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Developing human health exposure scenarios for petroleum substances under REACH

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ABSTRACT

This report describes the approaches that were adopted by CONCAWE to prepare the human exposure estimates in the chemical safety assessments of the REACH registration dossiers for petroleum substances based on all applicable regulatory guidance. Separate exposure estimates were developed for workers and for consumers and included inhalation and dermal routes. The complex nature of petroleum substances required various scientifically justified refinements of the regulatory guidance.

KEYWORDS

Chemical safety assessment (CSA), exposure scenarios (ES), REACH, petroleum products

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CONTENTS

SUMMARY

The EU REACH Regulation [18] requires registrants to demonstrate that their manufactured or imported chemical substances, including petroleum substances, can be used safely in identified applications. Demonstration of safe use requires the comparison of estimated inhalation, dermal, and in some cases oral exposure estimates with toxicological reference values. This report presents the main approaches that CONCAWE adopted in developing exposure estimates for workers and for consumers within the different categories of petroleum substances (for their identified uses).

A large number of identified uses of petroleum substances were described using a set of standardized titles of uses, aligned as far as possible with other industry titles and including the use descriptor terminology recommended by the European Chemicals Agency (ECHA). The applicable Use Descriptors are for workers Process Categories (PROCs) and for consumers Product Categories (PCs). For reasons of efficiency CONCAWE adopted as its principal worker exposure estimation tool the ECETOC Targeted Risk Assessment (TRA) (version 2) tool, which links simple and conservative estimates directly to Use Descriptors.

The risk management measures (RMM) available in the ECETOC tool are limited. During the development of its exposure estimates, CONCAWE identified the need to include additional RMM in its estimates based on control measures that are commonly used during the manufacture and use of petroleum substances. These additional control measures are presented in the form of standard phrases. Technical justification for these additional controls is provided in the report.

Several categories of higher boiling petroleum substances can be present in the breathing zone of workers as combined aerosol and vapour, depending on the mechanism by which they are released into air. For these substances, known as semi-volatiles, no exposure estimates are provided by the ECETOC TRA v2 or from more refined tools such as the Advanced REACH Tool. Actual representative measurement data are sparse, and in general, are not complete enough to be used for linkage to PROCs. CONCAWE therefore developed an approach to estimate these levels based on TRA v2 outputs for solids, supplemented by vapour estimates.

Several of the identified hazards of petroleum substances, such as e.g. skin irritation, have no identified no-effect levels and therefore chemical safety cannot be demonstrated based on quantitative assessment. The REACH regulatory guidance requires registrants to describe control measures that are proportionate to the severity of the hazard. CONCAWE developed such qualitative approaches specifically for several hazards, as described in this report.

1. INTRODUCTION

The REACH Technical Guidance Documents (TGD) [16] on Information Requirements and Chemical Safety Assessment (CSA) sets out the considerations and expectations of manufacturers/importers when developing Exposure Scenarios (ES) for any Registration dossier. The Guidance describes many of the assumptions that are expected to be applied. In many areas, however the Guidance either makes provision for the Registrant to identify information that best characterises the exposures associated with the identified uses of substances (in this case petroleum products), or allows the Registrants to apply alternative values when these are considered more appropriate. This report sets out where CONCAWE has identified exposure determinants that are not directly addressed within the TGD and where more appropriate alternatives have been applied.

The process adopted by CONCAWE in developing the human health portion of the CSA for petroleum products is described in **Figure 1** below and consists of 4 elements:

1. **Mapping and describing the uses of petroleum products**

   Petroleum products are mapped and described in a manner that aligns with the expectations of Part D and Chapter R12 of the REACH TGD. In this respect, CONCAWE made significant use of the European Solvents VOC (ESVOC) Generic Exposure Scenarios (GES) for solvents as a reference point for those non-fuel uses of petroleum products which might generally be described as "solvent-like". The rationale for this was that the ESVOC scenarios represented an accepted consensus between chemical manufacturers and downstream users (DU) on the form and content of ES. These ES were deemed sufficient in their scope to adequately cover the range of typical activities associated with the principle solvent uses and were written in a form that was understandable to the DU sector. Adopting the ESVOC GES mappings therefore enabled CONCAWE CSAs to remain consistent with those being developed by solvent manufacturers/importers, as well as representing an efficiency step within the CONCAWE process. For those areas of the ESVOC activity were a GES was unavailable (e.g. road and construction activities and use as fuel), CONCAWE initiated appropriate discussions with relevant DU associations in order to obtain the necessary understandings and consensus.

2. **Evaluation of human health risks associated with the uses**

   Human health risks associated with the uses of these petroleum products were evaluated and progressed in a manner consistent with the guidance contained within Chapters R14 and R15 of the TGD for those uses identified under #1 above. The CONCAWE activity used, as its basis, the exposure predictions contained within the ECETOC TRA model, but supplemented these in defined instances with actual exposure data contained within previous CONCAWE publications on exposures to petroleum products. The exposure predictions were then compared with relevant Derived No Effect Levels (DNELs) developed according to the Chapter R8 TGD [3]. Because of the nature of REACH, the DNELs address exposure routes which have not previously been quantitatively evaluated i.e., dermal. In addition, because of the nature of exposures arising from the use of petroleum products, CONCAWE 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. The basis of the

resulting ES, (in terms of the communicated Operational Conditions (OC) and RMM) used the ESVOC GESs as a starting point, but where appropriate, referred to alternative RMMs (of equivalent or better effectiveness) if these were deemed better descriptors for petroleum products.

3. Communication of safe use

The outputs of the quantitative CSAs were then transformed into narrative ES where the choice of standard phrases reflected the magnitude of exposure control required to manage associated risks. These phrases were sourced from the BDI EUPhraC phrase library or, where these were unavailable, then CONCAWE developed (and substantiated) suitable phrases for subsequent review and incorporation within the library.

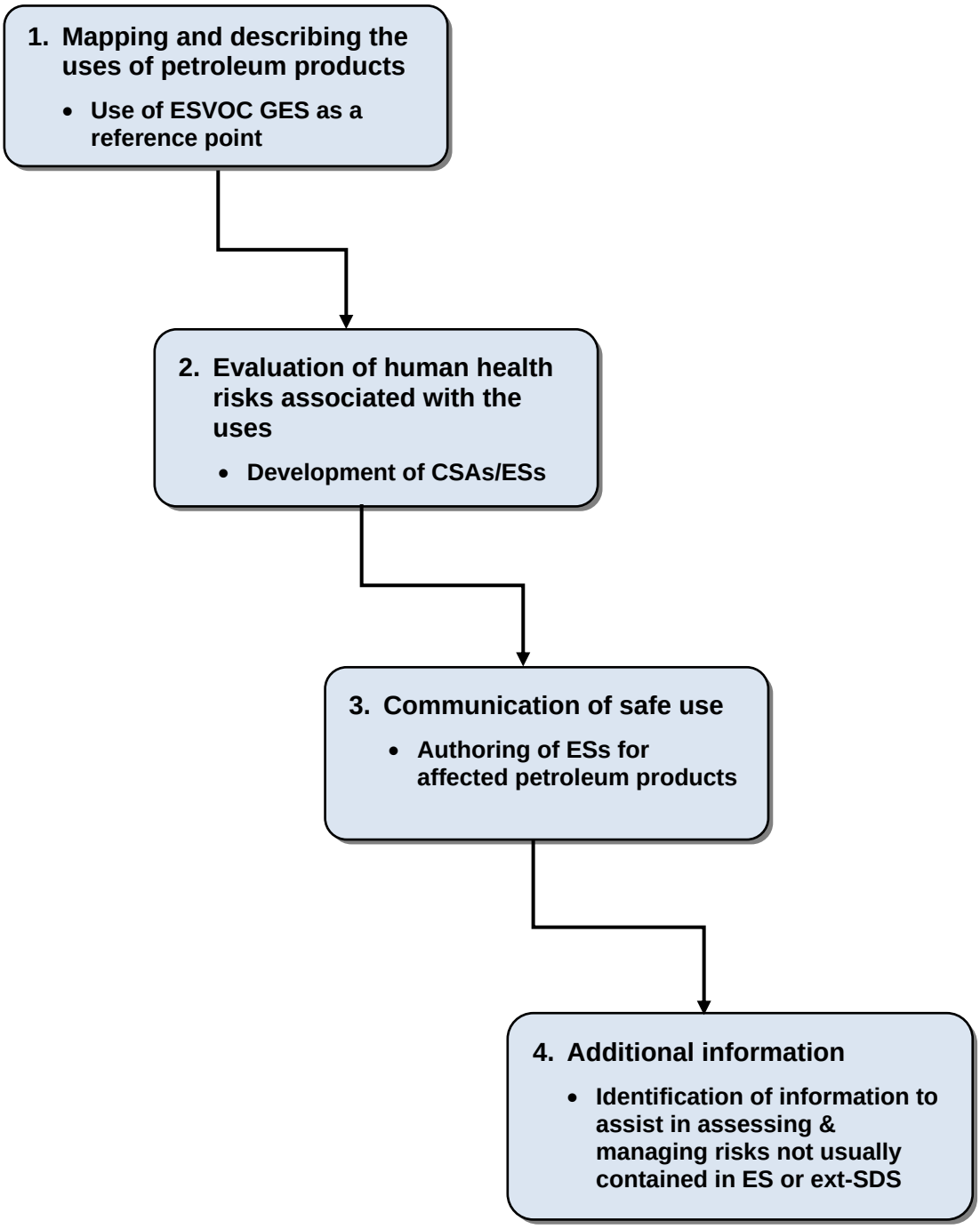
4. Additional information

During the course of developing the CSAs and supporting ES, additional information relevant for assessing and managing the health risks associated with the use of petroleum products was also identified e.g. monitoring and analytical methods for these materials. This information, whilst not directly required to be contained within ES, is relevant for users of these products.

The structure of this report reflects the four component parts of the process for developing human health CSAs and is detailed in the subsequent pages.

The first purpose of the developed ES was linked to the preparation by CONCAWE of the registration dossiers for petroleum substances by the first REACH deadline of 30 November 2010. These dossiers were subsequently also made available to CONCAWE member companies to construct the ES annexes of the Safety Data Sheets (SDS), so as to advise DU about the applicable OC and RMM. This report provides some additional help for DU to interpret ESs developed by CONCAWE where their OC/RMM does not exactly match the described parameters (see Chapter 4).

Figure 1 The process adopted by CONCAWE in developing the human health portion of the CSA for affected petroleum products



2. MAPPING AND DESCRIBING THE USES OF PETROLEUM PRODUCTS

2.1. IDENTIFYING USES FOR REACH

The REACH Regulation requires manufacturers and importers of chemical substances to register their uses[1] as they occur throughout their life cycle from manufacture, distribution, formulation, end use applications to waste disposal. For those substances that are sold at >10 tonnes per year and classified as dangerous, then ESs[2] are required to be developed for the identified uses as part of the registration. These scenarios describe the conditions which, if followed, ensure that the substance can be used safely i.e. without harm to man or the environment, and which are required to be communicated to DU as an Annex to the extended Safety Data Sheet (eSDS).

Although the main end use for most CONCAWE petroleum substances is as a fuel, there are also many other uses. The full list of uses that have been identified and registered for the different types of petroleum product is maintained in the REACH section of the CONCAWE website. The list has been developed following discussion between CONCAWE member companies and their customers. The titles used for the 'identified uses' align with those applied by other industrial sectors that supply solvent-like substances. In this respect CONCAWE has built on the work of the European Solvents Industry Group (ESIG) in order to ensure a consistency of how safe use is determined and communicated through similar supply chains.

It is important to note that the primary method of communication of 'identified use' under REACH is via the short title of the Exposure Scenario and its supporting explanatory scope statement, i.e. as a brief general description of use. ECHA has introduced Use Descriptors including Sectors of Use, PCs, PROCs and Environmental Release Categories (ERCs) to help further describe use. But 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 (and their role is described in greater detail in Chapter R12 of the TGD). The primary assessment of whether a use has been registered for a particular petroleum substance is determined by examination of the 'simple titles' rather than whether the 'use' includes the presence or absence of a particular Use Descriptor.

2.2. GENERIC EXPOSURE SCENARIOS (GES)

The REACH regulation (Annex II) requires information in the SDS to be written in a clear and concise manner. The experience gained in the discussions with the supply chain around identified uses preceding the registrations showed that the ECHA Use Descriptor system, in particular the PROCs, may be interpreted differently and would benefit from additional definition.

[1] Use as defined in the REACH regulation Article 3.24

[2] The full REACH definition for an ES (Article 3.37) is:
'ES' means the set of conditions, including OCs and RMM, that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends DUs to control, exposures of humans and the environment.

To develop an ES for each Use title, it is necessary to map the typical OCs and associated RMMs. CONCAWE has taken as its start point the generic mapping prepared by ESIG. These so-called 'GES' have been prepared in cooperation with the following DU associations (listed below) and utilise the ECHA Use Description System addressed in IR&CSA guidance Reference 12 including Sector(s) of Use, PCs, PROCs, ERCs and Article Categories, so far as they relate to a particular use.

- AISE, The International Association for Soaps, Detergents and Maintenance Products
- CEPE, European Confederation of Paint, Printing Ink and Artists' Colours Manufacturers Associations
- FEA, Federation of European Aerosol Associations
- FECC, The European Association of Chemical Distributors
- FEICA, Fédération Européenne des Industries de Colles et Adhésifs (for Adhesives & Sealants)

The details of the use mapping for each use title link to typical activities involving exposure. For workers these are termed Contributing Scenarios and are designed to describe tasks using common language, e.g. sampling, bulk transfers, equipment cleaning and maintenance. These in turn have been linked to an associated PROCs. For Consumer uses, these are linked to PCs which comprise end use applications, e.g. adhesives/sealants, coatings and paints, washing and cleaning products. Both PROCs and PCs also link to Tier 1 exposure estimates given in the ECETOC TRA-V2 to support the CSA.

The list of titles addresses Industrial, Professional and Consumer uses, so far as these are relevant to each title and based on the GES titles and supporting supply chain mapping of uses. The list of titles assigned to the CONCAWE Petroleum Substances, together with supporting Use Descriptors used in the Chemical Safety Report, is shown in http://www.concawe.org/content/default.asp?PageID=580&DocID=21599. The title also incorporates a scope statement providing a general overview of the activities covered by the ES to assist users in checking if the title addresses their own activities associated with the use.

3. EVALUATION OF HUMAN HEALTH RISKS ASSOCIATED WITH THE USES

3.1. DEVELOPMENT OF CHEMICAL SAFETY ASSESSMENTS (CSA) / EXPOSURE SCENARIOS (ES)

The format of the CSAs including OCs and RMMs follows the GES format as published by the European Chemical Industry Council (CEFIC) and described within Part D of the REACH TGD. The approach is comprehensive, yet aims to be simple as well as transparent. It allows the documentation of key assumptions, such as adopted Exposure Modifiers (EM) and resulting risk management advice, in a consistent fashion that is easier to follow than the fractionated format for the ES development in the Chemical Safety Report as required by REACH Annex I.

In developing the exposure assessments, CONCAWE has assumed that a good basic standard of occupational hygiene 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 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 is reflected in Section 2.1 of the ESs by use of the phrase ‘Assumes a good basic standard of occupational hygiene is implemented’ phrase code G1.

3.2. BASIS FOR THE JUSTIFICATION AND USE OF THE CONCAWE GES PHRASES

Consistent with the recommendations of Chapter R14 of the REACH TGD, the ECETOC TRA model was used at the Tier 1 level for estimating workplace exposures to petroleum products. The TRA model uses a limited range of input parameters (volatility at the operating temperature; condition of use [PROC] and sector of use [industrial or professional]) to provide both inhalation and dermal exposure estimates of the substance. A limited number of EM are then applied to the 'raw' estimate to derive a more refined value that accounts for whether the activity *occurs* indoors or outside; the presence of extract ventilation; the duration of the activity; the use of respiratory protection; and whether the substance is presented as the 'pure' material or within a mixture. Thus when using the TRA within the context of a CSA, it is possible to identify and describe a set of exposure conditions (termed 'OCs within REACH) and controls (termed 'RMM') that, when applied, ensure exposures (whether inhalation and/or dermal) are less than the relevant DNEL.

Because of the desire to ensure that OCs and RMMs can be consistently applied and communicated, a related discussion has taken place (primarily within the ESIG sector group of CEFIC) on how these variables can be described using standard phrases, in order that they may be readily incorporated into SDSs, including the need for their translation into Community languages. The outcome of the discussion has been the development of a library of standard GES phrases (which are included in the CEFIC ESCom Standard – Standard Phrase Library, http://www.cefic.org/Industry-support/Implementing-reach/Libraries) [5] (previously the BDI EUPhraC phrase library).

CONCAWE has used the EUPhraC phrase library in the development of ES for petroleum products. Tier 1 models are limited in the extent to which each iteration can be applied and in the number of “base” phrases that can be used. However, within the context of use conditions in the refining sector and for identified DU, it is possible to identify other commonly encountered systems of exposure control that would be more relevant to the use and hence better describe the OCs and RMMs for any DU. This fact is acknowledged within the TRA [15] and the application of these phrases must be consistent with the basis by which the TRA predicts exposure.

Table 1 summarises the supporting set of phrases (together with their scientific rationale) that CONCAWE has identified that serve to enhance the accuracy and relevance of the CSAs/ESs available for petroleum products. These phrases have been reviewed for their usefulness and integrity and now form part of the EUPhrac library.

Table 1 Other EMs for Use in the Exposure Assessment of Petroleum Products

Phrase Description	EUPhraC Phrase Codes Covered	Assigned Exposure Reduction (%)	Justification	Boundary of Application
Provision of drum pumps	E53 or E64	80*	The use of drum pumps for the transfer of liquid products has a significant impact on related exposures. Drum pumps essentially enable the closed transfer of the product and serve to reduce both inhalation and dermal exposures. Although no specific data for petroleum substances could be identified for their effectiveness, a value of 80% has been assigned consistent with that for basic LEV.	Only applicable for material transfers (essentially PROC8b). May also be used in conjunction with phrases for LEV.
Location of operator to minimise exposures	E77	80¥	Several papers have demonstrated the significant impact that worker location has in relation to associated exposures. The correct positioning of workers relative to the source and direction of emission sources can yield exposure reductions in excess of 90%, dependent on the job and work group. [31,19]. CONCAWE data on gasoline loading activities [14,11] also reflect these experiences. An exposure reduction value of 80% has been applied.	Primarily applicable to tasks associated with point source exposures .e.g. PROCs 6, 8a, 8b but may be applied to other scenarios dependent on expert judgement
Operating instructions on draining of equipment	E65 orE81	80*	The potential exposures associated with certain work tasks are either prevented (or at least substantially minimised) via the application of specific procedural controls. The draining of process equipment prior to maintenance or break-ins is one example of this. Comparison of CONCAWE data [14] on exposures resulting from maintenance activities to those arising from same/similar task when operating instruction has been invoked indicates that exposure reductions of at least 80% (and more typically 97+%) are attainable.	The application of this control is considered relevant for PROCs 8a and 8b
Operating	E55	90*	As above. An exposure	Only applicable to

Phrase Description	EUPhraC Phrase Codes Covered	Assigned Exposure Reduction (%)	Justification	Boundary of Application
instructions on draining and flushing of equipment			reduction value of 90% has been applied to reflect the higher confidence that can be placed on reliability of procedural controls in these settings	industrial scenarios
Specific operator training to reduce exposure	EI19 or C&H17	15¥	Several studies have demonstrated the positive impact that specific worker training has on associated exposures. Exposure reductions have been observed dependent on the job and work group [26,27]. An exposure reduction value of 15% has been applied, consistent with the lower bound of less successful group interventions	Only applies to PROCs that address task related exposures (e.g. PROCs 7, 10, 11, 13). It is relevant to either inhalation and/or dermal exposures.
Vapour recovery on road tanker or railcar loading operations	A7	80*	Although vapour recovery is aimed at environmental control, it has additional beneficial effect on reduction of operator exposure, comparable to an LEV. TNO derived an estimate of 80% from available CONCAWE data [20]	Applies principally to bulk transfer operations (e.g. PROCs 8a and 8b).
Wear suitable gloves tested to EN374 [PPE15].	PPE15	80[a]	This corresponds to conditions of 'proper functioning' and 'proper use' of gloves, as described by Brouwer et al. 2001 [4]	'Suitable gloves' refers to those made of materials offering permeation resistance to the substance. Appropriate materials are typically included within Section 8 of the SDS. It assumes appropriate selection and use of the glove for the task(s).

Phrase Description	EUPhraC Phrase Codes Covered	Assigned Exposure Reduction (%)	Justification	Boundary of Application
Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training [PPE16]	PPE16	90[a]	Workers trained in glove donning procedures minimize inadvertent contaminant transfer onto skin. Speiser-Rankine et al. 2006 [33] describe the positive impact of generic training on the level of protection achieved	'Chemically resistant gloves', as per 'suitable gloves'. 'Basic employee training' refers to training in the correct glove selection, donning/removal procedure to minimise skin contamination, glove cleaning and replacement regime, plus immediate hand washing following possible contamination.
Wear chemically resistant gloves (tested to EN374) in combination with specific activity training [PPE17]	PPE17	95 [a]	Klingner and Boeniger (2002) [24] describe the positive impact of specific activity training on the level of protection achieved	'Chemically resistant gloves', as above. 'Specific activity training' refers to supplementing 'basic employee training' with training carried out for a specific task to minimise potential for skin contact.
Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls [PPE18]	PPE18	98 [a]	High levels of protection (>99%) can be achieved with gloves, but may be compromised by a small percentage of workers refusing to wear PPE. Supervision leads to adherence to PPE requirements by 100% of the workforce [6].	In addition to the above, 'Intensive management supervision controls' refers to the active management of staff in assuring the ongoing use of gloves and associated procedures. Only applicable to industrial scenarios.

* Application has no bearing on related dermal exposure predictions
[a] Applies only to dermal exposure estimates
¥ Applies to both inhalation and dermal exposure estimates

In addition to the above, further explanation is given to the following general phrases to aid interpretation:

‘**General exposures**’ (phrase codes: CS1, CS15, CS16): This refers to potential exposures to background concentrations of dusts/gases/vapours which may result from low level emissions from equipment. It covers the time in the workplace when no specific tasks involving exposure are carried out, e.g. workplace inspection.

‘**No other specific measures identified’** (phrase code EI20): This refers to the fact that there are no additional (other) RMMs required beyond those associated with the following measures which are integral to the ES:

a. good basic standard of occupational hygiene measures, see definition under Section 3.1 above;

b. general measures applicable to all activities relevant to the ES, e.g. controls for carcinogens, skin irritants, eye irritants, where relevant. These are typically included at the start of the section ‘Control of Worker Exposure’;

c. certain controls are implicit for a particular Contributing Scenario and associated Process Category (PROC). For example:
    - General Exposures (closed system) - PROC1: operate in a closed system,
    - Bulk transfer, dedicated facility - PROC8b – carry out the bulk transfer using a dedicated transfer facility (designed for the purpose);

d. controls for flammability, where relevant to the substance. Flammability controls are typically included within the main sections of the SDS.

4. ESTIMATING EXPOSURE AND CONSTRUCTING THE EXPOSURE SCENARIO

4.1. EXPOSURE ESTIMATION

4.1.1. Worker exposures

4.1.1.1. Background

Exposure estimation for petroleum product CSAs has been undertaken using the inhalation and dermal exposure estimates contained within the ECETOC TRA model (ECETOC, 2009). The TRA is intended to provide realistic yet conservative point estimates of exposure at the so-called 'Tier 1' level. The tool provides separate estimates for particular activities ('PROCs') in industrial and professional work environments, that are determined by three broad classes of substance volatility (and which broadly align with those incorporated into the UK COSHH Essentials tool and the EMKG Tool of BAuA).

'Tier 2' assessments are more complex and may incorporate representative measured data, as well as analogous data or more sophisticated model predictions. As a consequence, they are significantly more resource intensive. During the activities leading to the development of the Registration dossiers, a balance was therefore sought between the effort invested in developing the exposure estimates with the level of accuracy, bearing in mind the ultimate goal is suitable protection of worker health.

4.1.1.2. Inhalation exposure

The TRA estimates are considered reasonably reliable for volatile mono-constituent substances, but their veracity is more limited for less volatile, and more complex substances [25]. The CONCAWE process has recognised this by incorporating information on actual exposure measurements contained in relevant CONCAWE Reports and sponsored publications [7,8,9,14,17,23,26,32]. This is summarised in **Table 2** below:

Table 2 Principle Sources of Exposure Data Used in CONCAWE CSAs

Product Category	References for Measured Exposure
Naphthas / Gasoline	[10,11,14]
Kerosines	[13,32]
Gas oils	[12]
Heavy fuel oils	[7] (only dermal)

In principle the exposure estimates assumed that the substance is handled at no more than 20°C above ambient conditions. In those cases where elevated handling temperatures are to be expected, then this was factored into the TRA exposure predictions (as described in ECETOC Technical Report No. 107) and noted in the CSA and ES. In those cases where further refinement of the assessment was required, the approach followed Chapter R14 by using either a higher Tier exposure

model such as ART (Advanced REACH Tool), or representative measurement data, or information available for analogous substances.

For heavier petroleum substances, exposure may be in the form of combined aerosol and vapour, see Section 4.3.

4.1.1.3. Dermal exposure

Dermal exposure estimates were developed based on the ECETOC TRA v2, except for Heavy Fuel Oils for which a small but representative measurement survey was undertaken in preparation of the REACH registrations [7]. In addition to the EM available for the dermal route in the TRA v2, the effect of the use of gloves was accounted for as described in further detail in **Table 1** in section 3.2 (phrases PPE 15-18) [2,7,24,25,27]. In line with the conservative nature of the TRA v2, no further corrections, e.g. for the likely evaporation from the skin of the lower boiling petroleum substances, were incorporated.

For those substances where it was not possible to derive a DNEL for the dermal endpoint, then as recommended by ECHA in Part E of the guidance for CSA (ECHA, 2010), account was taken of health hazard classifications to describe dermal exposure control in qualitative terms and proportionate to the severity of the hazard. Classifications that were addressed via this approach include carcinogenicity and skin irritation (and which are described in further details in sections 4.6.2 and 4.6.3).

4.1.2. Consumer exposures

The approach recommended in ECHA guidance (Chapter R15) for the exposure assessment of consumers, either at the Tier-1 level or using advanced tools such as CONSEXPO, does not readily cover all identified uses of petroleum substances. For example, in relation to the main use of several categories of petroleum substances, which is as an engine fuel (REACH use descriptor PC 13), the basic Tier-1 assessment assumes the complete evaporation of the amount of total fuel intended to go into a vehicle's tank during refuelling. Such an assumption, while conservative, is also wholly unrealistic.

In line with the basic considerations that need to be followed when conducting consumer exposure assessments (EAs) and CSAs CONCAWE therefore developed more refined information on key exposure determinants to characterise the nature of consumer risks to petroleum products. The tool selected for this purpose was the consumer exposure model published by the solvents sector group ESIG (http://www.esig.org/en/regulatory-information/reach/ges-library/consumer-gess).
The ESIG tool takes the default assumptions and algorithms (equations) described in the ECETOC TRA, and further develops these in a manner described in Appendix F of ECETOC Technical Report 107 i.e. as described in chapter R15 of the REACH guidance. A particularly important determinant is the fraction of product lost due to evaporation and spillage during refuelling of private vehicles. For gasoline this figure has been established in several independent research projects as 0.2% of the handled amount [21,28,30]. The fraction of product lost is described in the ESIG tool as the 'Inhalation Transfer Factor'. Refuelling normally takes place outdoors and the conservative exposure calculation is therefore based on a hypothetical room of 100 m^3 with a ventilation rate of 0.6 air changes per hour (ACH), in analogy with the Tier-1 tool for workers Stoffenmanager (ref. Chapter 14) of [35]).

Other fuel applications of petroleum substances include garden equipment, scooters, home heating devices and lamps. Refilling reservoirs of these appliances is considered less well controlled than automotive refuelling, therefore a conservative default figure of 2% has been assumed for the inhalation transfer factor. **Table 3** summarises the main exposure determinants used for the assessments of consumer exposures to fuels and their justifications. Following completion of the registration dossiers in 2010 a survey was undertaken in 2011 of consumer habits and practices in one of the EU countries. A summary of this survey is included in **Appendix 1**. The findings of the survey supported the initial assumptions.

Table 3 Consumer exposure determinants for petroleum substances

CONCAWE Product Category	Consumer Exposure Scenario	Default exposure determinant	Exposure Default adopted by CONCAWE	Rationale
LPG (Liquified Petroleum Gas)	Vehicle refuelling	Quantity used	45 kg	100 l LPG vehicle tank filled with 80 l LPG (to allow 20% expansion). Liquid LPG density 533 kg/m^3
		Product fraction	100%	Tier-1 assessment assumes 50%, but fuels are generally neat
		Inhalation transfer factor	0.0005	LPG re-fuelling via contained self-sealing nozzle due to flammability considerations. Hence leakage on nozzle insertion and withdrawal very low.
		Use frequency	Once per week	Analogy to gasoline data
		Dermal contact	None	LPG is a gas. Skin contact with liquid causes cold burns.
	Household LPG cylinder change	Quantity used	13 kg	Larger cylinders not routinely provided due to manual handling considerations. Scenario refers to use of typical 30 l domestic cylinder.
		Inhalation transfer factor	0.0005	LPG cylinder connection via sealed pipework due to flammability considerations. Losses of substances anticipated to be very small.
		Use frequency	Once per 2 weeks	Assumption
		Dermal contact	None	LPG is a gas. Skin contact with liquid causes cold burns.
	Cooking and space heating with LPG	N/a		LPG is used only as a fuel. No exposures to LPG can be expected apart from during bottle changes (see above).
Gas oils	Vehicle refuelling	Quantity used	37.5 kg	Estimated re-fuelling volume of 50 l converted using gasoil density of 745 kg/m3
		Product fraction	100%	Tier-1 assessment assumes 50%, but fuels are generally neat
		Exposure time	3 mins	97th percentile [34]

CONCAWE Product Category	Consumer Exposure Scenario	Default exposure determinant	Exposure Default adopted by CONCAWE	Rationale
		Inhalation transfer factor	0.002	Re-fuelling via contained nozzle. Inhalation exposures primarily due to displacement of vapour from fuel tank. Leakage on nozzle insertion and withdrawal very low. Estimate read-across from gasoline (gas oils are of lower volatility).
		Location of activity	Outdoors	Outdoor use assumed. 100 m^3 used as default volume with 0.6 ACH
		Use frequency	Once per week	Typical consumers not expected to fill vehicle daily
		Skin surface area	210 cm^2	Direct contact with product not anticipated. Scenario represents contact of palm of one hand with pump handle.
	Home space heating	Quantity used	2 litres	Analogy with kerosine
Gasoline	Motor vehicle refuelling	Quantity used	37.5 kg	Estimated re-fuelling volume of 50 l converted using gasoline density of 750 kg/m3
		Product fraction	100%	Tier-1 assessment assumes 50%, but fuels are generally neat
		Exposure time	3 mins	97th percentile [34]
		Inhalation transfer factor	0.002	Re-fuelling via contained nozzle. Inhalation exposures primarily due to displacement of vapour from fuel tank. Leakage on nozzle insertion and withdrawal very low.
		Use frequency	Once per week	Assumption
		Location of activity	Outdoors	Outdoor use assumed. 100 m^3 used as default volume with 0.6 ACH
		Skin surface area	210 cm^2	Direct contact with product not anticipated. Scenario represents contact of palm of one hand with pump handle.
	Refuelling scooter	Quantity used	3.75 kg	5 L is typical tank content for scooter
		Product fraction	100%	Tier-1 assessment assumes 50%, but fuels are generally neat
		Exposure time	2 mins	Shorter than car refuelling (smaller quantity)
		Inhalation transfer factor	0.02	Assumed as 10x the gasoline figure due to less well contained transfer.
		Use frequency	Once per week	Assumption
		Location of activity	Outdoors	Outdoor use assumed. 100 m^3 used as default volume with 0.6 ACH
		Skin surface area	210 cm^2	Direct contact with product not anticipated. Scenario represents contact of palm of one hand with pump handle.
	Refuelling garden equipment	Quantity used	0.75 kg	1 L assumed
		Product fraction	100%	Tier-1 assessment assumes 50%, but fuels are generally neat

CONCAWE Product Category	Consumer Exposure Scenario	Default exposure determinant	Exposure Default adopted by CONCAWE	Rationale
		Exposure time	2 mins	Shorter than car refuelling (smaller quantity)
		Inhalation transfer factor	0.03	Less well controlled than scooter refuelling
		Use frequency	Once per fortnight	Assumption
		Location of activity	Indoors	Garage of 34 m^3 with 1.5 ACH
		Skin surface area	420 cm^2	Direct contact with product not anticipated. Scenario represents contact of palm of both hands
Kerosine	Home space heating	Quantity used	2 litres	Daily use over Winter period assumed for internal home heating.
		Skin surface area	210 cm^2	Direct contact with product not anticipated. Scenario represents contact of face of one hand.
		Dermal transfer factor	0.1	Estimate based on 'low' volatility and direct contact with contaminated surfaces and incidental drips from pouring activity
		Inhalation transfer factor	0.02	Evaporative losses expected to be <2% based on equivalent gasoline values
Gas oils	Lubricants (PC24)	Use frequency	4 x per year	EPA EFAST model motor oil
		Dermal transfer factor	0.1	Estimate based on low volatility and direct contact with contaminated surfaces and incidental drips from pouring activity
		Inhalation fraction	0.05	Estimate of product lost to air during pouring based on elevated temperature (hot used oil)
		Duration of activity	10 mins	Estimated for applying lubricant paste (grease) to item

4.2. CONCAWE EXPOSURE SCENARIOS

In the CSA, the Registrant is required to identify OCs and RMM that enable the substance to be used safely. Descriptions of the conditions of use and common RMM in place at Registrants' and DUs' facilities were obtained from various sources, including liaison with DU organisations. These were considered to represent typical current situations i.e. ones considered likely as being appropriate for managing the risks associated with the use of petroleum products and which can be used readily by the vast majority of DU's. This 'snapshot' was then used to develop the CSAs for petroleum products registration dossiers i.e. a process that serves both to verify the adequacy of existing strategies or, where not, to identify any additional measures necessary to manage the risks.

DU are obliged to conform to the conditions laid out in the ES. This implies that they have to match the conditions under which they use a substance with those communicated in the eSDS. As CONCAWE's CSAs are based around the exposure predictions provided by the TRA, then, variations in the input parameters of the TRA

can be used by DU to check that their actual use falls within the boundaries of the described safe conditions. It is possible to categorise the input information into parameters which are substance-related and those which relate to the circumstances of safe use (and both of which are communicated in the ES). In REACH terminology, these parameters are referred to as EM and are communicated to the DU in the ES contained in the Annex of eSDS. In addition, CONCAWE has also identified some further EM that are capable of being applied for certain circumstances where petroleum products are handled. Those EM for workers are shown in **Table 1**.

4.3. TIER 1 ESTIMATES OF SEMIVOLATILE SUBSTANCE INHALATION EXPOSURES

4.3.1. Background

Semi-volatile substances are liquids that volatilise slowly at ambient temperature and pressure. When dispersed in air they may present a mixed atmosphere of aerosol and vapour. Some definitions of “semi-volatility” refer to substances with initial boiling point (IBP) of >250°C, others to >150°C. Petroleum products from gas oils and heavier fractions can be considered as semi-volatile organic compound (SVOC) with unknown, variable composition (UVCB).

The ratio aerosol/vapour in an atmosphere at thermodynamic equilibrium with a constant source depends on several aspects:

- Temperature of the atmosphere
- Boiling point distribution of the UVCB SVOC (typically 5th-95th percentile range is reported)
- Aerosol size distribution
- Concentration level with relatively more aerosols at higher levels

Exposures to aerosols of the substance can reasonably be anticipated during certain activities associated with the use of several petroleum products. The circumstances under which such exposures might be expected to occur will generally be associated with those where significant amounts of energy, whether kinetic or thermal, are applied to the substance.

The ECETOC TRAv2 does not explicitly include the ability to predict exposures to semi-volatile substances. There are also no other general models available nor are there comprehensive published measurement data. Therefore, in order that the CSAs for petroleum products can be considered to have addressed all relevant exposures for the uses of these substances, it has been necessary to adopt an approach which enables exposures to be estimated for semi-volatile petroleum substances.

For aerosol exposure to occur, the liquid droplet must remain airborne for a sufficient time to enable inhalation exposure to occur. However, for UVCBs, identifying which substances may present such exposure opportunities is not straightforward. For some substances with boiling points below a certain temperature, liquid droplets of a size relevant to worker health are only likely to persist in the workplace for more than a few seconds, whereas for substances above a certain boiling point (BP), the aerosol will undergo evaporation, with the rate depending on the substance and on particle size.

Hinds [22] presented droplet lifetimes for 4 substances of widely differing physical properties: ethanol, water, mercury and Di (2-ethylhexyl) phthalate (DOP). Hinds used numerical integration of a fairly complex equation to determine the lifetime (in sec) for particles of initial diameters of 0.01, 0.1, 1, 10 and 40 micrometers (µm) diameter, vapour pressure (VP) and BP properties [29].

Table 4 Droplet lifetimes for ethanol, water, mercury and DOP in vapour-free air at 20°C

Initial Droplet Diameter, µm	Droplet Lifetimes, second			
	Ethanol	Water	Mercury	DOP
0.01	4×10^{-7}	2×10^{-6}	0.005	1.8
0.1	9×10^{-6}	3×10^{-5}	0.3	740
1	3×10^{-4}	0.001	1.4	3×10^{4}
10	0.03	0.08	1200	2 x 1-^{6}
40	0.4	1.3	2×10^{4}	4×10^{7}

Source: Hinds, WC. Page 271. [22]

- Unstable aerosol: At 20°C, ethanol (VP = 5,865 Pa; BP 78.3°C) and water (VP = 18 mmH; or 2,394 Pa) would clearly evaporate quickly: a 10 µm droplet would evaporate in less than 0.08 sec for water; faster for ethanol (1 mmHg = 133 Pa)
- Stable aerosol: DOP (VP <1.3 Pa; BP = 386.1°C) would clearly remain an aerosol: the droplet lifetime was 1.8 sec for 0.01 µm droplet; 2x106 sec for a 10 µm droplet
- Intermediate: For mercury (VP <1.3 Pa, BP = 356.7°C), a 1 µm droplet would flash in 1.4 sec; a 10 µm droplet would be stable for 1200 sec.

Hinds' work [22] therefore provides an indication of how petroleum substances of different BP might be expected to behave as aerosols. As complex substances, petroleum substances do not have a fixed BP but cover a range. If the IBP of the substance is >340°C, then only aerosol exposure appears relevant. If the IBP of a substance is < 340°C but the final boiling point (FBP) is >340°C, then both vapour and aerosol exposures are relevant. Based upon these criteria, it is possible to characterise petroleum-derived UVCB products into one of four categories:

Table 5 Characterisation of the Nature of Inhalation Exposure Based on Volatility

Category	Exposure Characteristics	Indicative Boiling Range	Example Products	CONCAWE CSA Evaluation Criteria
Light products	Only vapour exposures likely	FBP <200^{o}C	Naphthas	Only vapour exposures assessed
Lower boiling products	Vapour exposures predominate. Some aerosol exposure may arise in certain high energy operations	IBP<200^{o}C FBP <340^{o}C	Kerosines	Vapour exposure assessed except where potential for aerosol generation identified
Moderate boiling products	Aerosol exposures predominate.	IBP >150^{o}C FBP >340^{o}C	Gas oils	Aerosol exposure assessed except where potential for significant vapour release and co-exposure identified
Heavier products	Only aerosol exposures likely	IBP >200°C FBP >340°C	Aromatic extracts, HFOs	Only aerosol exposures assessed

4.3.2. Semi-Volatile Exposure Predictions

In order that any exposure assessment under REACH can be seen to have adequately addressed such potentially mixed phase exposures, CONCAWE has determined the following approach for those petroleum PCs where aerosol exposures might reasonably be anticipated.

- For high and moderate volatility products, vapour exposures were predicted for all relevant PROCs. Aerosol exposures were predicted for lower volatility products.
- For low volatility products, in addition to aerosol exposures for selected PROCs vapour exposures were included consistent with TRA predictions for the substance.
- Those PROCs have been identified where significant exposures to aerosols might reasonably be anticipated. For each of these PROCs, the aerosol exposure has been predicted based on the assumption that the dynamics of the activity are equivalent to exposure to a moderately dusty solid. Although extensive exposure data are not available to verify the validity of these estimates for all affected PROCs, sufficient data are available for defined circumstances of use, e.g., use in metalworking, spraying of coatings, to provide some degree of assurance that the exposure predictions are conservative in nature.
- The associated TRA assumptions (e.g. magnitude of LEV and other RMM efficiencies) are accounted for as described previously.

Table 6 Basis for reduction of aerosol exposures to petroleum products for relevant uses/PROCs

PROC	PROC Description	Predicted Aerosol Exposure (no LEV) (mg/m^3)	Predicted Aerosol Exposure (with LEV) (mg/m^3)	Comments / Justification
4	Use in batch or other processes with exposure opportunities	5 (Indstrl)	0.5	Applied where processes undertaken at elevated temperatures and formation of condensation aerosols from higher boiling substances likely
		5 (Prfssnl)	1	
5	Mixing or blending in batch processes	5 (Indstrl)	0.5	Applied either where processes involves significant energy (e.g. shear mixing) or is undertaken at elevated temperatures and formation of condensation aerosols from higher boiling substances likely
		5 (Prfssnl)	1	
6	Calendaring operations	5 (Indstrl)	0.5	Applied due to formation of condensation aerosols from higher boiling substances. Vapour exposures not determined. Not appropriate for light and low boiling substances.
		5 (Prfssnl)	1	
7	Industrial spraying	20 (Indstrl)	1	Applied in all cases where identified
10	Rolling and brushing	5 (Indstrl)	0.5	Applied either where processes involves significant energy (e.g. high speed rollers) or is undertaken at elevated temperatures and formation of condensation aerosols from higher boiling substances likely
		5 (Prfssnl)	1	
11	Non-industrial spraying	20 (Prfssnl)	4	Applied in all cases where identified
17	Lubrication at high energy conditions	20 (Indstrl)	1	Applied in all cases where identified
		50 (Prfssnl)	5	
18	Greasing at high energy conditions	20 (Indstrl)	1	Applied in all cases where identified
		50 (Prfssnl)	5	

LEV local exhaust ventilation

4.4. TANK CLEANING

4.4.1. Tank cleaning exposures and risk management measures

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

4.4.2. Tanks at industrial premises

RMM 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.

4.4.3. 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, but are not commonly accepted in all regulations.

4.4.4. 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 (ref. http://lasi.osha.de/docs/lv39.pdf). 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 use of respirators. Dermal exposures may be significant. As the private tank owners are considered consumers under REACH they have no access to eSDS and hence cannot be expected to provide risk management advice to the tank cleaning and inspection personnel.

4.5. OIL PRODUCTS WHICH MAY RELEASE HYDROGEN SULPHIDE

A number of petroleum products including sulfur may release hydrogen sulphide, a toxic gas. The levels vary greatly depending on origin of the crude oil(s) and refinery processes. Exposure control advice for these substances is dependent on the hydrogen sulphide levels, but not as specific as the advice based on other identified hazards of these substances. Potential H_2S releases have therefore not been taken into account in the CSAs of relevant petroleum products. Instead, it has been agreed in CONCAWE to provide member companies text recommendations (see below) which they may include in the main body of the SDS.

Recommended standard text:

A specific assessment of inhalation risks from the presence of hydrogen sulphide in tank headspaces, confined spaces, product residue, tank waste and waste water, and unintentional releases must be made to help determine controls appropriate to local circumstances (phrase code E500). These controls may include (amongst others) - Segregation of areas; Access only to authorised persons; Permit to work systems; Confined space working procedures; Area H_2S alarms; Personal H_2S alarms; Personal escape sets; H_2S awareness training (phrase code E501).

4.6. QUALITATIVE CSA FOR ENDPOINTS WHERE NO DNEL EXISTS

Qualitative CSAs have been applied according to the ECHA guidance on Information Requirements & CSA (Part E) to identify appropriate RMM when there is no basis for setting a DNEL or derived minimal effect level (DMEL) for certain identified human health adverse effects.

The qualitative assessments aim to reduce/avoid contact or incidents with the substance proportional to the degree of concern related to its health hazard. Implementation of the selected RMMs will ensure that the likelihood of an event occurring due to the hazard of the substance is negligible, and the risk is considered to be controlled to a level of no concern.

Hazardous end points falling into this category were identified as: R20: harmful by inhalation; R45: May cause cancer; R38: Irritating to skin; R65: may cause lung damage if swallowed; R66: defatting to skin.

4.6.1. HARMFUL BY INHALATION (R20/H332)

This classification applies to petroleum substances which exhibit acute inhalation toxicity. The acute inhalation toxicity associated with high concentrations of the aerosol of these substances is the result of direct deposition of liquid into the airways giving the same effect as seen with aspiration. The associated DNELs for acute toxicity of these types of substances are typically in the order of 1500-5000 mg/m^3/15 minute aerosol.

Apart from their acute toxicity, these petroleum substances have potential to cause other effects for which long-term DNELs are available. Typically, the (long-term inhalation) DNELs for these effects are in the range of 0.1-70 mg/m^3/8hr aerosol. In comparing the acute DNELs to the long-term systemic effects inhalation DNELs, the long-term DNEL is ~60-300x less than the short-term acute inhalation toxicity DNEL.

In those instances where there is a difference of at least a factor of 30 (based on the fact that there are 32 15 minute periods during an 8-hour day) between the short-term (when expressed over 15 minutes) and the long-term DNEL (when expressed over 8 hours), i.e. the long-term DNEL is lower by at least 30x, then a quantitative assessment of short-term exposure has not be undertaken based on the following rationale:

- For any single short-term (ST) event to adversely influence the implementation of the long-term (LT) reference value (DNEL when available) in the CSA, then the single ST exposure must be 30x greater than the LT DNEL. Where the ST exposure might be repeated during the course of a work shift, then the contribution made by the ST exposures to the LT average would clearly be greater. Hence, provided shift average exposures are controlled to within the LT reference value, then this will also account for any potential risks arising from ST exposure.

Statement included in Section 10.x of CSR

A quantitative assessment of short term exposure has not been undertaken as there is a difference of at least a factor of 30 between the short term (when expressed over 15 minutes) and the long term DNEL (when expressed over 8 hours) DNELs.

4.6.2. SKIN IRRITATION (R38/H315)

For the hazard of skin irritation (R38) the qualitative risk characterisation conducted is consistent with the considerations and RMM identified in the **Table 7** below. The contents of **Table 7** relate to how dermal irritation is considered under Part E of the REACH Technical Guidance to represent a low hazard. **Table 7** also shows how many RMM are already communicated in the SDSs by virtue of the associated S/P phrases for the hazard.

Table 7 Elements of Qualitative CSA and Those Identified S/P Phrases for Dermal Irritancy

Components of the Qualitative Risk Assessment	Examples of Relevant S Phrases and P Statements
• Implementation of basic standards of occupational hygiene; • Avoid direct skin contact with product; • Wear gloves (tested to EN374) if direct hand contact with the substance is likely; wash off skin contamination immediately; • Avoid splashes and spills; • Avoidance of contact with contaminated tools and objects; • Clean up contamination/spills as soon as they occur; • Regular cleaning of equipment and work area; • Ensure suitable management/supervision is in place to check that the RMMs in place are being used correctly and OCs followed; • Train staff on good practice to prevent / minimise exposures and to report any skin problems that may develop; • Adopt good standards of personal skin hygiene. • Where activities may lead to aerosol release e.g. spraying, then additional skin protection measures such as impervious suits and face shields may be required.	• S24: Avoid contact with skin Prevention: • P264: Wash thoroughly after handling. • P280: Wear protective gloves. Response: • P280: Wear protective gloves/protective clothing/eye protection/face protection. • P302 + P352: IF ON SKIN: Wash with plenty of soap and water. • P321: Specific treatment (see on this label). • P332 + P313: If skin irritation occurs: Get medical advice/attention. • P362: Take off contaminated clothing and wash before re-use

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

- E3: Avoid direct skin contact with product. Identify potential areas for indirect skin contact. Wear gloves (tested to EN374) if direct hand contact with

substance likely. Clean up contamination/spills as soon as they occur. Wash off skin contamination immediately. Provide basic employee training to prevent / minimise exposures and to report any skin effects that may develop.

Together with (where there is the potential for additional and significant aerosol exposure):

- E4: 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.

Statement included in Section 10.x of CSR

- The implementation of relevant RMMs will ensure that the likelihood of an event occurring due to the substance hazard of skin irritation is negligible and the risk is considered to be controlled to a level of no concern.

4.6.3. CARCINOGENIC HAZARD (R45/H350)

EU legislation exists for the control of exposure to carcinogens in the workplace (substances classified as R45), and which establishes a framework of expectations that can be used as the basis for applying a qualitative approach for any CSA. Specifically Directive 2004/37/EC of the European Parliament and the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) 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 carcinogens or mutagens.

The R45 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 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 will be required.

This general qualitative CSA approach aims to reduce/avoid exposure or incidents with the substance consistent with the expectations of Directive 2004/37/EC. The general philosophy is twofold:

1. that the uses of any R45 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 (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 Directive 2004/37/EC.

2. That a stringent set of RMMs will be applied. Firstly, exposures should be controlled to at least the levels that represent an acceptable level of risk (i.e. represent a risk characterisation ratio (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), with the aim that the net outcome is the description of the RMMs that when implemented ensure that the likelihood of cancer occurring is minimised, and the risk is considered to be controlled.

For the cancer hazard a qualitative risk characterisation has been conducted consistent with the considerations and RMM identified in the Table 8 below.

Table 8 Elements of Qualitative CSA and Those Identified S/P Phrases for Carcinogenicity

Components of the Qualitative Risk Assessment	**Examples of Relevant S Phrases and P Statements**
Worker • Implement good standards of occupational hygiene • Consider technical advances and process upgrades • Minimise exposure using measures such as closed systems • Management/supervision to check that the RMMs in place are being used correctly and OCs followed • Restrict access to authorised persons; • Provide specific activity training • Regularly inspect, test and maintain all control measures • Consider the need for risk based health surveillance **Consumer** - Not supported unless marketed in a manner consistent with Article 56 of REACH	• S23: Do not breathe gas/fumes/vapour/spray • S24: Avoid contact with skin • S51: Use only in well-ventilated areas • S36/37: Wear suitable protective clothing and gloves. • S45: In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). • S53: Avoid exposure – obtain special instructions before use. Prevention: • P201: Obtain special instructions before use. • P202: Do not handle until all safety precautions have been read and understood. • P260: Do not breathe dust/fume/gas/mist/vapours/spray. • P281: Use personal protective equipment as required. Response: • P308 + P313: If exposed or concerned: Get medical advice/attention. Storage: • P405: Store locked up. Disposal: *P501 : Dispose of contents/container to.... in accordance with local/regional/ national/international regulations (to be specified)*

For any substance, classified as R45, these RMM are communicated via the ES by use of the following phrases:

For every ES, the following general phrase is included

- G20: 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.

In addition the following specific phrases are also applied, where the identified contributing scenarios are relevant within any ES.

Table 9 Specific Activities and Associated RMMs for Classified Carcinogenic Petroleum Substances

Contributing Scenarios	**Risk Management Measures (RMMs)**
CS2 Process sampling	Sample via a closed loop or other system to avoid exposure. E8.
CS14 Bulk transfers (incl. CS501) *And related phrases such as CS6, CS8.*	Ensure material transfers are under containment or extract ventilation. E66.
CS15 General exposures (closed systems) *And related phrases such as CS29,*	Handle substance within a closed system. E47.
CS507 Refuelling	Ensure material transfers are under containment or extract ventilation. E66.
CS36 Laboratory activities	Handle within a fume cupboard or implement suitable equivalent methods to minimise exposure. E12.
CS5 Equipment maintenance **OR** CS39 Equipment cleaning and maintenance	**Either:** Drain down and flush system prior to equipment break-in or maintenance. E55; **Or;** Drain down system prior to equipment break-in or maintenance. E65.

Contributing Scenarios	Risk Management Measures (RMMs)
	And; Retain drain downs in sealed storage pending disposal or for subsequent recycle. ENVT4. Clear spills immediately. C&H13.
CS67 Storage	Store substance within a closed system. E84.

4.6.4. ASPIRATION HAZARD (R65/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 R65 risk phrase (Harmful: may cause lung damage if swallowed) relates to potential for aspiration, a non-quantifiable hazard determined by physico-chemical properties (i.e. viscosity) that can occur during ingestion and also if it is vomited following ingestion. A DNEL 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. The risk can therefore be controlled by implementing RMM tailored to this specific risk. For any substance, classified as R65, these measures should be communicated via the SDS by use of the following phrase:

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

Furthermore it should be noted that where the substance is sold for use in lamp oils and grill lighters by the general public (Consumers), then these must be visibly, legibly and indelibly marked as follows, in accordance with REACH Annex XVII update of 1.4.2010:

- Keep lamps filled with this liquid out of the reach of children.
- Just a sip of lamp oil – or even sucking the wick of lamps may lead to life threatening lung damage.

For aspiration hazard a qualitative risk characterisation has been conducted consistent with the considerations and RMM identified in the **Table 10** below.

Table 10 Elements of Qualitative CSA and Those Identified S/P Phrases for Aspiration Hazard

Components of the Qualitative Risk Assessment	Examples of Relevant S Phrases and P Statements
Worker • Do not ingest • Implementation of basic standards of occupational hygiene • Avoid splashes and spills • Avoidance of contact with contaminated tools and objects • Management/supervision to check that the RMMs in place are being used correctly and OCs followed • Training for staff on good practice • Good standard of personal hygiene **Consumer** Do not ingest. For lamp oils and grill lighters, follow the provisions of REACH – Annex XVII, including: - Marketing in black opaque containers not exceeding 1 litre *Labelling with specific safe use instruction*	Response: • (S2): Keep out of the reach of children (for dangerous products sold to the general public must include this safety phrase) • S62: If swallowed, do not induce vomiting: seek medical advice immediately and show this container or label • P102: Keep out of reach of children. • P301 + P310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. • P331: Do NOT induce vomiting. Storage: • P405: Store locked up. Disposal: • P501 : Dispose of contents/container to.... in accordance with local/regional/ national/international regulations (to be specified)

For any substance, classified as R65, these RMM should be communicated via the SDS by use of the following phrase:

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

Statement included in Section 10.x of CSR

- The implementation of relevant RMMs will ensure that the likelihood of an event occurring due to the aspiration hazard of the substance is negligible and the risk is considered to be controlled to a level of no concern.

4.6.5. SKIN DEFATTING HAZARD (R66/H066)

The R66 risk phrase 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. R66 does not relate to a classifiable endpoint, and there is no standardized test method to quantify the effect. Thus, a DNEL cannot be derived.

Note that R66 is an “additional” risk phrase which means that it shall be applied only to substances or preparations that are already classified whilst assignment of the risk phrase R66 does not, in itself, have any impact on the formal classification of the substance. The skin defatting hazard is rated lower than the skin irritation hazard in that it is linked only to repeated and/or prolonged exposure.

For skin defatting a qualitative risk characterisation has been conducted consistent with the considerations and RMM identified in the **Table 11** below.

Table 11 Elements of Qualitative CSA and Those Identified S/P Phrases for Skin Defatting

Components of the Qualitative Risk Assessment	**Examples of Relevant S Phrases and P Statements**
• Implementation of basic standards of occupational hygiene; • Avoid repeated and/or prolonged skin contact with product; • Wear gloves (tested to EN374) if hand contamination likely, wash off any skin contamination promptly; • Avoid splashes and spills; • Avoidance of contact with contaminated tools and objects; • Clean up contamination/spills; • Regular cleaning of equipment and work area; • Management/supervision to check that the RMMs in place are being used correctly and OCs followed; • Training for staff on good practice to prevent / minimise exposures and to report any skin effects that may develop; • Good standard of personal hygiene.	No designated S and P phrases are assigned, though the following phrase may be appropriate: S24 Avoid contact with skin Response: • P280: Wear protective gloves/protective clothing/eye protection/face protection. • P281: Use personal protective equipment as required.

For any substance, classified as R66, these measures should be communicated via the SDS by use of the following phrase:

- PPE20: 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

Proposed statement to be included in Section 10.x of CSR

The implementation of relevant RMMs will ensure that the likelihood of an event occurring due to the substance hazard of skin defatting is negligible and the risk is considered to be controlled to a level of no concern.

5. GLOSSARY

ACGIH TLV	American Conference of Governmental Industrial Hygiene Threshold Limit Value
ACH	Air changes per hour
AISE	International Association of the Soap, Detergent and Maintenance Products Industries
BP	Boiling Point
CEFIC	European Chemical Industry Council
CEPE	European Confederation of Paint, Printing Ink and Artists' Colours Manufacturers Associations
CONSEXPO	ConsExpo a modeling tool for the estimation and assessment of exposure to substances from consumer products that are used indoor and their uptake by humans
COSHH	Control of Substances Hazardous to Health
CSA	Chemical Safety Assessment
DMEL	Derived Minimal Effect Level
DNEL	Derived No Effect Level
DOP	Di (2-ethylhexyl) phthalate (Di-octyl phthalate)
DU	Downstream User
ECETOC	European Centre for Ecotoxicology and Toxicology of Chemicals
ECHA	European Chemical Agency
EM	Exposure Modifier
ERC	Environmental Release Category
ES	Exposure Scenario
ESIG	European Solvents Industry Group
ESVOC	European Solvents VOC
EU	European Union
EUPhraC	European Phrase Catalogue
Ext-SDS	Extended Safety Data Sheet (eSDS)
FBP	Final Boiling Point
FEA	Federation of European Aerosol Associations

FECC	The European Association of Chemical Distributors
FEICA	Fédération Européenne des Industries de Colles et Adhésifs
GES	Generic Exposure Scenario
IBP	Initial Boiling Point
LEV	Local Exhaust Ventilation
LPG	Liquified Petroleum Gas
OC	Operational Condition
PCs	Product Categories
PPE	Personal Protective Equipment
PROCs	Process Categories
RCR	Risk Characterisation Ratio
REACH	Registration, Evaluation, Authorisation of Chemicals
RMM	Risk Management Measure
SDS	Safety Data Sheet
SVOC	Semi-Volatile Organic Compound
TGD	Technical Guidance Document
TNO	Netherlands Organisation for Applied Scientific Research
TRA	Targeted Risk Assessment
UVCB	Unknown, of Variable Composition or of Biological Origin
VP	Vapour Pressure

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APPENDIX 1 CONSUMER HABITS AND PRACTICES IN USE OF PETROLEUM PRODUCTS (FUELS, ENGINE LUBRICANTS)

Exposure of consumers during use of chemical substances can be measured directly or modelled on the basis of certain parameters such as frequency, duration, quantities involved and other OCs. Where the exposure estimate is intended to be representative of a population exposure distribution, it is necessary to obtain information describing consumer habits and practices. In the CSA under REACH it is necessary to produce an appropriately conservative estimate of the consumer exposure of the general population by combining various factors that will result in a 'reasonable worst case' exposure.

A market survey was commissioned by CONCAWE in 2011 to characterize the consumer habits and practices of EU inhabitants in their use of petroleum products, in particular fuels and engine lubricants. The survey was carried out by Alba Science Ltd. [1]. A sample of 250 United Kingdom inhabitants (all car drivers), aged 18 and above responded to an on-line questionnaire. The survey was limited but intended to be illustrative of habits and practices of EU consumers, rather than truly representative (e.g. the ability to further analyse the data by country of region).

Of the respondents, 97% used gasoline and/or diesel. Some had more than one vehicle, such that 80% refuelled with gasoline and 30% with diesel. Nearly all service stations that were visited were of the self-service type.

The principal findings of the survey are listed in **Table A3.1** below. It should be noted that these figures are self-reported and not actual measured values. By combining the various 90th percentiles for frequency, amount of fuel purchased and time spent refuelling the vehicle, the resulting exposure estimate is considered to be suitably conservative.

Table A3.1 Exposure determinants for consumers – fuel use

Parameter	Average	90th percentile
Refuelling frequency	3.1 times/month	5 times/month
Refuelling amount	30 litres	53 litres
Time spent at service station	4 min	7 min

Regarding dermal exposure, 60% responded that they have 'sometimes' skin contact with fuel. When disposable gloves are available, only 8% reported that they would always use them. Hence for the dermal exposure assessment it is not reasonable to factor in the presence of dermal protection into the exposure estimate.

Information on parameters relevant for estimating exposure to engine lubricants was targeted at the topping up of the engine reservoir and at lubricant changes. Most people questioned reported that they occasionally check the oil reservoir level of their car and would top up if necessary. 70% of the respondents do not themselves change oil, but 20% do it sometimes and this would result in some skin exposure to both old and fresh lubricant. **Table A3.2** shows the principal findings of the survey for consumer use of engine lubricants.

Table A3.2 Exposure determinants for consumers – engine lubricant use

Parameter	Average	90th percentile
Topping up frequency	Once/5.7 months	Once/month
Top up amount	0.7 litre	1.25 litre

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