Registration, Evaluation, Authorisation and Restriction of Chemicals Regulations (REACH)

Securing Your Supply Chain
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Securing Your Supply Chain

Introduction
From 2013, components you use in operations and manufacturing could be affected by REACH Regulations to the point where they may no longer be available. In short, it is likely that availability, price and technical characteristics of some of your components and even critical components will change significantly in the short and long term.

From June 2007, REACH impacted all industrial and business sectors in Ireland. The REACH regulations are European regulations aimed at controlling and organising the manufacturing and distribution of harmful substances.

Initially the focus on REACH was those who manufacture and import chemicals and substances in order that they can be registered and evaluated. For most employers the impact was therefore relatively small, outside of ensuring that their suppliers had registered the substances they use.

However, REACH is now at the Authorisation stage and with that comes a number of important deadlines. Substances that are carcinogenic, mutagenic or
harmful to reproduction, persistent, bioaccumulative, very persistent and very bioaccumulative (see Glossary for examples) will have to be authorised for use. Currently, the European Chemicals Agency (ECHA) has a Candidate List of over 130 substances that may, at some point, require employers to seek specific authorisation to use them. If Authorisation for use is not granted by a set deadline, then that substance cannot be used for that process.

This presents a major issue for all employers and not just those in the Chemical or Pharmaceutical industry. More importantly it will impact the availability, cost and technical characteristics of both substances and articles used in the manufacturing of components and it will impact all businesses in the supply chain. Even if the identified substance is used in small quantities as part of a specific process to manufacture a component that is then purchased and assembled into a larger product, if that substance has not been registered for that use and if there is no alternative substance, then employers will no longer be able to buy that component.

If that component is business critical, then this presents a significant business continuity issue.

The nearest next deadline, at the time of publishing, is August 2013. At that point, several substances will no longer be able to be used without Authorisation. Some of those substances, while used in small quantities, are still widely used in certain industries. Without any suitable alternative, unless each of those employers ensures that they or their suppliers gain authorisation, they will face a critical business continuity issue come the next Authorisation Deadline.

This guide will help employers evaluate the extent that the Authorisation issue may affect their business and to take steps to ensure that they secure their supply chain and operations as Authorisation is rolled out.
REACH: Securing Your Supply Chain

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REACH
Version 1 June 2013
Overview of Authorisation
What is Authorisation?
Authorisation is one of the processes established by the introduction of the REACH Regulations. The principle of this process is to make the use of certain substances subject to authorisation, therefore limiting their use, before eventually phasing out these substances as less harmful substitutes become available and practicable for businesses to use.

At this point, substances are not being “banned” for use, merely subject to manufacturers or users applying for the continued use of the substance in a specific set of circumstances and subject to demonstrable, stringent health and safety control measures.

The substances that will qualify for authorisation are known as Substances of Very High Concern (SVHC). These are substances known to cause cancer, have an effect on pregnancy, cause hereditary mutations, are persistent, bioaccumulative and Toxic, very persistent and very bioaccumulative. Following the initial stage of Registration, substances have been added to a Candidate List. This list highlights the SVHC and most, if not all, at some point will be subject to authorisation.

The main focus of this guide will be on the current Authorisation List, which lists those substances where a deadline has been set for manufacturers and users to apply for Authorisation (Application Date) and the date at which that substance can no longer be used without Authorisation (Sunset Date).

Who will be affected?
It is likely that many businesses will be affected eventually by the authorisation process, directly or indirectly. It is no longer the case that REACH is an issue for the Chemical Industry to deal with, Authorisation will affect all sectors in some way. Some could be impacted immediately by the upcoming Sunset Dates.

How could I be affected?
If a substance on the Authorisation/Candidate List is used in the manufacturing of a component you use then the availability, price and technical characteristics of these will change significantly in the short and long term.

However, the effect could be minimal or it could be significant. This will depend on several factors such as how critical a substance or article is to your business and whether or not your suppliers are going to seek authorisation.
For example, some of the substances listed for Authorisation go towards manufacturing inks and dyes. The impact on operations may be minimal as it isn’t critical that inks or dyes are of a very specific colour shade or hue. However, in some cases the same substances may be used to make enamel or glass frits which are then used to manufacture a product. If that frit is no longer available, then there could be significant business interruption trying to match enamelled components with painted parts, selling spare parts or even having to change entire product lines.

In addition, depending on how many different processes and suppliers the substances or articles you use as part of your business, the impact of Authorisation may be more difficult to detect, but the impact could still be as significant.

This will be the case where articles are assembled from a series of smaller articles. Industries like the automotive, electronic, computer, furniture, white goods, etc will probably find several components impacted by the Authorisation process.

It could be that a substance is used in very small quantities as part of an analytical process by a company who is a supplier to your supplier. If that substance is not Authorised and cannot be used, then that component may no longer be available to you or your supplier. Something as simple as a substance used in small quantities as part of the manufacture of a circuit board or processor could be subject to authorisation and could have a very significant impact on your supply chain.

There are very significant business continuity issues that may occur with the Authorisation process. It is fundamental that companies audit their supply chain to ensure that they will not be adversely impacted to the extent that they are left without critical components come August 2013.

The requirement to obtain an authorisation only applies for a substance that is used in the production of an article in the EU (i.e. authorisation is use based). If an article is imported from outside the EU and it contains a substance on the authorisation list, then the person who uses that article does not need to have an authorisation in place. Therefore when reviewing articles and components, it is only if the article is actually produced in the EU using a substance on the authorisation list that the potential affect on downstream uses may occur.

What do I need to do now?

This guide is designed to be a simple, step-by-step audit of your supply chain. Each step is accompanied by examples and blank forms that you can use to
record vital information so that you can establish if and to what extent the Authorisation process will impact your business.

In addition, the Authorisation list has been indexed to provide a non-exhaustive list of sectors and uses of the substances so that you can more easily identify if and where you will be effected.

This guide can help identify whether or not substances subject to authorisation could be used in the manufacture of a component you use; however there may be uses not captured in this document.

You should identify all critical components to your operations and even if you don’t feel that there is an impact from the information in this guide and you should still write to your suppliers to seek their assurance that this is the case.
Step One:

Identification of substances and articles
Step One – Identification of substances and articles

1.0 Introduction

The purpose of this inventory is to identify all the uses and manufacturing of substances and what they are, together with the production or importing of any articles (e.g. components). By listing all these items employers will have a record of everything the regulations and possibly Authorisation will affect. Completing a detailed inventory is vital to ensuring compliance and ensuring the identification of all substances and articles.

This stage takes a task-based assessment approach to activities and the “inputs” and “outputs” of those processes or tasks. In many cases, this will be a relatively simple process. Use of chemicals may be for cleaning or preparation of a task and here it is simply a matter of identifying those chemicals. However, where manufacturing is involved, then it may need a more detailed analysis as the input could be an article/component or the output the generation of a new substance.

For the purposes of this stage, “inputs” will be the use of substances/articles as part of a process or task. A simple example would be the cleaning of an office. In this example, the inputs will be the use of substances on their own or in preparations to clean the office and there will be no “outputs” as there are new substances or articles resulting from the process. Remember, waste products are not included as part of REACH unless they are being sold as a specific product.

For articles, this will be more complicated. However, the only way to really ensure that your supply chain is secured is to thoroughly exam production and processes to identify each component used in assembly, manufacturing or the operation. This may be more simple in the case where parts are manufactured on-site. For example, in the manufacturing and assembly of a cooker oven, the parts may be treated, painted and enamelled on site. Therefore, in the main, the same analysis can be conducted and the chemicals (pre-treatment, paint, frits, etc) can be identified. At the assembly stage, it may become more complicated as electrical circuit boards, digital clocks, etc are likely to come from external suppliers.

“Outputs” are therefore anything that comes out of a process. As these may be new substances unique to that employer’s operations, identifying these is important to establish the full range of duties under REACH. They could be products that are not exempt, articles or mixtures of substances.
1.1 Rationale for Stage One
A full audit of inputs into the business and operations is essential. Only when employers have identified all substances and articles that form part of their direct operations will they know if Authorisation is likely to have an impact.

For the purposes of this stage, it is prudent to identify all substances and articles that may be of very high concern (CMRs, etc). That way, while they may not currently be on a Candidate List or have a phased deadline for Authorisation at this point, the preparatory work will be completed if they are subjected to Authorisation in the future.

1.2 Who needs to complete this Stage?
All parties

2.0 Break down the task
For general health and safety purposes, employers may already have an analysis of the tasks and activities that occur as part of their operations and these will help form a basis for this part. The steps involved are:

- pick a task and break it down into the key stages.
- for each of those stages look at what substances are used (at this stage just identify the chemical) and/or what articles (in the form of parts or components) are used to make up part of or the whole product.

Once completed, employers should now have a list of all the substances/articles in a process. Where there are outputs from the process, similarly employers need to establish what they are and if they are a substance or an article.

Form 1.1 (Task Analysis) can be used to record the task analysis. Use a separate form for each task.

*Example Task Analysis – Screen Printing*

<table>
<thead>
<tr>
<th><strong>Key Steps</strong></th>
<th><strong>Inputs (Substances used in task or added to the process)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Cleaning screen pre printing.</td>
<td>Isopropyl Alcohol</td>
</tr>
<tr>
<td>Solvent applied with cloth and screen cleaned by hand.</td>
<td></td>
</tr>
<tr>
<td><strong>Key Steps</strong></td>
<td><strong>Inputs</strong> (Substances used in task or added to the process)</td>
</tr>
<tr>
<td>---------------------------------------------------</td>
<td>-------------------------------------------------------------</td>
</tr>
<tr>
<td>2. Applying inks</td>
<td>Solvent based inks:</td>
</tr>
<tr>
<td>Inks poured onto screen in requisite quantities. Screen is printed and the further applications as required.</td>
<td>Red</td>
</tr>
<tr>
<td></td>
<td>Blue</td>
</tr>
<tr>
<td></td>
<td>Black</td>
</tr>
<tr>
<td></td>
<td>Green</td>
</tr>
<tr>
<td>3. Fine finishing using brush applications</td>
<td>Solvent based inks:</td>
</tr>
<tr>
<td>When finer detailing is required for some printing, use of fine brushes and application by hand.</td>
<td>Red</td>
</tr>
<tr>
<td></td>
<td>Blue</td>
</tr>
<tr>
<td></td>
<td>Black</td>
</tr>
<tr>
<td></td>
<td>Green</td>
</tr>
<tr>
<td>4. Cleaning Screen post printing</td>
<td>Isopropyl Alcohol</td>
</tr>
<tr>
<td>As in step 1.</td>
<td></td>
</tr>
</tbody>
</table>
Step Two:

REACH Substance Analysis – Supplier information
Step Two – REACH Analysis – Supplier information

2.0 Introduction
For the direct and indirect inputs that have been identified in Step One, employers need to establish who the suppliers of these are.

2.1 Rationale for Step Two
There are many aspects to REACH that mean it is important for employers to know who they get their substances and components from. However, the most important aspect is to identify the use of CMRs, etc as a direct input and where there is a potential for the use of CMRs, etc in the manufacture of critical indirect inputs.

Once this is established, employers can take steps to contact suppliers to ensure Authorisation, where necessary, is completed for that specific use and that there will be a continuity of supply.

2.2 Who should complete Step Two?
All parties.

2.3 Identify suppliers
Existing records for chemicals substances will help in this stage. Any safety data sheet that accompanied the substances will identify the supplier and their address/location.

This should also be easily identified for indirect inputs through procurement information.

Using Form 2.1 (Supplier record), list all identified substances and components, and their suppliers of the substance.

It is important to especially identify suppliers from outside the EU where you use substances as a direct input, as they may not be familiar with Authorisation requirements. In the case of substances, where they are sourced from outside the EU, you would have a greater role under REACH than a downstream user. However, in the case of articles from outside the EU, there would be no further work to complete.

For articles, this will be more difficult as employers may not have information on their manufacturing. For articles, refer to the indexed Authorisation List and establish if any of the common uses for the substances on the list may impact your supply chain.
### Example Supplier Information – Screen Printing

<table>
<thead>
<tr>
<th>Substance</th>
<th>Supplier</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isopropyl Alcohol</td>
<td>World Chemicals</td>
<td>USA</td>
</tr>
<tr>
<td>Red Ink (PR1000)</td>
<td>Dublin Inks</td>
<td>Tallaght Dublin 24</td>
</tr>
<tr>
<td>Blue Ink (PR1001)</td>
<td>Dublin Inks</td>
<td>Tallaght Dublin 24</td>
</tr>
<tr>
<td>Green Ink (PR1002)</td>
<td>Dublin Inks</td>
<td>Tallaght Dublin 24</td>
</tr>
<tr>
<td>Black Ink (Ink992)</td>
<td>WVK Chemicals</td>
<td>Germany</td>
</tr>
</tbody>
</table>
Step Three:

REACH Substance Analysis – Direct Inputs
Hazard and Use Assessment
Step Three – REACH Substance Analysis – Direct Inputs
Hazard and Use Assessment

3.0 Introduction
This stage looks to identify the individual hazards and risks associated with the
direct input substances used. Most of this information is contained in the data
sheets that should be available for those substances.

3.1 Rationale for Step Three
This information will give employers a greater understanding of what the hazards
associated with those substances is. Substances can contain a wide variety of
ingredients and it is vital to establish if any, even if in very small quantities, are
CMRs, etc.

3.2 Who Should Complete Step Three?
All parties.

3.3 Record
From all the information gathered regarding the use and the substance itself,
complete Form 3.1 (REACH Substance Record) for each substance used as part
of operations.

This step will combine all the information gathered so far so that the employer
has one record sheet for each substance. The critical points for this exercise are
that the employer can:

- identify and trace all substances used by its CAS number
- identify those substances for which no CAS number exists
- identify the quantity of the substance used per calendar year
- identify if it is manufactured or imported
Silk Screen Example: Isopropyl Alcohol

<table>
<thead>
<tr>
<th>Substance Used</th>
<th>Hazard Classification</th>
<th>Maximum Exposure Limit/ Occupational Exposure Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isopropyl Alcohol</td>
<td>R11 Highly flammable R36 Irritating to eyes R37 Irritating to respiratory system</td>
<td>980 mg/m3 (UK OEL)</td>
</tr>
<tr>
<td>Synonyms:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- isopropanol,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- IPA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- propan-2-ol</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- rubbing alcohol</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAS Number</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td></td>
</tr>
<tr>
<td>67-63-0</td>
<td>Irritant, Harmful, Flammable</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Manufacturer/ Supplier Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Klondike Kemicals</td>
</tr>
<tr>
<td>Boston</td>
</tr>
<tr>
<td>USA</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Supplied from EU</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Quantities Used per calendar year</th>
<th>Data Sheet Available</th>
<th>Is it a CMR or of special concern?</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 Tonnes</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Is the substance used</th>
</tr>
</thead>
<tbody>
<tr>
<td>As supplied</td>
</tr>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Description of Work</th>
</tr>
</thead>
<tbody>
<tr>
<td>Applied to cloth and then used to clean screen. Used in well-ventilated area and exposure below OEL. Employees use disposable gloves and safety glasses. Waste clothes put into fire proof bin for disposal by incineration.</td>
</tr>
</tbody>
</table>
Silk Screen Example: Red Ink

<table>
<thead>
<tr>
<th>Substance Used</th>
<th>Hazard Classification</th>
<th>Maximum Exposure Limit/ Occupational Exposure Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Red Ink</td>
<td>Flammable</td>
<td>TWA 50ppm</td>
</tr>
<tr>
<td></td>
<td>Harmful</td>
<td>TWA 25ppm</td>
</tr>
<tr>
<td></td>
<td>Irritant</td>
<td></td>
</tr>
<tr>
<td>Petroleum blend</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Naphtha</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aluminium Dust</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAS Number</th>
<th>Number</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>8052-41-3</td>
<td></td>
<td>Irritant</td>
</tr>
<tr>
<td>64742-95-6</td>
<td></td>
<td>Toxic, May Cause Cancer</td>
</tr>
<tr>
<td>7429-90-5</td>
<td></td>
<td>Irritant, harmful, Flammable</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Manufactur er/ Supplier Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dublin Inks</td>
</tr>
<tr>
<td>Tallaght</td>
</tr>
<tr>
<td>Dublin 24</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Supplied from EU</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Quantities Used per calendar year</th>
<th>Data Sheet Available</th>
<th>Is it a CMR or of special concern?</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.5 Tonnes</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Is the substance used</th>
</tr>
</thead>
<tbody>
<tr>
<td>As supplied</td>
</tr>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Description of Work</th>
</tr>
</thead>
<tbody>
<tr>
<td>Applied to screen using applicator. Stored in small 5 litre containers in fireproof press. Used in well-ventilated area, employees wear disposable gloves and eye protection.</td>
</tr>
<tr>
<td>Waste containers disposed of in fireproof bin and disposed of as flammable waste.</td>
</tr>
</tbody>
</table>
The above example demonstrates why it is vital to audit all substances and their datasheets. The red ink is only labelled as flammable and harmful, therefore if an employer were to focus on warning labels or general information, it may be assumed that there are no concerns with this substance.

However, by checking each of the ingredients within the substance and their individual, not mixture-based classification, this employer would see that the solvent Naptha is classified as a carcinogen.

In addition, Naptha is also on the list of substances for Authorisation (see Appendix 1). Even though the quantities are small, and even though the Red Ink mixture does not carry a Carcinogen classification as a whole, the company will need to ensure that either the use of Naptha in Red Ink for their specific Screen Printing purposes is Authorised or that they can procure an alternative Naptha-free Red Ink.
Step Four:

REACH Article Analysis – Indirect Inputs
Hazard and Use Assessment
Step Four: REACH Article Analysis – Article Analysis

4.1 Introduction
Identification of substances directly used in a process is the least challenging part of this process given the detailed information that will be available for substances used. However, the more difficult aspect is if the employer uses components (articles) as part of a process or manufacturing assembly.

Unless a detailed audit has been undertaken of how these products are made by suppliers for the purposes of a supply chain impact assessment, most employers will not be aware of what substances are used in the manufacturing or how critical that substance is to the process.

Therefore, this stage will require detailed discussions with suppliers. Employers can ask suppliers to complete the same input task analysis that they have as part of this guidance to ensure that the information is accurate and identifying any potential authorisation issues.

However, given the number of suppliers an organisation may have as part of its procurement set-up, this stage will focus on narrowing down any potential Authorisation issues with indirect components or articles based upon ECHA’s Authorisation List.

The components that are likely to be impacted by REACH are plastics, PVCs, electronic equipment, batteries, processors, textiles, metal finishing, wood treatment, paper production, inks and dyes, etc.

4.2 Rationale for Stage Four
This could well be the largest overlooked impact of REACH and is likely to have a significant impact on many businesses, not just the chemical industry. It is vital that even if there are no likely issues with Authorisation for critical components, that this is identified.

Where there are potential supply issues, this must be identified as soon as is possible given the schedule for Authorisation deadlines.

4.4 Who Should Complete Step Four?
Employers should identify the critical components that may feature a substance on the Authorisation List as part of its manufacture or assembly.
4.3 Authorisation List
Appendix 1 to this Guide has details on the current Authorisation Lists, the substances and their common uses. However, note that this is not an exhaustive list of uses. Employers can compare the indirect components with the list via the identified uses of the substances. This should highlight areas where there are potential Authorisation issues.

4.4 Contacting Suppliers
Where there appears to be articles that an employer uses as a component that may use one of the listed substances in its manufacturing, then the employer must contact the relevant supplier for further information.

This may be asking Suppliers to provide a breakdown of the process using the forms in this guide for each component.
Step Five:

REACH Analysis - Authorisation
Step Five: REACH Analysis - Authorisation

5.1 Introduction
The authorisation procedure does not prohibit the use of substances, its aim is to ensure that the risks from Substances of Very High Concern are properly controlled. In addition, it is to encourage employers to progressively replace these substances with suitable alternatives where possible.

Substances with the following hazard properties may be identified as Substances of Very High Concern (SVHCs):

- Substances meeting the criteria for classification as carcinogenic, mutagenic or toxic for reproduction category 1A or 1B in accordance with Commission Regulation (EC) No 1272/2008 (CMR substances)
- Substances which are persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) according to REACH (Annex XIII)
- Substances identified on a case-by-case basis, for which there is scientific evidence of probable serious effects that cause an equivalent level of concern as with CMR or PBT/vPvB substances

Once a substance is listed as requiring authorisation, it cannot be placed on the market or used after a given date, unless an authorisation is granted for their specific use, or the use is exempted from authorisation.

Manufacturers, importers or downstream users of a substance on the Authorisation List can apply for authorisation.

5.2 Rationale for Stage Five
The Authorisation system will have two critical impacts on employers. The first is where they directly use substances that may be or may contain a substance listed for Authorisation. In those cases the employer themselves will need to apply for Authorisation for that specific use through ECHA.

The second is where the employer uses indirect components that may use a listed substance as part of its manufacturing within the EU. In those cases, the employer will need to seek proof from their supplier that this use has been authorised and that there will be a continuation in the supply chain.
It is very important to discuss the issue with suppliers as in some cases they may have chosen not to pursue Authorisation and so will no longer be in a position to supply you with that product.

If that is the case, then employers can seek their own Authorisation, or, where it is commonly used among a sector or similar employers, apply for Authorisation through a group or representation body.

### 5.3 Authorisation Process

There are two separate lists to be aware of with regards to Authorisations. The first is the Authorisation List.

These are substances that have been evaluated and ECHA has given an application window for employers to seek Authorisation and a “sunset date” where unless the substance has been Authorised, it will no longer be allowed to be placed on the market/used.

For employers looking to ensure short-term continuation of supply, this list is the most important.

In addition to this list, there is a Candidate List, which is a list of substances (over 130 at the moment) that may eventually require Authorisation in the near future.

The process for Authorisation is described by EHCA from their Website:

*After their "sunset date", substances on the Authorisation List will require an authorisation before they can be placed on the market or used.*

*Applications for authorisation will only be successful if applicants can demonstrate that the use of the authorised substance is necessary for their business and right for society as a whole.*

*The application process could require the investment of considerable time and resources, so companies should consider if this is the best course of action for their business or whether one of the range of alternatives available to your business might be more suitable than an authorisation.*

*A robust analysis can help you decide whether an authorisation is the best option for your business and will also be useful for compiling an argument to support your application.*

- *Submission windows*
ECHA establishes specific windows for submitting applications for authorisation.

- **Notification and pre-submission sessions**
  Notify ECHA well in advance of the date you intend to submit an application for authorisation. When notifying ECHA, you may also request a pre-submission information session with ECHA representatives to ask case-specific questions regarding the application process.

- **Preparing an application**
  Follow these steps to prepare all the documentation required to apply for an authorisation.

- **Submitting an application**
  Use these web forms to submit an application for authorisation.

- **Additional information**
  ECHA and its Committees have prepared a series of documents for clarifying the process. The documents will help potential applicants to better understand how their applications will be treated and evaluated during the opinion-making process of ECHA.
Glossary of Terms
Glossary of Terms
REACH contains a large section of specific definitions. These are important to employers as they define the roles within the regulations and help identify what substances and articles are part of the scope of REACH and those that are exempt.

The key definitions relevant to this guide can generally be broken down into the topics: what is being used, who does it and what is being done.

Definitions – What is being used
It is possibly easier to give details on what is exempt under REACH than to detail all that the regulations actually cover. Naturally, with a piece of legislation with as broad a scope as this, there may be room for confusion over what exactly REACH covers.

The Steps in this guide will help employers to identify what they use and which acts they perform and then evaluate which of these definitions applies to them:

- **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.

- **Preparation**: means a mixture or solution composed of two or more substances;

There is a clear distinction between a “substance” and a “preparation” in the regulations. Although in general health and safety, there is a tendency to use these terms interchangeably, the focus of REACH is on the substance rather than the preparation. When looking at a data sheet for something used in the workplace, employers will see that this contains a list of ingredients. These ingredients are the “substances” and they are combined to make the “preparation”. Using domestic bleach as an example, the bleach itself is the preparation as it is a mixing of several ingredients. The substances in bleach would be Sodium hypochlorite, Sodium carbonate anhydrous and water.

Therefore, employers need to identify what substances make up the preparations that they use. REACH requires the registration of the substance not the preparation.
• **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;

An article is more difficult to explain. The easiest examples would be electronic devices, even something as simple as a remote control, or a digital clock display for an oven are articles. However, this definition is so encompassing, that everything from a microchips to textiles are “articles”.

• **Monomer:** means a substance which is capable of forming covalent bonds with a sequence of additional like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process;

• **Polymer:** means a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following:

  (a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant;

  (b) less than a simple weight majority of molecules of the same molecular weight.

*In the context of this definition a "monomer unit" means the reacted form of a monomer substance in a polymer*

Although not particular to the majority of workplaces, these definitions relate to certain plastics. A polymer is the plastic as a whole and it refers to the composition and make-up of the plastic (i.e. long chains of molecules). Examples would be any material used that begins with the term “poly” such as polystyrene, polyester, polyvinyl chloride (PVC) etc. The monomer would be the individual molecule, so: in PVC, the polymer is the PVC material and the monomer is the individual vinyl chloride molecule. As a simple example, the polymer is the wall and the monomers are the individual bricks.

The reason for separately defining these is because of their different chemical compositions and in many cases the different toxicity of the two. The monomers can be very hazardous materials, such as vinyl chloride,
which is a carcinogen, but there can be a dramatic reduction in toxicity when combined to make the PVC polymer, which is much less toxic.

- **Carcinogens (Category I & II)**
  Substances deemed to cause or suspected of causing cancer are categorised based upon the information available. Generally, category I carcinogens are known to cause cancer in humans, in category II there is evidence of some cancers amongst humans and has been shown to cause cancer in animal studies. Category III (not included in REACH) are suspected of causing cancer in humans.

Information supplied with the substance will state if the classification of a substance is either a category I or II carcinogen. In addition, knowing the CAT number of the substance will also help in identifying the harm it could cause. The symbol for Category I & II carcinogens is the toxic sign (skull and crossbones pictogram) and the risk phrase R45: May cause cancer or R49: May cause cancer by inhalation. Category III carcinogens have the symbol for harmful (a black cross pictogram) and R40: Some evidence of cancer.

- **Mutagens (Category I & II)**
  Mutagens have a specific property that causes hereditary (i.e. the defect is passed on to future generations) changes to human DNA. As with carcinogens, there are different categories depending on current knowledge of the substance’s effects. The first identified mutagen was dichlorodiethyl sulfide, more commonly known as mustard gas.

- **Toxic for reproduction (Category I & II)**
  This is any substance that can affect the process of human reproduction in both men and women. For example, the fungicide Cycloheximide has an affect on both male and female reproductive systems. The most common example of substances that are toxic for reproduction is “teratogens”. These are substances that affect the unborn foetus or interfere with the development of the foetus and the most well known teratogen is thalidomide, the morning sickness drug that caused malformations in the developing foetus.
Bioaccumulative substances

Some substances can accumulate in both the body and the environment and have a “bio half-life”. This is the time taken for the substance in the body to reduce by half and this can be over a period of days or years. Naturally, where the substances takes a long period to leave the body, there is a risk of accumulation from repeated exposure to even relatively small amounts, which can eventually reach harmful levels. Examples of this are prolonged exposure to lead, mercury and dioxins. The body stores these and they are not completely metabolised or excreted, so that when there is further exposure, there is then an accumulation of the substance in the body. Substances can also accumulate in the food chain, so that even a small concentration in contaminated water can be concentrated up the food chain.

Definitions: What is being done with the substance?

There are several critical actions within REACH and these lead to prescribed roles and obligations within the regulations. Where substances or articles exist in the workplace, employers need to establish what happens to them and where did they come from.

- **Manufacturing:** means production or extraction of substances in the natural state

  This process refers to those who manufacture substances. Obvious examples relate to the chemical industry, however, where there is mixing of two substances as part of a process or task, then technically this is the creation of a new substance (where they react together to create a substance) and the employer becomes involved in manufacturing substances. If there is no reaction, then this would be manufacturing of a “preparation” and this is part of the scope of REACH.

- **Import:** means the physical introduction into the customs territory of the Community;

  The act of importing is a common one seen in many European wide regulations such as packaging waste. Where a substance or an article is brought in from outside of the EU, then this is “importing”. It does not relate to substances or articles purchased in the EU. Therefore, one employer uses digital display clocks in a microwave oven from China and the other from Germany. Only the clocks coming from China would be “imported”.

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- **Placing on the market:** means supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market;

  Although covered in other areas under roles of the various parties, the main issue with this definition is the “free of charge” statement. It has been the case that redundant substances and articles have been given or donated to schools, colleges and even between employers. They are still considered to be “placed on the market” under this definition.

- **Use:** means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation;

  A self-explanatory definition covering every possible scenario under which a substance or article is considered to be in use.

**Definition: Who is doing what?**
The roles that are contained within REACH are vital components of the regulations and one that employers must establish early on. These will prescribe the duties, actions and ultimately costs associated with REACH.

- **Manufacturer:** means any natural or legal person established within the Community who manufactures a substance within the Community;

  Using the above example of “manufacturing”, the employer described is a manufacturer of a substance.

- **Importer:** means any natural or legal person established within the Community who is responsible for import;

  As discussed above, when an employer imports the article or substance from outside the EU, they take on the role of “importer”.

- **Producer of an article:** means any natural or legal person who makes or assembles an article within the Community;

  This may seem self-explanatory, but the definition contains a very specific term: ‘assembles’. This therefore also includes the manufacturing of electronic equipment or other articles, but more significantly, it also means that where there is the assembly of pre-made, imported components, the employer is a “producer of an article”.
**Downstream user**: \textit{means any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 2(7) (c) shall be regarded as a downstream user;}

This will be the duty that will apply to all enterprises irrespective of size or operations. Hardly a business exists that does not use chemicals in the workplace. If there is a can of air freshener in the office, then the employer is a “downstream user”. Note, there is no role for users of “articles”, only those who make or import articles.

**Actors in the supply chain**: \textit{means all manufacturers and/or importers and/or downstream users in a supply chain.}

A generic term used when describing all parties having duties.

**Supplier of a substance or a preparation**: \textit{means any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a preparation, or a preparation;}

**Supplier of an article**: \textit{means any producer or importer of an article, distributor or other actor in the supply chain placing an article on the market;}

Any person involved in the sale or distribution (remember “place on market” also includes giving it away free of charge) of article or substances, becomes the supplier and will have a role under these regulations.

**Abbreviations:**

- **CAS number** - the Chemicals Abstracts Service number for a chemical and is unique to that substance. Only the substance is assigned a CAS number and not the preparation.
- **EINECS** - the European Inventory of Existing Commercial Chemical Substances and is a list of all chemical substances on the EU market up to 1981
- **ELINICS** - the European List of Notified Chemical Substances and is a list of substances which have been notified in the EU in accordance with Directive 67/548/EEC
- **CMR** - Carcinogens, Mutagens, Toxic to Reproduction
- **PBT** - Persistent, Bioaccumulative and Toxic
- **VPVB** - very persistent and very bioaccumulative (vPvBs)
- **SvHC** - substances of very high concern
Forms and Checklists
## Form 1.1 (Task Analysis)

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<th>Record No:</th>
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<td>Person Completing Task Analysis</td>
<td>Signature:</td>
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<th>Direct Inputs (Substances directly used in task or added to the process)</th>
<th>Critical Component?</th>
<th>Indirect Inputs (third party supplied components used in a task or process)</th>
<th>Critical Component?</th>
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Form 2.1 (Supplier Record)

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### Form 3.1 (REACH Substance Record)

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<th>Substance Used</th>
<th>Hazard Classification</th>
<th>Maximum Exposure Limit/ Occupational Exposure Standard</th>
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<th>Manufacturer/ Supplier Details</th>
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<th>Supplied from EU</th>
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<th>Data Sheet Available</th>
<th>Is it a CMR or of special concern?</th>
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<th>Is the substance used</th>
<th>As supplied</th>
<th>Diluted</th>
<th>Mixed*</th>
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### Description of Work

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**REACH: Securing Your Supply Chain**

**Form 3.1 (REACH Substance Record)**

- Substance Used
- Hazard Classification
- Maximum Exposure Limit/ Occupational Exposure Standard

- CAS Number
  - Number
  - Classification

- Manufacturer/ Supplier Details

- Supplied from EU
  - Yes
  - No

- Quantities Used per calendar year
  - Data Sheet Available
  - Is it a CMR or of special concern?

- Is the substance used
  - As supplied
  - Diluted
  - Mixed*

- Description of Work

---

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### Authorisation List

<table>
<thead>
<tr>
<th>Substance Name</th>
<th>EC Number</th>
<th>Sunset date</th>
<th>Latest application date</th>
<th>Exempted uses</th>
<th>Indicative Uses</th>
</tr>
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</table>
| Ammonium dichromate      | 232-143-1 | 21/09/2017   | 21/03/2016               |                                                                              | • Chemical reagent  
  • Intermediate in the production of pigments, catalysts, chemicals,  
  • magnetic tapes  
  • mordant in dyeing for textiles |
| Potassium chromate       | 232-140-5 | 21/09/2017   | 21/03/2016               |                                                                              | • inhibitor coating for aluminium powder  
  • manufacture of zinc  
  • Manufacture of reagents and chemicals  
  • preparation and spinning of textile fibres,  
  • textile mordant  
  • oxidizing agent for dyes  
  • stripping solution for wool dyeing  
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  • Tanning and dressing of leather  
  • Manufacture of pigments/inks: used in paints and metal primers, and as colorants in |
<table>
<thead>
<tr>
<th>Substance Name</th>
<th>EC Number</th>
<th>Sunset date</th>
<th>Latest application date</th>
<th>Exempted uses</th>
<th>Indicative Uses</th>
</tr>
</thead>
</table>
| 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 | 21/09/2017  | 21/03/2016               |                             | • Electroplating - hard chrome plating, decorative or bright-chrome plating, conversion coatings - passivation of zinc, aluminium, cadmium and brass, pickling  
• Wood preservation products  
• Catalyst manufacture,  
• Chromium dioxide manufacture  
• Pigment manufacture  
• Paints, varnishes and inks putty (anticorrosive, dye)  
• Oxidant in organic chemistry  
• Electronic component manufacturing (silicon wafers)  
• Production of polyethylene and other plastics  
• Metallurgy of nonferrous metals (elaboration of chromium metal)  
• Soap, detergents and cleaning agents |
<table>
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<th>EC Number</th>
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<td>Chromium trioxide</td>
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<td>21/09/2017</td>
<td>21/03/2016</td>
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<td>• Electroplating - hard chrome plating, decorative or bright-chrome plating, conversion coatings - passivation of zinc, aluminium, cadmium and brass, pickling</td>
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<td>• Wood preservation products</td>
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<td>• Catalyst manufacture,</td>
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<td>• Chromium dioxide manufacture</td>
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<td>• Pigment manufacture</td>
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<td>• Paints, varnishes and inks putty (anticorrosive, dye)</td>
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<td>• Oxidant in organic chemistry</td>
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<td>• Electronic component manufacturing (silicon wafers)</td>
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<td>• Production of polyethylene and other plastics</td>
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<td></td>
<td>• Metallurgy of nonferrous metals (elaboration of chromium)</td>
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<tr>
<td>Substance Name</td>
<td>EC Number</td>
<td>Sunset date</td>
<td>Latest application date</td>
<td>Exempted uses</td>
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<td>metal)</td>
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<td>• Soap, detergents and cleaning agents</td>
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<td>• Organic basic chemicals</td>
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<td>• Inorganic hardening agent layer of photosensitive galantine</td>
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<td>• Jewellery (production of synthetic sapphire)</td>
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<td>• Hardening of microscopic preparation</td>
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<td>• Oxidizer (Jones reagent, Sarret reagent)</td>
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<tr>
<td>Potassium dichromate</td>
<td>231-906-6</td>
<td>21/09/2017</td>
<td>21/03/2016</td>
<td></td>
<td>• Alloys and nickel super-alloys manufacturing (aeronautics – such as engine turbines- and nuclear sector)</td>
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<td>• Physical vapour deposition (PVD)</td>
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<td>• Treatment and coating of metals</td>
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<td>• Cleaning glassware and etching materials</td>
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<td>• An ingredient in cement</td>
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<td>• reagents and chemicals used for many applications such as infra analysis, instrumental calibrations, routine checks, metal finishing processes,</td>
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<tr>
<td>Substance Name</td>
<td>EC Number</td>
<td>Sunset date</td>
<td>Latest application date</td>
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</tbody>
</table>
| Sodium chromate      | 231-889-5   | 21/09/2017    | 21/03/2016               |               | • Analytical reagent (titrating agent)  
• Ethanol determination:  
• Tanning and dressing of leather:  
• Manufacture of textile: potassium  
• Photolitography  
• Wood treatment  
• Corrosion inhibitor in cooling systems  
• Chemical intermediate for pigments and catalysts,  
• Corrosion inhibitor (sealed water in cooling systems, oil-well drilling muds, protection of iron),  
• Mordant for dyes, dying paint pigment (in manufacture of pigments/inks  
• Drilling mud additive,  
• Component of cells for chlorate manufacture,  
• Leather tanning  
• Pharmaceuticals for the determination of circulatory red cell volume.  
• Aluminium etchant ingredient. |
<p>| Sodium dichromate    | 234-190-3   | 21/09/2017    | 21/03/2016               |               | • Tanning salts intermediate |</p>
<table>
<thead>
<tr>
<th>Substance Name</th>
<th>EC Number</th>
<th>Sunset date</th>
<th>Latest application date</th>
<th>Exempted uses</th>
<th>Indicative Uses</th>
</tr>
</thead>
</table>
| Trichloroethylene | 201-167-4 | 21/04/2016 | 21/10/2014 | • Metal finishing non-intermediate  
• pigments intermediate  
• Chromium metal intermediate  
• Anticorrosive additive in coating non-intermediate  
• Wood preservative  
• Mordant for wool dye  
• Montan wax production **  
• Vitamin K production  
• Cleaning agent | |
| Hexabromocyclododecane (HBCDD), alpha-hexabromocyclododecane, beta-hexabromocyclododecane, gamma-hexabromocyclododecane | 221-695-9, 247-148-4 | 21/08/2015 | 21/02/2014 | • Flame retardant  
• Residential and commercial furniture (flat and pile) e.g. chairs, sofas, pillows, carpets, floor tiles.  
• Interior textiles and furnishings such as roller blinds and pillows.  
• Bedding and mattress ticking.  
• Draperies and wall coverings.  
• Upholstered seating and interior fabrics in cars.  
• Distribution boxes for electrical lines  
• Video cassette recorder housing |
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<tr>
<th>Substance Name</th>
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<th>Sunset date</th>
<th>Latest application date</th>
<th>Exempted uses</th>
<th>Indicative Uses</th>
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</thead>
<tbody>
<tr>
<td>2,4 – Dinitrotoluene (2,4-DNT)</td>
<td>204-450-0</td>
<td>21/08/2015</td>
<td>21/02/2014</td>
<td></td>
<td>• Chemical intermediate for flexible polyurethane foams</td>
</tr>
<tr>
<td>Tris(2-chloroethyl)phosphate (TCEP)</td>
<td>204-118-5</td>
<td>21/08/2015</td>
<td>21/02/2014</td>
<td></td>
<td>• Rigid and flexible polyurethane foams and systems</td>
</tr>
<tr>
<td>Diarsenic pentaoxide</td>
<td>215-116-9</td>
<td>21/05/2015</td>
<td>21/11/2013</td>
<td></td>
<td>• Wood preservation</td>
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<td>• Glass and Glass Products</td>
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<td>• Intermediate for other arsenic compounds</td>
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<tr>
<td>Lead sulfochromate yellow (C.I. Pigment Yellow 34)</td>
<td>215-693-7</td>
<td>21/05/2015</td>
<td>21/11/2013</td>
<td></td>
<td>• Colorant in plastics</td>
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<td>• Colorant in yellow paint</td>
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<tr>
<td>Lead chromate molybdate sulphate red (C.I. Pigment Red 104)</td>
<td>235-759-9</td>
<td>21/05/2015</td>
<td>21/11/2013</td>
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<td>• Colorant in plastics</td>
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<td>• Colorant in red paint</td>
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<tr>
<td>Diarsenic trioxide</td>
<td>215-481-4</td>
<td>21/05/2015</td>
<td>21/11/2013</td>
<td></td>
<td>• Additive in wood, metal, glass and plastics</td>
</tr>
<tr>
<td>Lead chromate</td>
<td>231-846-0</td>
<td>21/05/2015</td>
<td>21/11/2013</td>
<td></td>
<td>• Colorant in plastics</td>
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<td>• Colorant in paint</td>
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<td></td>
<td>• Dye,</td>
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<td>• Pigment,</td>
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<td>• Paint,</td>
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<td>• Ink,</td>
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<td>• Adhesive,</td>
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<td>• Lubricant</td>
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<td>Substance Name</td>
<td>EC Number</td>
<td>Sunset date</td>
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<td>Exempted uses</td>
<td>Indicative Uses</td>
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<tr>
<td>Bis(2-ethylhexyl) phthalate (DEHP)</td>
<td>204-211-0</td>
<td>21/02/2015</td>
<td>21/08/2013</td>
<td>Packaging of medicinal products</td>
<td>Plasticizer, Dye, Pigment, Paint, Ink, Adhesive, Lubricant</td>
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<td>and/or Directive 2001/83/EC.</td>
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<tr>
<td>Dibutyl phthalate (DBP)</td>
<td>201-557-4</td>
<td>21/02/2015</td>
<td>21/08/2013</td>
<td>Packaging of medicinal products</td>
<td>Plasticizer, Dye, Pigment, Paint, Ink, Adhesive, Lubricant</td>
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<td>and/or Directive 2001/83/EC.</td>
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<tr>
<td>Diisobutyl phthalate (DIBP)</td>
<td>201-553-2</td>
<td>21/02/2015</td>
<td>21/08/2013</td>
<td></td>
<td>Plasticizer, Dye, Pigment,</td>
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<td>and/or Directive 2001/83/EC.</td>
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<td>Substance Name</td>
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<tr>
<td>5-tert-butyl-2,4,6-trinitro-m-xylene (Musk xylene)</td>
<td>201-329-4</td>
<td>21/08/2014</td>
<td>21/02/2013</td>
<td>• Paint, • Ink, • Adhesive, • Lubricant</td>
<td>• Cosmetic products • Detergents, • Fabric softeners, • Household cleaning products • Other fragranced products</td>
</tr>
<tr>
<td>4,4’-Diaminodiphenylmethane (MDA)</td>
<td>202-974-4</td>
<td>21/08/2014</td>
<td>21/02/2013</td>
<td></td>
<td>• Polyurethane foams • Hardeners in epoxy resins and adhesives • High-performance polymers</td>
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</tbody>
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