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# Managing the Health Risks of Solvent Exposure



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Each company based on its own decision making process may decide to use the Guidance in full, partially or not, as it suits its needs.

European Solvent Industry Group (ESIG) www.esig.org

### **1. INTRODUCTION**

This document is the first of a series of 'Best Practice Guidelines' published by the European Solvents Industry Group (ESIG). It aims to assist solvent users, particularly Small and Medium Size Enterprises (SMEs), in using both hydrocarbon and oxygenated solvents safely. This series of guides replaces those published between 2001 and 2003 in order to update and adapt the guidance to take account of the significant changes to the regulatory landscape that have been introduced over the last decade. In addition, there have been some significant changes in the composition and uses of commercially available solvents over this period. For example, solvent grades are now offered with reduced concentrations of hazardous components such as n-hexane and naphthalene, providing customer choice. Also there has been a general move away from aromatic-containing white spirits to dearomatised products and the appetite for solvents containing toluene and xylene has reduced due to product classification drivers.

The information provided in this guide is consistent with European Chemicals Agency guidance at the date of print.

#### **1.1 SCOPE AND OBJECTIVES**

This guide addresses the management of health risks from exposure to solvents via inhalation and via skin or eye contact in the workplace. It does not address safety hazards, such as flammability or environmental impact. For more information on flammability see ESIG BPG4: Flammability – A safety guide for users (REF 1), or individual product safety data sheets (SDS). Also, it is standard industry practice to ensure the environmentally sound use of solvents by implementing engineering and procedural measures to minimise releases, in order to comply with regulatory requirements, including the VOC directive (REF 2).

The new regulatory framework, influenced in particular by the introduction of REACH (REF 3), is complex. The intention of this guide is to provide simple and practical guidance to solvent users regarding their regulatory obligations and the activities and measures required to continue to ensure that health risks from use of solvents are controlled.

### 2. THE REGULATORY LANDSCAPE

The complexity of the regulatory landscape applicable to the manufacture and use of chemicals has increased significantly in the last decade due to the introduction of European Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), and European Regulation (EC) No 1272/2008 on the Classification, Labelling and Packaging of Substances and Mixtures (CLP, REF 4). These regulations apply directly to the member states and require no transposition into national legislation. They apply in addition to existing national legislation based on the EU Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work (the Chemical Agents Directive – CAD, REF 5) which was adopted on 5 May 1998 (the fourteenth individual Directive adopted under the framework directive on safety and health of workers) (REF 6) and required member states of the European Union to implement its provisions by 5 May 2001.

### 2.1 CAD

This framework directive places responsibility on employers to protect the health and safety of workers from the risks of all chemical agents, including those such as fume generated by processes, and substances that become hazardous because of the way they are used. CAD requires employers to identify, assess and control such risks, if possible by elimination or substitution (for example the substitution of aromatised by dearomatised products). Central to this process is the employer's risk assessment, drawing on information

such as labels, safety data sheets (SDS) or published guidance, to identify and implement control measures appropriate to the way the chemical agent is used in their workplace. In addition CAD outlines a clear hierarchy of the available workplace controls with the aim of ensuring that the most reliable and appropriate measures are applied in each situation. See Appendix 1 for further information.

(In the rest of this Guide, the term 'CAD' is used as a surrogate for the actual national legislation which implements CAD in the EU member states, e.g. in the UK the Control of Substances Hazardous to Health Regulations – known as COSHH.)

### 2.2 REACH

This EU regulation came into force on 1st June 2007 replacing a number of previous EU directives and regulations. It applies to chemical substances (on their own, in preparations, or in articles) manufactured or imported into the EU in quantities of 1 tonne or more per year (although some categories of substance are specifically excluded).

A major part of REACH is the requirement for Manufacturers or Importers (M/I) of substances to register them with the European Chemicals Agency (ECHA). The registration package for any substance must be supported by a standard set of toxicological data on that substance and all registrations at 10 tonnes or more per year must be accompanied by a Chemical Safety Assessment (CSA). The CSA must include an assessment of the risks (to human health or the environment) throughout the life cycle of the substance, i.e. covering manufacture, distribution, formulation, and all identified subsequent uses, and detail the measures which should be implemented to control identified risks. The CSA is in effect a product risk assessment that describes safe use conditions for a series of identified substance is registered, then the M/I is expected to communicate the ES to the downstream user (DU) in an Annex to the SDS (then known as the ext-SDS).

Downstream user (DU) is defined in Article 3(13) as: 'any person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities.'

Formulator	Blends substances to make mixtures (such as paints) and places them on the market. Customers may include industrial or professional users (see below) or another formulator (e.g. the supply of an additive dissolved in a solvent which is used to formulate a finished product).
Re-filler (Re-packager)	Transfers solvents or mixtures containing solvents from one container to another (such as re-packaging a solvent cleaner into small containers for supply to consumers).
Industrial User	Operates at industrial sites and uses solvents that do not remain in the product (such as use of a surface cleaner prior to electroplating).
Professional User	End users of solvents or solvent-containing mixtures during professional activities (such as flooring contractors and painters using solvent based products).

### TABLE 1: Downstream User (DU) roles relevant to solvent use

Another key change introduced by REACH is that DUs now have a legal obligation under Article 37 to follow the advice contained within the ES for their use of the solvent. If their use or use conditions are not covered, DUs should develop their own CSA, or inform their supplier of their use/use conditions and request an update. This approach differs to the previous regime where the information contained within the SDS was advisory. A summary of the key obligations of solvent users under REACH is given in Table 2 (from ECHA Guidance for Downstream Users, REF 7).

	OBLIGATIONS/ACTIONS	TIMING
Communication in the Supply Chain	Identify DU roles under REACH. Make 'uses' known to the registrants/ suppliers (voluntary action).	June 2007 onwards. By 31 May 2017 for the phase-in substances to be registered by 31 May 2018.
	Identify and apply appropriate measures to control the risks communicated in supplier's SDS or other information supplied.	Within 12 months of receiving a SDS for a registered substance
	Check if own use is covered in the supplier's exposure scenario, and take further action in the event that your use is not covered.	6 months to report unsupported use to ECHA, 12 months to implement measures after receiving SDS for a registered substance.
	Communicate to the supplier, information that might call into question the appropriateness of the risk management measures in any exposure scenario received.	Without undue delay.
	Inform suppliers of any new information on hazards, including classification and labelling.	Without undue delay.
Additional obligations for formulators and re-fillers only	Provide information to your customers, including retailers / consumers, to enable safe use of substances or mixtures. This should be in accordance with Title IV of the Regulation (Requirements for SDS).	Without undue delay, when an SDS requires to be updated as specified in Article 31(9).

### TABLE 2: Summary of key obligations of solvent users under REACH

REACH therefore requires additional information flows both up and down the supply chain. Although REACH introduces a responsibility for registrants (importers and manufacturers) to identify risk management measures when necessary for safe use of a substance, the duties of employers under CAD remain. For example, employers will still have to undertake the workplace risk assessments required by CAD and ensure that adequate controls are in place. The additional information generated by registrants and supplied to downstream users under REACH should improve the way risks are managed in the workplace. (A detailed overview of the duties of DU under CAD and REACH along with practical guidance is included in Section 7.)

### 2.3 CLP

This regulation implements the UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS – REF 8) in the EU. This aims to ensure that the information on the hazardous properties of chemicals is consistently assessed and communicated throughout the world in order to enhance the protection of

human health and the environment during the handling, transport and use of chemicals. CLP came into force on 20 January 2009 and its provisions have been introduced in the EU in stages up to 1 June 2015. This was intended to help suppliers and users of chemicals transition from the current EU classification and labelling system based on the Dangerous Substances Directive (DSD, REF 9) and the Dangerous Preparations Directive (DPD) to the new GHS-based system. Appendix 2 lists the CLP classification phrases (known as Hazard Statements, for example H336: May cause drowsiness or dizziness) typically relevant to hydrocarbon and oxygenated solvents. Since 1 June 2015 it is only required for the hazard classifications according to the CLP regulation to be displayed in Safety Data Sheets.

### **3. HEALTH EFFECTS AND PROPERTIES OF SOLVENTS**

Exposure to solvents in the workplace can occur via contact of the liquid with the skin or eyes, or via inhalation of vapour or mist. These exposures can be either acute (i.e. short term, high level), often limited to a single event, or chronic (i.e. prolonged or repeated exposures at levels that do not cause acute effects and occur in the course of normal use). Effects from chronic exposure are typically solvent specific and need to be considered on a solvent-by-solvent basis. Acute effects are more consistent across solvents and can be addressed generically as a common or similar mechanism of action is involved.

Solvent contact with skin can lead to absorption through the skin, which could lead to systemic toxicity, or a local response at the site of contact, such as irritation or dermatitis, often from repeated or prolonged exposure. Inhalation of solvent vapour can cause respiratory tract irritation, effects on the nervous system (such as dizziness and headaches), whilst very high exposures may cause unconsciousness and even death. However, the selection and use of appropriate exposure controls allows solvents to be used safely and with confidence for all the uses supported by suppliers.

### 3.1 EFFECTS OF SOLVENTS VIA SKIN AND EYE CONTACT

Irritant contact dermatitis is a skin reaction leading to inflammation at the site of contact and can develop after regular contact with mild irritants such as detergents, weak acids or alkalis, and some solvents. Dry, red and itchy skin is a common first sign. Swelling, flaking, blistering, cracking and pain may follow. Usually, the inflammation subsides once the skin has healed. However, repeated contact may lead to 'hyper-irritability' – the skin becomes inflamed more readily than normal.

Industrial skin disease is still common. Although exposure to solvents may contribute to this statistic, they are not among the main causative agents. However, a significant number of solvents carry the cautionary classification for skin hazard (EUH066: 'Repeated exposure may cause skin dryness or cracking'). A few, including n-hexane and a number of other light aliphatic hydrocarbon solvents as well as some oxygenated solvents (e.g. n-butanol and cyclohexanol) could result in a slightly more severe response following dermal exposure and have been assigned a classification for skin irritancy (H315: Causes skin irritation). Therefore appropriate measures must always be taken to minimise skin contact during use of solvents.

Some substances, such as n-hexane (a constituent of some hydrocarbon solvents), can be absorbed into the body through intact skin. Absorption via this route can contribute to systemic effects (diseases in other parts of the body) caused by inhalation of solvent vapour. In such cases, skin absorption becomes more significant where exposure by inhalation is well controlled.

Solvents which can be absorbed via the skin may require Hazard Statement H312: Harmful in Contact with Skin, or H311: Toxic in contact with skin, for example ethylene glycol butyl ether (H312) and methanol (H311). For more information on controlling skin exposure, see UK HSE publication 'Managing skin exposure risks at work' (REF 10).

In addition to effects on the skin, many solvents are capable of causing effects on the eye. Many oxygenated solvents have been assigned Hazard Statements H318: Causes serious eye damage or H319: Causes serious eye irritation, for example n-Propanol (H318) and Methyl Ethyl Ketone (MEK) (H319).

#### 3.2 EFFECTS VIA INHALATION

When inhaled in sufficient quantities, most volatile solvents are capable of causing effects on the central nervous system (drowsiness, dizziness, lack of coordination, headaches, etc.). However, some are not volatile enough to generate sufficient vapour to cause these effects under normal (ambient) temperatures. Those that are volatile enough have been classified for narcotic effects - H336: May cause drowsiness or dizziness.

Exposure to solvents via inhalation can also result in irritation of the respiratory tract. Solvents that cause this effect are assigned Hazard Statement H335. Examples include n-Butanol and 'Hydrocarbons, C9, Aromatics'.

A few solvents have been assigned additional classifications as they are capable of causing other health effects. These effects can be observed following either acute or chronic exposures. For example, methanol may cause damage to the optic nerve and has been assigned Hazard Statements H301, H311 and H331 indicating that it can be dangerous via ingestion, skin absorption and inhalation following acute/short-term exposures. Whereas, n-hexane can damage the peripheral nervous system following prolonged and repeated exposures and requires Hazard Statement H373: May cause damage to organs through prolonged or repeated exposure. Not all hazards associated with solvents have been discussed in this section. Appendix 2 lists the classification phrases that are commonly applied to hydrocarbon and oxygenated solvents based on their hazard profiles. Therefore, not only is it important to ensure that exposure to solvent vapours is controlled well within appropriate workplace exposure limit values recommended by national authorities or suppliers, but it is also important to prevent skin and eye contact and ingestion.

### 3.3 CLASSIFICATION AND LABELLING OF SOLVENTS

Substance suppliers are required to submit classification and labelling proposals to ECHA under the CLP regulations. For many substances the classification is subsequently agreed by independent experts at EU level resulting in 'harmonised classifications' which are legally binding and must be used by all suppliers and contained in Annex VI to CLP (Ref 11). Harmonised values have been derived for some but by no means all hydrocarbon and oxygenated solvents. Where a harmonised classification is not available the supplier will provide his own recommendation on the SDS.

A data base of all classification information submitted to ECHA under CLP known as the classification and labelling inventory, is maintained on the ECHA website. See <u>http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database</u>. This inventory lists all information submitted much of which is either conflicting or erroneous. However, the harmonised entries can be relied on and these are clearly identified.

Appendix 3 and 4 list the Hydrocarbon and Oxygenated Solvents registered under REACH, including classification and labelling information. Harmonised values from CLP Annex VI are listed if available, otherwise the latest industry recommendation is provided.

### 3.4 HAZARD AND RISK

These principles are fundamental to ensuring the safe use of solvents:

HAZARD is the potential of a substance to cause an adverse health effect. The most common EXPOSURE routes for solvents are inhalation of vapour and skin contact with liquids.

RISK is the chance of an adverse effect occurring under the actual conditions of use and is therefore a function of both HAZARD and EXPOSURE i.e.:

RISK = function [(HAZARD) x (EXPOSURE)]

Consequently the RISK can be controlled by reducing the HAZARD (e.g. by the use of a less hazardous solvent) or the EXPOSURE (by implementing improved engineering, procedural and/or personal protective equipment controls), or both.

The potential for exposure via inhalation can be estimated from how readily the solvent forms a vapour (i.e. its VOLATILITY), and the amount that is used. However, even if the solvent does not readily form a vapour, it may still present a risk to health under conditions involving high energy (e.g. spraying or machining, or where elevated temperatures are involved), or if it can be absorbed through the skin. Ensuring safe use is therefore a balance between a number of factors including the hazard of the solvent (its intrinsic ability to cause harm), its volatility, the amount used, the exposure time, and the controls which are applied during use of the solvent in the workplace. The aim of legislation to control health risks in the workplace is to ensure that adequate information is available on the hazards of substances and to ensure that this balance is identified and maintained.

# **4. EXPOSURE SCENARIOS (ES) – BASIC PRINCIPLES**

Under REACH an ES describes the conditions under which it is considered that the risk is controlled and includes the risk management measures and operational conditions that need to be followed to ensure 'safe use' for the specified activity. Depending on the properties of the substance the ES would address health and/ or environmental risks, but this guide only covers health risks.

Exposure Scenarios are prepared by the solvent registrant (often the supplier of the product) if the substance is classified as hazardous and is manufactured at greater than 10 tonnes/year, and cover all uses which the registrant has been informed of by downstream users (and which he does not specifically list as 'not recommended' uses).

Therefore, if you are a downstream user (DU) and you use solvents classified as hazardous (on their own or in mixtures), the SDS provided by your supplier will include a summary exposure scenario based on the Chemical Safety Assessment (CSA), incorporating any recommended measures to control exposure via inhalation and contact with the skin or eyes.

Most solvents are classified as hazardous due to their aspiration or skin defatting risk and are classified H304 ('May be fatal if swallowed and enters airways'), and/or EUH066 ('Repeated exposure may cause skin dryness or cracking') based on their inherent physical chemical properties. Generic controls for these basic hazards are applicable to all uses and main sections of SDS will advise to avoid ingestion and take appropriate skin care measures.

In addition there are a number of good practice measures that are recommended for all solvents even those which are non-hazardous. These general good practice measures include those listed in Table 3 below:

### TABLE 3: Good practice measures for safe handling of solvents

- Conduct risk assessment of local workplace activities
- Implement procedures supporting safe handling measures and maintenance of controls
- Educate and train workers to understand the hazards and control measures relevant to their activities
- Provide adequate general ventilation
- Ensure good housekeeping and prompt clearance of spillages
- Ensure appropriate selection, testing and maintenance of equipment used to control exposure, e.g. Local Exhaust Ventilation, Personal Protective Equipment (PPE),
- Drain equipment prior to maintenance; retain drained material in sealed storage pending disposal or recycling
- Arrange regular supply and laundering of work clothing; provide suitable washing and changing facilities;
- Allow eating and smoking only in designated areas separate from the workplace to prevent ingestion

#### 4.1 DEVELOPING AN ES

The ES is an output of the CSA that is typically developed using a risk assessment tool. ESIG members mainly used the Cefic CSA Tool (REF 12) for this purpose which allows a set of conditions to be identified for a specified use which ensure that exposure to the substance is safe and within the Derived No Effect Level (DNEL), i.e.

Key information is entered into the CSA tool on the substance (e.g. the DNEL and the volatility), the operational conditions (OC) (e.g. duration of use) and the normal risk management measures (RMM) for the use (e.g. degree of process enclosure, extract ventilation). Algorithms within the tool then calculate whether the risk characterisation ratio (RCR) is acceptable (<1). If not then the OCs and RMMs can be adjusted until an acceptable RCR is obtained. If acceptable conditions cannot be described in this way, the use will become 'not advised'. For example, it may not be possible to control exposure to an acceptable level using reasonable control measures in a professional setting for a volatile hazardous solvent such n-hexane for coating large surface areas in an enclosed space.

For some hazardous end points such as irritation, it may not be possible to derive a DNEL value. In this case, it is necessary to carry out a qualitative, rather than quantitative, assessment and determine appropriate exposure controls (Ref 24). Qualitative assessments have been carried out for the following health hazard end points for the relevant hydrocarbon and oxygenated solvents:

- Eye irritation
- Skin irritation and skin defatting
- Aspiration

The form an ES should take is not defined in the regulations but has been addressed in guidance (REF 13) and is likely to include the following information:

- Title: An overall description of the use
- Scope: Additional details about the tasks and activities covered
- Operational Conditions: Assumptions about key variables, e.g. the time and duration of exposure, the volatility, the operating temperature, etc.
- Risk Management Measures for specific activities/tasks: e.g. the need for extract ventilation or personal protective equipment
- Other information: e.g. further information to enable the DU to determine whether his current controls are aligned with the ES

An example of a supplier ES for a hydrocarbon solvent containing n-hexane (>5 - 80%) is given in Appendix 5.

As well as being a requirement under REACH, this information is clearly important, along with other information in the SDS, in reviewing/undertaking the workplace risk assessment required by CAD.

### 4.2 SOLVENTS' MANUFACTURERS MEET THE CHALLENGE OF DEVELOPING ES

The development of Exposure Scenarios represented a significant challenge for the solvents industry. Solvents manufacturers (represented by ESIG) are responsible for the supply of more than 1,000 different solvents that are used in many hundreds of applications. Developing individual ES to support this myriad of uses would have resulted in endless descriptions of different solvent/use combinations that would have created an enormous resource burden to manage effectively within the ambitious REACH deadlines. In addition it would inevitably have caused confusion for downstream customers if the advice differed between different suppliers of the same substance, as well as across similar solvents.

To meet this challenge, early in 2008 ESIG began developing the approach of Generic Exposure Scenarios (GES) in cooperation with representatives of their network of Downstream User trade associations, including AISE for Soaps & Detergents, CEPE for Paints & Coatings, FEA for Aerosols, FECC for Distribution and FEICA for Adhesives & Sealants. Downstream User trade associations act as a useful surrogate for individual companies within their sectors in defining uses of solvents and associated use conditions. GES are described in more detail in the next section.

# 5. THE SOLVENTS INDUSTRY APPROACH TO REACH

REACH presented some major challenges to the solvents industry and these were addressed via the wellestablished industry association groupings. ESIG is comprised of two (main) sub-groups, namely:

- HSPA the Hydrocarbon Solvents Producers Association.
- OSPA the Oxygenated Solvents Producers Association

Key amongst these challenges was the development of a new naming convention for hydrocarbon solvents and the development of Generic Exposure Scenarios for common solvent uses.

### 5.1 NAMING CONVENTION FOR HYDROCARBON SOLVENTS

REACH has a specific emphasis on substance identification which goes beyond the traditional substance descriptions provided in the European Inventory of Existing Commercial Substances (EINECS), in which each entry is associated with a unique Chemical Abstracts Service number (CAS number) and description. The CAS number is the unique identifier for chemicals and related substances, including petroleum derived materials, on a global basis.

EINECS and CAS numbers adequately describe broad cut hydrocarbons from standard refinery processes, but they are less useful when it comes to more narrow cuts and highly refined hydrocarbon solvents. Therefore HSPA has developed a naming convention that more precisely defines hydrocarbon solvents based on the chemical composition of the substance. These new substance definitions and a category approach for the toxicological assessments are the basis both for the registration as well as the classification and labelling of those substances.

Appendices 3 and 4 list the solvents registered under REACH by HSPA and OSPA respectively and include the following information:

- Solvent name
- REACH Registration Number/CAS Number
- CLP classification for Health Hazard only (physical and/or environmental hazard classifications may also apply but are not included)
- Basis for the classification Industry recommendation or EU Harmonised
- Volatility band

### 5.2 DEVELOPMENT OF GENERIC EXPOSURE SCENARIOS (GES).

A GES describes the typical operational conditions (OCs) and risk management measures (RMMs) which are required to control the risks to human health associated with the use (or uses) of a group of substances/ products with a similar risk profile within a general area of industry. A GES aggregates the safe use conditions for the various tasks, known as Contributing Scenarios (CS), that make up a typical activity involving the use of solvents. For example, if the solvent is used for printing, then the GES is likely to cover associated storage, transfer and maintenance activities as well as the printing operations themselves. GESs were developed by the European Solvents Industry Group (ESIG) in partnership with DU associations.

The value of the GES approach is recognised within ECHA's technical guidance and supported by the European Chemical Industry Council (Cefic) as an efficient and meaningful way of representing the vast majority of impacts of commodity substances such as solvents on workers, consumers and the environment. (See 'Developing Generic Exposure Scenarios under REACH', REF 14)

A key advantage of this kind of standardisation is that it supports a harmonized and simplified communication between suppliers and downstream users, leading to substantial savings of time, resources and costs along the value chain. Without this collaborative approach, each supplier would have had to create an ES for each solvent/ use combination and this in turn would have led to the provision of potentially conflicting/confusing advice to DU as well as massive duplication of effort. The ability to develop GESs was helped by the creation by ECHA of the Use Descriptor System (UDS) which aims to standardise the description of uses in the supply chain.

#### 5.2.1 The Use Descriptor System (UDS) (REF 15)

The UDS describes 'use' via a number of standardised codes. The most important of these from the perspective of managing the health risks of solvents are:

**Sector of use (SU):** describes the type of place where the substance is used. There are three SUs that represent the Main User Groups relevant for all applications, namely SU3: industrial, SU22: professional, and SU21: consumer. These represent the minimum information needed to describe the sector and also comprise the key Life Cycle Stages together with Manufacture and Formulation. As Solvents are widely used across all sectors it is not considered necessary to define further the types of places of use by the identification of specific Sectors of Use. It should also be noted that solvents are intended to evaporate following application so do not end up being present in articles. For this reason, the Life Cycle Stage of 'Service Life' is not generally applicable.

**Process Category (PROC):** describes the application techniques or process types, i.e. how the substance is used. The PROC, in combination with the OC's and RMM's, is the prime determinant for the level of occupational exposure. Examples relevant to solvent use include:

PROC2: Use in closed, continuous process, with occasional controlled exposure

PROC5: Use in batch or other process (synthesis) where opportunity for exposure arises

PROC8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities

PROC10: Roller application or brushing

**Product Category (PC):** describes the types of chemical products in which a substance is used. The PC in combination with the OC's and RMM's determines the level of consumer exposure. Examples relevant to solvents include:

PC9a: Coatings and paints, thinners, paint removers

PC24: Lubricants, greases, release products

PC31: Polishes and wax blends

PC35: Washing and Cleaning Products (including solvent based products)

The PC is also used to describe the Market Sector into which the substance is sold.

A full description of the UDS, including all the available codes, can be found on the ECHA website (REF 15).

#### 5.2.2 The ESIG GES Library

The basic approach adopted by ESIG in the development of GES involves the clustering of solvents by hazard and volatility according to the type of application, e.g. uses in coatings, cleaning agents, lubricants, fuels. For each application the typical operational conditions (OCs) and any risk management measures (RMMs) have been described for each Contributing Scenario (CS) and linked to a particular Process Category (PROC). This enables a consistent basis for input to the Chemical Safety Assessment (CSA), allowing DUs to identify their uses readily and judge the adequacy of their existing control measures. The GESs were reviewed and agreed by representatives of downstream user trade associations to ensure they were realistic.

ESIG CSAs utilise the Cefic CSA Tool (REF 12), incorporating the GES use mapping as described above, for conducting worker exposure risk assessments (see Section 4.1) which incorporates the ECETOC TRA exposure modelling approach. Exposure estimates based on the relevant PROC code and main user group (industrial or professional) are compared with an indicative DNEL for the substance representing a hazard band. If the Risk Characterisation Ratio (RCR) is <1, the CSR Tool provides a narrative ES in the form of a series of standard phrases, including any OCs and RMMs required for the safe use of the product, for uniform communication to DUs.

A library of GESs covering the typical solvents uses divided into low/moderate/high volatility and covering industrial and professional uses has been prepared. The GES titles are listed in Appendix 6 along with the associated end-use applications and examples of solvent types likely to be relevant for these applications. These titles cover more than 90% of the known solvent uses and have been made available on the ESIG website at <u>www.esig.org</u>

It should be noted that some other sectors of industry have also developed GESs for their sector that may include solvent applications. These GES should complement those available through ESIG.

Each GES title is also supported by a Specific Environmental Release Category (SpERC) for the associated environmental assessment. These GES (and supporting SpERCs) were made available in early 2010 in order for Consortia to apply them in the development of REACH substance Chemical Safety Assessments. (For further information on SpERCs see the ESIG website <u>www.esig.org</u> and the CEFIC SpERC Guidance (REF 16).

### **6. EXPOSURE LIMIT VALUES FOR SOLVENTS**

#### 6.1 OELs AND DNELs

In order to determine risk it is necessary to assess exposure versus a quantitative limit value. These take various forms including occupational exposure limits (OEL) established by regulatory processes or recommended by suppliers, and new Derived No-Effect Levels (DNEL) required by REACH. These are not identical in their derivation or interpretation, but they all have similar aims.

REACH requires manufacturers and importers to establish 'Derived No-Effect Levels' (DNELs) as part of their chemical safety assessment (CSA) for any chemical substances for which thresholds for safe exposure can be derived and which are used in quantities of 10 tonnes or more per year. DNELs are defined as the dose above which humans should not be exposed and separate DNELs apply to all routes of exposure (oral, dermal or inhalation) and all populations (workers, consumers and indirect human exposure via the environment, including certain sub-populations such as children or pregnant women). DNELs should be set out in the registrant's Chemical Safety Report and the supplier's ext-SDS should quote the DNELs as well as any relevant OEL. 'Adequate control' within REACH means exposure below a DNEL for humans. Under REACH for the first time there is a requirement to develop quantitative reference values to assess the risks of dermal exposure (the Dermal DNEL) as well as inhalation.

Occupational exposure limits (OELs) are reference levels for control of exposure to substances. An OEL is the level that describes 'adequate control of exposure by inhalation' and represents an airborne concentration at which it is unlikely that significant adverse health effects occur in the overwhelming majority of an exposed workforce. OELs are established by regulatory authorities using extensive scientific input. Indicative Occupational Exposure Limit Values (IOELVs) and Binding Occupational Exposure Limit Values (BOELVs) have been established by the EU under the Chemical Agents Directive (CAD) and adopted in Commission Directives. Member States are required to set national exposure limits that take account of these limits.

DNELs are derived for registered REACH substances and used to formulate recommendations to DUs on safe conditions of use that are then communicated in the ES included in the extended-SDS. Employers are expected to take account of these requirements in their CAD workplace risk assessments by following the recommendations in their supplier's ES for their specific use.

OELs have been set by some national authorities for some solvents. Where available these must also be taken account of in CAD workplace risk assessments. The CAD risk assessment should also take account of any other relevant information, including any supplier recommended OELs, the SDS and other technical guidance.

#### 6.2 INDUSTRY BASED OEL'S FOR HYDROCARBON SOLVENTS

In view of the lack of 'official' OELs for many hydrocarbon solvents, HSPA set up a project in the mid 1990's to make recommendations for a consistent and soundly based approach for how OELs for different hydrocarbon solvents might be derived. Because most hydrocarbon solvents have complex compositions and detailed toxicological information may only be available on a few of the constituents, the proposed solution was to group constituents with similar physical, chemical, and toxicological properties and to assign "guidance values" to each group. A unique OEL can then be calculated for each solvent, using a reciprocal calculation procedure (RCP) based on the liquid composition. This procedure follows the widely accepted methodology published by American Conference of Governmental Industrial Hygienists' (ACGIH, REF 17) and is endorsed by many national authorities (e.g. the U.K. Health and Safety Executive) for calculating OELs for complex mixtures (REF 18). The RCP is justified as the toxicological properties of the constituents are additive and the differences between the vapour and liquid compositions do not substantially affect the calculated exposure limits. The guidance values are based principally on acute central nervous system depression and eye and respiratory tract irritation, i.e. the effects that are the most sensitive indicators of hydrocarbon solvent exposure. This approach to assigning OELs to substances has been available for use by the major European solvent suppliers for the last twenty years as the basis for their hydrocarbon solvent OEL recommendations provided in SDS and other product literature. The methodology was summarised in a paper published in 2005 (REF 19).

Following the completion of the first phase of REACH registrations, it was decided that this methodology would be reviewed in the light of new data that has become available. Further information will be communicated when the results of this review are available.

### 7. RESPONSIBILITIES OF SOLVENT USERS

The new regulatory landscape results in a number of key duties for solvent users under CAD and REACH. These are given in Table 4. 'Users' in this context includes blenders, formulators, packagers and distributors as well as the final user of formulated products (e.g. adhesives, paints, etc.) which contain solvents.

The actions outlined in Table 4 are valid if the following assumptions are correct:

• The solvent you are using has already been registered under REACH.

- A CAD risk assessment has been undertaken for the activity (i.e. these are existing/ongoing operations categorised as industrial or professional use).
- You have informed your supplier of your 'use' (of the substance or mixture) or you have decided not to.
- You have received an SDS for the substance or mixture, which includes an ES. It should be noted that methodologies for developing safe use advice for mixtures under REACH are still being developed so a variety of approaches are currently possible. Further discussion on the development of ES for mixtures is provided in Appendix 7.
- If you are using a formulated product (mixture), for which the presence of the solvent is responsible for classification of the mixture. See Appendix 7 for additional discussion of the implications of REACH for suppliers of formulated products.

### TABLE 4: Key Actions for Solvent Users under REACH and CAD

	REACH ACTION	CAD ACTION	EXAMPLE
1	Check whether the new SDS/ES covers your use. If it does not, contact your supplier. He may be able to confirm that your uses in fact covered by the supplied ES due, for example, to differences in terminology or definition, or by an alternative ES.		The ES entitled 'Uses in Coatings' may cover use of a solvent containing varnish.
2	If the supplier/registrant confirms your use is not covered, your use is 'not supported'. If the registrant has shown that the use is 'unsafe' you should change to an alternative less hazardous solvent. If the registrant has not considered the use you may be able to find an alternative supplier who does support the use. Another approach, if you have evidence to show use of the current solvent is safe, is to prepare a downstream user Chemical Safety Assessment (CSA) and provide certain information to ECHA before commencing or continuing with the particular use (REF 7, Chapter 5)		Example of a use that would not be supported. Substitution of a lower volatility substance with a higher volatility alternative in an open coating application, e.g. applying floor carpet adhesive, where there is inadequate ventilation to control vapour release.

	REACH ACTION CAD ACTION		EXAMPLE
3		Following receipt of a new SDS from your supplier with an ES relevant to your use, you should review your CAD risk assessment and confirm that it is consistent with the new information.	The new SDS/ES recommends use of LEV, which you do not currently use. However, if you use the solvent in smaller quantities, at a lower concentration, or for a shorter duration than is specified in the ES, your use may still be safe.
4		Assess whether use of each hazardous solvent can be eliminated or substituted by a less hazardous alternative. (See Appendix 1 for the hierarchy of controls required by CAD.)	In the past chlorinated solvents were commonly used for degreasing activities. These have now largely been replaced by less hazardous hydrocarbon solvents.
5	Where use of a hazardous solvent is unavoidable, study the information on REACH risk management measures provided in your supplier's SDS and the associated ES for the solvent/use applicable to your situation. Under REACH Article 37 you must review the suppliers ES to determine whether it is consistent with your use and conditions of use. If not you should implement improved controls consistent with the ES.	Amend the CAD RA to reflect the improved controls, or demonstrate equivalent Scaling.	Example of improved controls. Local exhaust ventilation required at a filling station, when previously not specified.
6	Measures described in the ES are designed to meet the DNEL derived via the REACH process.	Additional exposure assessment such as air monitoring to determine whether exposure of workers to solvent vapour is within relevant national or supplier recommended OELs may be required to demonstrate that the controls required by the CAD risk assessment are adequate and to reassure those working with solvents.	This is especially important when higher volatility solvents are used in situations where control 'at source' is not practicable, e.g. when applying a solvent based coating to a large surface area. See Guide 2 in this series (REF 20) for additional information on measuring solvent vapour concentrations.

	REACH ACTION	CAD ACTION	EXAMPLE
7	If you have good evidence that the existing controls derived under CAD are adequate you must take one of Steps 8 or 9 below.	Remember the hierarchy of controls required by CAD is unlikely to allow long term use of RPE.	To control exposure to solvent X to below the UK OEL of Y, a painter spraying hanging objects moving past him is required to use a respirator for in excess of 4 hours per day without adequate breaks. This is not acceptable under CAD. The ES is likely to recommend a ventilated spray booth to control exposure.
8	Check the suppliers ES again to ensure that it is directly applicable to your use. For example, it is possible that adjustments can be made (e.g. due to smaller quantities of solvent, shorter exposure duration, etc.) by the application of scaling (see NOTE 1 below).		Local exhaust ventilation is indicated as being required to control vapours from a filling operation. This control is relevant for the substance at 100%. However, the filling operation in this case is for a formulation that only contains the solvent at 1%. If the supplier's assessment has been carried out using the ECETOC TRA modelling tool, it is possible to scale the exposure. In this example the solvent concentration at 1% equates to a control efficiency of 90%, which is equivalent to the efficiency of the local exhaust ventilation, so is a suitable alternative means of control.
9	If the supplier/registrant has confirmed that the ES he provided is applicable to your use (see Step 1) and adjustments are not possible via scaling (see Step 8), in order to continue using the solvent you should prepare a downstream user's Chemical Safety Assessment (CSA). The ESIG GES library is likely to be a useful resource to assist you with this task (see Section 5.4)		

### NOTE 1:

In practice, conditions of use at downstream user sites are likely to differ in some way from those specified in the exposure scenario yet the risk may still be adequately controlled. It may be possible to demonstrate this by compensating for a variation in one particular condition by a variation in other conditions. This process is called scaling. For additional information see the ECHA Guidance for Downstream users (REF 7) or the ECHA Practical Guide 13 How downstream users can handle exposure scenarios (REF 22). However it should be noted that ECHA guidance is still under development in this area.

### 8. ROLE OF SOLVENT VAPOUR MONITORING

Solvent vapour monitoring is required to confirm that workplace exposures are within appropriate limit values and is especially important when higher volatility solvents are used in situations where control 'at source' is not practicable, e.g. when applying a solvent based coating to a large surface area. Results of solvent vapour monitoring are essential to confirm that the controls in place are effective and to reassure those working with the solvents. They are also an essential input to the CAD workplace risk assessment.

Additional information on solvent vapour monitoring will be given in a further guide in this series entitled:

Guide 2: Strategies and Techniques for Measuring Solvent Vapour Concentrations in the Work Environment (REF 20).

### 9. KEY MESSAGES

- 1 REACH will improve worker health and safety by providing better information on substances, by establishing new channels of communication between employers and suppliers and by removing substances of very high concern from the market.
- 2 Although REACH is a new system, and a new way of thinking, the requirements of CAD still apply. If new or additional information is provided by REACH, the CAD based workplace risk assessment must be reviewed and may require revision.
- 3 For solvents classified as hazardous, registrants are likely to have prepared exposure scenarios for all uses they support as part of their REACH registration and will communicate safe use conditions via an ES Annex to the SDS.
- 4 An ES describes the conditions under which the risk is considered to be controlled for a specified use (or uses) and includes the necessary risk management measures and operational conditions over and above standard good practice measures.
- 5 Employers must implement the controls recommended in the ES or demonstrate that equivalent measures are in place. It is important to ensure adequate control of exposure via skin or eye contact as well as inhalation of vapour. The hierarchy of controls specified in CAD should be followed in general PPE should not be used as the primary control.
- 6 Solvents which are considered by the supplier to represent an unacceptable risk and therefore not suitable for certain uses will be listed as 'Uses advised against' in Section 1.2 of their SDS. If you wish to continue to use the solvent for a 'not advised' use and if there is no alternative supplier, you can undertake a DU CSA and notify ECHA. As long as you can define an ES that demonstrates that safe conditions of use can be achieved, you can continue to use the solvent.
- 7 A library of GES which are estimated to cover at least 90% of solvent uses is available via the ESIG website. This is a useful resource for downstream users who wish to conduct their own CSA for reasons of confidentiality, or if suppliers have not registered their use.
- 8 An assessment of solvent vapour exposures should be undertaken periodically to determine that the control measures are working correctly and solvent vapour levels are within the recommended limit values. This may require solvent vapour measurements, the results of which should be recorded and retained.

- 9 Any relevant limit values established by national regulations or recommended by your supplier should be taken into account when undertaking your CAD workplace risk assessment. If any unacceptable or unexpected results are obtained, conduct an investigation immediately to determine the reason and, if necessary, take appropriate action to improve controls. Record and retain the results of such investigations.
- 10 If any adverse effects are reported by the workforce (such as eye or respiratory tract irritation, headaches or other symptoms described in the SDS for the product) an immediate investigation should be undertaken (which may involve solvent vapour monitoring) to determine whether appropriate controls are still in place and being used effectively.

ACGIH	American Conference of Governmental Industrial Hygienists
AISE	International Association for Soaps, Detergents and Maintenance Products
BOELV	Binding Occupational Exposure Limit Values
CAD	Chemical Agents Directive
CAS	Chemical Abstract Service
CS	Contributing Scenario
CEFIC	European Chemical Industry Council
CEPE	European Council of the Paint, Printing Ink and Artists' Colours Industry
CLP	Classification, Labelling and Packaging Directive
сознн	Control of Substances Hazardous to Health
CSA	Chemical safety assessment
DNEL	Derived No Effect Level
DPD	Directive 1999/45/EC (Dangerous Preparations Directive)
DSD	Directive 67/548/EEC (Dangerous Substances Directive)
DU	Downstream user
ECETOC	European Centre for Ecotoxicology and Toxicology of Chemicals
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ES	Exposure Scenario
ESIG	European Solvents Industry Group
EU	European Union
FEA	European Aerosol Federation
FECC	European Association of Chemical Distributors
FEICA	Federation of European Adhesives Manufacturers
	l.

## **10. LIST OF ACRONYMS**

GES	Generic Exposure Scenario
GHS	Globally Harmonised System of classification and labelling of chemicals
HSPA	Hydrocarbon Solvents Producers Association
IOELV	Indicative Occupational Exposure Limit Values
LEV	Local exhaust ventilation
M/I	Manufacturer/Importer
ос	Operational Condition
OEL	Occupational Exposure Limit
OSPA	Oxygenated Solvents Producers Association
РВТ	Persistent, Bioaccumulative, Toxic
PC	Product Category
PPE	Personal Protective Equipment
PROC	Process category
RA	Risk assessment
RCP	Reciprocal calculation procedure
RCR	Risk characterisation ratio
REACH	Registration, evaluation, authorisation and restriction of chemicals
RMM	Risk Management Measure
SU	Sector of Use
SDS	Safety Data Sheet
Ext-SDS	Extended SDS
SMEs	Small or Medium sized enterprises
SpERC	Specific Environmental Release Category
TRA	Task Risk Assessment
UDS	Use Descriptor System
UN	United Nations
VCI	Verband der Chemischen Industrie (German Chemical Industry Association)
voc	Volatile Organic Compound
vPvB	very Persistent, very Bioaccumulative

*NOTE:* An explanation of many of the REACH related terms listed above can be found in a Glossary on the UK health and Safety executive website: <u>http://www.hse.gov.uk/reach/definitions.htm</u>

### **11. REFERENCES**

- 1 Flammability: A safety guide for users. Safe working with industrial solvents. ESIG Best Practice Guidelines n°4, version 3, June 2013.
- 2 Council Directive 1999/13/EC of 11 March 1999 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain activities and installations.
- 3 European Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).
- 4 European Regulation (EC) No 1272/2008 on the Classification, Labelling and Packaging of Substances and Mixtures.
- 5 EU Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.
- 6 EU Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work.
- 7 Guidance for downstream users (Version 2.1, October 2014), ECHA.
- 8 Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Second revised edition, United Nations New York and Geneva, 2007.
- 9 EU Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.
- 10 Managing skin exposure risks at work, UK HSE, 2009.
- 11 Annex VI to European Regulation (EC) No 1272/2008 on the Classification, Labelling and Packaging of Substances and Mixtures.
- 12 Worker Chemical Safety Assessment (CSA) Template (Generic Exposure Scenarios Liquids) Version 3, March 2013, CEFIC.
- 13 Guidance on information requirements and chemical safety assessment. Part D: Exposure Scenario Building. ECHA, October 2012.
- 14 Developing Generic Exposure Scenarios (GES) under REACH, Cefic, July 2009.
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- 17 Guide to Occupational Exposure Values, ACGIH, 2015.
- 18 EH40/2005: Workplace exposure Limits, HSE, 2011 (second edition).

- 19 McKee RH, Medeiros AM, Daughtrey WC. (2005) A proposed methodology for setting occupational exposure limits for hydrocarbon solvents. J Occup Environ Hyg; 2: 524–42.
- 20 Strategies and Techniques for Measuring Solvent Vapour Concentrations in the Work Environment, ESIG Best Practice Guide (in preparation).
- 21 Methodology for the identification of substances that represent the dominant risks to human health and/or the environment and the drivers for risk management measures. June 2009, CEFIC.
- 22 How downstream users can handle exposure scenarios, ECHA Practical Guide 13, Version 1.
- 23 ECHA Guidance on the Compilation of Safety Data Sheets, Version 2.1, February 2014.
- 24 ECHA Practical Guide 15 : How to undertake a qualitative human health assessment and document it in a CSA.

## APPENDIX 1: OVERVIEW OF CONTROL APPROACHES FOR SOLVENTS/REQUIRED BY CAD

In general the following hierarchy (which is incorporated in and required by CAD) should be applied when a risk assessment indicates that controls are required for use of a hazardous solvent:

- Use an alternative solvent with a reduced hazard or lower volatility. However, care should be taken in the choice of an alternative solvent to ensure that the substitute does not introduce new and/or greater overall health, safety or environmental risks (e.g. PBT or vPvB issues, increased flammability hazard).
- Modify the process to reduce exposure, e.g. lower the operating temperature to reduce vapour generation, increase automation to eliminate or minimise the need for manual tasks which could give rise to skin contact, reduce the amount of solvent used, etc.
- Use appropriate equipment design and operation to minimise vapour release, solvent handling and solvent spillage (to reduce the possibility of skin or eye contact), e.g. by enclosure, automation, etc.
- Remove solvent vapours by either local extract or general ventilation to a safe point away from occupied working areas.
- Set a limit on the time for which workers can conduct certain tasks to limit the exposure potential.
- Keep the number of people exposed to solvent vapours to a minimum by restricting access to the vicinity of the activity.
- Where risks cannot be controlled by other means (such as for occasional maintenance and cleaning tasks) control exposure by the use of appropriately selected personal protective equipment (PPE), such as gloves and respirators.
- Where it is necessary to use gloves to control exposure to solvents, this should be backed up by an appropriate skin care programme. See Box below:
- Health surveillance to check for early signs of disease. This can be as simple as routine skin checks by a responsible person to identify early signs of dermatitis.

#### Examples of Good Skin Care practice

- Accidental contamination should be washed away promptly.
- At breaks and after work, employees should wash areas of skin that may have been exposed to hazardous substances. They should wash the skin with warm water and dry thoroughly.
- Provision of clean washing facilities as near as possible to the area of work.
- Provision of the least aggressive cleaning products that will do the job and never allow solvents or very abrasive products to be used for skin cleaning.
- Pre-work creams can be applied before starting work or on returning from a break.
- After-work creams should be used to replace the natural oils that the skin can lose when washed or when it comes into contact with detergents, solvents, etc.

### **APPENDIX 2: CLP CLASSIFICATION PHRASES FOR SOLVENTS**

The table below gives the CLP based classification Hazard 'H' phrases that may be relevant to hydrocarbon and oxygenated solvents for health effects. There are numerous additional phrases that are unlikely to apply to solvents. Where relevant, only a small number of the phrases below will apply to any specific solvent.

#### CLP CLASSIFICATION

H301	Toxic if swallowed
H302	Harmful if swallowed
H304	May be fatal if swallowed and enters airways
H311	Toxic in contact with skin
H312	Harmful in contact with skin
H315	Causes skin irritation
H318	Causes serious eye damage
H319	Causes serious eye irritation
H331	Toxic if inhaled
H332	Harmful if inhaled
H335	May cause respiratory irritation
H336	May cause drowsiness or dizziness
H351	Suspected of causing cancer
H361	Suspected of damaging fertility or the unborn child
H373	May cause damage to organs through prolonged or repeated exposure
EUH066	Repeated exposure may cause skin dryness or cracking

# APPENDIX 3: HYDROCARBON SOLVENTS REGISTERED UNDER REACH – KEY DATA

This list is for information. Please see the latest available information from ECHA Reach dissemination portal

Substance Name	REACH Registration Number	EU-CLP Classification - Health Hazard only (See Appendix 2 for H phrase descriptions)	Basis for Classification (Note 1)	Volatility Band ECETOC TRA Vapour Pressure Bands (VP at 20 deg C (kPa): High: >10 Medium: >0.5 - 10 Low: <= 0.5 Negligible: <0.00001
CATEGORY 1: C9	AROMATICS			
Hydrocarbons, C9, aromatics	01-211 9455851-35	Aspiration Tox 1 (H304) STOT SE 3 (H335 + H336)) [EUH066 skin defatting statement]	Industry recommendation	Low
CATEGORY 2: C1	0-C12 AROMATICS			
Hydrocarbons, C10, aromatics, >1% naphthalene	01-2119463588-24	Aspiration Tox 1 (H304) STOT SE 3 (H336) Carcinogenicity Cat 2 (H351) [EUH066 skin defatting statement]	Industry recommendation	Low
Hydrocarbons, C10, aromatics, <1% naphthalene	01-2119463583-34	Aspiration Cat 1 (H304) STOT SE 3 (H336) [EUH066 skin defatting statement]	Industry recommendation	Low
Hydrocarbons, C10, aromatics, <1% naphthalene	01-2119463583-34	Aspiration Cat 1 (H304) STOT SE 3 (H336) [EUH066 skin defatting statement]	Industry recommendation	Low
Hydrocarbons, C10-C13, aromatics, >1% naphthalene	01-2119451151-53	Aspiration Tox 1 (H304) Carcinogenicity Cat 2 (H351) [EUH066 skin defatting statement]	Industry recommendation	Low

Substance Name	REACH Registration Number	EU-CLP Classification - Health Hazard only (See Appendix 2 for H phrase descriptions)	Basis for Classification (Note 1)	Volatility Band ECETOC TRA Vapour Pressure Bands (VP at 20 deg C (kPa): High: >10 Medium: >0.5 - 10 Low: <= 0.5 Negligible: <0.00001
CATEGORY 3: C9	-C14 ALIPHATICS (2	-25% Aromatics)		
Hydrocarbons, C8-12, n-alkanes, isoalkanes, cyclics, aromatics (2-25%)	Not registered	Aspiration Tox 1 (H304) STOT SE 3 (H336) [EUH066 skin defatting statement]		Low
Hydrocarbons, C9-C10, n-alkanes, isoalkanes, cyclics, aromatics (2-25%)	Not registered	Aspiration Tox 1 (H304) STOT SE 3 (H336) STOT RE 1 (H372) [EUH066 skin defatting statement]	Industry recommendation	Low
Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, aromatics (2-25%)	01-2119473977-17	Aspiration Tox 1 (H304) STOT RE 1 (H372) [EUH066 skin defatting statement]	Industry recommendation	Low
Hydrocarbons, C9-C12, n-alkanes, isoalkanes, cyclics, aromatics (2-25%)	01-2119458049-33	Aspiration Tox 1 (H304) STOT SE 3 (H336) STOT RE 1 (H372) [EUH066 skin defatting statement]	Industry recommendation	Low
Hydrocarbons, C11-C14, n-alkanes, isoalkanes, cyclics, aromatics (2-25%)	01-2119458869-15	Aspiration Tox 1 (H304) [EUH066 skin defatting statement]	Industry recommendation	Low
CATEGORY 4: C1	4-C20 ALIPHATICS (	2-30% Aromatics)		
Hydrocarbons, C14-C18, n-alkanes, isoalkanes, cyclics, aromatics (2-30 %)	01-2119448343-41	Aspiration Tox 1 (H304) [EUH066 skin defatting statement]	Industry recommendation	Low
Hydrocarbons, C16-C20, n-alkanes, isoalkanes, cyclics, aromatics (2-30 %)	01-2119455996-19	Aspiration Tox 1 (H304) [EUH066 skin defatting statement]	Industry recommendation	Low

Substance Name	REACH Registration Number	EU-CLP Classification - Health Hazard only (See Appendix 2 for H phrase descriptions)	Basis for Classification (Note 1)	Volatility Band ECETOC TRA Vapour Pressure Bands (VP at 20 deg C (kPa): High: >10 Medium: >0.5 - 10 Low: <= 0.5 Negligible: <0.00001				
CATEGORY 5: C5 Aliphatics								
Normal-Pentane	Normal-Pentane 01-2119459286-30		Harmonised	High				
lso-Pentane	01-2119475602-38	Aspiration Tox 1 (H304) STOT SE 3 (H336) [EUH066 skin defatting statement]	Harmonised	High				
Cyclopentane	01-2119463053-47	Aspiration Tox 1 (H304) STOT SE 3 (H336) [EUH066 skin defatting statement]	Industry recommendation	High				
Hydrocarbons, C5, n-alkanes, isoalkanes	01-2119464207-37	Aspiration Tox 1 (H304) STOT SE 3 (H336) [EUH066 skin defatting statement]	Industry recommendation	High				
CATEGORY 6: C	5 Aliphatics							
Hydrocarbons, C5-C7, n-alkanes, isoalkanes, n-hexane rich	01-2119497828-14	Aspiration Tox 1 (H304) Skin Irritation 2 (H315) STOT SE 3 (H336) STOT RE 2 (H373) Reproductive Tox Cat 2 (H361f)	Industry recommendation	High				
Hydrocarbons, C5-C7, n-alkanes, n-hexane rich	Not registered	Aspiration Tox 1 (H304) Skin Irritation 2 (H315) STOT SE 3 (H336) STOT RE 2 (H373) Reproductive Tox Cat 2 (H361f)	Industry recommendation	High				
Hydrocarbons, C6, n-alkanes, isoalkanes, cyclics, n-hexane rich	01-2119474209-33	Aspiration Tox 1 (H304) Skin Irritation 2 (H315) STOT SE 3 (narcosis) (H336) STOT RE 2 (H373) Reproductive Tox Cat 2 (H361f)	Industry recommendation	High				

Substance Name	REACH Registration Number	EU-CLP Classification - Health Hazard only (See Appendix 2 for H phrase descriptions)	Basis for Classification (Note 1)	Volatility Band ECETOC TRA Vapour Pressure Bands (VP at 20 deg C (kPa): High: >10 Medium: >0.5 - 10 Low: <= 0.5 Negligible: <0.00001
n-hexane	01-2119480412-44	Aspiration Tox 1 (H304) Skin Irritation 2 (H315) STOT SE 3 (H336) STOT RE 2 (H373) Reproductive Tox Cat 2 (H361f)	Harmonised	High
Hydrocarbons, C6, isoalkanes, <5% n-hexane	01-2119484651-34	Aspiration Tox 1 (H304), Skin Irritation 2 (H315) STOT SE 3 (H336)	Industry recommendation	High
Hydrocarbons, C6-C7, isoalkanes, cyclics, <5% n-hexane	01-2119486291-36	Aspiration Tox 1 (H304) STOT SE Cat 3 (H336) [EUH066 skin defatting statement]	Industry recommendation	High
CATEGORY 7: C7	-C9 Aliphatics			
Hydrocarbons, C6-C7, n-alkanes, isoalkanes, cyclics, >5% n-hexane	01-2119472127-39	Aspiration Tox 1 (H304) Skin Irritation 2 (H315)) STOT SE 3 (H336) STOT RE 2 (H373) Reproductive Tox Cat 2 (H361f)	Industry recommendation	High
Hydrocarbons, C6-C7, n-alkanes, isoalkanes, cyclics, <5% n-hexane	01-2119475514-35	Aspiration Tox 1 (H304); Skin Irrititation 2 (H315) STOT SE 3 (H336)	Industry recommendation	Medium
Hydrocarbons, C6-C10, n-alkanes, isoalkanes, >5% n-hexane	To be registered	Aspiration Cat 1 (H304) Skin IrritationCat 2 (H315) STOT SE Cat 3 (H336) STOT RE Cat 2 (H373) Reproductive Tox Cat 2 (H361f)	Industry recommendation	
Hydrocarbons, C7, n-alkanes, isoalkanes, cyclics	01-2119475515-33	Aspiration Tox 1 (H304) Skin Irritation 2 (H315) STOT SE 3 (H336)	Industry recommendation	Medium

Substance Name	REACH Registration Number	EU-CLP Classification - Health Hazard only (See Appendix 2 for H phrase descriptions)	Basis for Classification (Note 1)	Volatility Band ECETOC TRA Vapour Pressure Bands (VP at 20 deg C (kPa): High: >10 Medium: >0.5 - 10 Low: <= 0.5 Negligible: <0.00001
Hydrocarbons, C7-C9, n-alkanes, isoalkanes, cyclics	01-2119473851-33	Aspiration Tox 1 (H304) STOT SE 3 (H336) [EUH066 skin defatting statement]	Industry recommendation	Medium
Hydrocarbons, C7- C8, n-alkanes, <2% aromatics	To be registered			
Hydrocarbons, C7-C8, cyclics	01-2119486992-20	Aspiration Cat 1 (H304) STOT SE 3 (H336)	Industry recommendation	Medium
Hydrocarbons, C7-C9, isoalkanes	01-2119471305-42	Aspiration Tox 1 (H304) Skin Irritation 2 (H315) STOT SE 3 (H336)	Industry recommendation	Medium
Heptane	01-2119457603-38	Aspiration Tox 1 (H304) Skin Irrititation 2 (H315) STOT SE 3 H336 (H336)	Harmonised	Medium
Iso-Heptane	01-2119457601-42	Aspiration Tox 1 (H304) Skin Irrititation 2 (H315) STOT SE 3 (H336)	Harmonised	Medium
Octane	01-2119463939-19	AspirationTox 1 (H304) Skin Irritation 2 (H315) STOT SE 3 (H336)	Harmonised	Medium
2,2,4- trimethylpentane (Iso-Octane)	01-2119457965-22	AspirationTox 1 (H304) Skin Irritation 2 (H315) STOT SE 3 (H336)	Harmonised	Medium
Nonane	01-2119463259-31	Aspiration Tox 1 (H304) Skin Irritation 2 (H315) STOT SE 3 (H336)	Industry recommendation	Medium

Substance Name	REACH Registration Number	EU-CLP Classification - Health Hazard only (See Appendix 2 for H phrase descriptions)	Basis for Classification (Note 1)	Volatility Band ECETOC TRA Vapour Pressure Bands (VP at 20 deg C (kPa): High: >10 Medium: >0.5 - 10 Low: <= 0.5 Negligible: <0.00001				
CATEGORY 8: C9-C14 Aliphatics < 2% Aromatics								
Hydrocarbons, C9-C11, n-alkanes, isoalkanes, cyclics, <2% aromatics	01-2119463258-33	Aspiration Tox 1 (H304) STOT SE 3 (H336) [EUH066 skin defatting statement]	Industry recommendation	Low				
Hydrocarbons, C9-C10, n-alkanes, isoalkanes, cyclics, <2% aromatics	01-2119471843-32	Aspiration Tox 1 (H304) STOT SE 3 (H336) [EUH066 skin defatting statement]	Industry recommendation	Low				
Hydrocarbons, C9-C11, isoalkanes, cyclics, <2% aromatics	01-2119480153-44	Aspiration Tox 1 (H304) STOT SE 3 (H336) [EUH066 skin defatting statement]	Industry recommendation	Low				
Hydrocarbons, C9-C11, n-alkanes, <2% aromatics	To be registered							
Hydrocarbons, C9-C11, cyclics, <2% aromatics	01-2119472436-34	Aspiration Tox 1 (H304) Skin Irritation 2 (H315) STOT SE 3 (H336)	Industry recommendation	Low				
Decane	01-2119474199-26	Aspiration Tox 1 (H304) [EUH066 skin defatting statement]	Industry recommendation	Low				
Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, <2% aromatics	01-2119457273-39	Aspiration Tox 1 (H304) [EUH066 skin defatting statement]	Industry recommendation	Low				
Hydrocarbons, C10-C13, isoalkanes, cyclics, <2% aromatics	01-2119474196-32	Aspiration Tox 1 (H304) [EUH066 skin defatting statement]	Industry recommendation	Low				
Hydrocarbons, C10-C12, isoalkanes, <2% aromatics	01-2119471991-29	Aspiration Tox 1 (H304) [EUH066 skin defatting statement]	Industry recommendation	Low				

Substance Name	REACH Registration Number	EU-CLP Classification - Health Hazard only (See Appendix 2 for H phrase descriptions)	Basis for Classification (Note 1)	Volatility Band ECETOC TRA Vapour Pressure Bands (VP at 20 deg C (kPa): High: >10 Medium: >0.5 - 10 Low: <= 0.5 Negligible: <0.00001
Hydrocarbons, C10-C13, n-alkanes, < 2% aromatics	01-2119475608-26	Aspiration Tox 1 (H304) [EUH066 skin defatting statement]	Industry recommendation	Low
Hydrocarbons, C10-C14, n-alkanes, isoalkanes, < 2% aromatics	01-2119458951-30	Aspiration Tox 1 (H304) [EUH066 skin defatting statement]	Industry recommendation	Low
Hydrocarbons, C10-C14, n-alkanes, <2% aromatics	Not registered	Aspiration Tox 1 (H304) [EUH066 skin defatting statement]	Industry recommendation	Low
Undecane	01-2119486569-17	Aspiration Tox 1 (H304) [EUH066 skin defatting statement]	Industry recommendation	Low
Hydrocarbons, C11-C12, isoalkanes, <2% aromatics	01-2119472146-39	Aspiration Tox 1 (H304) [EUH066 skin defatting statement]	Industry recommendation	Low
Hydrocarbons, C11-C13, n-alkanes, <2% aromatics	To be registered			
Hydrocarbons, C11-C13, isoalkanes, <2% aromatics	01-2119456810-40	Aspiration Tox 1 (H304) [EUH066 skin defatting statement]	Industry recommendation	Low
Hydrocarbons, C11-C14, n-alkanes, isoalkanes, cyclics, <2% aromatics	01-2119456620-43	Aspiration Tox 1 (H304) [EUH066 skin defatting statement]	Industry recommendation	Low
Hydrocarbons, C11-C14, isoalkanes, cyclics, <2% aromatics	01-2119480162-45	Aspiration Tox 1 (H304) [EUH066 skin defatting statement]	Industry recommendation	Low
Hydrocarbons, C11-C14, n-alkanes, < 2% aromatics	01-2119485647-22	Aspiration Tox 1 (H304) [EUH066 skin defatting statement]	Industry recommendation	Low

Substance Name	REACH Registration Number	EU-CLP Classification - Health Hazard only (See Appendix 2 for H phrase descriptions)	Basis for Classification (Note 1)	Volatility Band ECETOC TRA Vapour Pressure Bands (VP at 20 deg C (kPa): High: >10 Medium: >0.5 - 10 Low: <= 0.5 Negligible: <0.00001
Dodecane	01-2119486573-28	Aspiration Tox 1 (H304) [EUH066 skin defatting statement]	Industry recommendation	Low
Hydrocarbons, C4, 1,3-butadiene- free, polymd., triisobutylene fraction, hydrogenated [New name: 2,2,4,6,6- pentamethylheptane	01-2119490725-29	Aspiration Tox 1 (H304) [EUH066 skin defatting statement]	Industry recommendation	Low
Hydrocarbons, C12-C15, n-alkanes, isoalkanes, cyclics, < 2% aromatics	Not registered	Aspiration Tox 1 (H304) [EUH066 skin defatting statement]	Industry recommendation	Low
Hydrocarbons, C12-C16, isoalkanes, cyclics, <2% aromatics	01-2119456372-30	Aspiration Tox 1 (H304) [EUH066 skin defatting statement]	Industry recommendation	Low
Tridecane	01-2119487446-26	Aspiration Tox 1 (H304) [EUH066 skin defatting statement]	Industry recommendation	Low
Hydrocarbons, C13-C15, n-alkanes, isoalkanes, cyclics, <2% aromatics	01-2119458943-27	Aspiration Tox 1 (H304) [EUH066 skin defatting statement]	Industry recommendation	Low
Tetradecane	01-2119485515-31	Aspiration Tox 1 (H304) [EUH066 skin defatting statement]	Industry recommendation	Low

Substance Name	REACH Registration Number	EU-CLP Classification - Health Hazard only (See Appendix 2 for H phrase descriptions)	Basis for Classification (Note 1)	Volatility Band ECETOC TRA Vapour Pressure Bands (VP at 20 deg C (kPa): High: >10 Medium: >0.5 - 10 Low: <= 0.5 Negligible: <0.00001				
CATEGORY 9: C14-C20 Aliphatics < 2% Aromatics								
Hydrocarbons, C13-C16, n-alkanes, isoalkanes, cyclics, <2% aromatics	To be registered	Aspiration Tox 1 (H304) [EUH066 skin defatting statement]	Industry recommendation	Low				
Hydrocarbons, C13-C16, isoalkanes, cyclics, <2% aromatics	01-2119458871-30	Aspiration Tox 1 (H304) [EUH066 skin defatting statement]	Industry recommendation	Low				
Hydrocarbons, C13-C18, n-alkanes, isoalkanes, cyclics, <2% aromatics	01-2119496246-29	Aspiration Tox 1 (H304) [EUH066 skin defatting statement]	Industry recommendation	Low				
Hydrocarbons, C14-C17, n-alkanes, < 2% aromatics	01-2119487513-33	Aspiration Tox 1 (H304) [EUH066 skin defatting statement]	Industry recommendation	Low				
Hydrocarbons, C14-C18, n-alkanes, isoalkanes, cyclics, <2% aromatics	01-2119457736-27	Aspiration Tox 1 (H304) [EUH066 skin defatting statement]	Industry recommendation	Low				
Hydrocarbons, C14-C19, isoalkanes, cyclics, <2% aromatics	01-2119459347-30	Aspiration Tox 1 (H304) [EUH066 skin defatting statement]	Industry recommendation	Low				
Hydrocarbons, C14-C20, n-alkanes, isoalkanes, <2% aromatics	Not registered	Aspiration Tox 1 (H304) [EUH066 skin defatting statement]	Industry recommendation	Low				
Hydrocarbons, C14-C20, n-alkanes, < 2% aromatics	01-2119485174-35	Aspiration Tox 1 (H304) [EUH066 skin defatting statement]	Industry recommendation	Low				
Pentadecane	01-2119977102-41	Aspiration Tox 1 (H304) [EUH066 skin defatting statement]	Industry recommendation	Low				
Hexadecane	01-2119936836-25	Aspiration Tox 1 (H304) [EUH066 skin defatting statement]	Industry recommendation	Low				

Substance Name	REACH Registration Number	EU-CLP Classification - Health Hazard only (See Appendix 2 for H phrase descriptions)	Basis for Classification (Note 1)	Volatility Band ECETOC TRA Vapour Pressure Bands (VP at 20 deg C (kPa): High: >10 Medium: >0.5 - 10 Low: <= 0.5 Negligible: <0.00001
Hydrocarbons, C4, 1,3-butadiene- free, polymdl, tetraisobutylene fraction, hydrogenated (New name: 2,2,4,4,6,8,8- heptamethylinonane)	01-219486102-45	Aspiration Tox 1 (H304) Acute Tox Inhalation 4 (H332) [EUH066 skin defatting statement]	Industry recommendation	Low
Hydrocarbons, C16-C20, n-alkanes, isoalkanes, cyclics, <2% aromatics	01-2119457735-29	Aspiration Tox 1 (H304) [EUH066 skin defatting statement]	Industry recommendation	Low
n-Heptadecane	To be registered	Aspiration Tox 1 (H304) [EUH066 skin defatting statement]	Industry recommendation	Low
Octadecane	01-2119936912-33	Aspiration Tox 1 (H304) [EUH066 skin defatting statement]	Industry recommendation	Low
lcosane (Eicosane)	01-2119938337-31	Aspiration Tox 1 (H304) [EUH066 skin defatting statement]	Industry recommendation	Low
Isoeicosane (Hydrocarbons, C4, 1,3- butadiene-free, polymd., pentaisobutylene fraction, hydrogenated) Eicosane, branched	01-2119987314-30	Aspiration Tox 1 (H304) [EUH066 skin defatting statement]	Industry recommendation	Low

### NOTE 1:

Harmonised values are from Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation).

# APPENDIX 4: OXYGENATED SOLVENTS REGISTERED UNDER REACH - KEY DATA

This list is for information. Please see the latest available information from ECHA Reach dissemination portal

Substances	CAS Number	REACH Registration Number	CLP classification - Health Hazard only (See Appendix 2 for H phrase descriptions)	Basis for Classification (Note 1)	Volatility Band ECETOC TRA Vapour Pressure Bands (VP at 20 deg C (kPa): High: >10 Medium: >0.5 - 10 Low: <= 0.5 Negligible: <0.00001
OSPA SOL	/ENTS				
KETONES					
4-methylpentan- 2-one (MIBK)	108-10-1	01- 2119473980-30	Eye Irrit. 2 (H319); Acute Tox. 4 (H332); STOT SE 3 (H336)	Harmonised	Medium
Butanone, Ethyl Methyl Ketone (MEK)	78-93-3	01- 2119457290-43	Eye Irrit. 2 (H319); STOT SE 3 (H336)	Harmonised	High
Methyl Amyl Ketone	110-43-0	01- 2119902391-49	Acute Tox. 4 (H302, H332); STOT SE 3 (H336)	Industry Recommendation	Low
acetone	67-64-1	01- 2119471330-49	Eye Irrit. 2 (H319); STOT SE 3 (H336)	Harmonised	High
ALCOHOLS					
Isopropyl Alcohol (IPA)	67-63-0	01- 2119457558-25	Eye Irrit. 2 (H319); STOT SE 3 (H336)	Harmonised	Medium
n-butanol (n-BuOH)	71-36-3	01- 2119484630-38	Skin Irrit. 2 (H315); Eye Dam. 1 (H318); Acute Tox. 4 (H302); STOT SE 3 (H335, H336)	Harmonised	Medium
Butan-2-ol (SBA)	78-92-2	01- 2119475146-36	Skin Irrit. 2 (H315); Eye Dam. 1 (H318); STOT SE 3 (H335, H336)	Harmonised	Medium
n-Propanol (n-ProH)	71-23-8	01- 2119486761-29	Eye Irrit. 1 (H318); STOT SE 3 (H336)	Harmonised	Medium
Phenoxyiso- propanol (PPh)	770-35-4	01- 2119486566-23	Eye Irrit. 2 (H319)	Industry Recommendation	Low

Substances	CAS Number	REACH Registration Number	CLP classification - Health Hazard only (See Appendix 2 for H phrase descriptions)	Basis for Classification (Note 1)	Volatility Band ECETOC TRA Vapour Pressure Bands (VP at 20 deg C (kPa): High: >10 Medium: >0.5 - 10 Low: <= 0.5 Negligible: <0.00001
2-Propanol, 1-butoxy- (PnB)	5131-66-8	01- 2119475527-28	Skin Irrit. 2 (H315); Eye Dam. 2 (H319)	Harmonised	Low
2-Propanol, 1-methoxy- (PM)	107-98-2	01- 2119457435-35	STOT SE 3 (H336)	Harmonised	Medium
2-Propanol, 1-methoxy-, 2-acetate (PMA)	108-65-6	01- 2119475791-29	Not classified for human health	Harmonised	Low
2-Propanol, 1-propoxy- (PnP)	1569-01-3	01- 2119474443-37	Eye Irrit. 2 (H319)	Harmonised	Low
ESTERS					
ethylacetate (ETAC)	141-78-6	01- 2119475103-46	Eye Irrit. 2 (H319); STOT SE 3 (H336)	Harmonised	Medium
n-Propyl Acetate (n-PrAc)	109-60-4	01- 2119484620-39	Eye Irrit. 2 (H319); STOT SE 3 (H336)	Harmonised	Medium
n-butyl acetate (n-BuAc)	123-86-4	01- 2119485493-29	STOT SE 3 (H336)	Harmonised	Medium
Isobutyl acetate (iBuAc)	110-19-0	01- 2119488971-22	STOT SE 3 (H336) [EUH066 skin defatting statement]	Harmonised + Industry Recommendation	Medium
GLYCOL ETHE	RS/ESTERS				
Dipropyleneglycol monomethyl ether (DPGME)	34590- 94-8	01- 2119450011-60	Not classified	Industry Recommendation	Low
Dipropyleneglycol n-butyl ether (DPGBE)	29911- 28-2	01- 2119451543-42	Not classified	Industry Recommendation	Low
Tripropyleneglycol monobutyl ether (TPGBE)	55934- 93-5	01- 2119453620-46	Not classified	Industry Recommendation	Low
Tripropyleneglycol monomethyl ether (TPGME)	25498- 49-1	01- 2119450087-41	Not classified	Industry Recommendation	Low

Substances	CAS Number	REACH Registration Number	CLP classification - Health Hazard only (See Appendix 2 for H phrase descriptions)	Basis for Classification (Note 1)	Volatility Band ECETOC TRA Vapour Pressure Bands (VP at 20 deg C (kPa): High: >10 Medium: >0.5 - 10 Low: <= 0.5 Negligible: <0.00001
Ethylene glycol butyl ether (EGBE)	111-76-2	01- 2119475108-36	Acute Tox. 4 (H302, H312, H332); Skin Irrit. 2 (H315); Eye Irrit. 2 (H319)	Harmonised	Low
Ethylene glycol butyl ether acetate (EGBEA)	112-07-2	01- 2119475112-47	Acute Tox. 4 (H302, H312)	Industry Recommendation (Note 2)	Low
Diethylene glycol butyl ether (DEGBE)	112-34-5	01- 2119475104-44	Eye Irrit. 2 (H319)	Harmonised	Low
Diethylene glycol butyl ether acetate (DEGBEA)	124-17-4	01- 2119475110-51	Not classified	Industry Recommendation	Low
Diethylene glycol ethyl ether (DEGEE)	111-90-0	01- 2119475105-42	Not classified	Industry Recommendation	Low
Propylene glycol ethyl ether (PGEE)	1569-02-4	01- 2119462792-32	STOT SE 3 (H336) Eye Irrit. 2 (H319)	Industry Recommendation	Medium
Propylene glycol ethyl ether acetate (PGEEA)	54839-24-6	01- 2119475116-39	STOT SE 3 (H336)	Harmonised	Low
Dipropylene glycol dibenzoate (DPGDB)	27138- 31-4	01- 2119529241-49	Not classified	Industry Recommendation	Negligible
Triethylene glycol bis (2-ehtyl hexanoate) (TEGEH)	94-28-0	01- 2119475524-34	Not classified	Industry Recommendation	Negligible

Substances	CAS Number	REACH Registration Number	CLP classification - Health Hazard only (See Appendix 2 for H phrase descriptions)	Basis for Classification (Note 1)	Volatility Band ECETOC TRA Vapour Pressure Bands (VP at 20 deg C (kPa): High: >10 Medium: >0.5 - 10 Low: <= 0.5 Negligible: <0.00001
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### SOME NON-OSPA SOLVENTS OF INTEREST

ALCOHOLS					
methanol	67-56-1	01- 2119433307-44	Acute Tox. 3 (H301, H311, H331); STOT SE 1 (H370)	Harmonised	High
ethanol	64-17-5	01- 2119457610-43	Not classified for human health	Harmonised	Medium
tert-Butanol	75-65-0	01- 2119444321-51	Eye Dam. 2 (H319); Acute Tox. 4 (H332); STOT SE 3 (H335)	Harmonised	Medium
hexanol (hexan-1-ol)	111-27-3	01- 2119487976-12	Acute Tox. 4 (H302);	Harmonised	Low
cyclohexanol	108-93-0	01- 2119447488-26	Skin Irrit. 2 (H315); Acute Tox.4 (H302, H332); STOT SE 3 (H335)	Harmonised	Low
Amyl Alcohol (1-pentanol)	71-41-0	01- 2119491284-34	Skin Irrit. 2 (H315); Acute Tox. 4 (H332); STOT SE 3 (H335)	Harmonised	Low
diacetone alcohol (DAA)	123-42-2	01- 2119473975-21	Eye Irrit. 2 (H319)	Harmonised	Low
2,2,4-trimethyl- 1,3-pentanediol mono(2-methyl- propanoate)	25265- 77-4	01- 2119441305-48	Not classified	Industry Recommendation	Low
methyl isobutyl carbinol (MIBC)	108-11-2	01- 2119473979-13	STOT SE 3 (H335)	Harmonised	Low

Substances	CAS Number	REACH Registration Number	CLP classification - Health Hazard only (See Appendix 2 for H phrase descriptions)	Basis for Classification (Note 1)	Volatility Band ECETOC TRA Vapour Pressure Bands (VP at 20 deg C (kPa): High: >10 Medium: >0.5 - 10 Low: <= 0.5 Negligible: <0.00001
KETONES					
Isophorone (3,5,5- trimethylcyclo- hex-2-enone)	78-59-1	01- 2119497282-32	Acute Tox. 4 (H302, H312); Eye Irrit. 2 (H319); STOT SE 3 (H335); Carc. 2 (H351)	Harmonised	Low
Methyl iso Amyl ketone (5-methylhexan- 2-one)	110-12-3	01- 2119472300-51	Acute Tox. 4 (H332);	Harmonised	Medium
2,6-dimethyl- heptan-4-one (DIBK)	108-83-8	01- 2119474441-41	STOT SE 3 (H335)	Harmonised	Low
ESTERS					
methyl acetate	79-20-9	01- 2119459211-47	Eye Irrit. 2 (H319); STOT SE 3 (H336)	Harmonised	High
2,2,4-tri-methyl- 1,3-pentanediol diisobutyrate	6846-50-0	01- 2119451093-47	Not classified	Industry Recommendation	Low
Isopropyl acetate (iPrAc)	108-21-4	01- 2119537214-46	Eye Irrit. 2 (H319); STOT SE 3 (H336)	Harmonised	Medium

*NOTE 1:* Harmonised values are from Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation). *NOTE 2:* An outdated Harmonised Classification exists for EGBEA which is still to be aligned with the EU Risk Assessment Report.

# APPENDIX 5: EXAMPLE ES FOR A HYDROCARBON SOLVENT CONTAINING N-HEXANE (>5 - 80%)

SECTION 1	EXPOSURE SCENARIO TITLE
Title	Formulation & (re)packing of substances and mixtures – Industrial
Use Descriptor	Sector of Use: SU3, 10
	Process Categories: PROC1, PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b, PROC9, PROC14, PROC15
	Environmental Release Categories: ERC2 ESVOC SpERC 2.2.v1
Processes, tasks, activities covered	Formulation, packing and re-packing of the substance and its mixtures in batch or continuous operations, including storage, materials transfers, mixing, tableting, compression, pelletization, extrusion, large and small scale packing, sampling, maintenance and associated laboratory activities.
SECTION 2	OPERATIONAL CONDITIONS AND RISKS MANAGEMENT MEASURES
SECTION 2.1	CONTROL OF WORKER EXPOSURES
Product characteristics	
Physical form of product	Liquid, vapour pressure > 10 kPa at STP
Concentration of substance in product	Covers percentage substance in the product up to 100 % (unless stated differently)
Frequency and duration of use	Covers daily exposures up to 8 hours (unless stated differently)
Other Operational Conditions af- fecting worker exposure	Assumes use at not > 20°C above ambient temperature (unless stated differently)
	Assumes a good basic standard of occupational hygiene has been implemented

RISK MANAGEMENT MEASURES	
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.
General exposures (closed systems) PROC1, PROC2, PROC3	Ensure material transfers are under containment or extract ventilation
General exposures (open systems) PROC4	Provide extract ventilation to points where emissions occur
Batch processes at elevated tem- peratures Operation is carried out at elevated temperature (> then 20°C above ambient temperature) PROC3	Ensure material transfers are under containment or extract ventilation
Process sampling PROC3	Ensure material transfers are under containment or extract ventilation, or; Avoid carrying out activities involving exposure for more than 1 hour
Laboratory activities PROC15	Handle in a fume cupboard or under extract ventilation
Bulk transfers PROC8b	Ensure material transfers are under containment or extract ventilation
Mixing operations (open systems) PROC5	Provide extract ventilation to points where emissions occur
Manual Transfer from/pouring from containers. Non-dedicated facility PROC8a	Provide extract ventilation to points where emissions occur
Drum/batch transfers Dedicated facility PROC8b	Provide extract ventilation to points where emissions occur
Production or preparation or articles by tableting, compression, extrusion or pelletisation PROC14	Handle substance within a predominantly closed system provided with extract ventilation
Drum and small package filling PROC9	Fill containers/cans at dedicated fill points supplied with local extract ventilation

Equipment cleaning and maintenance PROC8a	Drain down and flush system prior to equipment break-in or maintenance
Material storage PROC1	Store substance within a closed system
Material storage PROC2	Store substance within a closed system. Ensure operation is undertaken outdoors. Avoid carrying out activities involving exposure for more than 4 hours
SECTION 3	EXPOSURE ESTIMATION
SECTION 3.1	HEALTH

The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated.

SECTION 4	GUIDANCE TO CHECK COMPLIANCE WITH THE EXPOSURE SCENARIO	
SECTION 4.1	HEALTH	

Predicted exposures are not expected to exceed the DN(M)EL when the Risk Management Measures/ Operational Conditions outlined in Section 2 are implemented.

Available hazard data do not enable the derivation of a DNEL for dermal irritant effects. Risk Management Measures are based on qualitative risk characterisation.

Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.

# APPENDIX 6: LIST OF COMMON SOLVENT USES MATCHED TO ESIG GENERIC EXPOSURE SCENARIO (GES) TITLE WITH EXAMPLES OF RELEVANT SOLVENT TYPES

GES (Use) TITLE (alphabetical)	GES n°	END-USE APPLICATIONS	EXAMPLES (not an exhaustive list)	EXAMPLE HYDROCARBON SOLVENTS CATEGORIES TYPICALLY RELEVANT FOR USE (not an exhaustive list) - see Note 1	EXAMPLE OXYGENATED SOLVENTS CATEGORIES RELEVANT FOR USE (not an exhaustive list) - see Note 1
Use in <b>Agrochemicals</b>	11	Biocidal protection products	E.g. Carriers, co- solvents, Coupling agents, emulsifiers in plant protection products, pesticide/ insecticide formulations	1, 2, 7, 8, 9	Ketones; Alcohols; Glycol ethers/esters
		Insecticides	E.g. Carriers, co- solvents, coupling agents, emulsifiers in plant protection products, pesticide-, insecticide formulations	7, 8	Ketones; Alcohols; Glycol ethers/esters
		Plant protection products	E.g. Carriers, co- solvents, coupling agents, emulsifiers in plant protection products, pesticide/ insecticide formulations	1, 2, 7, 8, 9	Ketones; Alcohols
Use in <b>Binders</b> and release agents	10	Foundry mould release products	E.g. Anti-set-off, anti- adhesive or release agents for foundry purposes (solvents for coatings applied to (sand) moulds	1, 2, 6, 7, 8, 9	Ketones; Alcohols
		Mould release agents	E.g. Anti-set-off, anti- adhesive or release agents, e.g.concrete relase agents	1, 2, 6, 7, 8, 9	Alcohols
Blowing agents	9	Blowing agents	E.g. Blowing agents in manufacture of e.g. polystyrene	5	Ketones

GES (Use) TITLE (alphabetical)	GES n°	END-USE APPLICATIONS	EXAMPLES (not an exhaustive list)	EXAMPLE HYDROCARBON SOLVENTS CATEGORIES TYPICALLY RELEVANT FOR USE (not an exhaustive list) - see Note 1	EXAMPLE OXYGENATED SOLVENTS CATEGORIES RELEVANT FOR USE (not an exhaustive list) - see Note 1							
Use in Cleaning Agents	4	Cleaning products	E.g. Substance used in detergents, metal (parts) cleaners, electronic cleaners, laundry cleaners, degreasers etc.	7, 8	Ketones; Alcohols; Glycol ethers/ esters							
		Degreasing formulations	E.g. Substances used in Engine (parts) cleaning, brake cleaning, metal degreasing formulations	6, 7, 8	Ketones; Alcohols; Glycol ethers/ esters							
			_						Dry cleaning formulations	E.g. Solvents in dry-cleaning formulations	8	n/a
		Wipes	E.g. Wipes for cleaning purposes	7, 8 Toluene, Xylene	Ketones; Alcohols; Glycol ethers/ esters							

GES (Use) TITLE (alphabetical)	GES n°	END-USE APPLICATIONS	EXAMPLES (not an exhaustive list)	EXAMPLE HYDROCARBON SOLVENTS CATEGORIES TYPICALLY RELEVANT FOR USE (not an exhaustive list) - see Note 1	EXAMPLE OXYGENATED SOLVENTS CATEGORIES RELEVANT FOR USE (not an exhaustive list) - see Note 1	
Use in <b>Cleaning</b> Agents	3	Adhesives	E.g. Solvents, fillers, plasticisers, emulsifiers, dispersants in e.g. adhesives	1, 2, 6, 7, 8, 9	Ketones; Glycol ethers/esters	
		Inks	E.g. Carriers for all types of water and solventborne inks.	1, 2, 7, 8, 9	Glycol ethers/ esters	
		Metal surface treatment products	E.g. Anti-corrosion- protection oils, other surface treatment products, temporary coatings	8, 9		
		Non-metal surface treatment products	E.g. Anti-corrosion-, protection oils, other surface treatment products, temporary coatings wood protection oils, parquet oils	8, 9	n/a	
		Paint removal products	E.g. Carriers in paint stripper formulations	1, 2	Ketones; Glycol ethers/esters	
		Paints	E.g. Substances used in Bitumen linings or lacquers, paints, Inks, stains, varnish, primers	1, 2, 3, 6, 7, 8, 9	Ketones; Alcohols; Glycol ethers/ esters	
		Plastisols	E.g. PVC plastisols for wallpaper, coatings for construction materials	8	n/a	
			Parquet oils	E.g. Coalescence, carrier, emulsifiers, dispersants for all types of Parquet oils	8	n/a
		Polish & wax blends	E.g. Carriers emulsifiers, dispersants in shoe polish, car wax , floor and furniture polishes, other surface treatment products	1, 2, 7, 8	Alcohols; Glycol ethers	

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Use in Cleaning Agents	3	Putties	E.g. Carriers, fillers, plasticisers, emulsifiers, dispersants in sealants / putties	8, 9	Ketones; Glycol ether esters
		Sealants	E.g. Carriers, fillers, plasticisers, emulsifiers, dispersants in sealants / putties	8, 9	
		Thinners	E.g. Carriers in thinners	1, 2, 6, 7, 8	Ketones; Alcohols; Glycol ethers/ esters
		Wood protection oils	E.g. Teak oils, outdoor garden furniture treatment products, parquet oils	8	n/a
De-icing and anti-icing applications	14	De-icing products	E.g. Substances used in de-icing products for aviation, vehicles, conveyor belts, coal industry	n/a	Alcohols; Glycol ethers
Formulation & (re) packing of solvent based mixtures	2	Inclusion of solvents as a component in mixtures/ formulations	E.g. Blending of substances in solvents, also relevant for end use applications such as 'denaturants', and use in production of animal food and fodder.	All Hydrocarbon solvents	All Chemical solvents All Glycol ethers/ esters
Uses in <b>Fuels</b>	12	Catalytic lamp oils	E.g. Formulations that are combusted catalytically, Fragrance lamp oils, Perfume lamp oils,	n/a	Alcohols
		Fuel additives	E.g. Carriers, dispersants used in fuel formulations	1, 2, 8	Ketones; Alcohols
		Fuels	E.g. Barbeques oils, Lamp oils, fire gels, lighter fluids, heater oils, acetylene solvent	8	Ketones; Alcohols

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Functional Fluids	13	Brake fluids	E.g. Brake fluids for automotive vehicles	n/a	Glycol ethers
		Coolants	E.g. Industrial heat exchangers, automotive	8	
		Heat transfer fluids	E.g. Industrial heat exchangers, refrigerants, air conditioners	5, 8	n/a
		Hydraulic fluids	E.g. as blend component in all kinds of hydraulic installations	8	Ketones; Glycol ethers/esters
		Refrigerants	E.g. Refrigerants, air conditioners	5	n/a
		Catalytic lamp oils	E.g. Formulations that are combusted catalytically, Fragrance lamp oils, Perfume lamp oils	n/a	Alcohols
		Fuel additives	E.g. Carriers, dispersants used in fuel formulations	1, 2, 8	Ketones; Alcohols
Use in <b>Laboratories</b>	17	Laboratory chemicals	E.g. General use of substance as laboratory chemical, glass rinsing/cleaning	Various hydrocarbon solvents, mostly pentane, heptane Toluene	Ketones; Alcohols
Lubricants	6	Lubricant formulations	E.g. Carriers and solvents in all types of lubricating oils, e.g. engine oils, greases, metal working fluids (or: Use of HCS as carriers for additives used in the manufacture of finished lubricants.)	1, 2, 5, 8, 9	Alcohols

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Manufacture (including use as a Process Chemical or Extraction	1	Catalyst deactivator, deashing agents	Process chemical e.g. agents, to inhibit reaction progress	n/a	Alcohols									
Solvent)		Damping agent	E.g. Alcohols in nitrocellulose formulations	n/a	Alcohols									
		Explosives (nitrocellulose)	Process chemical e.g. Dampening agents, in extrudation processes	n/a	Ketones; Alcohols; Glycol ethers/ esters									
		Inhibitor	Process chemical, e.g. solvents, to inhibit reaction progress	n/a	Alcohols									
		Intermediates	Intermediate e.g. for the production of e.g. bulk chemicals, fine chemicals, pharmaceuticals, fragrances, dyes etc.	1, 2	Ketones; Alcohols; Glycol ethers/ esters									
											Lub oil dewaxing	Extraction agent, e.g. to extract wax / paraffins form mineral oils, crude oils	n/a	Ketones
								Photo chemicals manufacture	Process chemical e.g. for the production of toner, photo copy solvents	n/a	Ketones; Alcohols			
														Photographic film manufacture
		Pigment manufacture	Process chemical, e.g. dispersion agents, carriers, grinding aids, metal pastes	1, 2, 7, 8	Alcohols; Glycol ethers									

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Manufacture (including use as a Process Chemical or Extraction Solvent)	1	Polymerisation processes	Process chemical, e.g. process aids catalyst carrier, reaction media, reaction inhibitor, catalyst deactivators, Intermediate in polymerisation processes	5, 6, 8, 9	Alcohols
		Chemical manufacture	E.g. production of hydrogen peroxide	1, 2	n/a
		Resin manufacture	Process chemical e.g. in resin manufacturing process	1, 2, 8	Ketones; Alcohols; Glycol ethers/ esters
		Extraction	Extraction agents for use in production of e.g. seed oil, fragrances, proteins, caffeine and others.	6, 7	MEK, MIBK, Acetone, IPA
Metal working fluids / rolling oils	7	Metal working fluids	E.g. Carriers, lubricating agents in metal working oils, rolling oils, cutting oils quenching oil formulations, metal surface treatment products	8, 9	n/a
Mining Chemicals	22	Metal solvent extraction	E.g. Diluent in metal solvent extraction processes	2, 6, 7, 8, 9	Ketones
		Flotation	E.g. Flotation frother	n/a	Ketones; Glycol ethers
Use in Oil and gas field drilling and production operations	5	Drilling and fracturing operations	E.g. Base fluids, emulsifiers, shale inhibitors, other additives in drilling muds.	8, 9	Ketones; Glycol ethers
		Oilfield chemicals	E.g. Base fluids, well treatment products, shale inhibitors, lubricants, asphalthene inhibitors, demulsifiers	1, 2, 8	Ketones; Alcohols; Glycol ethers

GES (Use) TITLE (alphabetical)	GES n°	END-USE APPLICATIONS	EXAMPLES (not an exhaustive list)	EXAMPLE HYDROCARBON SOLVENTS CATEGORIES TYPICALLY RELEVANT FOR USE (not an exhaustive list) - see Note 1	EXAMPLE OXYGENATED SOLVENTS CATEGORIES RELEVANT FOR USE (not an exhaustive list) - see Note 1
Road and Construction operations	15	Bitumen Road repair, roofing	E.g. Carriers for bitumen emulsions / solutions	1, 2	n/a
Rubber Production and Processing	19	Rubber processing aids	Process chemical e.g. Compounding aids	3, 6, 7, 8, 9	n/a
Polymer Processing	23	Polymer processing aids	Process chemical e.g. Compounding aids	1, 2, 3, 4, 6, 7, 8, 9	n/a
Water treatment chemicals	21	Flocculant formulations	E.g. Carriers in flocculant formulations	1, 2, 8, 9	n/a

### NOTE 1:

These are examples of the solvent categories typically relevant for the identified applications and covered by each GES Title. Refer to your supplier for the names of specific solvents that are appropriate for each application. You may also review the list of Use Titles included within the REACH Registration for specific solvents via the ECHA Dissemination Portal (<u>http://echa.europa.eu/information-on-chemicals/registered-substances</u>).

### **APPENDIX 7: MIXTURES**

Commercial products supplied to users (e.g. paints, adhesives, etc.) often contain numerous substances, including more than one solvent. If the preparation is hazardous, or contains hazardous substances, the supplier must provide his customers with an SDS including advice on safe use of the product.

The manufacturer (or blender) of these products will receive SDSs for all the raw materials that are used in the manufacture of the preparation, and these may include ES for those products that comprise single REACH registered substance, if the substance is hazardous. For example, the manufacturer/importer of a solvent may provide an ES indicating that if it is used in a certain manner e.g. as a component of a car paint (within a defined concentration range) then it should be applied in a spray painting booth. However the controls recommended by the solvent M/I can only take account of his substance, and so may not be appropriate or adequate for other more hazardous components in the solvent preparation.

Therefore it is the responsibility of the preparation manufacturer to assess the overall mixture (using the information in the extended-SDS provided by his raw material suppliers) and to provide his customers with an SDS including information on the hazards of the mixture and the conditions of safe use including appropriate risk management advice.

Various options are offered in REACH guidance (Ref 23, Section 3.23), including:

- Attach the exposure scenarios that you have received for the individual substances contained in the preparation to your SDS. A summary and cross reference should be included in the core sections of the SDS. ESIG do not recommend this approach for numerous reasons, but in particularly because it does not provide unambiguous guidance to the downstream user.
- Consolidate safe use information for the mixture (using exposure scenarios received for the component registered substances and/or your downstream user CSA as the starting point) and attach 'a mixture ES' to your SDS. These details replace the exposure scenarios provided by your supplier.
- Integrate information to provide for safe use of the hazardous substances in the mixture into the core sections of the SDS.

A number of CEFIC groups saw the need for a methodology to address the development of guidance for the consolidation of ES safe use information for mixtures as this is not covered adequately in the official guidance. This resulted in development of the 'DPD+ Method' which is described in detail in a paper entitled: REACH Exposure scenarios for preparations - Methodology for the identification of substances that represent the dominant risks to human health and/or the environment and the drivers for risk management measures (REF 21). This method is currently under review, with an up-dated tool expected to be issued as a joint effort by Cefic/VCI by end Quarter 1/2016, titled 'Cefic/VCI LCID (Lead Component Identification) Methodology.

In summary, the method enables a lead substance to be identified within the mixture for each exposure route (inhalation or skin contact). The information provided in the respective substance ES for the relevant use and exposure pathway is then used to prepare the ES for the preparation.

However, it should be noted that methodologies for developing safe use advice for mixtures under REACH are still being developed. In the meantime it is likely that formulators will continue to work with industry groups representing their downstream users to ensure that consistent and targeted advice on safe use is provided in their SDS. End users should follow the advice provided whether it is incorporated in the body of the SDS or in the form of an ES attachment.



The Best Practice Guidelines are produced by the European Solvents Industry Group

European Solvents Industry Group (ESIG) <a href="http://www.esig.org">www.esig.org</a>

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