Provide personal escape sets. Provide awareness training.

OR

General measures (gas release): Product may release hydrogen sulphide; Product may release sulfur dioxide; Minimise exposure by product design, such as encapsulation or pelletisation. [*Only for Use in Agrochemicals ES - Professional, Sulfur*]

- Assumes a good basic standard of occupational hygiene is implemented.

3.6.3. Tank Cleaning

For the reasons described below, no CSs for internal tank cleaning operations were included in the substance-specific ES of the petroleum substances.

3.6.3.1. Tanks at industrial premises

RMMs for tank cleaning and inspection operations at industrial premises are well-established as part of operating within a confined space and subject to control *via* a permit to work; they are applicable to broad classes of substances rather than being substance-specific. Separate legislation and/or guidance is available within individual Member States, e.g. UK Confined Spaces Regulations 1997 and supporting guidance.

3.6.3.2. Tanks at professional premises

Environmental regulations in a number of EU countries require periodic, e.g. three-yearly, assessment of the continued integrity of storage tanks, e.g. underground tanks for gasoline and automotive diesel at service stations. Current requirements may prescribe physical entrance of the inspector inside the tank to carry out tests. In those instances, the tank has been emptied and prepared for inspection, including appropriate atmospheric tests. The inspections are carried out by specialist companies who apply well-established safe working procedures. These include respiratory protection. Advanced inspection technologies exist which do not require human entrance in tanks and which can greatly reduce exposures;

3.6.3.3. Tanks at private premises

As for professional premises, environmental regulations in some EU countries require periodic testing of tanks at private premises, in particular for home-heating oil (*e.g.* LASI, 2005). Inspections are carried out by professional workers and require temporary removal of the tank contents as well as any deposits. Both cleaning and inspection activities involve tank entrance. Described work practices are basic. In addition to simple ventilation arrangements, exposure control relies to a large extent on the use of respirators. Dermal exposures may be significant. As the private tank owners are considered consumers under REACH, they have no access to the eSDS and hence cannot be expected to provide risk management advice to the tank cleaning and inspection personnel.

4. CREATING EXPOSURE SCENARIOS FOR COMMUNICATION

The CHESAR tool version 3.3 has been used for the creation of the reference SDS Annexes for petroleum substances.

4.1. USE DESCRIPTION

The ESIG GES use description phrases have been used to provide a brief description on the processes, tasks and activities covered by the respective ES.

For substances classified for the hazard of “May cause cancer” (H350) and/or “May cause genetic defects” (H340) and/or “Suspected of damaging fertility; Suspected of damaging the unborn child” (H361fd), use description phrases have been chosen that clearly state that the processes, tasks and activities covered by the ES have to be carried out in “closed or contained systems”.

4.2. OPERATIONAL CONDITIONS

To reduce the complexity of the ES for communication, OCs have only been included in a specific CS, if they deviated from the default value. The default OCs were included in the ES section that is applicable to all CS. This approach was taken for the (i) physical form of the product, (ii) concentration of substance in product, (iii) duration of use/exposure, and (iv) operating temperature.

To this end, the following default OCs CoU were included in all CS of the respective ES in CHESAR:

(1) Liquid, vapour pressure > 10 kPa at Standard Temperature and Pressure

OR

(2) Liquid, vapour pressure < 0.5 kPa at Standard Temperature and Pressure. With potential for aerosol generation
(3) Covers percentage substance in the product up to 100 % (unless stated differently)
(4) Covers daily exposures up to 8 hours (unless stated differently)
(5) Covers use at ambient temperatures (unless stated differently)

These phrases are displayed in Section 2 of the ES for communication, *i.e.* in the section that is applicable to all CS.

4.3. IDENTIFYING CONDITIONS OF USE FOR COMMUNICATION

4.3.1. Qualitative Hazards

For worker ES, the outcome of the CSA for each H Statement (see **Section 3.3.2**) was summarized in a CoU and included in each CS of the respective ES. By doing so, it was possible to include the relevant general phrases in the ES section that is applicable to all CS.

For consumer ES, the outcome of the CSA for each H Statement (see **Section 3.3.3**) was included manually in each CS. This was done, because it is not possible to add

CoU to CS based on SCEDs and because CHESAR does not recognise an ES section that is applicable to all CS for consumer ES.

4.3.2. Quantitative and Semi-quantitative Hazards

The RMMs determined in the quantitative and semi-quantitative exposure and risk assessment (see **Section 3.4** and **Section 3.5**) are communicated in Section 2 of the ES for communication. For each CS the respective RMMs are communicated separately.

4.3.2.1. Worker Exposure Scenarios

For worker ES, only those RMMs have been communicated in the ES for communication that:

- May be considered a deviation from default/standard/typical RMMs at a site AND do lead to refinement of a default exposure prediction in the TRA model;
- Were not yet covered by RMMs communicated with general phrases based on qualitative hazards.

In case that the quantitative or semi-quantitative CSA concluded that a LEV is required in a CS, the specific ESCom phrase listed in ***Table 23*** for the specific PROC was communicated in the ES for communication. These phrases have been considered more descriptive and practical as compared to the ESCom phrase applied by default by CHESAR (*i.e.* "Local exhaust ventilation; Inhalation - minimum efficiency of xx%").

Table 23. ESCom phrases for LEV per PROC and LSC

Applicable PROC	Life Cycle Stage	Assigned Exposure Reduction (%)	Assigned ESCom Phrase(s)
2	Industrial	90%	Provide extract ventilation to points where emissions occur.
2	Professional	80%	Provide extract ventilation to points where emissions occur.
3	Industrial	90%	Provide extract ventilation to points where emissions occur.
4	Industrial	90%	Provide extract ventilation to points where emissions occur. OR* Minimise exposure by partial enclosure of the operation or equipment and provide extract ventilation at openings. *Operation of solids filtering equipment:* Provide the operation with a properly sited receiving hood.
4	Professional	80%	Provide extract ventilation to points where emissions occur.
5	Industrial	90%	Provide extract ventilation to points where emissions occur.
5	Professional	80%	Provide extract ventilation to points where emissions occur.
6	Industrial	90%	Provide extract ventilation to points where emissions occur. OR*

			Minimise exposure by partial enclosure of the operation or equipment and provide extract ventilation at openings. OR* Provide extract ventilation to material transfer points and other openings.
6	Professional	80%	Provide extract ventilation to points where emissions occur. OR* Minimise exposure by partial enclosure of the operation or equipment and provide extract ventilation at openings.
7	Industrial	95%	*Manual spraying*: Carry out in a vented booth or extracted enclosure. *Machine/automatic spraying*: Minimise exposure by partial enclosure of the operation or equipment and provide extract ventilation at openings.
8a	Industrial	90%	Provide extract ventilation to points where emissions occur.
8b	Professional	90%	Provide extract ventilation to points where emissions occur.
9	Industrial	90%	*Filling lines:* Fill containers/cans at dedicated fill points supplied with local extract ventilation. *Process sampling:* Provide extract ventilation to points where emissions occur. *Small scale weighing:* Carry out in a vented booth or extracted enclosure.
10	Industrial	90%	Provide extract ventilation to points where emissions occur.
10	Professional	80%	Provide extract ventilation to points where emissions occur. OR* Minimise exposure by partial enclosure of the operation or equipment and provide extract ventilation at openings.
11	Professional	80%	*Manual spraying*: Carry out in a vented booth or extracted enclosure. *Machine/automatic spraying*: Minimise exposure by partial enclosure of the operation or equipment and provide extract ventilation at openings. *Tractor spraying:* Apply within a vented cab supplied with filtered air under positive pressure and with a protection factor of >20.
13	Industrial	90%	Provide extract ventilation to points where emissions occur. OR* Minimise exposure by partial enclosure of the operation or equipment and provide extract ventilation at openings.
13	Professional	80%	Minimise exposure by partial enclosure of the operation or equipment and provide extract ventilation at openings.
14	Industrial	90%	*Tabletting, compression, extrusion or palletisation:* Handle substance within a predominantly closed system provided with extract ventilation. *Mold forming:* Provide extract ventilation to points

			where emissions occur.
14	Professional	80%	Provide extract ventilation to points where emissions occur.
15	Industrial	90%[#]	Handle within a fume cupboard or implement suitable equivalent methods to minimise exposure.
17/18	Industrial	80%	Minimise exposure by partial enclosure of the operation or equipment and provide extract ventilation at openings.
17/18	Professional	90%	Provide extract ventilation to points where emissions occur. OR* Minimise exposure by partial enclosure of the operation or equipment and provide extract ventilation at openings.

* These phrases have been used interchangeable
[#] In some instances an exposure reduction efficiency of 99% was applied (see **Table 3**)

In case no specific RMM was identified in the quantitative CSA that solely applies to the respective CS, the phrase "No other specific measures identified" was communicated.

In addition, additional good practice advice was communicated for specific activities, which are not the result of the quantitative exposure and risk assessment. The respective phrases are summarised in ***Table 4***.

4.3.2.2. Consumer Exposure Scenarios

For consumer ES, only RMMs and OCs have been communicated in the ES that:

- May be considered a deviation from default/standard/typical RMMs at a site AND do lead to refinement of a default exposure prediction in the TRA model;
- Have been defined in the respective SCED.

Dermal, oral and inhalation transfer factors have not been communicated in any instance. These can be found in the respective SCED documents.

4.4. GUIDANCE TO DOWNSTREAM USER

In Section 4 of the ES for communication, additional information is presented that aims to support the downstream user in interpreting the provided RMMs and OCs in the corresponding ES. In ***Table 24***, the respective standard phrases and basis for inclusion of these phrases are listed.

Table 24. Standard phrases provided in Section 4 of the ES in the eSDS and respective justification

ESCom standard phrase	Rationale
Predicted exposures are not expected to exceed the DN(M)EL when the risk management measures/operational conditions outlined in section 2 are implemented.	A quantitative and/or semi-quantitative risk assessment has been carried out for the ES.
Where other risk management measures/operational conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.	A quantitative and/or semi-quantitative risk assessment has been carried out for the ES.
Available hazard data do not enable the derivation of a DNEL for aspiration effects.	A qualitative risk assessment has been carried out for the ES for the hazard of "May be fatal if swallowed and enters airways" (H304).
Available hazard data do not enable the derivation of a DNEL for dermal irritant effects.	A qualitative risk assessment has been carried out for the ES for the hazard of “Causes skin irritation” (H315).
Available hazard data do not enable the derivation of a DNEL for eye irritant effects.	A qualitative risk assessment has been carried out for the ES for the hazard of “Causes serious eye irritation” (H319).
Available hazard data do not support the need for a DNEL to be established for other health effects.	A qualitative risk assessment has been carried out for the ES for the hazard of “Suspected of causing cancer” (H351).
Available hazard data do not enable the derivation of a DNEL for carcinogenic effects.	A qualitative risk assessment has been carried out for the ES for the hazard of “May cause cancer” (H350) and/or “May cause genetic defects” (H340).
Risk management measures are based on qualitative risk characterisation.	At least one qualitative risk assessment has been carried out for the ES.
ECETOC TRA worker v3	The ECETOC TRA has been used to carry out all or some of quantitative occupational exposure and risk assessments that are the basis of the RMMs and OCs in section 2 of the ES.
ECETOC TRA consumer v3	The ECETOC TRA has been used to carry out all or some of quantitative consumer exposure and risk assessments that are the basis of the RMMs and OCs in section 2 of the ES.
If scaling reveals a condition of unsafe use (i.e., RCRs > 1), additional RMMs or a site-specific chemical safety assessment is required.	A quantitative exposure and risk assessment has been carried out to determine the RMMs and OCs in section 2 of the ES.

4.5. ESCOM STANDARD PHRASE CATALOGUE

To the extent possible, ESCom standard phrases were used in the ES for communication. However, some phrases required to unequivocally communicate the safe use of petroleum substances are not currently available in the latest version of the ESCom standard phrase catalogue[23]. The phrases listed in ***Table 25*** are currently not yet included into the ESCom standard phrase catalogue, but have been applied in the reference SDS Annexes for petroleum substances.

[23] Available at: https://cefic.org/guidance/reach-implementation/escom-package-guidance/

Table 25. Phrases for communication currently not available in the ESCom standard phrase catalogue

Phrase for communication	Phrases required for the following categories
Applicable if classified as H224 or H225 or H226, refer to section 2 of the SDS*	CrackedGO, Kerosine, OtherGO, SRGO, VHGO
Applicable if classified as H304, refer to section 2 of the SDS*	HFO, LBO, SRGO, TDAE, UATO, UDAE, VHGO
Assumes that potential dermal contact is limited to palm of one hand	Naphtha, VHGO, SRGO, LBO, HRBO, OtherGO
Assumes that potential dermal contact is limited to two fingertips	LBO, HRBO, OtherGO
Covers percentage benzene in the final product up to <XX%	Naphtha
Covers percentage benzene in the substance up to <XX%	Naphtha
Covers percentage n-hexane in the final product up to <3%	Naphtha
Covers percentage n-hexane in the substance up to <3%	Naphtha
Covers percentage toluene in the final product up to <3%	Naphtha
Covers percentage toluene in the substance up to <3%	Naphtha
Covers transfer rate	HFO
DMSO extractables of the final substance as measured by IP346 assay: <3.0%*	LBO, TDAE
Ensure displaced vapours are vented to a safe location	HFO
Exposure scenario applies to substances not classified as H350, refer to section 2 of the SDS*	OtherGO
Liquid at elevated operating temperature	Sulfur
Solid at standard temperature and pressure	Sulfur
Ensure labelling complies with regulations	Sulfur
Minimise exposure by product design, such as encapsulation or pelletisation	Sulfur
Provide clear instructions for use	Sulfur

* Phrases may only be needed in the Concawe reference ES for communication. For the marketed substance, the substance properties will determine if the respective ES and/or CS are applicable or not.

5. GLOSSARY

AE	Assessment Entity
AEG	Assessment Entity Group
AISE	Association Internationale de l'industrie du Savon, des Détergents et des Produits d'entretien (Association for Soaps, Detergents and Maintenance Products)
APF	Assigned Protection Factor
ART	Advanced REACH tool
ATIEL	Association Technique de l'Industrie Européenne des Lubrifiants (The Technical Association of the European Lubricants Industry)
C&L	Classification and Labelling
CHESAR	CHEmical Safety Assessment and Reporting
CLP	Regulation on Classification, Labelling and Packaging of substances and mixtures (Regulation (EC) No 1272/2008)
CM	Carcinogenic and/or Mutagenic
CMD	Carcinogens and Mutagens Directive (Directive 2004/37/EC)
CoU	Condition of Use
CrackedGO	Cracked gas oils
CS	Contributing Scenario
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
DMEL	Derived Minimum-Effect Level
DNEL	Derived No-Effect Level
ECETOC	European Centre for Ecotoxicology and Toxicology of Chemicals
ECHA	European Chemicals Agency
EGRET	ESIG GES Risk and Exposure Tool
EPI Suite	Estimation Program Interface Suite
ES	Exposure Scenario
ESCom	Exposure Scenario Communication
eSDS	Extended Safety Data Sheet (SDS with Annex containing ES)
ESIG	European Solvents Industry Group
FEICA	Fédération Européenne des Industries de Colles Adhesifs (Association of the European Adhesive & Sealant Industry)
GCxGC	Comprehensive two-dimensional gas chromatography
GES	Generic Exposure Scenarios
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HH	Human Health
H Statement	Hazard Statement
HFO	Heavy Fuel Oil Components
HRBO	Highly Refined Base Oils
LBO	Lubricant Base Oils
LEV	Local Exhaust Ventilation
LCS	Life Cycle Stage
MK1	Miljöklass 1 Diesel (Swedish Environmental Class 1 Diesel)
MW	Molecular Weight
OC	Operational Condition
OtherGO	Other Gas Oils
P Statement	Precautionary Statement
PC	Product Category
PPE	Personal Protective Equipment
PROC	Process Category
RCR	Risk Characterisation Ratio

RAE	Residual Aromatic Extracts
REACH	Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (Regulation (EC) No 1907/2006)
RMM	Risk Management Measure
SCED	Specific Consumer Exposure Determinant
SDS	Safety Data Sheet
SIP	Substance Identity Profile
SRGO	Straight-Run Gas Oils
SU	Sector of Use
TDAE	Treated Distillate Aromatic Extracts
TRA	Targeted Risk Assessment
UATO	Unrefined/Acid Treated Oils
UDAE	Untreated Distillate Aromatic Extracts
UVCB	Unknown or Variable composition, Complex reaction products or of Biological materials
VHGO	Vacuum Gas Oils, Hydrocracked Gas Oils and Distillate Fuels
VP	Vapour Pressure

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7. ANNEX

7.1. ANNEX I: AEG OF LOW VOLATILE PETROLEUM SUBSTANCES FOR OCCUPATIONAL USES

The AEG composition for low volatile petroleum substance categories requiring a CSA under REACH are summarised in Table 26-37.

In principle, the composition is based on the GCxGC data of a worst-case substance within the petroleum substance category, which was determined based on the SIP of all substances falling within this substance category. For aromatic extracts, *i.e.* UDAE, RAE, TDAE, the GCxGC data is often limited due to the high molecular weight and viscosity of these substances. Thus, for these three petroleum substance categories, a worse-case assumption based on the SIP was made to determine the composition of the AEG. Consequently, vapour exposure for these categories, in particular at elevated temperatures, was overestimated in the CSA.

AEs with a fraction of < 0.5 % at 40 ºC have not been considered in the CSA.

For most activities, the TRA tool does not account for aerosol formation, with the exception of spraying (PROC 7 and PROC 11), and greasing and lubrication at high energy conditions (PROC 17 and PROC 18). For these four PROCs, the default TRA tool predictions for vapour have been used for molecules with a VP below 500 Pa. To this end, the fraction of the "Aerosol" AE and "Vapour 10500 Pa" AE were summed up in the respective AEG. As the TRA tool predictions for the very low and low volatility band (<500 Pa) for these four PROCs do not differ, the combination of these two AE in the risk assessment does not impact the outcome of the CSA.

In accordance with the REACH Guidance R14 (ECHA, 2016c), for calendaring operations (PROC 6) the AEG at 20°C was always used in risk assessment, independently of the operating temperature that is defined for the assessed process.

For tasks involving the handling of petroleum substances with an operating temperature of more than 60°C, dermal exposure was typically not assessed. This is in alignment with the ECETOC Technical Report 107 Appendix D-3 (ECETOC, 2009), which states that *"available evidence indicates that at operating temperatures above 60°C, dermal exposures can be considered as unlikely to occur as any exposed individual will receive burns from (direct) skin contact"*. The ECETOC report also suggests that any quantitative estimate may be set at the level of PROC 1 and/or 3 to account for any indirect/incidental dermal exposure that may occur from touching contaminated surfaces or removing the gloves. The default dermal exposure estimate (without dermal PPE) for PROC 1 in ECETOC TRA is 0.03 mg/kg/day, which is generally lower than the dermal DNELs for petroleum substances. PROC3 default estimate in TRA is considered overly conservative to represent indirect/incidental dermal exposure, as it is 2-fold higher than exposures predicted for more routine tasks involving direct dermal contact (e.g. PROC16).

Furthermore, for tasks where dermal exposure has been assessed, including tasks with significant direct dermal exposure at ambient temperature, the risk assessment is performed assuming typically 8h exposure. Any secondary indirect/incidental skin contact in tasks at temperatures >60oC should be considered negligible as no risk was already shown from 8h dermal exposure in tasks involving direct dermal contact.

Table 26. SRGO – AEG composition (%) according to operating temperature

AE	@ 20°C	@ 40°C	@ 50°C	@ 60°C	@ 80°C	@ 120°C	MW @ 20°C
Aerosol (<10 Pa)	95.96	91.21	88.04	83.55	74.04	46.60	271.87
10-500 Pa	3.67	7.93	10.78	14.91	23.02	45.20	175.11
500-10,000 Pa	0.37	0.84	1.13	1.48	2.60	7.13	116.89
>10,000 Pa	0.01	0.02	0.05	0.07	0.33	1.07	84.16
Dermal and oral	100.00	100.00	100.00	-	-	-	267.73

Table 27. CrackedGO – AEG composition (%) according to operating temperature

AE	@ 20°C	@ 40°C	@ 50°C	@ 60°C	@ 80°C	@ 120°C	MW @ 20°C
Aerosol (<10 Pa)	81.55	65.20	54.68	49.69	44.63	35.22	230.95
10-500 Pa	16.76	29.32	39.01	42.37	43.49	39.03	164.12
500-10,000 Pa	1.68	5.46	6.25	7.75	10.30	19.75	113.64
>10,000 Pa	0.00	0.03	0.06	0.19	1.58	6.00	72.15
Dermal and oral	100.00	100.00	100.00	-	-	-	217.77

Table 28. OtherGO – AEG composition (%) according to operating temperature

AE	@ 20°C	@ 40°C	@ 50°C	@ 60°C	@ 80°C	@ 120°C	MW @ 20°C
Aerosol (<10 Pa)	74.12	54.38	47.23	37.24	25.48	6.64	225.36
10-500 Pa	24.03	41.34	46.72	54.47	56.36	50.65	172.10
500-10,000 Pa	1.86	4.24	5.96	8.10	16.77	37.46	120.35
>10,000 Pa	0.00	0.04	0.09	0.18	1.39	5.24	72.15
Dermal and oral	100.00	100.00	100.00	-	-	-	210.62

Table 29. VHGO – AEG composition (%) according to operating temperature

AE	@ 20°C	@ 40°C	@ 50°C	@ 60°C	@ 80°C	@ 120°C	MW @ 20°C
Aerosol (<10 Pa)	74.58	59.59	53.70	46.07	35.91	19.17	241.16
10-500 Pa	23.49	33.53	36.66	41.71	44.44	43.74	167.99
500-10,000 Pa	1.91	6.85	9.54	12.05	18.17	28.72	120.78
>10,000 Pa	0.01	0.03	0.09	0.17	1.47	8.37	83.19
Dermal and oral	100.00	100.00	100.00	-	-	-	221.64

Table 30. LBO – AEG composition (%) according to operating temperature

AE	@ 20°C	@ 40°C	@ 50°C	@ 60°C	@ 80°C	@ 120°C	MW @ 20°C
Aerosol (<10 Pa)	98.41	97.23	96.49	95.38	93.39	85.41	367.06
10-500 Pa	1.35	2.27	2.86	3.84	5.38	12.03	165.71
500-10,000 Pa	0.23	0.47	0.61	0.71	1.02	1.98	114.91
>10,000 Pa	0.00	0.03	0.04	0.07	0.21	0.58	72.15
Dermal and oral	100.00	100.00	100.00	-	-	-	363.74

Table 31. HRBO – AEG composition (%) according to operating temperature

AE	@ 20°C	@ 40°C	@ 50°C	@ 60°C	@ 80°C	@ 120°C	MW @ 20°C
Aerosol (<10 Pa)	100.00	100.00	100.00	100.00	99.99	99.67	398.06
10-500 Pa	0.00	0.00	0.00	0.00	0.01	0.32	72.15
500-10,000 Pa	0.00	0.00	0.00	0.00	0.00	0.00	72.15
>10,000 Pa	0.00	0.00	0.00	0.00	0.00	0.00	72.15
Dermal and oral	100.00	100.00	100.00	-	-	-	398.06

Table 32. Footsoil – AEG composition (%) according to operating temperature

AE	@ 20°C	@ 40°C	@ 50°C	@ 60°C	@ 80°C	@ 120°C	MW @ 20°C
Aerosol (<10 Pa)	99.95	99.92	99.89	99.81	99.58	97.23	373.42
10-500 Pa	0.05	0.08	0.09	0.16	0.39	2.70	148.85
500-10,000 Pa	0.00	0.00	0.02	0.02	0.03	0.07	72.15
>10,000 Pa	0.00	0.00	0.00	0.00	0.00	0.00	72.15
Dermal and oral	100.00	100.00	100.00	-	-	-	373.31

Table 33. UDAE – AEG composition (%) according to operating temperature

AE	@ 20°C	@ 40°C	@ 50°C	@ 60°C	@ 80°C	@ 120°C	MW @ 20°C
Aerosol (<10 Pa)	97.75	93.25	86.50	77.50	55.00	52.25	251.12
10-500 Pa	2.25	6.75	13.50	22.50	45.00	41.00	72.15
500-10,000 Pa	0.00	0.00	0.00	0.00	0.00	6.75	72.15
>10,000 Pa	0.00	0.00	0.00	0.00	0.00	0.00	72.15
Dermal and oral	100.00	100.00	100.00	-	-	-	251.12

Table 34. RAE – AEG composition (%) according to operating temperature

AE	@ 20°C	@ 40°C	@ 50°C	@ 60°C	@ 80°C	@ 120°C	MW @ 20°C
Aerosol (<10 Pa)	100.00	100.00	96.75	93.50	87.00	74.00	358.27
10-500 Pa	0.00	0.00	3.25	6.50	13.00	26.00	72.15
500-10,000 Pa	0.00	0.00	0.00	0.00	0.00	0.00	72.15
>10,000 Pa	0.00	0.00	0.00	0.00	0.00	0.00	72.15
Dermal and oral	100.00	100.00	100.00	-	-	-	358.27

Table 35. TDAE – AEG composition (%) according to operating temperature

AE	@ 20°C	@ 40°C	@ 50°C	@ 60°C	@ 80°C	@ 120°C	MW @ 20°C
Aerosol (<10 Pa)	100.00	100.00	100.00	98.50	95.50	77.50	311.25
10-500 Pa	0.00	0.00	0.00	1.50	4.50	22.50	72.15
500-10,000 Pa	0.00	0.00	0.00	0.00	0.00	0.00	72.15
>10,000 Pa	0.00	0.00	0.00	0.00	0.00	0.00	72.15
Dermal and oral	100.00	100.00	100.00	-	-	-	311.25

Table 36. UATO – AEG composition (%) according to operating temperature

AE	@ 20°C	@ 40°C	@ 50°C	@ 60°C	@ 80°C	@ 120°C	MW @ 20°C
Aerosol (<10 Pa)	99.84	99.28	98.69	97.39	93.48	71.53	340.07
10-500 Pa	0.16	0.71	1.31	2.59	6.44	27.80	191.07
500-10,000 Pa	0.00	0.00	0.00	0.01	0.08	0.67	72.15
>10,000 Pa	0.00	0.00	0.00	0.00	0.00	0.00	72.15
Dermal and oral	100.00	100.00	100.00	-	-	-	339.83

Table 37. HFO – AEG composition (%) according to operating temperature

AE	@ 20°C	@ 40°C	@ 50°C	@ 60°C	@ 80°C	@ 120°C	MW @ 20°C
Aerosol (<10 Pa)	97.07	95.14	93.93	92.40	89.43	87.36	364.20
Vapour (>10 Pa)	2.93	4.86	6.07	7.60	10.57	12.64	153.07
Dermal and oral	100.00	100.00	100.00	-	-	-	358.00

7.2. ANNEX II: AEG OF LOW VOLATILE PETROLEUM SUBSTANCES FOR CONSUMER USES

The consumer exposure to petroleum substances has solely been modelled using the consumer TRA tool. The exposure predictions of the consumer TRA tool are typically based on the worst-case assumptions on product usage. For example, the TRA tool assumes that the vapour fraction of the petroleum substance, *i.e.* molecules with a VP of 10 Pa, volatilise immediately upon use. For molecules below 10 Pa, the TRA tool assumes a gradual decrease in the release to air, i.e. a banding approach is used. The bands are summarised in Table 4 of the TRA Guidance document (ECETOC, 2009). As these volatility bands do not align with the worker module of the TRA tool, the AE as defined in **Section 3.2.2.1** for worker exposure assessment cannot be directly used in the CSA of consumer uses. To simplify the AEG for consumer uses, the AEs have thus been combined manually to reflect the volatility bands of the consumer TRA tool.

In a first step, for the inhalation route a distinction has been made between molecules with a vapour fraction below 10 Pa (represented by the "Aerosol" AE) and above 10 Pa (represented by the sum of the "Vapour 10-500 Pa" AE, "Vapour 500-10,000 Pa" AE and "Vapour >10,000 Pa" AE) at ambient temperature. The total release to air has been determined according to the following equation:

$$Totalfractionreleasedair = (fraction\text{<}10\ \text{Pa}) * 0.1 + (fraction > 10\ \text{Pa}) \quad \text{eq.1}$$

The AEG for the petroleum substance categories requiring a quantitative CSA for consumer uses are summarised in **Table 38.**

Table 38. Consumer AEG composition (%) for relevant petroleum substance categories

AE	SRGO @ 20°C	VHGO @ 20°C	OtherGO @ 20°C	LBO @ 20°C	HRBO @ 20°C	MW @ 20°C
VP<10 Pa	96.0	74.6	74.1	98.4	100.0	n.a.
VP>10 Pa	4.0	25.4	25.9	1.6	0.0	n.a.
Vapour*	13.6	32.9	33.3	11.4	10.0	n.a.
Dermal and oral	100.0	100.0	100.0	100.0	100.0	n.a.

***Corresponds to total fraction released to air calculated using eq.1**. As the "Aerosol" AE for workers (with VP<10 Pa) was linked to the physical state "Solid", the "Vapour 10-500 Pa" AE was used for the inhalation route in the creation of the consumer AEG.
n.a. – not applicable. Since the DNEL/DMEL are based on mg/m^3, the molecular weight (MW) is not required for consumer CSA.

Specifically for OtherGO, LBO and HRBO, however, the consumer AEG had to be refined to demonstrate safe use of some consumer products. Namely, further break down of constituents with VP<10 Pa into (lower) volatility bands defined in the consumer TRA model was performed. Similarly to the approach of defining the AEs for worker exposure assessment (see **Section 3.2.2.1**), GCxGC data of the worst-case substance within the petroleum substance category and EPI Suite™ v4.11 tool have been used to assign constituents to different volatility bands based on their predicted vapour pressure. The total release to air has been determined then according to the following equation:

$$Totalfractionreleasedair = (fraction\text{<}0.1\ \text{Pa}) * 0.001 + (fraction 0.1\text{-}1\ \text{Pa}) * 0.01 + (fraction 1\text{-}10\ \text{Pa}) * 0.1 + (fraction > 10\ \text{Pa}) \quad \text{eq.2}$$

The refined consumer AEG for OtherGO, LBO and HRBO are summarised in **Table 39.** For consumer uses for which a SCED has been used, the refined AEG was only applied if inhalation transfer factor in SCED was set to 1. This is due to the fact that the transfer factors defined in SCEDs often already inherently consider limited volatilisation.

Table 39. Refined consumer AEG composition (%) for some petroleum substance categories

AE	OtherGO refined @ 20°C	LBO refined @ 20°C	HRBO refined @ 20°C	MW @ 20°C
VP<0.1 Pa	15.2	91.0	99.8	n.a.
VP 0.1-1 Pa	23.3	4.6	0.2	n.a.
VP 1-10 Pa	35.7	2.8	0.0	n.a.
VP>10 Pa	25.9	1.6	0.0	n.a.
Vapour*	29.7	2.0	0.1	n.a.
Dermal and oral	100.0	100.0	50.8	n.a.

* **Corresponds to total fraction released to air calculated using eq.2.** As the "Aerosol" AE was linked to the physical state "Solid", the "Vapour 10-500 Pa" AE was used for the inhalation route in the creation of the consumer AEG.
n.a. – not applicable. Since the DNEL/DMEL are based on mg/m^3, the molecular weight (MW) is not required for consumer CSA.

For dermal and oral exposure assessment, 100% of the substance has been assumed in all but HRBO instances.

As described in **Section 3.4.2.2**, the dermal and oral route have been refined for HRBO considering the decreased dermal and intestinal absorption of hydrocarbons with more than 35 carbon atoms, respectively. For these large hydrocarbons, it was conservatively assumed that less than 10% are dermally and intestinally absorbed. Due to the difficulty to analyse hydrocarbons with more than 30 carbon atoms with GCxGC, the compositional data was supplemented with gas chromatography-field ionization mass spectrometry (GC-FIMS) data from the respective HRBO substance. Refined dermal/oral AEG for HRBO was only applied if dermal/oral transfer factor in SCEDs (where used) was set to 1. This is due to the fact that the transfer factors defined in SCEDs often already inherently consider limited dermal and oral absorption.

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