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Basics of REACH Regulation

and how to comply with it

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Abstract

REACH regulation, (EC) 1907/2006, is an EU chemical legislation which came to force in 2007. It addressed the production and use of chemical substances and their possible impacts on both humans and the environment. The thesis aims to briefly introduce the main topics of the regulation and its impacts to supply chains.

The main information sources for the desktop research were the publications of the European Chemicals Agency which is in charge of the information collected under REACH and the evaluation of this information. Other sources were legal texts and national authorities that are in charge of monitoring the use of chemicals.

Every case of implementing REACH requirements to company's workflows is different but the thesis outlines the main points that should be considered. Further study would be required in order to get a thorough guide but the thesis is intended for those who need basic information on the regulation. The main points for any company are to know what the aim of REACH is and to be able to understand the requirements and obligations that fall to the company because of the regulation.

Keywords
REACH, ECHA, SVHC, regulation, European Union, authorisation, chemical

Miscellaneous

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Tiivistelmä

REACH-asetus, (EC) 1907/2006, on EU:n kemikaalilainsäädäntö, joka astui voimaan 2007. Asetuksen tavoitteena on valvoa kemikaalien valmistusta ja käyttöä sekä niiden mahdollisia vaikutuksia niin terveyteen kuin ympäristöönkin. Opinnäytetyö pyrkii lyhyesti esittelemään asetuksen pääaiheet ja niiden vaikutukset toimitusketjussa.

REACH-asetuksen vaatiman tietomäärän hallintaan ja tarkastamista varten perustettiin Euroopan kemikaalivirasto, jonka julkaisut olivat opinnäytetyön tärkeimpiä tietolähteitä. Muina päälähteinä olivat aiheeseen liittyvät lakitekstit sekä kemikaalien valvonnasta vastuussa olevien kansallisten viranomaisten tuottama materiaali.

REACH-vaatimusten noudattamiselle ei ole yhtä ainutta ja oikeaa toteutustapaa, joten opinnäytetyössä keskitytään pääkohtiin, jotka tulee ottaa huomioon työelämän toteutusta suunniteltaessa. Tärkeintä mille tahansa yhtiölle on tietää, mikä on REACH-asetuksen tavoite sekä ymmärtää mitä yhtiö on velvoitettu tekemään noudattaakseen säädöstä. Opinnäytetyö on tarkoitettu perustiedoksi sitä tarvitseville. Lisätutkimuksia vaaditaan, jos halutaan perusteellinen ja kaikenkattava opas REACH-säädöksestä.

Avainsanat (asiasanat)
REACH, ECHA, SVHC, Euroopan Unioni, kemikaalilainsäädäntö, kemikaali

Muut tiedot

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ABBREVIATIONS

CAS number	Chemical Abstract Service index number
CLP	Classification, Labelling and Packaging of substances and mixtures
CMR	Carcinogenic, Mutagenic or toxic to Reproduction
CSR	Chemical Safety Report
EAA	European Economic Area
EC	European Community
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
NLP	No-longer Polymers
N-R50-53	Substances dangerous to aquatic organisms or the environment
O5A	“Once an article, always an article”
PBT	Persistent, Bioaccumulative or Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals (earlier also REACh)
RoHS	Restriction of the use of certain Hazardous Substances in Electrical and Electronic Equipment
SDS	Safety Data Sheet
SIEF	Substance Information Exchange Forum
SVHC	Substances of Very High Concern
vPvB	very Persistent and very Bioaccumulative
w/w	weight by weight
WEEE	Waste Electrical and Electronic Equipment Directive

GLOSSARY OF TERMS

Annex XIV – Annex of REACH listing all substances which are subject to authorisation under REACH regulation. The use and placing on the market of Annex XIV substances is prohibited after the sunset date unless an authorisation has been granted or an exemption applies.

article – in REACH terminology an item whose function is defined more by its shape, surface or design than by its chemical composition

Authorisation List – see Annex XIV

Candidate List (of Substances of Very High Concern for Authorisation) – a list of substances that are identified as SVHC, inclusion of the substance to this list is the first step for the authorisation process

mixture – in REACH terminology a mixture or solution composed of two or more substances (earlier *preparation* was used instead)

SEA route – the socio-economic route for applying an authorisation

SIN List – Substitute It Now! list managed by the International Chemical Secretariat and it contains substances that are likely to be restricted under the REACH regulation (a so-called prelist for Annex XIV)

substance – in REACH terminology a chemical element and its compounds

sunset date – the date after which the placing on the market and the use of a substance on the Annex XIV is prohibited

1 INTRODUCTION

Practical training in REACH related tasks inspired to learn more about this European Union's chemical legislation that came into force in 2007. The basics of the regulation are easy to grasp but when deeper understanding is required, the task quickly comes demanding. Daily work as a part of a company's REACH team showed in how many levels the regulation affects the daily operations of a big international company. It is not only about the chemical compositions of an item which is being produced; REACH is present at just about every step of the journey. In order for the company's final product to be REACH compliant everyone from the design engineers to purchasing, from logistic and warehousing personnel to assembly line workers and from sales and marketing to maintenance people need to be aware of the regulation. Naturally, not everyone needs to know everything but it is vital to understand how REACH might affect different operations and why some ways of working need to be changed.

Although the regulation came to force already in 2007 it is still, years later, not uncommon to work with suppliers that are not aware of it and do not know what they are expected to do. Of course the situation is getting better all the time but there is always room for improvement. In order to have a career with REACH related tasks in future one needs to know a lot about the topic. It is a specific area of expertise but as it affects so many sides of any company's operations (especially in manufacturing) it gives the possibilities to use and implement that knowledge in various different tasks and positions.

This thesis is not a thorough study of the REACH regulation but rather a guide for those who need information about the subject. The aim is also to try and pinpoint the most important topics and their implications to a company's operations. Possible ways to implement REACH requirements will also be discussed.

The information is up-to-date at the time of writing but due to the nature of the regulation changes might have occurred so the best source for updated official information is always ECHA's own homepage http://echa.europa.eu/.

2 REACH AND ECHA

REACH is an acronym from "***R**egistration, **E**valuation, **A**uthorisation and Restriction of **Ch**emicals*" and it is a regulation of the European Union which addresses the production and use of chemical substances with possible impacts on humans and the environment. The Regulation (EC) 1907/2006 was approved in December 2006 and entered into force in June 1, 2007. The regulation is very complex but in a nutshell, it requires all companies that manufacture or import chemical substances into the European Economic Area (EEA; composed of Iceland, Liechtenstein, Norway and the 27 European Union Member States) in quantities of one or more tonnes per year to register the substances with the European Chemicals Agency.

In order to manage REACH, there was a need to establish an EU agency for the task. The European Chemicals Agency (ECHA) is based in Helsinki, Finland and started its work in June, 2007 when the regulation entered into force. The composition and tasks of ECHA are defined in the Regulation under *TITLE X Agency* which covers Articles 75-111. The main bodies of the agency are defined in Article 76 as:

- Management Board
- Executive Director
- Committee for Risk Assessment
- Committee for Socio-economic Analysis
- Member State Committee
- Forum on Exchange of Information on Enforcement
- Secretariat
- Board of Appeal.

The reason why REACH was created was that earlier there were multiple European Directives and Regulations concerning chemicals and there was a need to harmonize the field with a single system. REACH repealed the following Regulations and Directives:

- Council Regulation (EEC) No 793/93 - *evaluation and control of the risks of existing substances*

- Commission Regulation (EC) No 1488/94 - *principles for the assessment of risks to man and the environment of existing substances*
- Council Directive 76/769/EEC - *on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations*
- Commission Directive 91/155/EEC - *defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations*
- Commission Directive 93/67/EEC - *principles for assessment of risks to man and the environment of substances notified in accordance with Council Directive 67/548/EEC*
- Commission Directive 93/105/EC - *laying down Annex VII D, containing information required for the technical dossier referred to in Article 12 of the seventh amendment of Council Directive 67/548/EEC*
- Commission Directive 2000/21/EC - *concerning the list of Community legislation referred to in the fifth indent of Article 13(1) of Council Directive 67/548/EEC*.

After seeing the list it should be apparent why there was a need to merge these different legislations and why the outcome, the REACH regulation, is so massive and complex.

The EU had chemical registers already before REACH:

- EINECS (European Inventory of Existing Commercial Chemical Substances) – all chemical substances on the EC market 1.1.1971-18.9.1981
- ELINCS (European List of Notified Chemical Substances) – all chemicals notified within the EC, final edition from 2009
- NLP (No-longer Polymers) – list of substances that were considered polymers for EINECS but after a change in definition are no longer considered as polymers.

Chemicals from EINECS were pre-registered with ECHA as REACH “phase-in” substances and those chemicals which were on the ELINCS list went straight to

registration. More in-depth information about the registration stages will be in chapter 2.1.

REACH does not only concern companies dealing with pure chemicals but also chemicals in articles as referred to in REACH terminology, so any company that manufactures or imports goods into the area can be affected by the regulation.

The legal text contains several hundred pages and is composed of 141 articles followed by 17 annexes. The articles are grouped under 15 Titles which cover the steps of REACH process as well as other important factors such as fees, tasks and composition of the Agency, and enforcement (see Appendix 1 for the content of the regulation with the division to Titles and Annexes).

In order to fully understand REACH it is important to know what is meant with the following basic terms as defined in Article 3(1-3):

- "substance: *means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition"*
- "mixture: *means a mixture or solution composed of two or more substances"*
- "article: *means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition"*.

Even though the definition of an article seems coherent it is in fact unambiguous, there can be differences in its interpretation. The current discussion revolves around the question whether or not an article still remains as an individual article after it has become a part of another article – "once an article, always an article" (sometimes the abbreviation O5A is used for this). ECHA's interpretation is that an assembled item is one article but there are countries which keep with the "once an article, always an article" approach. The meaning of this question for supply chains comes evident in chapter 4.2.

In essence, there are four stages within REACH: registration, evaluation, authorization and restriction. The aim of the regulation is to assure that the risks of chemical substances are controlled and that harmful substances are gradually replaced by better alternative substances or technologies if economically and technically possible. FIGURE 1 shows the whole route for those substances that are considered harmful and need to be restricted. The process starts with the registration of substances (currently ECHA has 10,561 registered substances in its database). Those that are classified as substances of very high concern, SVHC, are included to the Candidate List. The most harmful substances will be included to the Authorisation List and they will be given a sunset date after which the use and placing on the market of that substance is forbidden. More information about the different phases and lists will be in following chapters.

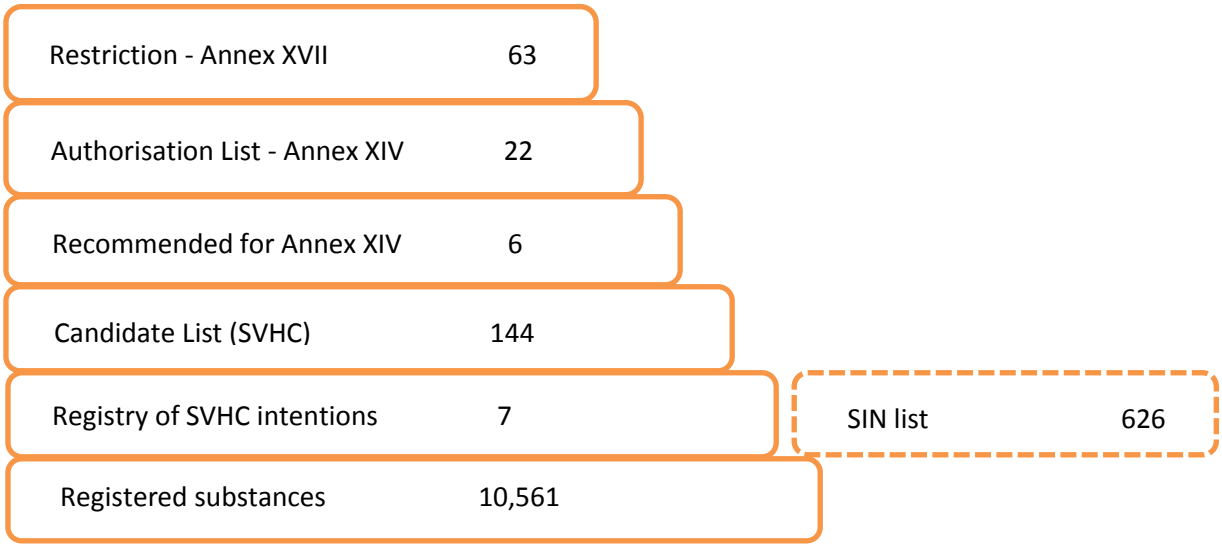


FIGURE 1. Steps of substance restriction with the number of substances (situation at the end of 2013)

2.1 Registration

Registration process for REACH has been divided into stages with their own deadlines depending on the tonnage and classification of the substance in question (see FIGURE 2). There is also a division of the substances into *phase-in* and *non-phase-in*

categories. Phase-in substances are defined in Article 3(20) and are substances that meet at least one of the following criteria:

- already listed in EINECS
- manufactured in EU but not placed on EU market after 1.6.1992.
- substances that are “no-longer polymer”.

All substances that do not fulfil the classification of phase-in substances are considered to be non-phase-in substances.

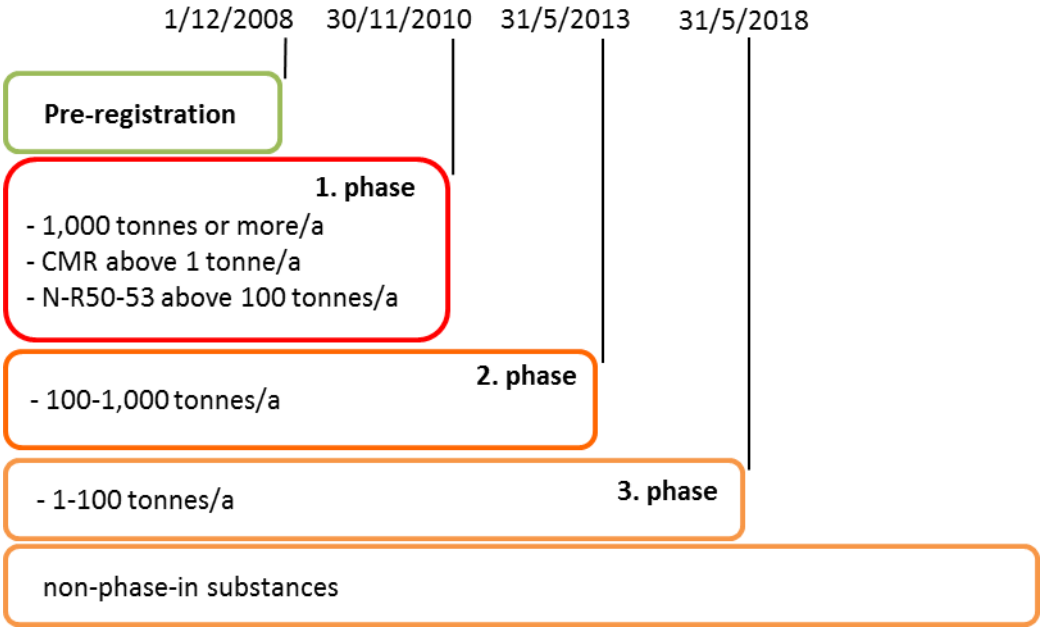


FIGURE 2. Registration deadlines

Phase-in substances

Pre-registration phase allowed manufacturing and importing of phase-in substances without immediate registration. After REACH came into force substances can be manufactured or imported only if they have been registered, so a 6-month pre-registration period was created for these substances that were already on the market. By pre-registering a substance there was (and still is) the possibility to

continue manufacturing and importing the substance until the registration deadline, e.g. a substance belonging to the third phase category could be pre-registered before 1.12.2008, continue usage/import and be finally registered almost ten years later in 2018.

Pre-registration also allows the registrants to share data with others through Substance Information Exchange Forum, SIEF. The aim of SIEF is to help with sharing data required for registration and thus also preventing duplicate studies, and also in case of a disagreement between the registrants helping with the classification and labelling of a substance which are part of the required registration dossier. The participants can jointly fulfil the REACH requirements and even send their registration as a joint submission. All this sharing of information and tasks naturally eases the burden caused by REACH and also cuts costs by dividing them between the participants. Further savings come from joint submissions as the fees are set lower for those as shown on the next table (as set in Regulation (EU) No 254/2013, even lower fees apply to micro, small and medium-sized enterprises). Especially when the tonnage range grows the impact of the savings is bigger and thus further encourages to co-operation.

TABLE 1. Standard fees for registration

	individual submission	joint submission
1 to 10 tonnes	1 714 €	1 285 €
10 to 100 tonnes	4 605 €	3 454 €
100 to 1 000 tonnes	12 317 €	9 237 €
above 1 000 tonnes	33 201 €	24 901 €

Non-phase-in substances

Non-phase-in substances have normally not been manufactured, placed on the market or used in the EU before 1.6.2008 and can therefore also be referred to as new substances. Manufacturers or importers of these non-phase-in substances need

to register the substance before manufacturing or importing it in order to comply with REACH. The difference with non-phase-in substances and those phase-in substances that were not pre-registered is that the registrants need to first inquire from ECHA if a registration has already earlier been submitted for the same substance. If the substance has not been registered earlier or if not all required information is available, the registrant can continue with the registration process. If on the other hand the substance has already been registered, ECHA will start the data sharing process with all relevant registrants. The outcome will either be a joint submission or an individual submission in cases where only one registrant decides to follow through the registration process.

Registration dossier

The registration dossier for a substance is composed of two parts: a technical dossier and a chemical safety report, CSR. The technical dossier is required for all substances that are to be registered. It should contain all information that is available on the properties, classification, labelling, manufacture and uses of the substance as well as guidance on safe use. If relevant, it also includes further testing suggestions and information related to exposure for substances registered in quantities of one to ten tonnes. The CSR has detailed information on the human health and environmental hazard properties of the substance and if an assessment is required, then it should also contain an assessment of exposure and risk. For a CSR format see Appendix 4. By examining the CSR requirements it should also be evident why joint submissions are encouraged – by dividing the required work (tests, reports and other paperwork) all registrants save resources and time.

Exemptions

There are exemptions to the registration obligation which are set in Article 2. The reason why some substances are exempted is that there are other legislations or regulations that control the production and use of the substances in question. For example radioactive substances, cosmetic products, medical products and substances used in food fall under other regulations and are thus exempted. In addition to these, substances that are included in Annex IV or covered by Annex V are also exempted.

2.2 Evaluation

The figure below shows an overview of the second step of REACH process. After receiving a registration dossier ECHA will evaluate together with the Member States the submitted information. ECHA assesses the technical side of the dossier: testing proposals and compliance checks; while Member States perform the substance evaluation. The list of each Member State's competent authorities (CARACAL – Competent Authorities for REACH and CLP) can be found on ECHA's pages. Finland has only one competent authority for REACH which is the Finnish Safety and Chemicals Agency (Tukes) whereas for example Portugal has three: Directorate-General of Health, Portuguese Environment Agency and General Directorate for Economical Activities. If the dossier passes the evaluation and the substance poses a risk, the next step depends on the severity of the risk. The substance can be proposed as SVHC or in extreme cases straight as a substance to be restricted (inclusion to Annex XVII).

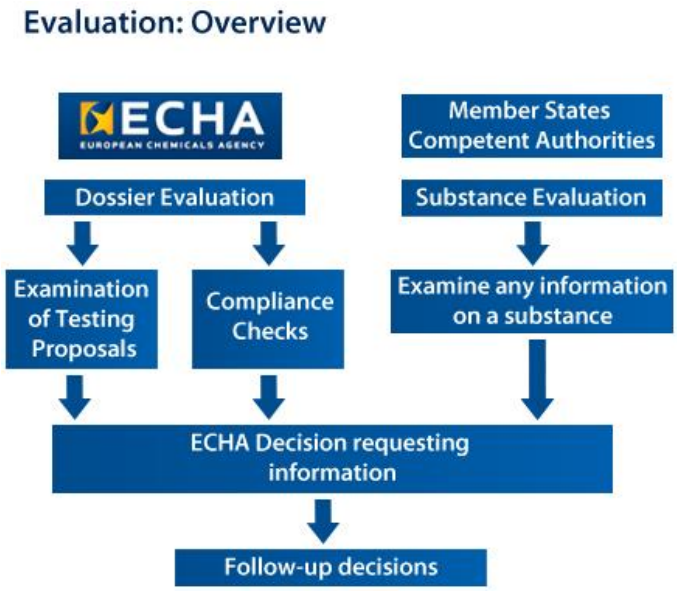


FIGURE 3. Overview of the Evaluation process[1]

[1] Source: European Chemicals Agency, http://echa.europa.eu/

SVHCs are the following substances:

- Carcinogenic, Mutagenic or toxic to Reproduction (CMR)
- Persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) (as defined in Annex XIII) and/or
- Individually identified substances which based on scientific evidence are likely to cause as serious effects as CMR or PBT/vPvB substances, for example endocrine disrupters.

2.3 Authorisation

The purpose of the authorisation phase is to make sure that the use of substances that pose risks is controlled. The authorisation phase is divided into two steps. First, a substance can be suggested to be identified as a SVHC by a Member State or ECHA. If the substance fulfils the criteria, then it is added to the Candidate List of Substances of Very High Concern for Authorisation. The updated Candidate List can be found online at ECHA's pages. The list is at the moment updated twice a year and by then end of 2013 it included 151 substances. FIGURE 4 shows few lines of the list: entries include the chemical name of the substance, EC[2] and CAS[3] numbers which independently identify the substance, date of inclusion to the Candidate List, reason for inclusion, decision number and further information about the substance.

[2] Given by the Commission of the European Communities to replace EINECS/ELINCS/NLP numbers

[3] Chemical Abstract Service index number, defines only one substance, a unique identifier

Substance Name	EC Number	CAS Number	Date of inclusion	Reason for inclusion	Decision number	IUCLID 5 Substance Dataset	
1,2,3-Trichloropropane	202-486-1	96-18-4	2011/06/20	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)	ED/31/2011		Details
1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich	276-158-1	71888-89-6	2011/06/20	Toxic for reproduction (article 57c)	ED/31/2011		Details
1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters	271-084-6	68515-42-4	2011/06/20	Toxic for reproduction (article 57c)	ED/31/2011		Details
1,2-Benzenedicarboxylic acid, dipentylester, branched and linear	284-032-2	84777-06-0	2012/12/19	Toxic for reproduction (Article 57 c)	ED/169/2012		Details

FIGURE 4. Candidate List[4]

When a substance has been included to the Candidate List, it requires some actions from companies that are dealing with that substance (see chapter 3).

Second part of the authorisation process is the recommendation and inclusion of a substance to the Authorisation List (Annex XIV). ECHA sends recommendations of substances to be included to the list to the European Commission which makes the final decision. Substances on the Candidate List are prioritized with PBT or vPvB substances being first in line together with substances that are widely used or in high volumes. Next figure shows an excerpt of the Authorisation List which looks similar to the Candidate List but has few different columns:

- Sunset date is the date after which the substance cannot be used or placed on the market any longer
- Latest application date is the last date to apply for an authorisation if it is wanted before the sunset date (latest application date is 18 months prior to the given sunset date).

[4] Source: European Chemicals Agency, http://echa.europa.eu/

Substance Name	EC Number	CAS Number	Sunset date	Latest application date	Exempted (categories of) uses	
Ammonium dichromate	232-143-1	7789-09-5	21/09/2017	21/03/2016		Details
Potassium chromate	232-140-5	7789-00-6	21/09/2017	21/03/2016		Details
Acids generated from chromium trioxide and their oligomers Group containing: Chromic acid, Dichromic acid, Oligomers of chromic acid and dichromic acid	231-801-5, 236-881-5	7738-94-5, 13530-68-2	21/09/2017	21/03/2016		Details
Chromium trioxide	215-607-8	1333-82-0	21/09/2017	21/03/2016		Details
Potassium dichromate	231-906-6	7778-50-9	21/09/2017	21/03/2016		Details

FIGURE 5. Authorisation List[5]

The updated Authorisation List is also to be found online at ECHA's pages and by the end of 2013 it had 22 entries. Once a substance has been included to the Authorisation List it cannot be used after its sunset date unless an authorisation is granted. The process of applying for an authorisation is explained in chapter 2.6 Applying for authorisation.

2.4 Restriction

Substances that are on the List of Restriction (Annex XVII) are those which are either banned in the EU or then the manufacture, placing on the market or use is limited due to the high risk to human health or the environment. The list includes substances that were restricted by the previous legislation (76/769/EEC) as well as those added under REACH. New substances that pose unacceptable risks can be added to the list by a Member State or ECHA (on behalf of the Commission). In some cases it can be concluded already during the authorisation process that restriction of a substance would be more suitable than its inclusion to the Authorisation List. Substances that have been included to the Authorisation List and given a sunset date will be evaluated by ECHA after that date in order to determine if a restriction is still needed

[5] Source: European Chemicals Agency, http://echa.europa.eu/

for the substance in question. FIGURE 6 shows a part of the Restriction list which looks similar to the Candidate List and the Authorisation List.

Entry no	Substance / group of substances / mixture	EC Number	CAS Number	Consolidated text	Appendix	New amendment (EU Regulation)	Q&A
10a	(a) Ammonium sulphide	235-223-4	12135-76-1	Page 219			
10b	(b) Ammonium hydrogen sulphide	235-184-3	12124-99-1	Page 219			
10c	(c) Ammonium polysulphide	232-989-1	9080-17-5	Page 219			
11a	Volatile esters of bromoacetic acids: (a) Methyl bromoacetate	202-499-2	96-32-2	Page 219			
11b	Volatile esters of bromoacetic acids: (b) Ethyl bromoacetate	203-290-9	105-36-2	Page 219			
11c	Volatile esters of bromoacetic acids: (c) Propyl bromoacetate		35223-80-4	Page 219			

FIGURE 6. Restriction List[6]

2.5 Enforcement

Enforcement and supervision of REACH is not ECHA's duty, it falls to Member State authorities. In Finland a new law (599/2013) came to force on 1.9.2013 and it redefines which authorities are responsible for the enforcement of REACH within Finland:

- Finnish Safety and Chemicals Agency (Tukes)
  -supervision of market
- Regional State Administrative Agencies (AVI)
  -use of chemicals at workplaces
- Centres of Economic Development, Transport and the Environment (ELY) together with Municipal Environmental Authorities
  -protection of the environment
- Customs
  -supervision of import and export.

[6] Source: European Chemicals Agency, http://echa.europa.eu/

There are no set penalties for violations of REACH as Article 126 only states that they need to be "*effective, proportionate and dissuasive*". Because of the lack of harmonized penalty levels and the fact that the regulation is still in its early steps the Environment Directorate-General of the European Commission wanted a study to be made about the situation of Member States. "*Report on penalties applicable for infringement of the provisions of the REACH Regulation in the Member States*" by Milieu Ltd. revealed unsurprisingly that the implementation differs between Member States. While the type of penalties and the amount of fines varied between countries (e.g. the UK was found to have unlimited maximum fines) Milieu Ltd. also noticed that on national level REACH sanctions were relatively comparable to breach of other legislation. Based on the results it is evident that Member States would benefit from more harmonized methods of enforcement and penalties, though setting exact fines might not be the best solution. For example the registration fees discussed in chapter 2.1 are defined in Regulation (EC) No 254/2013 and are thus the same for all but this method does not take into consideration the varying levels of countries' living standards. Common sanctions would help the enforcement of REACH but the decisions should not be made at someone's expense. Best solution would probably be some kind of proportional penalties.

2.6 Applying for authorisation

Even if a substance has been added to the Authorisation List and given a sunset date there is still a possibility to continue manufacturing and using it, if an authorisation is granted for that purpose. An application for authorisation needs to be made before the latest application date of the substance in question if there is a need to be able to continue its use right after the sunset date (applications that are still being processed after the sunset date do not give the right to continue the use of the substance). An authorisation is not given lightly as the substance in question has already been identified as a risk. There are two possible routes to an authorisation:

- Adequate control route: if it can be shown that the risk caused by the substance can be adequately controlled

- Socio-economic (SEA) route: if it can be shown that the socio-economic benefits outweigh the risk and that there are no suitable alternative substances or technologies.

Both the Risk Assessment Committee (RAC) and the Committee for Socio-Economic Analysis (SEAC) of ECHA give their opinion on the application and based on their final opinions the European Commission will make final decision about granting an authorisation and define the conditions for it. All granted authorisations have a time-limited review period which is determined individually for each case. An authorisation can also be reviewed at any point if there are changes in the socio-economic impact or in the risks caused by the substance or if new alternatives emerge. Granted authorisation gives top-down use coverage within the supply chain (see FIGURE 7) so that also downstream users can use the authorised substance, given that they do comply with the decision and notify ECHA about their use of the substance.

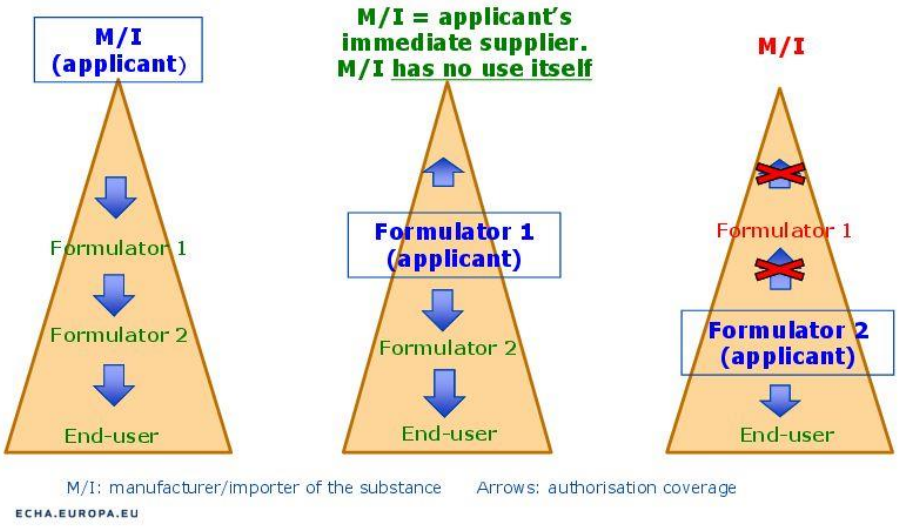


FIGURE 7. Use coverage of authorisation within supply chain[7]

[7] Source: European Chemicals Agency, http://echa.europa.eu/

Before applying for an authorisation the need should be thoroughly considered as compiling the application is time-consuming and expensive and there is no guarantee that an authorisation will be granted – and even when granted, there are reviews to be paid and also the possibility of cancellation if circumstances change. In the following table there are the current fees for applications as set in Regulation (EU) No 254/2013, Annex VI (review charges of an authorisation are the same – 254/2013, Annex VII).

TABLE 2. Fees of applications for authorisation

	standard fees	medium enterprises[8]	small enterprises	micro enterprises
base fee	53 300 €	39 975 €	23 985 €	5 330 €
additional fee/substance	10 660 €	7 995 €	4 797 €	1 066 €
additional fee/use	10 660 €	7 995 €	4 797 €	1 066 €

The reason why making the application consumes time and resources is the amount of paperwork that is required. The application must have among others a CSR (see Appendix 4 for format), analysis of alternatives, substitution plan and socio-economic analysis. Thus, it is advisable to be alert about the substances that are going through the REACH process in order to try to substitute them before they are included to the Authorisation Lists and to only tackle the application process if there truly are no other possibilities. It should be kept in mind that research for substitution should be continued even if an authorisation is granted as it can be cancelled.

[8] The European Commission defines the size of an enterprise as follows (2003/361/EC, Article 2):

- medium: employs fewer than 250 persons with turnover not exceeding €50 million, and/or annual balance sheet total not exceeding €43 million
- small: employs fewer than 50 persons with annual turnover and/or balance sheet total not exceeding €10 million
- micro: employs fewer than 10 persons with annual turnover and/or balance sheet total not exceeding €2 million

3 OBLIGATIONS FOR COMPANIES DUE TO REACH

The REACH regulation demands actions from companies that are in its scope. The main obligations can be roughly divided into two categories: need for registration and obligation to inform about these registered substances. As mentioned already previously, not all companies are affected by the regulation so it is important to understand the company's position and identify the obligations that might come with that position.

The following regulation Articles that are discussed do not contain all the actions required by the regulation but rather form a group of the most important Articles for any company's operations. For example, requirements concerning monomers or polymers are left out intentionally.

3.1 Register

As mentioned earlier, the first half of the REACH obligations concern the need to register used substances whether they are on their own, in mixture or in an article. In order to be able to comply with these requirements, companies need to have a good grasp on the substances they are using and the amounts of those substances.

3.1.1 Article 5 – No data, no market

Article 5 of the regulation, which is also titled as "*No data, no market*", forbids a substance (no matter whether it is on its own, in a mixture or in an article) to be manufactured or placed on the market unless it has been registered accordingly. This means that companies have to make sure that the substances they use or have in their articles have been registered (or at least pre-registered in case of phase-in substances that fall into the 3rd registration phase which still has its registration deadline ahead) if they wish to continue their operations. At this point it does not matter if the substances are considered dangerous or not, the main point is to get all the substances in use registered.

3.1.2 Articles 6 and 7(1)

Article 6 demands a manufacturer or importer of a substance (no matter if it is on its own or in one or more mixtures) to register it with the Agency if the yearly amount is one tonne or more.

A company that produces or imports articles is obligated by Article 7(1) to register any substance in those articles if

- the quantity of the substance in articles is over one tonne per year per producer/importer
  AND
- it is intended that the substance will be released in normal use.

This registration needs not to be done if the substance has been already registered for the same use (paragraph 6 of Article 7). Intended release means here that an article is meant to discharge a substance during its use. The main task for the company in this case is to determine if their articles fall under this definition, for example scented articles with a main function belong to this group because the article is designed for the main function and the scent is only an additional feature i.e. without the scent the article could still be used. Articles with a main function of releasing substance or mixture are not considered here as articles with intended release.

3.2 Inform

The second half of the obligations is about informing ECHA as well as giving information within the supply chain (both up and down the supply chain) and making sure that the people who work with these substances are well-informed and that the information is readily available.

3.2.1 Article 7 (2)

ECHA needs to be informed when a company produces or imports articles which contain SVHC:

- in quantity of over one tonne of the substance per year per producer/importer
  AND
- the substance concentration is above 0,1% w/w.

Here the problem is to identify all the used substances within every produced/imported article and to be able to define both the total quantity and the concentration. Other actors in the supply chain are required to deliver some information concerning their products but as it will be shown in the next chapters, that information does not have to be as detailed as sometimes would be needed i.e. a company might be informed that an article supplied to them contains over 0,1% w/w of SVHC but not the exact amount which means further research for the receiving company in order to determine if the threshold of 0,1% w/w is reached if that article is for example used in producing another new article. The whole process gets complicated easily when production is considered and multiple SVHC are present.

3.2.2 Article 33

The supplier of an article which contains SVHC over 0,1 % w/w is required to give the recipient of that article sufficient amount of information concerning the safe use of the article. The minimum information set by Article 33 is only the name of the substance. A consumer of the article is also entitled to this information by requesting it from the supplier which needs to give the information within 45 days without any charges.

3.2.3 Article 31 – Safety Data Sheet

A supplier of a substance or a mixture is required to compile a Safety Data Sheet as set in Annex II (see Appendix 2 for format and Appendix 3 for an example) and deliver it to the recipient if the substance/mixture is classified as dangerous (PBT, vPvB, Annex XIV substances or substances classified as dangerous by Directives 67/548/EEC or 1999/45/EC).

The supplier is required to deliver this SDS at recipient's request also if the substance is not classified as dangerous but it contains one of the following:

- at least one substance with human health or environmental hazard in an individual concentration of
    - non-gaseous mixtures: at least 1 % by weight
    - gaseous mixtures: at least 0,2 % by volume
- at least one substance which is PBT or vPvB or included to Annex XIV in an individual concentration of 0,1 % or more by weight (non-gaseous mixtures)
- a substance for which Community workplace exposure limits are set.

It should also be noted that the article demands that the SDS's are to be presented in the official language of the Member States where the substance or mixture is placed on the market. That means then that the supplier of the substance might need to get the SDS's translated in order to comply with the article.

3.2.4 Article 32 – down the supply chain

In cases where the SDS is not required to be delivered to the recipient the supplier still needs to provide some information on the substances. The recipient should be informed about the registration numbers of the substances, whether the substances are under authorisation, information on any granted/denied authorisations within the supply chain in question as well as information about any restrictions and any other relevant information which would help in managing risks caused by the use of the substances.

3.2.5 Article 34 – up the supply chain

All actors in the supply chain are required to inform the next actor up the supply chain of any new information on hazardous properties of a substance or a mixture and any other information which seems to question the quality of risk management measures set in the SDS.

3.2.6 Articles 35 and 36

Articles 35 and 36 set the requirements for storing information and making sure that it is accessible. According to Article 35 all workers who use or might be exposed to substances or mixtures during their work need to have an access to the related information i.e. to Safety Data Sheets or other information defined by Article 32.

Article 36 in turn requires that actors in the supply chain have to gather and keep available all information needed to comply with REACH and it also has to be stored at least for 10 years after the last manufacture, import, supply or use of a substance or mixture.

4 ACTIONS NEEDED DUE TO THE REGULATION

As said earlier, the main focus of the REACH regulation is to control substances which can have an impact on humans and the environment but in addition to that it also tries to increase chemical awareness and change people's attitudes in order to make working with chemical substances safer.

4.1 Starting

First thing for any company that is new to REACH is to define where they stand in relation to the regulation. Are there articles imported or manufactured that have substances which fall under REACH supervision? Operators that are in scope of the regulation need acknowledge their situation and take needed actions.

In the beginning it was pointed out that REACH does not only affect one part of the company's operations but rather touches just about everything that happens in the company. This is why it is important to thoroughly examine the situation and get help if it is needed. There are currently a multitude of consulting companies that are specialized in REACH and other related regulations (such as RoHS and WEEE).

4.2 Getting data

For a REACH implementation case a manufacturing company would be a good example. Once it is identified that the company is in scope of the regulation the real work starts. In order to understand the current situation the company needs to gather information from its suppliers concerning the supplied items as well as get an overall view of the amounts of items/substances it uses yearly.

Already here rises a problem. According to Article 33 a supplier of SVHC contaminated item is only required to give the name of the substance which is present in the item in over 0,1 % w/w. The regulation does not even define how the information should be delivered. This means that the data formats used by companies can range from Excel sheets (easy to use and work with) to several hundred individual pages of pdf or in worst case scenarios an online search page where items need to be searched one by one. Depending on the supplier and the amount of data that needs to be checked this step might take some time. Of course, the bigger the company and the smaller the supplier, the more there is leverage to get the data in the format wanted.

The suppliers are required to give the information to the recipient but can that be trusted? What if they are not familiar with the regulation? Is there perhaps a need to be proactive, contact the suppliers and ask what the situation is? Are there resources for that? It might sounds simple on paper – supplier gives needed information with delivery but the real world makes it complicated.

When the information is gathered it needs to be stored in some register so that it can be seen what are the yearly tonnage limits (is there a need for registration) and what is the substance content of the finished products (is there a SVHC concentration of over 0,1 % w/w). Here again problems might arise. The suppliers only need to tell if the item they supply passes the threshold of 0,1 % but not the exact amount. Then there is also the question of “once an article, always an article” which has been mentioned already earlier. The company needs to decide which approach it takes (some countries have already determined how the regulation should be interpreted) and then proceed accordingly. To make the problem clearer an example case can be studied with the following TABLES 3 and 4. Items A-E are needed to manufacture a final product F. The suppliers have informed that items A-D are SVHC contaminated. Even if the mass of each item would be known the calculated data would not tell for sure that in the final product none of the SVHC reaches the 0,1 % limit because the percentages shown are the minimums calculated with that 0,1 %. In order to get the exact values the manufacturer would have to find a way to determine the SVHC concentrations.

TABLE 3. Situation A without exact percentages

item	substance #	>0,1%	mass	mass of SVHC	min. %
A	25-0	yes	10	0,0100	0,002 %
B	13-9	yes	25	0,0250	0,005 %
C	98-4	yes	30	0,0300	0,006 %
D	01-1	yes	47	0,0470	0,009 %
E	-	no	400	-	78,125 %
			512		

If on the other hand the exact percentages are known, then the situation is clearer (see TABLE 4). All the items still contain SVHC in concentrations which are above the limit but in this case the final product contains only one SVHC which goes over the limit. If now the policy is that “once an article, always an article”, then the company needs to inform its recipient that the final product F contains these items A-D which are SVCH contaminated and deliver the needed information on all of those. If on the other hand the final product F is seen as one article, then the company is required to only inform that it contains substance 01-1 in a concentration which exceeds the limit of 0,1 %.

TABLE 4. Situation B with exact percentages

item	substance #	>0,1%	mass	mass of SVHC	min. %
A	25-0	0,60 %	10	0,060	0,012 %
B	13-9	0,20 %	25	0,050	0,010 %
C	98-4	0,15 %	30	0,045	0,009 %
D	01-1	1,20 %	47	0,564	0,110 %
E	-	no	400	-	78,125 %
			512		

Both cases have their problems and a lot also depends on the “once an article, always an article” decision.

The focus should not be only on the supplier side as the company also has obligations to its own customers and to ECHA. The data that is gathered is needed when the required SDS’s and other information need to be compiled and conveyed to other parties. It should also be remembered that for example according to Article 31 SDS’s need to be presented in the official language of the country where they are placed on market which means that the SDS’s might even need to be translated to several languages and then all the versions have to be kept updated also. It is yet another piece of data which requires careful management and resources.

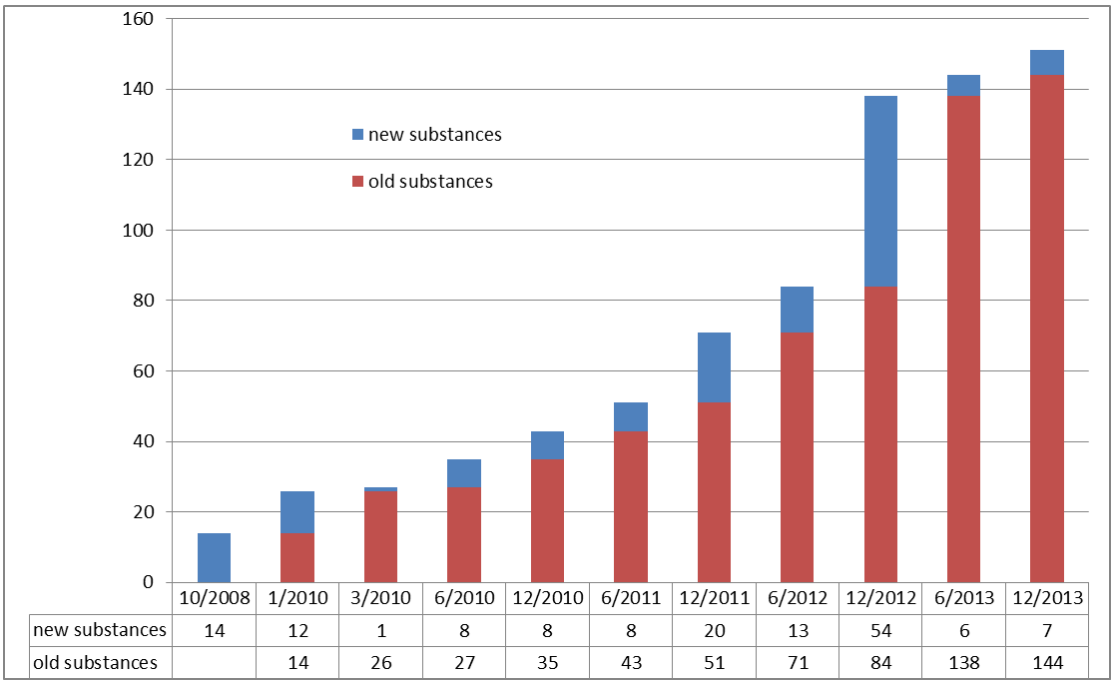
4.3 Information flows

Correct information and working information flows are vital when working with REACH. The internal registers (chemical registers, bill of materials, purchase orders etc.) need to be maintained properly so that the information there is correct and up-to-date. It is not only the internal information which changes but also suppliers modify or change the items they deliver and ECHA also updates its lists regularly. This is why the data gathering phase needs to be done well and the registers designed so that changes can be made easily.

Information flows need to work in all directions. Engineering needs to know if there is a need to re-engineer something due to a substance which is already banned or on its way to the Authorisation List. Naturally any of these changes need to reach the procurement so that they can purchase accordingly. This also shows why it would be good to train most of the personnel about REACH because it affects so many different stages of the whole manufacturing process. The warehousing and logistic personnel need to be aware of the regulation too so that they understand why for example two identical looking items should not be mixed up (because the older version is SVHC contaminated but the new delivery has been modified so that it does not contain SVHCs anymore). Sales and marketing personnel need to also know about REACH as they are in contact with the customer and have to know what to tell about the product in respect to the regulation.

4.4 Up-to-date – preparing for future

When the needed information is available, correct and updated, then it is time to make sure that the company will keep being up-to-date and is preparing for the future. As said, nothing concerning REACH and ECHA is set in stone. The Candidate List is currently updated twice a year and the number of substances in it keeps on increasing. FIGURE 8 shows how the size of the Candidate List has grown relatively steadily over the years. Currently there are 151 substances on the list but as December 2012 shows with 54 new added substances, there is no certainty that the amount of new substances would always be around 10-20. The growing numbers make information management harder as there is need to search and search again the items in use when new substances are announced.



	10/2008	1/2010	3/2010	6/2010	12/2010	6/2011	12/2011	6/2012	12/2012	6/2013	12/2013
new substances	14	12	1	8	8	8	20	13	54	6	7
old substances		14	26	27	35	43	51	71	84	138	144

FIGURE 8. Substances on the Candidate List

It is not only the Candidate and Authorisation Lists that need to be watched for but also the SIN-list (see FIGURE 1) is a good indicator of those substances that need to be observed. The sooner it is observed that some of the items used in manufacturing contain substances that might end up in the Authorisation List, the easier it is to prepare for that. If there is the possibility that substances/items become obsolete, then re-engineering is usually the easiest option. Once a substance is identified as SVHC it does not mean that it takes a certain time before it goes to the Authorisation List – it might happen extremely rapidly if conditions so require or it might also take longer (at the moment the shortest time from inclusion to the Candidate List to Authorisation and finally to the sunset date is little less than 4 years, longest is over 8 years and none of the first included substances got the first sunset date – in fact one of the first substances has currently the longest time until its sunset date). This is why there is a need to act quickly rather than believing that there is enough time before the possible sunset date. Researching possible alternatives consumes resources and in case there are no acceptable results then applying for authorisation is the only option left with substances that have already gotten their sunset dates. In chapter 2.6 the application process was discussed and it was pointed out that it is not an easy option (though, it should be remembered that in cases where authorisation is granted up in the supply chain it covers also the downstream users). In any case, a proactive stance is the best as both research and applying for an authorisation consume time and resources.

5 CONCLUSIONS

As mentioned earlier, not all requirements and obligations of REACH are discussed here but the focus was has rather been on the main points. It should be evident now that REACH affects the whole supply chain and that being proactive is the best way to prevent a company from losses. Active approach and up-to-date information are the key elements in implementing REACH as well as fulfilling the requirements of the regulation.

The burden of registration should ease at least to some degree by time as the most commonly used substances will be already registered and the companies have also

registered themselves and their substances in use. Naturally there will of course always come new substances to the market that need to be thoroughly examined and tested according to REACH requirements. The burden of proof of the safety of chemicals has now been shifted to the industry and it is yet to be seen whether REACH will fulfill its aims. At least it has managed to increase chemical awareness and made companies to look into the substances and items they are using and forced them to redesign or to search for alternatives for dangerous substances. Though, what has been the cost of all this and who has had to pay it? It will be interesting to follow the development and discussions around REACH – will the tonnage limits someday be lowered below 1 tonne, how reliable the information compiled for REACH actually is, will all companies ever be REACH compliant and what happens when majority of the used chemicals have been registered and dangerous ones authorised, does REACH compliance then turn into mere data updates and information management.

While it is worthwhile to consider what the future might bring, especially with REACH as being up-to-date is one of those crucial points, it is equally important to focus on the current situation. To analyse own operations and the related supply chains in order to identify possible REACH related bottlenecks and act on them before they turn into real problems.

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APPENDICES

Appendix 1. Content of REACH Regulation

Articles

TITLE I **GENERAL ISSUES** (Articles 1-4)	
	Chapter 1 Aim, scope and application
	Chapter 2 Definitions and general provision
TITLE II **REGISTRATION OF SUBSTANCES** (Articles 5-24)	
	Chapter 1 General obligation to register and information requirements
	Chapter 2 Substances regarded as being registered
	Chapter 3 Obligation to register and information requirements for certain types of isolated intermediates
	Chapter 4 Common provisions for all registrations
	Chapter 5 Transitional provisions applicable to phase-in substances and notified substances
TITLE III **DATA SHARING AND AVOIDANCE OF UNNECESSARY TESTING** (Articles 25-30)	
	Chapter 1 Objectives and general rules
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	Chapter 3 Rules for phase-in-substances
TITLE IV **INFORMATION IN THE SUPPLY CHAIN** (Articles 31-36)	
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TITLE VI **EVALUATION** (Articles 40-54)	
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TITLE VII **AUTHORISATION** (Articles 55-66)	
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TITLE VIII **RESTRICTIONS ON THE MANUFACTURING, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES AND MIXTURES** (Articles 67-73)	
	Chapter 1 General issues
	Chapter 2 Restrictions process
TITLE IX **FEES AND CHARGES** (Article 74)	
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TITLE XI **CLASSIFICATION AND LABELLING INVENTORY** (Articles 112-116)	
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TITLE XIV **ENFORCEMENT** (Articles 125-127)
TITLE XV **TRANSITIONAL AND FINAL PROVISIONS** (Articles 128-141)

Annexes

ANNEX I **GENERAL PROVISIONS FOR ASSESSING SUBSTANCES AND PREPARING CHEMICAL SAFETY REPORTS**
ANNEX II **GUIDE TO THE COMPILATION OF SAFETY DATA SHEETS**
ANNEX III **CRITERIA FOR SUBSTANCES REGISTERED IN QUANTITIES BETWEEN 1 AND 10 TONNES**
ANNEX IV **EXEMPTIONS FROM THE OBLIGATION TO REGISTER IN ACCORDANCE WITH ARTICLE 2(7)(a)**
ANNEX V **EXEMPTIONS FROM THE OBLIGATION TO REGISTER IN ACCORDANCE WITH ARTICLE 2(7)(b)**
ANNEX VI **INFORMATION REQUIREMENTS REFERRED TO IN ARTICLE 10**
ANNEX VII **STANDARD INFORMATION REQUIREMENTS FOR SUBSTANCES MANUFACTURED OR IMPORTED IN QUANTITIES OF 1 TONNE OR MORE**
ANNEX VIII **STANDARD INFORMATION REQUIREMENTS FOR SUBSTANCES MANUFACTURED OR IMPORTED IN QUANTITIES OF 10 TONNES OR MORE**
ANNEX IX **STANDARD INFORMATION REQUIREMENTS FOR SUBSTANCES MANUFACTURED OR IMPORTED IN QUANTITIES OF 100 TONNES OR MORE**
ANNEX X **STANDARD INFORMATION REQUIREMENTS FOR SUBSTANCES MANUFACTURED OR IMPORTED IN QUANTITIES OF 1 000 TONNES OR MORE**
ANNEX XI **GENERAL RULES FOR ADAPTATION OF THE STANDARD TESTING REGIME SET OUT IN ANNEXES VII TO X**
ANNEX XII **GENERAL PROVISIONS FOR DOWNSTREAM USERS TO ASSESS SUBSTANCES AND PREPARE CHEMICAL SAFETY REPORTS**
ANNEX XIII **CRITERIA FOR THE IDENTIFICATION OF PERSISTENT, BIOACCUMULATIVE AND TOXIC SUBSTANCES, AND VERY PERSISTENT AND VERY BIOACCUMULATIVE SUBSTANCES**
ANNEX XIV **LIST OF SUBSTANCES SUBJECT TO AUTHORISATION**
ANNEX XV **DOSSIERS**
ANNEX XVI **SOCIO-ECONOMIC ANALYSIS**
ANNEX XVII **RESTRICTIONS ON THE MANUFACTURE, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES, MIXTURES AND ARTICLES**

Appendix 2. Safety Data Sheet Format (Annex II)

SAFETY DATA SHEET FORMAT

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

- 1.1. Product identifier
- 1.2. Relevant identified uses of the substance or mixture and uses advised against
- 1.3. Details of the supplier of the safety data sheet
- 1.4. Emergency telephone number

SECTION 2: **Hazards identification**

- 2.1. Classification of the substance or mixture
- 2.2. Label elements
- 2.3. Other hazards

SECTION 3: **Composition/information on ingredients** (only one: 3.1. OR 3.2.)

- 3.1. Substances
- 3.2. Mixtures

SECTION 4: **First aid measures**

- 4.1. Description of first aid measures
- 4.2. Most important symptoms and effects, both acute and delayed
- 4.3. Indication of any immediate medical attention and special treatment needed

SECTION 5: **Firefighting measures**

- 5.1. Extinguishing media
- 5.2. Special hazards arising from the substance or mixture
- 5.3. Advice for firefighters

SECTION 6: **Accidental release measures**

- 6.1. Personal precautions, protective equipment and emergency procedures
- 6.2. Environmental precautions
- 6.3. Methods and material for containment and cleaning up
- 6.4. Reference to other sections

SECTION 7: **Handling and storage**

- 7.1. Precautions for safe handling
- 7.2. Conditions for safe storage, including any incompatibilities
- 7.3. Specific end use(s)

SECTION 8: **Exposure controls/personal protection**

- 8.1. Control parameters
- 8.2. Exposure controls

SECTION 9: **Physical and chemical properties**

- 9.1. Information on basic physical and chemical properties
- 9.2. Other information

SECTION 10: **Stability and reactivity**

- 10.1. Reactivity
- 10.2. Chemical stability

Appendix 3. An example of a SDS

NESTE OIL

SAFETY DATA SHEET
NESSOL LIAV 250
Date 18.9.2013 Previous date: 10.8.2012

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EN

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

1.1.1 Commercial Product Name
NESSOL LIAV 250

1.1.2 Product code
(ID 10527), 135140, 753000, 897200
REACH Registration Number
01-2119456620-43-0004
Hydrocarbons, C11-C14, n-alkanes, isoalkanes, cyclics, < 2% aromatics

1.2 Relevant identified uses of the substance or mixture and uses advised against

1.2.1 Recommended use
Manufacture of substance
Distribution of substance
Formulation & (re)packing of substances and mixtures
Uses in Coatings
Use in Cleaning Agents
Use in Oil and Gas field drilling and production operations
Lubricants
Metal working fluids / rolling oils
Use as binders and release agents
Use in Agrochemicals
Use as a fuel
Functional fluid
Road and construction applications
Other Consumer Uses
Use in laboratories
Explosives manufacture & use
Rubber production and processing
Polymer processing
Water treatment chemicals
Mining chemicals
De-icing and anti-icing applications
Propellant

See the PROC/SU/ERC codes of the identified uses in Section 16.

1.3 Details of the supplier of the safety data sheet

1.3.1 Supplier

	Neste Oil Oyj
Street address	Keilaranta 21
Postcode and post office	Espoo FINLAND
Postcode and post office	P.O.B. 95 FIN-00095 NESTE OIL FINLAND
Telephone	+358-10 45811
Telefax	+358-10 45 84442
Business ID	1852302-9
Email	KTTR@nesteoil.com (chemical safety)

1.4 Emergency telephone number

1.4.1 Telephone number, name and address
+358-9-471 977, +358-9-4711, Poison Information Centre/HUS
P.O.B 340 (Tukholmankatu 17) 00029 HUS (Helsinki, Finland)

2. HAZARDS IDENTIFICATION

May be fatal if swallowed and enters airways. (Asp. tox 1, H304)
Repeated exposure may cause skin dryness or cracking. (EUH066)

2.1 Classification of the substance or mixture

1272/2008 (CLP)
Asp. Tox. 1, H304
EUH066

67/548/EEC - 1999/45/EC
Xn; R65-66

2.2 Label elements

ADDITIONAL LABELLING OF RETAIL PACKAGES: Keep away from children. Just a sip of grill lighter may lead to life-threatening lung damage.

The package shall be marked with text: "Warning ! Do not pour on hot barbecue or coals; the liquid may burst into flames". RETAIL PACKAGES SHALL BE EQUIPPED WITH CHILD-RESISTANT FASTENINGS AND TACTILE WARNINGS OF DANGER.

1272/2008 (CLP)
GHS08

Signal word **Danger**

Hazard Statements

H304	May be fatal if swallowed and enters airways.
EUH066	Repeated exposure may cause skin dryness or cracking.

Precautionary Statements

P262	Do not get in eyes, on skin, or on clothing.
P301+P310	IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
P331	Do NOT induce vomiting.

2.3 Other hazards

Combustible liquid. Vapours may cause irritation to the eyes, respiratory system and the skin. Evaporates slowly. Risk of soil and ground water contamination.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

-

CAS number	Chemical name of the substance	Concentration	Classification
-	Hydrocarbons, C11-C14, nalkanes, isoalkanes, cyclics, < 2% aromatics	100 %	CLP: Asp. tox 1, H304; EUH066 DSD-DPD: Xn; R65, R66

3.3 Other information

Contains aromatic hydrocarbons max. 1 vol. %.
Identity outside the EU (CAS number and name of the substance): 64742-47-8, Distillates (petroleum), hydrotreated light. Previous EC number 265-149-8 Registration number, See chapter 1.1.2.

4. FIRST AID MEASURES

4.1 Description of first aid measures

4.1.2 Inhalation

If vapour is inhaled, remove the person to fresh air. If symptoms persist, call a physician. If breathing has stopped, apply artificial respiration.

4.1.3 Skin contact
Remove contaminated clothing. Wash the skin with plenty of water and soap. If skin irritation persists, consult a physician.

4.1.4 Eye contact
Rinse immediately with plenty of water, also under the eyelids. Continue irrigation for several minutes while moving eyes to extreme positions. P337 + P313 - If eye irritation persists: Get medical advice/attention.

4.1.5 Ingestion
DO NOT INDUCE VOMITING. Consult a physician (risk of aspiration into the lungs especially if nausea or irritation occurs).

4.2 Most important symptoms and effects, both acute and delayed
Aspiration of ingested product into lungs can cause fatal chemical pneumonitis. Prolonged or repeated contact causes drying and irritation of the skin.

4.3 Indication of immediate medical attention and special treatment needed
Aspiration into the lungs can cause fatal chemical pneumonitis.

5. FIREFIGHTING MEASURES

5.1 Extinguishing media
5.1.1 Suitable extinguishing media
Water spray, foam, dry powder, carbon dioxide.

5.1.2 Extinguishing media which must not be used for safety reasons
Water jet

5.2 Special hazards arising from the substance or mixture
Explosion risk due to pressure increase if product containers or tanks are subjected to fire. Strong heating or fire can produce carbon monoxide and other products resulting from uncomplete combustion.

5.3 Advice for firefighters
Cool product containers and tanks near the fire with water spray from a sufficiently safe distance. Prevent fire extinguishing water from contaminating surface water or the ground water system.

5.4 Specific methods
Precautions for fire-fighting: Self-contained breathing apparatus and full protective clothing.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures
Avoid inhalation of vapour and contact with skin. Wear adequate protective equipment at all operations. Evacuate people upwind from the spill area. Provide efficient ventilation.

6.2 Environmental precautions
Try to restrict the release and prevent spread of the product into the environment. Collect liquid before it spreads into drains, the ground and waters. In case of spill, immediately contact local authorities. Risk of soil and ground water contamination.

6.3 Methods and materials for containment and cleaning up
Immediately start clean-up of the liquid and contaminated soil. Large spills should be collected mechanically (remove by pumping) for disposal. Small amounts can be collected using absorbent material. Pay attention to the fire, explosion and health hazards caused by the product. In case of spillage in the water, collect the product by skimming or other suitable mechanical means. The use of dispersants should be advised by an expert, and, if required, approved by local authorities

6.4 Reference to other sections
Product waste should be disposed according to national regulations (item 13). For personal protection see section 8.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Handle the product in closed systems or provide sufficient ventilation. Avoid inhalation of vapour and contact with skin. Wear protective equipment when needed. Do not taste or swallow. When using, do not eat, drink or smoke. Wash hands before breaks and at the end of workday. Spills and leaks: Sweep up to prevent slipping hazard. During tank operations follow special instructions (risk of oxygen displacement and hydrocarbons).

This material is a static accumulator. Keep away from sources of ignition. Take precautionary measures (e.g. earthing) against static discharges.

7.2 Conditions for safe storage, including any incompatibilities

In a tank or a store suitable for flammable liquids. Keep containers tightly closed in a cool, well-ventilated place. Take precautionary measures to prevent product spills into drains, the ground or waters. Store retail batches in tightly sealed, labelled containers which are impermeable to hydrocarbons. Keep away from food and drink.

Suitable materials and coatings (chemical compatibility):
Teflon, polypropylene, polyethylene, stainless steel, carbon steel.
Unsuitable materials and coatings:
Butyl rubber, natural rubber, ethylene-propylene-diene monomer (EPDM), polystyrene.

7.3 Specific end use(s)

None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

8.1.1 Threshold limits

Solvent naphtha, group 1	500 mg/m^3 (8 h) HTP 2011/FIN

8.1.2 Other information on limit values

The occupational exposure monitoring method:SFS-3861, SFS-EN689
The individual limit values can also be applied for the petrol hydrocarbons.

8.1.4 DNELs

DNEL derivation is not justified.

8.1.5 PNECs

No information available.

8.2 Exposure controls

8.2.1 Appropriate engineering controls

Handle the product in closed systems or provide sufficient ventilation. Wear protective equipment when needed. Handle in accordance with good industrial hygiene and safety practice.

8.2.2 Individual protection measures

8.2.2.1 Respiratory protection

Filter device/Half mask (organic vapour filter, type A2). Filter device could be used maximum 2 hours at a time. Filter devices must not be used in conditions where the oxygen level is low (< 17 vol.-%). At high concentrations a breathing apparatus must be used (self-contained or fresh air hose breathing apparatus). Filter must be changed often enough. Respirators according to standards EN 140 and EN 141.

8.2.2.2 Hand protection

Protective gloves (e.g. of nitrile rubber). Breakthrough time >240, Protection class 5. Change protective gloves regularly. Attention: PVA does not resist water. Protective gloves according to standards EN 420 and EN 374.

8.2.2.3 Eye/face protection

Tightly fitting safety goggles.

8.2.2.4 Skin protection
Protective clothing (antistatic), splash-proof chemical protective clothing when needed.

8.2.3 Environmental exposure controls
Any possible leakage is considered by constructing collecting pools and sewerage systems as well as by surfacing the loading and unloading stations.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

9.1.1	**Appearance**	Liquid
9.1.2	**Odour**	A mild characteristic odour.
9.1.3	**Odour threshold**	no data available
9.1.4	**pH**	no data available
9.1.5	**Melting point/freezing point**	(Melting/pour point) < -20 °C (ASTM D 5950)
9.1.6	**Initial boiling point and boiling range**	200 - 250 °C (EN ISO 3405)
9.1.7	**Flash point**	Minimum 76 °C (EN ISO 2719)
9.1.8	**Evaporation rate**	no data available
9.1.9	**Flammability (solid, gas)**	no data available
9.1.10	**Explosive properties**	
9.1.10.1	**Lower explosion limit**	0,6 vol-%
9.1.10.2	**Upper explosion limit**	7 vol-% (estimated)
9.1.11	**Vapour pressure**	0,02 kPa (20 °C)(estimated)
9.1.12	**Vapour density**	> 3 (air= 1)
9.1.13	**Relative density**	0,77-0,87 (15°C; water= 1,4°C) (ISO 12185)
9.1.14	**Solubility(ies)**	
9.1.14.1	**Water solubility**	Slightly soluble (~ 10 mg/l)
9.1.14.2	**Fat solubility (solvent /oil to be specified)**	No data
9.1.15	**Partition coefficient: n-octanol/water**	Kerosine hydrocarbons log Kow = 3...above 6.
9.1.16	**Auto-ignition temperature**	>200 °C (estimated)
9.1.17	**Decomposition temperature**	no data available
9.1.18	**Viscosity**	Kinematic viscosity 2,0-3,5 mm²/s (20 °C; ASTM D 7042)
9.1.19	**Explosive properties**	Not explosive
9.1.20	**Oxidising properties**	Not oxidizing

9.2 Other information
Molecular Weight 178
Surface tension 24-26 mN/m 25 °C. (Wilhelmy plate method)

10. STABILITY AND REACTIVITY

10.1 Reactivity
Stable under normal conditions.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Stable under normal conditions.

10.4 Conditions to avoid
Avoid heat, sparks and open flames.

10.5 Incompatible materials
Strong oxidizing agents

10.6 Hazardous decomposition products
No decomposition if used as directed.

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

11.1.1 Acute toxicity
Very low toxicity when swallowed LD50 > 5000 mg/kg, (rat)(OECD 401),
in contact with skin LD50 > 2000 mg/kg, (rat), LD50 >3160 mg/kg(rabbit)(OECD 402)
and when inhaled LC50(4h) >4950 mg/m3(rat) (OECD403)

11.1.2 Irritation and corrosion
Not classified. (OECD404, 405). Prolonged or repeated contact causes drying and irritation of the skin.

11.1.3 Sensitisation
Not a skin sensitizer. (OECD 406).

11.1.4 Subacute, subchronic and prolonged toxicity
Not classifiable as a human carcinogen. (OECD 453)
Genotoxicity tests (in vitro and in vivo) have been negative.
(Ames-test/OECD471,OECD479,473,476,478,474)
Damage to fetus not classifiable (OECD 414).
No toxicity to reproduction (OECD 421).

11.1.5 STOT-single exposure
No known effect.

11.1.6 STOT-repeated exposure
No known effect. (OECD 408, 413, 422)

11.1.7 Aspiration hazard
May be fatal if swallowed and enters airways. Aspiration into the lungs can cause fatal chemical pneumonitis.

11.1.8 Other information on acute toxicity
Toxicological data are based on tests with corresponding products or components

12. ECOLOGICAL INFORMATION

12.1 Toxicity

12.1.1 Aquatic toxicity
Very low toxicity.

Acute aquatic toxicity :
fish: LL50/24h > 1000 mg/l; LL0/96h = 1000 mg/l (OECD203)
crustacean : EL50/24h > 1000 mg/l; EL0/48h = 1000 mg/l (OECD 202)
alga :EL50/72h > 1000 mg/l; NOELR/72h = 1000 mg/l (OECD 201)

Chronic aquatic toxicity :
fish : NOELR/28d = 0,173 mg/l (QSAR)
crustacean :NOELR/21d = 1,22 mg/l (QSAR)

12.2 Persistence and degradability

12.2.1 Biodegradation
Readily biodegradable (OECD306, 301F)

12.2.2 **Chemical degradation**
Does not hydrolyze in water. Volatile hydrocarbons are degradable by atmospheric chemistry.

12.3 Bioaccumulative potential
There is no data available for this product.

12.4 Mobility in soil
Product evaporates slowly from surface soil and water. Product can penetrate soil until reaching the surface of ground water. Degradation occurs extremely slowly under anaerobic conditions. High-molecular hydrocarbons can be adsorbed onto organic material in soil or sediment (log Kow > 3).

12.5 Results of PBT and vPvB assessment
This substance is not considered to be persistent, bioaccumulating nor toxic (PBT). This substance is not considered to be very persistent nor very bioaccumulating (vPvB).

12.6 Other adverse effects
Product causes fouling, and direct contact produces harmful effects e.g. to birds and vegetation.Information given is based on data on the components and the ecotoxicology of similar products.

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods
Product waste is hazardous waste. It should be treated according to national regulations and local authorities' advice. When handling the waste note the hazards and take care of necessary safety measures, labelling and information.

13.2 Waste from residues / unused products
Empty containers may contain combustible product residues Empty containers should be taken for local recycling or waste disposal.

14. TRANSPORT INFORMATION

14.1	**UN number**	Not dangerous goods in the meaning of ADR/RID, ADNR, IMDG-Code, ICAO/IATA-DGR
14.2	**UN proper shipping name**	-
14.3	**Transport hazard class(es)**	-
14.4	**Packing group**	-

14.5 Environmental hazards
-

14.6 Special precautions for users
-

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Bulk (MARPOL 73/78, Annex II): Noxious liquid, NF, (7), n.o.s.(LIAV 250 contains Iso- and cyclo-alkanes (C10-C11)). ST3, Cat. Y. According to MARPOL: "Non-solidifying substance".

15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
EC/1907/2006 (REACH), Annex XVII: Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles.

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006. Updated according to regulation (EU) N:o 453/2010 amending regulation (EC) N:o 1907/2006 (REACH).

15.2 Chemical safety assessment

A Chemical Safety Assessment has been carried out for this substance. The substance is classified H304 (May be fatal if swallowed and enters airways). There are no routine anticipated exposures by ingestion related to any supported uses of this substance. The risk can therefore be controlled by implementing the risk management measures represented in this Safety Data Sheet, and exposure scenarios are not required.

16. OTHER INFORMATION

16.1 Additions, Deletions, Revisions

Paragraph 1: Emergency telephone
Paragraph 2: Classification of the substance

16.2 Key or legend to abbreviations and acronyms

CLP= Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006
DSD= Council Directive (67/548/EEC) on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances
DPD= Directive 1999/45/EC of the European Parliament and of the Council concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations

DNEL = Derived No-Effect Level
PNEC = Predicted No-Effect Concentration
SU = Sector of Use
PROC = Process Category
PC = Product Category
ERC = Environmental Release Category
.

16.3 Key literature references and sources for data

Regulations, databases, literature, own research. Chemical Safety Report 2012.

16.5 List of relevant R phrases, hazard statements, safety phrases and/or precautionary statements

R65	Harmful: may cause lung damage if swallowed.
R66	Repeated exposure may cause skin dryness or cracking.
H304	May be fatal if swallowed and enters airways.

16.7 Recommended restrictions

Identified uses:
Manufacture of substance, Industrial use (PROC 1, 2, 3, 4, 8a/b, 15; ERC 1, 4)
Distribution of substance, Industrial use (PROC 1, 2, 3, 4, 8a/b, 9, 15; ERC 1, 2, 3, 4, 5, 6a/b/c/d, 7)
Formulation & (re)packing of substances and mixtures, Industrial use (PROC 1, 2, 3, 4, 5, 8a/b, 9, 14, 15; ERC 2)
Uses in Coatings:
Industrial use (PROC 1, 2, 3, 4, 5, 7, 8a/b, 9, 10, 13, 14, 15; ERC 4)
Professional use (PROC 1, 2, 3, 4, 5, 8a/b, 10, 11, 13, 15, 19; ERC 8a/d)
Consumers (PC 1, 4, 8, 9a/b/c, 15, 18, 23, 24, 31, 34; ERC 8a/d)
Use in Cleaning Agents:
Industrial use (PROC1, 2, 3, 4, 7, 8a/b, 10, 13; ERC 4)
Professional use (PROC 1, 2, 3, 4, 8a/b, 10, 11, 13; ERC 8a/d)
Consumers (PC 3, 4, 8, 9a/b/c, 24, 35, 38; ERC 8a/d)
Use in Oil and Gas field drilling and production operations:
Industrial use (PROC 1, 2, 3, 4, 8a/b; ERC 4)
Professional use (PROC 1, 2, 3, 4, 8a/b; ERC 8d, 9b)
Lubricants:
Industrial use (PROC 1, 2, 3, 4, 7, 8a/b, 9, 10, 13, 17, 18; ERC 4, 7)
Professional use (PROC 1, 2, 3, 4, 8a/b, 9, 10, 11, 13, 17, 18, 20; ERC 8a/d, 9a/b)
Consumers (PC 1, 24, 31; ERC 8a/d, 9a/b)
Metal working fluids / rolling oils:
Industrial use (PROC 1, 2, 3, 4, 5, 7, 8a/b, 9, 10, 13, 17; ERC 4)
Professional use (PROC 1, 2, 3, 5, 8a/b, 9, 10, 11, 13, 17; ERC 8a/d)
Use as binders and release agents:
Industrial use (PROC 1, 2, 3, 4, 6, 7, 8b, 10, 13, 14; ERC 4)
Professional use (PROC 1, 2, 3, 4, 6, 8a/b, 10, 11, 14; ERC 8a/d)
Use in Agrochemicals, Consumers (PC 12, 27; ERC 8a/d)
Use as a fuel:
Industrial use (PROC 1, 2, 3, 8a/b, 16; ERC 7)
Professional use (PROC 1, 2, 3, 8a/b, 16; ERC 9a/b)
Consumers (PC 13; ERC 9a/b)
Functional fluid:
Industrial use (PROC 1, 2, 3, 4, 8a/b, 9; ERC 7)
Professional use (PROC 1, 2, 3, 8a, 9, 20; ERC 9a/b)
Consumers (PC 16, 17; ERC 9a/b)
Road and construction applications, Professional use (PROC 8a/b, 9, 10, 11, 13; ERC 8d/f)
Other Consumer Uses, Consumers (PC 28, 39; ERC 8a/d)
Use in laboratories:
Industrial use (PROC 10, 15; ERC 2, 4)
Professional use (PROC 10, 15; ERC 8a)
Explosives manufacture & use, Professional use (PROC 1, 2, 3, 5, 8a/b; ERC 8e)
Rubber production and processing, Industrial use (SU 10; PROC 1, 2, 3, 4, 5, 6, 7, 8a/b, 9, 13, 14, 15, 21; ERC 1, 4, 6d)
Polymer processing:
Industrial use (SU 10; PROC 1, 2, 3, 4, 5, 6, 8a/b, 9, 13, 14, 21; ERC 4)
Professional use (PROC 1, 2, 6, 8a/b, 14, 21; ERC 8a/d)
Water treatment chemicals:
Industrial use (PROC 1, 2, 3, 4, 8a/b, 13; ERC 3, 4)
Professional use (PROC 1, 2, 3, 4, 8a/b, 13; ERC 8f)
Mining chemicals, Industrial use (PROC 1, 2, 3, 4, 5, 8a/b, 9; ERC 4)
De-icing and anti-icing applications, Professional use (PROC 1, 2, 8a/b, 11; ERC 8d)
Propellant, Consumers (PC 1, 3, 4, 5, 9a/b/c, 10, 24, 31, 35; ERC 8a/d)

16.8 Further information

ADDITIONAL INFORMATION AVAILABLE FROM: Neste Oil Corporation, Solvents and Special Fuels, tel. int.+358-10 45811, e-mail: solvents.operations@nesteoil.com

Appendix 4. Chemical Safety Report Format (Annex I, section 7)

CHEMICAL SAFETY REPORT FORMAT

PART A

1. SUMMARY OF RISK MANAGEMENT MEASURES
2. DECLARATION THAT RISK MANAGEMENT MEASURES ARE IMPLEMENTED
3. DECLARATION THAT RISK MANAGEMENT MEASURES ARE COMMUNICATED

PART B

1. IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES
2. MANUFACTURE AND USES
    - 2.1. Manufacture
    - 2.2. Identified uses
    - 2.3. Uses advised against
3. CLASSIFICATION AND LABELLING
4. ENVIRONMENTAL FATE PROPERTIES
    - 4.1. Degradation
    - 4.2. Environmental distribution
    - 4.3. Bioaccumulation
    - 4.4. Secondary Poisoning
5. HUMAN HEALTH HAZARD ASSESSMENT
    - 5.1. Toxicokinetics (absorption, metabolism, distribution and elimination)
    - 5.2. Acute toxicity
    - 5.3. Irritation
    - 5.4. Corrosivity
    - 5.5. Sensitisation
    - 5.6. Repeated dose toxicity
    - 5.7. Germ cell mutagenicity
    - 5.8. Carcinogenicity
    - 5.9. Toxicity for reproduction
    - 5.10. Other effects
    - 5.11. Derivation of DNEL(s)
6. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICOCHEMICAL PROPERTIES
    - 6.1. Explosivity
    - 6.2. Flammability
    - 6.3. Oxidising potential
7. ENVIRONMENTAL HAZARD ASSESSMENT
    - 7.1. Aquatic Compartment (including sediment)
    - 7.2. Terrestrial Compartment
    - 7.3. Atmospheric Compartment
    - 7.4. Microbiological Activity in Sewage Treatment Systems
8. PBT AND VPVB ASSESSMENT
9. EXPOSURE ASSESSMENT
    - 9.1. [Title of Exposure Scenario 1]