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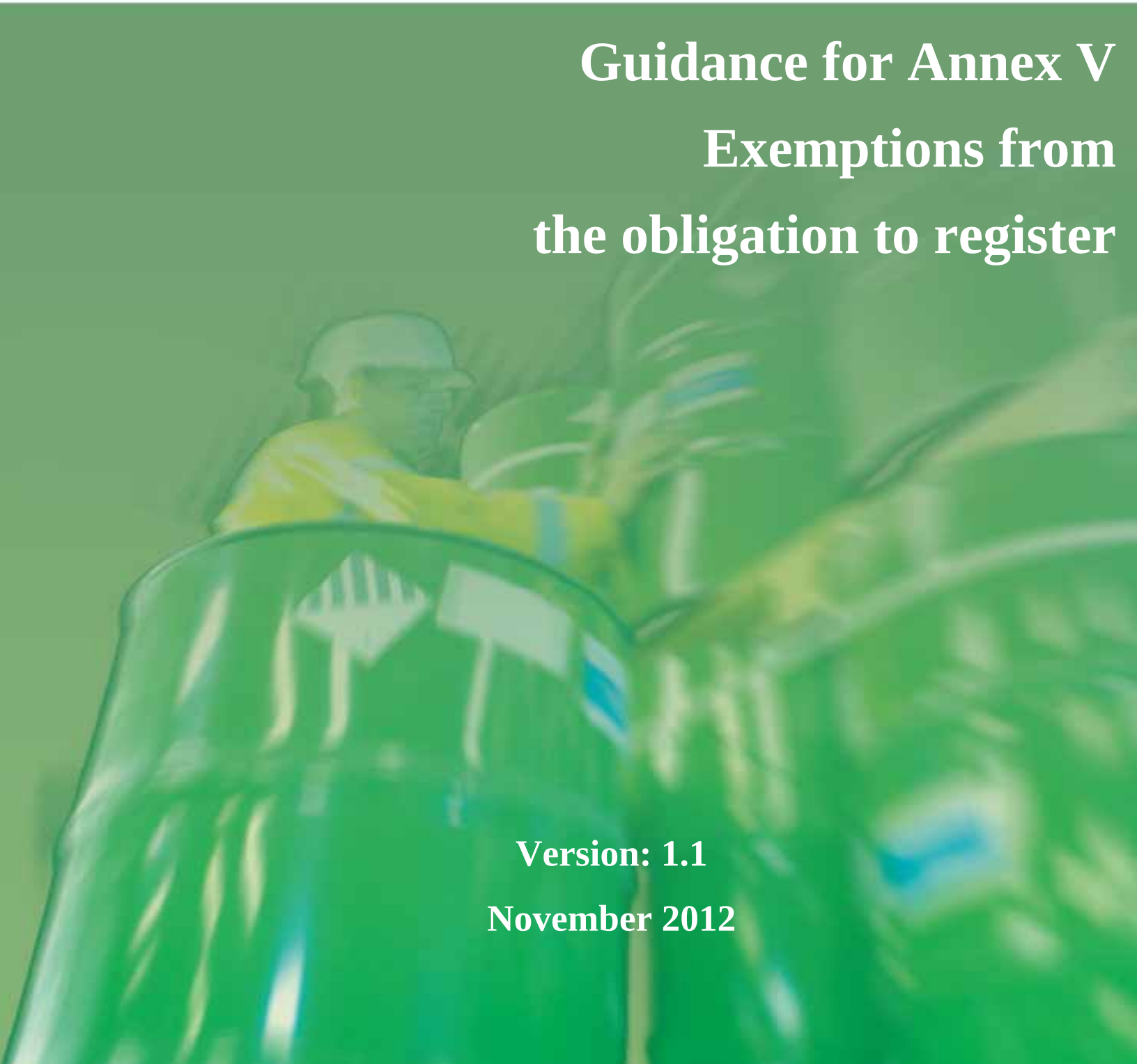
# Guidance for Annex V Exemptions from the obligation to register



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**November 2012**

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***Guidance for Annex V***
***Exemptions from the obligation to register***

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# PREFACE

Article 2(7)(b) of the Regulation (EC) No 1907/2006 (REACH) and its amendment by Regulation (EC) No 987/2008 of 8 October 2008 sets out criteria for exempting substances covered by Annex V from the registration, downstream user and evaluation requirements. These criteria are formulated in a very general way. This guidance is intended to give more explanations and background information for applying the different exemptions and give clarifications when an exemption could be applied and when not. It should be noted that the companies benefiting from an exemption must provide the authorities (on request) with appropriate information to show that their substances qualify for the exemption. Where reaction products are exempted under Annex V as amended by Regulation (EC) No 987/2008, the occurrence of which is, however foreseeable and which may have consequences for risk management measures, appropriate safety information must be communicated through the supply chain in accordance with title IV of the Regulation.

The guidance below follows the same order of the entries in Annex V of the REACH regulation as amended by Regulation (EC) No 987/2008[1].

[1] The reference to Regulation (EC) No 987/2008 amending Regulation (EC) No 1907/2006 is implicitly assumed by mentioning of Annex V in this guidance document.

| Version | Comment | Date |
|---|---|---|
| Version 1 | | 31/03/2010 |
| Version 1.1 | Corrigendum covering the following:<br><br>Removal of the part of the footnote (footnote 15 on page 30 of version 1.0) concerning vegetable oils, fats and waxes obtained from genetically modified plants stating that “Guidance on this topic is under development”.<br><br>Update of legal references in the text discussing entry 8<br><br>Minor editorial corrections<br><br>(Please note that references to Directive 67/548/EEC and 1999/45/EC have not been amended in the discussion of entries in Annex V for which the legal text still refers to this legislation). | November 2012 |

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# ENTRY 1

**Substances which result from a chemical reaction that occurs incidental to exposure of another substance or article to environmental factors such as air, moisture, microbial organisms or sunlight.**

Most substances present a certain level of instability upon exposure to environmental factors such as air, moisture, microbial organisms and the irradiation from sunlight. Any reaction products thus formed do not have to be registered as it would be inappropriate; they are generated incidentally and without the awareness of the manufacturer or importer or downstream user of the original substance.

For example, the reaction products from the incidental hydrolysis of substances (e.g. esters, amides, acryl halides, anhydrides, halogenated organosilanes, etc.) in contact with the moisture from the environment are exempted from registration as they fall within this criterion. Another example is diethyl ether which may form peroxides after exposure to air or light. The peroxides thus formed do not have to be registered by the manufacturer or importer of diethyl ether, or by any downstream user or distributor of the substance on its own, in a preparation or in an article. Note however that the potential risks associated with the reaction products formed in this manner must be taken into account in the assessment of the original substance.

Finally, the decomposition products from paint, where the decomposition is caused by the activity of mould and the products from the bleaching of coloured textiles, which occurs due to the exposure to sunlight, could also be seen as examples falling under this entry.

# ENTRY 2

**Substances which result from a chemical reaction that occurs incidental to storage of another substance, preparation or article.**

Substances may present a certain level of inherent instability. The reaction products resulting from the inherent decomposition of substances do not need to be registered as it would be impractical; they are generated incidentally and without the awareness of the manufacturer or importer of the original substance.

An example of substances that could be covered by this entry are peroxides that are formed from ethers (e.g. diethyl ether, tetrahydrofuran), not only when these are exposed to light and air (see point 1 above), but also upon storage. These peroxides do not need to be registered. Note however, that the potential risks associated with the presence of peroxides in ethers must be taken into account in the assessment of the ethers. Other examples include partially polymerised drying oils (e.g. linseed oil) and decomposition of ammonium carbonate to form ammonia and carbon dioxide (especially if stored above 30°C).

# ENTRY 3

**Substances which result from a chemical reaction occurring upon end use of other substances, preparations or articles and which are not themselves manufactured, imported or placed on the market.**

This entry covers substances which are generated during the end use of other substances, preparations or articles.

The end use of a substance on its own, in a preparation or in articles can result in an intended (or unintended) chemical reaction. However, provided that the reaction products obtained can neither be regarded as having been generated by any kind of manufacturing process nor being intentionally isolated after the "end use reaction" or having been placed on the market, then these reaction products are exempted from the registration provisions.

End use means the use of a substance as such, in a preparation or in articles, as a last step before the end-of-life of the substance, namely before the substance enters into the service life of an article, is consumed in a process by reaction, or is emitted to waste streams or the environment[2]. Please note that the term "end use" is not limited to the use of a substance by professional or private consumers but includes any intended downstream use of a substance in the supply chain, provided it is not part of a manufacturing[3] process of a substance.

Examples of substances covered by this entry are the products resulting from the end use of adhesives and paints, combustion products of fuels during their use in vehicles, and the reaction products of bleaching agents during washing of textiles.

**Example:**

A specific example is sodium percarbonate used in the detergent industry as a bleaching agent. During the washing process sodium percarbonate decomposes into hydrogen peroxide and sodium carbonate. These two substances are reaction products obtained during the end use of sodium percarbonate and are therefore exempted from the registration obligation whereas sodium percarbonate requires registration.

[2] Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system, page 8.
[3] According to Article 3(8) "Manufacturing: means production or extraction of substances in the natural state". This means that all intended generations or isolations of substances should be regarded as manufacture. See also Guidance on Registration, page 17.

# ENTRY 4

**Substances which are not themselves manufactured, imported or placed on the market and which result from a chemical reaction that occurs when:**

**(a) a stabiliser, colorant, flavouring agent, antioxidant, filler, solvent, carrier, surfactant, plasticiser, corrosion inhibitor, antifoamer or defoamer, dispersant, precipitation inhibitor, desiccant, binder, emulsifier, de-emulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutraliser, sequesterant, coagulant, flocculant, fire retardant, lubricant, chelating agent, or quality control reagent functions as intended; or**

**(b) a substance solely intended to provide a specific physicochemical characteristic functions as intended.**

In some cases the mode of action of a substance performing a specific function involves a chemical reaction. The aim is not to manufacture the substance which is thus formed, but for example to prevent an unwanted reaction such as oxidation or corrosion (which otherwise would take place) or to promote processes such as aggregation, adhesion. Therefore, provided that this reaction is not a deliberate manufacturing process of the substance(s) resulting from this chemical reaction, they do not need to be registered as the risks of the substances generated will be assessed through the assessment of the precursors of the reaction.

Some substances may be covered by both entries 4(a) and 4(b). It is the responsibility of the user of the exemption to determine where the substance best fits and document the decision.

It is important to note:

- The exemption only applies to the substances generated when the substances listed in Annex V(4)(a) and (b) function as intended, but it does not apply to the substances listed in Annex V(4)(a) and (b) themselves. In other words, the registration obligations apply to the manufacture or import of the groups of substances listed in Annex V(4)(a) and (b) and where a chemical safety report is required, it should cover the intended uses and the risks of the substance(s) generated during the use.

- The substances resulting from a chemical reaction that occurs when a substance belonging to one of the groups listed in Annex V(4)(a) or (b) functions as intended are exempted. But the substances thus formed are subject to registration whenever the chemical reaction is part of the manufacturing process of the resulting substance which is either further processed or placed on the market on its own, in preparations or in articles. For example, a neutralisation reaction for the purpose of manufacturing a substance is not covered by this rule

# Subparagraph (a)

In section (a) of this entry, a comprehensive list of groups of precursors for substances exempted in accordance with this paragraph is provided. This list of precursors, given in alphabetic order for easy retrieval, includes:

## Adhesion promoters

An adhesion promoter is a substance which is applied to a substrate to improve the adhesion of a product to the substrate. The adhesion is created by the formation of strong bonds (including both covalent and non-covalent bonds) between the adhesion promoter and the surfaces of the products to be bound. In addition, some adhesion promoters in a first step chemically react to generate the adhesion properties. The substances thus formed during the use of an adhesion promoter are exempted from the registration provisions.

While the adhesion promoter itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reaction when the adhesion promoter functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

**Example:**

- Silanes are applied to a substrate and hydrolyse into silanols in contact with moisture. The substance thus obtained acts as adhesion promoter in a second step.

## Agglomerating agents

An agglomerating agent is a substance that binds solid particles together to form an agglomerate. The agglomeration process can involve chemical reactions between the agglomeration agent and the solid particles to be agglomerated.

While the agglomerating agent itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reaction when the agglomerating agent functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

## Antifoamer or defoamer

An antifoamer or defoamer is an additive which is used to prevent or reduce foam formation. They work by reducing the surface tension of the liquid to the extent that the foam bubbles collapse and thereby destroy the foam which is already formed.

While the antifoamer or defoamer itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reaction when

the antifoamer functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

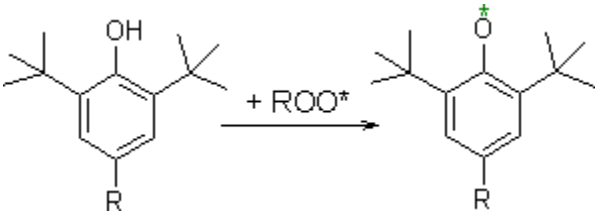
## Antioxidants

An antioxidant is a substance capable of slowing down or preventing the unwanted modification of other molecules (substances) caused by oxidation. Antioxidants inhibit oxidation reactions by being oxidized themselves or by removing free radicals. As a result, antioxidants are often reducing agents.

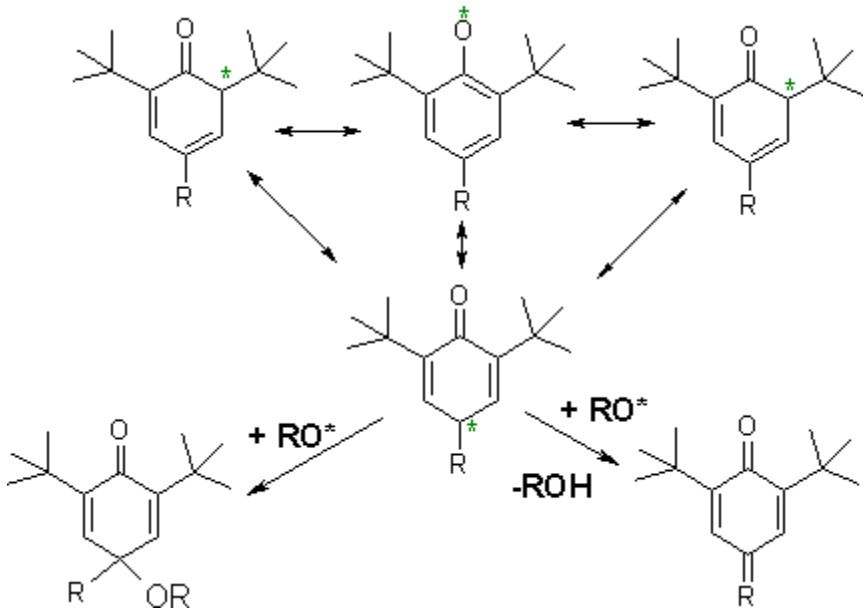
While the antioxidant itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reaction when the antioxidant functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

**Example:**

- Phenols used as antioxidants, for example 2,6-bis(tert-butyl)-4-methyl-phenol (EC No: 204-881-4; CAS No: 128-37-0). This substance will react rapidly with any adventitious radicals to form very stable phenoxy radicals which eventually become quinone type substances. Neither the radicals nor the resultants quinone type substances are subject to registration.




The phenoxy radicals generated are very stable due to their ability to build numerous mesomeric forms and are not subject to registration.




The end-products of the oxidation reaction are also not subject to registration.

Another example of this could be the production of the reaction product of the antioxidant tert-butyl-4-methoxyphenol (EC No: 246-563-8; CAS No: 25013-16-5), used to protect fatty acids from oxidation (with oxygen from air).

## Binder

A binder is a substance used to bind different aggregates and other particles together and thereby adding strength to material. The reaction taking place can be either chemical or physical.

While the binder itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reaction when the binder functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

## Carrier

A carrier is used to facilitate the transport of another product especially in a technical process. Typical examples are:

Dyes can be chemically bonded to an inorganic support to facilitate the delivery of colour to paper in ink jet printing;

Catalysts can be chemically bound to the support material upon which they are held.

While the carrier itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reaction when the carrier functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

## Chelating agents

The function of chelating agents, also called ligands, chelants, chelators or sequestering agents is to form a complex.

While the chelating agent itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reaction when the chelating agents functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

It has to be clarified that complexes consisting of chelated ions must be registered if they are themselves manufactured, imported or placed on the market.

**Examples:**

- The chelating agent dimethylglyoxime is used as a detecting agent in laboratories for detecting nickel via its ability to bind nickel ions into complex compounds. The manufacture and import of dimethylglyoxime is subject to registration. However, when this chelating agent is used to complex nickel ions in industrial processes, the resulting nickeldimethylglyoxime complex does not need to be registered, unless this complex is manufactured or imported deliberately or placed on the market itself (e.g. by a formulator or importer).

- Ethylenediaminetetraacetic acid (EDTA) is widely used to chelate metal ions in industrial processes. For example, in the textile industry, it prevents metals ions from modifying the colours for dyed products. It is also used in the production of chlorine-free paper where it chelates Mn2+ ions thus preventing the catalytic decomposition of the bleaching agent, hydrogen peroxide. While the general registration provisions apply to the manufacture or import of EDTA, the substances generated when EDTA functions as intended, are not subject to registration provided they are not themselves manufactured, imported or placed on the market.

## Coagulants and flocculants

A coagulant is a chemical substance used to contribute to the molecular aggregation of substances present in a solution into particles.

A flocculant is a chemical substance used to promote the aggregation of suspended particles present in a liquid into a macroscopic mass called floc.

Coagulation and flocculation are two techniques commonly combined and are used for instance to remove dissolved organic matter and particles in suspension from water.

While the coagulant or flocculant itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reaction when the coagulant or flocculant functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

**Example:**

- Aluminium sulphate (EINECS[4] no 233-135-0; CAS no 10043-01-3) is a coagulant used for the coagulation/flocculation process in the purification of water. When aluminium sulphate is added to the water to be treated, a complex series of reactions (including the hydrolysis of aluminium sulphate) take place that are required for the purpose of coagulation and flocculation. While the general registration provisions apply to the manufacture or import of aluminium sulphate, the substances derived from aluminium sulphate in the coagulation/flocculation process are not subject to registration.

It should be noted that this entry does not specifically mention anti-coagulants, as used e.g. to stabilise blood by preventing it from clotting.

## Colorant

A colorant is used for inducing a change of colour in a product. Examples of colorants are dyes or pigments.

While the colorant itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reaction when the colorant functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

**Example:**

- When applied to cellulose type fibres (e.g., cotton) the dyes known as 'reactive triazine dyes' chemically bind to the cellulose. This gives then high colourfastness. The cellulose-dyestuff reaction product does not need to be registered.

## Corrosion inhibitors

A corrosion inhibitor is a substance that, when added, even in small concentrations, stops or slows down corrosion of metals and alloys. One can distinguish between anodic and cathodic inhibitors depending on which reaction should be inhibited but both types of reaction products are exempted. Chemical corrosion inhibitors build a protective layer on the metal by a chemical reaction between the metal which has to be protected and the inhibitor.

While the corrosion inhibitor itself is subject to registration, if it meets the necessary requirement, any substance generated as a result of chemical reaction when the corrosion inhibitor functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

[4] EINECS is short for the European Inventory of Existing commercial Chemical Substances.

## De-emulsifiers

A de-emulsifier is a substance used to facilitate the separation of two (or more) immiscible liquid phases present as an emulsion. A general mechanism of action for the de-emulsification is based on the interaction between the de-emulsifier and the substance causing the emulsion, and results in the destabilisation of this emulsion. The interaction between the de-emulsifier and the emulsifier may for instance consist of a chemical reaction between the two substances.

While the de-emulsifier itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reaction when the de-emulsifier functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

## Desiccant

A desiccant is a hygroscopic substance that functions as a drying agent, i.e. it withdraws moisture from other materials. It can retain water through capillarity or adsorption or by reacting chemically. Desiccants are used to dry solvents, gases and solids and lose their function as their water retention increases. Silica gel and molecular sieves are examples of commonly used desiccants.

While the desiccant itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reaction when the desiccant functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

**Example:**

- Calcium hydride (CaH2) is commonly used as desiccant. The mode of action of this drying agent is based on the chemical reaction taking place between calcium hydride and water, which results in the formation of calcium hydroxide (Ca(OH)2). While the registration provisions apply to the manufacture or import of calcium hydride, the calcium hydroxide formed as a result of its use as desiccant is exempted from registration as such.

## Dewatering agent

Dewatering agent is a very general term for substances added during chemical treatment to improve the efficiency of water removal, e.g. clarifiers, flocculants, surfactants, etc.

While the dewatering agent itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reaction when the dewatering agent functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

## Dispersant

A dispersant is a substance that can promote the formation of a dispersion or stabilize the dispersion. The term dispersion is applied to a system of several phases in which one is continuous and at least one other is finely distributed. If two or more phases that are insoluble or only slightly soluble are finely distributed in one another, the term disperse system or, more simply, dispersion is used.

A dispersant generally does not change the solubility of the substance to be dispersed, but is often used to disperse sparingly soluble solids in water and keep them finely dispersed. Dispersants can be used to prevent a solution from turning into a colloidal dispersion.

[Strictly speaking one would consider this a suspending agent as a solid is finely dispersed in a liquid (emulsion)]

Dispersants are generally polyelectrolytes that are readily soluble in water, e.g. alkali-metal polycarbonates, polysulfonates, or polyphosphates, usually sodium salts. Ligninsulfonates and condensation products of aromatic sulfonic acid with formaldehyde are also widely used.

Dispersants are used in the following fields, e.g.: production of polymer dispersions, adhesive dispersions, dispersion of dyes (textile industry), pigment dispersion (industrial paints, printing inks), cosmetic, pharmaceutical and photographic industry, detergents, cleaning and polishing products.

While the dispersant itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reaction when the dispersant functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

## Filler

A filler is usually added to materials, such as polymers, to lower the consumption of more expensive binders or to improve the properties of the material, e.g. better mechanic properties (rubber used for tyres), to improve viscosity of resins (epoxy resins), or to control cost and/or viscosity or increase its strength (polymers), or tenacity and volume (dry wall).

Common fillers are:

- carbon black or 'soot' used in rubber tyres
- microspheres used in epoxy resins
- glass fibres used in polymers
- minerals, e.g. kaolin, limestone, gypsum used in paper

While the filler itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reaction when the filler functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

## Fire retardants

A fire retardant is a substance used to protect a combustible material, for instance certain plastics or wood, against fire. The mechanism of action generally involves chemical reactions with the fire retardants under the conditions of a fire.

While the fire retardant itself is subject to registration, if it meets the necessary requirements, when heated under fire conditions they release substances that quench

the flame and thus prevent the fire from taking hold. The substances formed in such reactions do not need to be registered, provided it is not itself manufactured, imported or placed on the market.

## Flavouring agent

A flavouring agent can be understood as a substance that gives another substance flavour.

While the flavouring agent itself is subject to registration[5], if it meets the necessary requirements, any substance generated as a result of chemical reaction when the flavouring agent functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

**Examples:**

- Denatonium benzoate, is a flavouring agent that imparts a bitter taste. It is commonly added to products to deter human consumption.

- Cigarettes contain, besides tobacco leaves, flavouring agents that give cigarettes particular aromas.

## Flow modifier

A flow modifier is a substance added to a material (mainly liquids but also soft solids or solids under conditions in which they flow) in order to alter its flow characteristics. One example of the use of a flow modifier is in surface coatings in order to avoid surface defects such as craters, pinholes and orange peel when the coating is applied to a surface.

While the flow modifier itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reaction when the flow modifier functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

## Lubricants

A lubricant is a substance applied between two moving surfaces to reduce the friction and wear between them. A lubricant provides a protective thin film which allows two surfaces to be separated while performing certain functionality by reducing the friction between them, improving efficiency and reducing wear. They may also have the function of dissolving or transporting foreign particles and of distributing heat. An example of one of the largest applications for lubricants in form of motor oil is to protect the internal combustion engines in motor vehicles and powered equipment. Lubricants, such as 2-cycle oil, are also added to some fuels.

[5] Note: Substances used as flavouring in foodstuffs within the scope of Directive 88/388/EEC are exempted from registration (Article 2(5)(b) ii of REACH).

While the components of the lubricant itself (e.g. 2-cycle oil) are subject to registration, if they meet the necessary requirements, any substance generated as a result of chemical reaction when the lubricant functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

**Example:**

- Zinc dithiophosphates (ZDDPs) are substances commonly used in the formulation of lubricating oils for engines. Their mode of action includes the formation of a boundary layer to the surface to be lubricated and is known to require the chemical reaction of the ZDDPs. While the registration provisions apply to the manufacture or import of ZDDPs, the substances formed upon their use as lubricant and which contribute to the lubrication process are exempted from registration as such.

## pH Neutralisers

A pH neutraliser is a substance used to adjust the pH-value of a solution, generally an aqueous solution, to the intended level. pH neutralisers are for instance used to balance the pH of drinking water or to discharge water from industrial processes. A pH neutraliser is not necessarily meant to be used to achieve pH neutrality but may in principle be used to achieve any pH value.

The neutralisation mechanism is based on acido-basic reaction between the pH neutraliser and the liquid to be treated. The reaction products from the pH neutraliser are exempted from the registration provisions. This does not apply to the deliberate formation of salts from acids or bases.

While the pH neutraliser is subject to registration, if it meets the necessary requirements, any substance generated as a result of the chemical reaction when the pH neutraliser functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market. Additional background information on the conditions under which these substances may qualify for such an exemption is provided in Attachment 1.

## Plasticiser

A plasticiser is a substance that, when added increases flexibility, workability and elasticity of materials such as polymers or cement. They can chemically react or physically interact with polymers and thereby determine the physical properties of the polymer products.

Plasticisers can be used to lower the glass transition temperature of adhesives or sealants in order to improve for example low temperature performance or they can be added to cement in order to improve low temperature performance and workability. Plasticiser exhibit flexibility and elongation and thus improve materials (where introduced) to thermal expansion differences due to seasonal and daily temperature variations.

While the plasticiser itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reaction when the plasticiser functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

**Example:**

- Dioctyl adipate (DOA) is used as plasticiser in food packaging material as it has a good stability to temperature (heat and cold) characteristics.

## Precipitation inhibitors

Precipitation is the process of separating a substance from a solution as a solid. Inhibitors are substances which inhibit or prevent the processes needed for this to take place. Therefore precipitation inhibitors inhibit or prevent the formation of a solid in a solution.

While the precipitation inhibitor itself is subject to registration, if it meets the necessary requirements,, any substance generated as a result of chemical reaction when the precipitation inhibitor functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

## Quality control agents

A quality control agent is a substance used to qualitatively or quantitatively determine a specified parameter in a product for keeping an established quality.

While the quality control agent itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reaction when the quality control agent functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

**Example:**

- Examples of quality control agents include solutions used for the Karl-Fisher titration techniques. In accordance with these techniques, a series of chemical reactions take place which involve water and the substances constituting the quality control preparations. While the substances in the preparation are subject to registration, the reaction products obtained as a result of the titration are exempted from registration.

## Solvent

A solvent is a substance, which is used to dissolve a solid, liquid or gaseous substance (solute), forming a solution.

While the solvent itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reaction when the solvent functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

**Example:**

- Polyethylene glycols can form solvation complexes with metal salts when they are dissolved in the glycol. The products of these solvation reactions that occur upon end use do not need to be registered (unless the complex itself is placed on the market).

## Stabiliser

A stabiliser is a substance which, when added, prevents unwanted changes of other substances.

While the stabiliser itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reaction when the stabiliser functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

**Example:**

- Examples of stabilisers are polymerisation inhibitors. For instance, tert-butyl catechol is added to styrene, a monomer susceptible to polymerise spontaneously in the presence of a radical source. The mechanism of action of tert-butyl catechol is based on its ability to chemically react with radicals and by this mean scavenging the initiation of the polymerisation.

While the registration provisions apply to the manufacture or import of tert-butyl catechol, the substances formed upon its reaction with radical initiators are exempted from registration as such.

## Surfactants

A surfactant is a surface active agent, i.e. a substance that, because of its design, seeks out the interface between two distinct phases, thereby altering significantly the physical properties of those interfaces through the modification of some superficial or interfacial activity. The interfaces can independently be liquid, solid or gaseous immiscible liquids, a solid and a liquid.

While the surfactant itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reaction when the surfactant functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

**Example:**

- The manufacture or import of a surfactant used for the waterproofing treatment of leather is subject to registration. However, when the surfactant chemically reacts with the surface of the leather the substances that are generated in this reaction are exempted from registration, provided they are not themselves manufactured, imported or placed on the market.

# Subparagraph (b)

In this section, the group of substances exempted from the registration provisions is an extension of the list of substances provided in subparagraph (a). Whenever a substance is used with the aim of providing a specific physicochemical characteristic and where a chemical reaction takes place for the purpose of this application, the substances thus produced do not have to be registered, provided that these substances are not themselves manufactured or placed on the market. The substance produced and its risks shall be assessed through the life-cycle assessment of the precursors/reactants of the reaction.

## Emulsifier

An emulsifier is a substance which stabilises an emulsion, frequently a surfactant.

For example detergents are a class of surfactants that physically interact with both oil and water, thus stabilising the interface between oil or water droplets in suspension.

While the emulsifier itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reactions when the emulsifier functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

## Lubricants

A **lubricant** (as already described in section 4a xix) is a substance that reacts with the surface of a metal to provide a physically attached 'oil' layer. Non-liquid lubricants include grease, powders (e.g. graphite, PTFE, molybdenum disulfide, tungsten disulfide), teflon tape used in plumbing, air cushion and others.

While the components of the lubricant itself are subject to registration, if they meet the necessary requirements, any substance generated as a result of chemical reactions when the lubricant functions as intended is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

## Viscosity modifiers

A viscosity modifier is a substance that is widely used to control the flow of liquids in industrial processes. For example, in oil drilling polyanionic cellulose is added to water-based drilling fluids as thickeners to modify fluid flow. In the lubrication industry, viscosity modifiers are added to lubricant oils to vary the fluid flow as a function of temperature. In the latter case, the modifiers are typically polymeric molecules that are heat sensitive, in that the contract or relax depending on temperature.

While the viscosity modifier itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reactions when the modifier functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

## Solvent

A solvent is a substance, which is used to dissolve a solid, liquid or gaseous substance (solute), forming a solution.

While the solvent itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reaction when the solvent functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

For example, if water is added to a salt (e.g. $CuSO_4$), ionic pairs in equilibrium are formed in solution as a result. Further examples concerning ionic mixtures where water is used as solvent and functioned as intended are given in Attachment 1 at the end of this guidance document.

Note: Water is listed in Annex IV of Regulation (EC) No 1907/2006 as amended by Regulation (EC) No 987/2008 of 8 October 2008 and therefore exempted from registration.

# ENTRY 5

**By-products, unless they are imported or placed on the market themselves.**

Article 5 of Directive 2008/98/EC ("Waste Framework Directive") defines by-products as: *"A substance or object, resulting from a production process, the primary aim of which is not the production of that item, […] if the following conditions are met:*

*(a) further use of the substance or object is certain;*

*(b) the substance or object can be used directly without any further processing other than normal industrial practice;*

*(c) the substance or object is produced as an integral part of a production process; and*

*(d) further use is lawful, i.e. the substance or object fulfils all relevant product, environmental and health protection requirements for the specific use and will not lead to overall adverse environmental or human health impacts."*

# ENTRY 6

Hydrates of a substance or hydrated ions, formed by association of a substance with water, provided that the substance has been registered by the manufacturer or importer using this exemption.

Hydrates of a substance are characterised by the fact that water molecules are linked, in particular by hydrogen bonds, to other molecules or ions of the substance. A substance that does not contain any water is referred to as anhydrous. Solid hydrates contain water of crystallization in a stoichiometric ratio, an example of which would be $NiSO_4{:}7H_2O$. The chemical formula expresses the fact that one molecule of NiSO4 can crystallise with seven molecules of water.

| Examples | | | | |
|---|---|---|---|---|
| **Name** | **Formula** | **CAS number** | **EC number** | **Rule** |
| Copper sulphate | $CuSO_4$ | 7758-98-7 | 231-847-6 | |
| Copper sulphate pentahydrate | CuSO4 . 5H2O | 7758-99-8 | | This substance is covered by its anhydrous form (EC number: 231-847-6) |

It is important to note:

- The manufacturer or importer relying on this exemption registers the substance in the anhydrous form. It is recommended to make reference to the hydrated form(s) in the registration dossier.

- Companies changing the hydration state of a substance (i.e. changes the number of water molecules associated with the substance), are considered as downstream users provided that the anhydrous form of the substance has already been registered by the manufacturer or importer up the supply chain. These hydration or drying processes should be covered in any applicable exposure scenario in the registration by the manufacturer or importer.

- A registrant who wants to make use of the exemption under this entry needs to add up the quantities of the anhydrous form and the different hydrated forms in his technical dossier (but excluding the water which is attached to the parent molecule).

# ENTRY 7 & 8 – general considerations

**Entries 7 and 8 cover naturally occurring substances, if they are not chemically modified. Therefore the definitions 'substances which occur in nature' and 'not chemically modified substance' are here first explained and concern both of the exemptions.**

This group of substances is characterised via the definitions given in Articles 3(39) and 3(40):

According to Article 3(39), *'substances which occur in nature'* means *'a naturally occurring substance as such, unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which is extracted from air by any means'*.

It should be noted as background explanation that prior to REACH naturally occurring substances shared a single EINECS entry which is wider than the current interpretation under REACH:

EINECS No: 310-127-6, CAS No: 999999-99-4

*Naturally occurring substances*

*Living or dead material occurring in nature as such which is chemically unprocessed, or which is extracted from air by any means or physically processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation or by heating solely to remove water.*

The REACH definition can be split into several parts in order to obtain a clear understanding:

- **Naturally occurring substances as such**: means, substances obtained, for example, from plants, micro-organisms, animals, or certain inorganic matter such as minerals, ores and ore concentrates, or organic matter such as crude oil, coal, natural gas. It should be noted that whole living or unprocessed dead organisms (e.g. yeast (see Attachment 2), freeze-dried bacteria) or parts thereof (e.g. body parts, blood, branches, leaves, flowers etc.) are not considered as substances, preparations or articles in the sense of REACH and are therefore outside of the scope of REACH. The latter would also be the case if these have undergone digestion or decomposition resulting in waste as defined in Directive 2008/98/EC, even if, under certain circumstances, these might be seen as non-waste recovered materials[6].

- **Naturally occurring substances unprocessed**: no treatment at all of the substance takes place.

- **Processed only by manual, mechanical or gravitational means**: parts of the substance as such may for instance be removed by hand or by machine (e.g. by centrifugation). If minerals are processed *only* by mechanical methods, e.g. by grinding, sieving, centrifugation, flotation, etc., they are still considered to be the same naturally occurring minerals as originally mined.[7]

- **By dissolution in water**: the only solvent which can be used is water. The dissolution by any other solvent or mixture of solvents or mixture of water with other solvents disqualifies the substance as naturally occurring.

- **By flotation**: physical separation process taking place in water or in a liquid such as oil without chemical reaction.

- **By extraction with water**: separation process which is based on the different distribution of a certain constituent or constituents from a material by using water with or without conditioners (flocculants, emulsifiers, etc) that only exploit differences in physical behaviour of the constituents in water without chemical reaction.

- **By steam distillation**: distillation of naturally occurring substances with water vapour as carrier for the separation of certain constituent(s) without chemical reaction.

- **Heating solely to remove water**: purification or concentration of a substance by removing water by heat while no chemical reaction occurs.

[6] This explanation is without prejudice to discussions and decisions to be taken under Community waste legislation on the status, nature, characteristics and potential definition of such materials, and may need to be updated in the future.

[7] (ECHA, 2012) Guidance for identification and naming of substances under REACH and CLP (ver. 1.2), pages 33-34.

- **Extracted from air by any means**: substances which occur naturally in air, extracted by applying any methods and solvents as far as no chemical reaction occurs.

According to Article 3(40), a *'**not chemically modified** substance'* means '*a substance whose chemical structure remains unchanged, even if it has undergone a chemical process or treatment, or a physical mineralogical transformation, for instance to remove impurities'*.

The exemption under point 7 and 8 requires that the substances are *substances which occur in nature, if they are not chemically modified*. This requirement implies that in order to decide if the exemption applies to a particular substance, both the criteria of:

- 'a substance that occurs in nature' according to the definition in Article 3(39) and
- 'not chemically modified' according to the definition in Article 3(40)

have to be fulfilled.

Therefore, in order to benefit from the exemptions under points 7 and 8, a substance must be naturally occurring, which means only processed in accordance with a process listed in Article 3(39). In addition, it must not have undergone a chemical modification as defined by Article 3(40).

This means that, in a first step it needs to be assessed whether the substance in question (e.g. menthol) has been extracted solely with a process listed in Article 3(39). If this is the case, it needs to be assessed in a second step whether the substance has been chemically modified during or after extraction according to Article 3(40)[8]. It should be noted that processes intended solely to remove impurities are not considered to be a chemical modification, as long as the chemical structure of the molecule is not modified.

However, where a substance undergoes a chemical modification of one or more of the constituents originally present in the naturally occurring substance, hence resulting in a change of chemical structure, a substance would no more be covered by the exemption because it does not conform with the conditions in Article 3(40), even if it was extracted only by the means listed in Article 3(39).

Note that the exemptions in points 7 and 8 do not apply to synthetic versions of the substances described in the relevant sections as such substances do not meet the definition of substances which occur in nature and hence these synthetic versions would

[8] Please note that some of the processes mentioned under Article 3(39) may change the chemical structure and thus result in a chemical modification: e.g. simple heating may result in isomerisation which is a chemical modification making the combination of both, the condition of a 'substance which occurs in nature' as mentioned under Article 3(39) and the condition 'not chemically modified' as mentioned in Article 3(40) meaningful.

be subject to registration if they meet the necessary requirements (see example 4 below).

The following examples illustrate circumstances under which a substance does or does not meet the requirement of s*ubstances which occur in nature, if they are not chemically modified.*

**Example 1:**

A substance is obtained in accordance with a steam distillation process of the leaves from *Mentha arvensis*. The chemical analysis of the *Mentha arvensis* extract thus manufactured indicates that this substance consists of several stereo-isomers including the constituent (-)-menthol (i.e. (1R,2S,5R)-5-methyl-2-(propan-2-yl)cyclohexanol). All the constituents in the substance were originally present in the leaves. This substance fulfils the requirements for *substances which occur in nature, if they are not chemically modified*.

**Example 2:**

The substance isolated in example 1 is further processed by crystallisation[9] in water and ethanol to isolate (-)-menthol and to remove other constituents. Although this process did not result in the chemical modification of the substance within the meaning of Article 3(40), the substance does nevertheless not fulfil the requirements for *substances which occur in nature, if they are not chemically modified*. Therefore the substance does not fulfil the requirements for *substances which occur in nature, if they are not chemically modified*.

**Example 3:**

The substance isolated in example 1 is heated solely to remove water. Upon heating the substance isolated in example 1 under vacuum it is converted into a mixture of different constituents including (-)-menthol. Although the isolated substance fulfils the definition of a substance which occurs in nature, it has been chemically modified and therefore does not fulfil the requirements for *substances which occur in nature, if they are not chemically modified*.

**Example 4:**

A multi-step synthesis is used for the manufacturing of (-)-menthol. Although this substance consists of the same constituent as the one found in the leaves of *Mentha arvensis*, it is not a substance which occurs in nature and does therefore not fulfil the requirements for *substances which occur in nature, if they are not chemically modified*.

[9] Crystallisation is not a chemical modification as the chemical structure remains unchanged. Recrystallisation, when done from any solvent other than water (which is often the case), disqualifies such substances from being a "substance which occurs in nature".

# ENTRY 7

**The following substances which occur in nature, if they are not chemically modified: Minerals, ores, ore concentrates, raw and processed natural gas, crude oil, coal.**

This exemption includes only the above listed groups of substances provided that they occur in nature as defined in Article 3(39), if they are not chemically modified as defined in Article 3(40), irrespective of whether or not they are classified as dangerous according to Directive 67/548/EEC or hazardous according to Regulation (EC) No 1272/2008.

The specific substances covered by the exemption are:

## Minerals

Minerals are substances. They may be mono- or multi-constituent or in some cases UVCB substances. A mineral is defined as a combination of inorganic constituents as found in the earth's crust, with a characteristic set of chemical compositions, crystalline forms (from highly crystalline to amorphous) and physical properties. In general minerals are inorganic and most of them are crystalline. In a first step it needs to be assessed whether the mineral has been mined/manufactured in accordance with any method mentioned in the definition of 'substances which occur in nature'. If it is the case, it needs to be assessed in a second step whether the minerals have not been chemically modified during or after mining/manufacturing according to Article 3(40).

Minerals which occur in nature are covered by the exemption if they are not chemically modified. This applies to naturally occurring minerals, which have undergone a chemical process or treatment, or a physical mineralogical transformation, for instance to remove impurities, provided that none of the constituents of the final isolated substance has been chemically modified. Thus, if both the above conditions are fulfilled, then the mineral is exempted from the obligation to register.

An example of minerals is asbestos. Asbestos is the common name of a number of naturally occurring, hydrated silicate minerals like: Crocidolite (CAS: 12001-28-4); Amosite (CAS: 12172-73-5); Anthophyllite (CAS: 77536-67-5); Actinolite (CAS: 7536-66-4); Tremolite (CAS: 77536-68-6) & Chrysotile (CAS: 12001-29-5 and 132207-32-0).

Asbestos is exempted from registration provisions, because these minerals occur in nature and are not further chemically modified. However, they are not exempted from other obligations of REACH. Furthermore, asbestos fibres are listed in Annex XVII of REACH 'restrictions on the manufacture, placing on the market and use of certain dangerous substances preparations and articles'.

<u>Note:</u> Chrysotile is not entirely restricted as it is exempted from the Annex XVII entry for the placing on the market and use of diaphragms containing chrysotile (point (f)) for existing electrolysis installations until they reach the end of their service life, or until suitable asbestos-free substitutes become available, whichever is the sooner.

Other examples of minerals include (but are not limited to):

Dolomite (CAS number 16389-88-1) $CaCO_3$ . $MgCO_3$, a rock-forming mineral;

Limestone (CAS number 1317-65-3), which consists principally of calcium carbonate and may also contain magnesium carbonate;

Barite (CAS number 13462-86-7), which principally consists of barium sulfate;

Fluorapatite (CAS number 1306-05-4), the most common phosphate rock mineral.

Note: The exemption does not apply to synthetic substances having the same structures as the natural occurring minerals.

## Ores

Ores is a general expression for mineral aggregates or rocks from which metals or metal components can be extracted as well as for mineral aggregates whose mining have an economical benefit.

The ores themselves can be regarded as substances which occur in nature and which therefore are exempted from the obligation to register. It should be noted however, that when ores are extracted with methods not mentioned in the definition of 'substances which occur in nature', or with methods which modify the chemical structure of the final substance, the final 'product' of the treatment can normally not be regarded as a substance which occurs in nature and hence will need to be registered. However, ores are exempted when processed only by means mentioned in Article 3(39) subsequently undergo a chemical process or treatment, or a physical mineralogical transformation, for instance to remove impurities, provided that none of the constituents of the final isolated substance has been chemically modified.

**Example:**

The iron ore type 'banded ironstone formation (BFI)' which is composed predominantly of magnetite ($Fe^{2+}Fe_2^{3+}O_4$) and quartz is processed mechanically in the first steps by means of coarse crushing and screening, followed by rough crushing and fine grinding to comminute the ore to the point where the crystallised magnetite and quartz are fine enough that the quartz is left behind when the resultant powder is passed under a magnetic separator. Up to this stage all substances, including the original ore, created through the whole process are regarded as substances which occur in nature.

To convert magnetite to metallic iron it must be smelted or sent through a direct reduction process. Magnetite (or any other iron ore) must be powdered and mixed with coke. During the process in the blast furnace various reduction or oxidation-reactions take place that result in the production of metallic iron, oxides of carbon and other materials collectively known as 'slag:

Air blast and coke: $2C + O_2 \rightarrow 2CO$

Carbon monoxide (CO) is the principal reduction agent

Stage One: $3Fe_2O_3 + CO \rightarrow 2Fe_3O_4 + CO_2$

Stage Two: $Fe_3O_4 + CO \rightarrow 3FeO + CO_2$

Stage Three: $FeO + CO \rightarrow Fe + CO_2$

During this manufacturing process different treatments take place which disqualify the final iron as a substance occurring in nature that is not chemically modified:

- Heating was not solely applied for removing water
- The iron oxide is subject to a reduction/oxidation reaction which is a chemical reaction leading to a new/different substance from the starting material

As a consequence, iron is regarded as a substance for which the registration obligations need to be fulfilled. If analogous processes take place for other metals then also for those metals registration obligations will need to be fulfilled.

## Ore concentrates

Ore concentrates are extracted from the original ore mostly by mechanical measures or flotation resulting in mineral-rich fraction which is used for further processing of e.g. metals. Such processes include, but may not be limited to, sorting; magnetic separation; electrostatic separation; preferential crushing, grinding and milling; sieving and screening; hydrocycloning; filtration and flotation.

Therefore ore concentrates are generally regarded as substances which occur in nature provided the manufacturing processes are only mechanical and/or by flotation (e.g. grinding, sieving, centrifugation, etc.). Such naturally occurring ore concentrates are exempted from the obligation to register if they are not chemically modified. Thus, for example, naturally occurring ore concentrates, which have undergone a chemical process or treatment, or a physical mineralogical transformation, for instance to remove impurities, provided that none of the constituents of the final isolated substance has been chemically modified, are exempted.

## Raw and processed natural gas

Natural gas is a gaseous fossil fuel which consists predominantly of saturated hydrocarbons. Natural gas can have different compositions depending on the source and can be divided into following groups:

- natural gas from pure natural gas deposits is composed of methane and small amounts of ethane;
- natural gas from coal deposits is composed of methane, small amounts of ethane and variable amounts of nitrogen and carbon dioxide;
- natural gas from crude oil deposits generally contains in addition larger amounts of ethane, propane, isobutane, hexane, heptane, carbon dioxide, hydrosulfides, helium, nitrogen and arsenic compounds;
- natural gas from condensate and distillate deposits which contains besides methane and ethane also higher amounts of hydrocarbons with more than 7 C-atoms.

However, raw natural gas has to be processed to make it suitable for the use by residential, commercial and industrial consumers. The processed natural gas is almost pure methane and is very much different from the raw natural gas.

The EINECS lists one entry for natural gas which gives the following description:

EINECS number: 232-343-9, CAS number: 8006-14-2

*Natural gas*

*Raw natural gas, as found in nature, or gaseous combination of hydrocarbons having carbon numbers predominantly in the range of C1 through C4 separated from raw natural gas by the removal of natural gas condensate, natural gas liquid, and gas condensate/natural gas.*

The raw natural gas itself, without further processing, can normally be regarded as a substance which occurs in nature. In addition, the processed natural gas is only exempted under this entry if it does not undergo any chemical modification and thereby satisfies the criteria for Article 3(40).

Note: It has to be emphasised that only methane which is processed from raw natural gas can be regarded as natural gas. Methane processed from other sources than fossil, is not regarded as natural gas.

## Crude oil

Crude oil is constituted of complex lipophilic hydrocarbon structures, which is incorporated into the earth's crust. Crude oil can consist of more than 17,000 constituents and is one of the most complex mixtures of organic compounds. The formation of crude oil is based on sapropel of flat inshore waters emanated from carbohydrates, proteins and fats from small animals and small plants under the influence of bacteria, enzymes, pressure, mineral catalyst etc. The crude oil production is based on mechanical means which qualifies crude oil as a substance which occurs in nature.

However, when processing and separating crude oil, the constituents or mixtures of constituents arising from these processes can normally **no longer** be regarded as substances which occur in nature which are not chemically modified. EINECS contains many of such substances obtained from crude oil, for example:

EINECS number: 272-871-7, CAS number: 68918-99-0

*Gases (petroleum), crude oil fractionation off*

*A complex combination of hydrocarbons produced by the fractionation of crude oil. It consists of saturated aliphatic hydrocarbons having carbon numbers predominantly in the range of C1 through C5.*

For example: Diesel, in general a fuel used in diesel engines, is a specific fractional distillate of petroleum fuel oil, derived from petroleum. Diesel is obtained by chemical modification of petroleum and therefore not exempt from registration.

The EINECS lists diesel fuels which give the following descriptions:

EINECS number: 269-822-7, CAS number: 68334-30-5

*Fuels, diesel*

*A complex combination of hydrocarbons produced by the distillation of crude oil. It consists of hydrocarbons having carbon numbers predominantly in the range of C9 through C20 and boiling in the range of approximately 163°C to 357°C (325°F to 675°F).*

EINECS Number: 270-676-1, CAS number: 68476-34-6

*Fuels, diesel, no. -2*

*A distillate oil having a minimum viscosity of 32.6 SUS at 37.7°C (100°F) to a maximum of 40.1 SUS at 37.7°C (100°F).*

## Coal

Coal is a solid fossil fuel formed by carbonisation of plants. There are two types of coal: brown coal and black coal which differ in their carbon content. Brown coal contains 60 – 80 % carbon and black coal contains 80 – 98 % carbon. Coal is usually processed only by mechanical means which qualifies coal as a substance which occurs in nature and may benefit from the exemption if it is not chemically modified.

Charcoal obtained by thermal decomposition of wood is not regarded as a substance which occurs in nature and therefore it is not covered by this exemption.

# ENTRY 8

Substances which occur in nature other than those listed under paragraph 7, if they are not chemically modified, unless they meet the criteria for classification as dangerous according to Regulation (EC) No 1272/2008[10] or unless they are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII or unless they were identified in accordance with Article 59(1) at least two years previously as substances giving rise to an equivalent level of concern as set out in Article 57(f).

This exemption includes 'substances occurring in nature' if they are not chemically modified, and which are not listed in paragraph 7, unless they meet the criteria for classification as dangerous (hazardous) according to Regulation (EC) No 1272/2008.

To determine if a substance fulfils the requirements for this exemption, the following points should be considered:

- The substances *must* meet the definition of a 'substance which occurs in nature' as defined in Article 3(39)[11]; and

- The substance must *not* be chemically modified as defined in Article 3(40). Chemical modification includes but is not limited to hydrogenation, neutralization, oxidation, esterification, and amidation; and

- The substances must *not* meet the criteria for classification as dangerous (hazardous) according to Regulation (EC) No 1272/2008. A naturally occurring substance is not covered by this exemption if it is either on Annex VI of Regulation (EC) No 1272/2008 or the manufacturer or importer of the substance has determined that it meets the criteria set out in Parts 2 to 5 of Annex I of Regulation (EC) No 1272/2008. In addition, a naturally occurring substances meeting the criteria for PBTs and or vPvBs in Annex XIII is also not exempted. A substance giving rise to an equivalent level of concern according to Article 57(f) and included on the candidate list (according to Article 59(1)) at least two years previously, is no longer subject to an exemption under this point and should be registered[12].

In all cases, the burden of proof rests with the manufacturer/importer that wishes to use this exemption for his substance. An absence of information on the properties of a

[10] From 1 December 2010 onwards the reference to Directive 67/548/EEC in entry 8 of Annex V was replaced by Regulation (EC) No 1272/2008.
[11] See entries 7 and 8 for guidance on this definition.
[12] In the latter case if a substance occurring in nature is identified according to Article 57(f) and included in the candidate list it is no longer subject to an exemption under this point from a date two years after its inclusion (on the candidate list) and should be registered by that date. The date of inclusion is indicated in the candidate list on the ECHA web site.

substance *cannot* be equated to the absence of hazardous properties. Many substances that might fall into the 'substances which occur in nature' category have insufficient information available on them to be able to conclude that they are not dangerous. To exempt such substances would undermine the aims of REACH to gather information on substances in order to determine their potential hazards.

Examples of substances that are *not* covered by this exemption include but are not limited to, e.g. fermentation products which are isolated by other means as those given in Article 3(39). In these examples, the substances have undergone chemical modification, i.e. solvent extraction (bonemeal), fermentation products (enzymes), or are dangerous and thus not exempt from registration.

Examples of substances that are covered by this exemption include but are not limited to cotton, wool, with the provision that fulfils the conditions of Articles 3(39) and 3(40) and not meeting the classification criteria to be dangerous (hazardous) according to Regulation (EC) No 1272/2008.

If the classification of a substance is changed from not meeting the criteria to meeting the criteria for classification due to new information and the substance therefore meets the criteria for classification as dangerous (hazardous) according to Regulation (EC) 1272/2008, the exemption from registration provisions no longer applies and thus the substance needs to be registered.

# ENTRY 9

**The following substances obtained from natural sources, if they are not chemically modified, unless they meet the criteria for classification as dangerous according to Directive 67/548/EEC[13] with the exception of those only classified as flammable [R10], as a skin irritant [R38] or as an eye irritant [R36] or unless they are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII or unless they were identified in accordance with Article 59(1) at least two years previously as substances giving rise to an equivalent level of concern as set out in Article 57(f):**

**Vegetable fats, vegetable oils, vegetable waxes; animal fats, animal oils, animal waxes; fatty acids from C6 to C24 and their potassium, sodium, calcium and magnesium salts; glycerol.**

This exemption applies only to vegetable fats, vegetable oils, vegetable waxes; animal fats, animal oils, animal waxes; fatty acids from $C_6$ to $C_{24}$ and their potassium, sodium, calcium and magnesium salts; glycerol. It comprises these substances in so far that they are obtained from natural sources if they are not chemically modified, unless they meet the criteria for classification as dangerous according to Directive 67/548/EEC, with the exception of those only classified as flammable [R10], as a skin irritant [R38] or as an eye irritant [R36] or a combination thereof. A substance meeting the criteria for PBTs and vPvBs in Annex XIII is also not exempted. A substance giving rise to an equivalent level of concern according to Article 57(f) and included on the candidate list (according to Article 59(1) at least two years previously, is no longer subject to an exemption under this point and should be registered.

In all cases, the burden of proof rests with the manufacturer/importer that wishes to use this exemption for his substance. An absence of information on the properties of a substance *cannot* be equated to the absence of hazardous properties. Many substances that might fall into the 'substances obtained from natural sources' category have insufficient information available on them to be able to conclude that they are not dangerous. To exempt such substances would undermine the aims of REACH to gather information on substances in order to determine their potential hazards.

This exemption is not limited to ‘naturally occurring substances’ in the sense of the definition of Article 3(39). This means that the specified substances falling under this

[13] Directive 67/548/EEC will be fully repealed by Regulation (EC) No 1272/2008 with effect from 1 June 2015.

exemption can also be obtained through other processes than those described in Article 3(39)[14].

In this exemption 'obtained from natural sources' means that the original source must be a natural material (plants or animals). 'Not chemically modified' means that the substances covered by this exemption, once obtained from a natural source, are not further chemically modified.

In particular 'fatty acids from $C_6$ to $C_{24}$, and their potassium, sodium, calcium and magnesium salts' are listed in Annex V(9). They have to be obtained from natural sources to be covered by this exemption, and also they must not be further chemically modified. This means that the chemical structure of the 'fatty acids from $C_6$ to $C_{24}$, and their potassium, sodium, calcium and magnesium salts' substance cannot be changed.

Note: The exemption does not apply to synthetic materials.

In general, fats and oils derived from natural sources such as plants or animals are mainly composed of triglycerides (up 97% triglyceride (i.e., triesters of glycerol with fatty acids); up to 3 % diglycerides and up to 1 % monoglycerides). The triglycerides of naturally occurring fats and oils contain saturated and unsaturated fatty acids.

Note: Hydrogenated fats and hydrogenated oils' are not considered as vegetable or animal fats and oils but substances, which have undergone a chemical modification of the original fats and oils and are therefore not covered by this entry.

Groups of substances covered by this exemption are:

## Vegetable fats and vegetable oils

Vegetable fats and oils[15] are substances that are generally obtained from the seeds of oilseed plants (rape, flax, sunflower etc), although some other parts of the plants may also yield oils. Vegetable oils and fats are mainly composed of triglycerides, which contain a range of fatty acids of different chain lengths; for example they can be rich in palmitic, oleic or linoleic acid.

[14] The wording 'substances obtained from natural sources' is not identical with 'substances which occur in nature'. In particular, the term 'substances obtained from natural sources' is not restricted to the definition of Article 3(39).

[15] The European Commission clarified its interpretation regarding vegetable oils derived from GMOs in a document titled "Status of vegetable oils obtained from Genetically Modified Plants under REACH Regulation (EC) No. 1907/2006" presented at the 4th Meeting of Competent Authorities for REACH and CLP (CARACAL). MSCAs provided comments on this document.

For example, cocoa butter, contains a high proportion of $C_{16}$– $C_{18}$ fatty acids and $C_{18}$ unsaturated fatty acids, whereas coconut oil contains a high proportion of $C_6$– $C_{16}$ fatty acids and $C_{18}$ unsaturated fatty acids.

Note: This exemption exclusively applies to vegetable fats and vegetable oils but does not cover essential oils. Essential oils are hydrophobic liquids of complex composition, derived from plants, containing volatile organic compounds, such as alcohols, aldehydes, ketones, phenols, esters, ethers and terpenes, in varying proportions.

## Vegetable waxes

Vegetable waxes are composed of non-glycerolic esters of long chain fatty acids esterified with long chain fatty alcohols, triterpenic alcohols and sterols. An example for a vegetable wax is carnauba wax derived from the leaves of the carnauba palm.

## Animal fats and animal oils

Animal fats and animal oils can be obtained from the tissue fats of a variety of animals.

For example, fats such as tallow and lard, mainly composed of triglycerides, contain predominantly $C_{16}$ and $C_{18}$ fatty acids, whereas milk fat (butterfat) contains a high proportion of $C_6$– $C_{12}$ fatty acids.

Animal oils obtained from fish or other sea creatures tend to have a higher proportion of polyunsaturated fatty acids than other animal fats/oils. The distribution of chain lengths is also different, with a chain length of $C_{16}$ – $C_{24}$ being more common. They are also richer in omega-3 fatty acids (e.g. fish oils and whale oil) than other animal fats.

## Animal waxes

Animal waxes are composed of nonglycerolic esters of long chain fatty acids esterified with long chain fatty alcohols, triterpenic alcohols and sterols. Examples are beeswax and lanolin from sheep wool.

Note: This exemption does not apply to synthetic materials such as silicone wax that exhibit similar properties or any synthetic waxes manufactured from by distillation from natural petroleum or completely synthetic waxes.

## Fatty acids from C6 to C24 and their potassium, sodium, calcium and magnesium salts

Although free fatty acids do occur in nature, they are typically present only in very small quantities in oils of fats. They are generally present in a chemically bonded form as triglycerides in natural sources, hence oils, fats and waxes as a combinations of various fatty acids with varying proportions depending on the origin of the fats, oils or waxes. In higher plants and animals, due to the process by which they are formed, these fatty acids are predominantly even-numbered, unbranched, aliphatic monocarboxylic acids with chain lengths ranging from $C_6$ to $C_{24}$. The chains can be either saturated or

unsaturated. Unsaturated fatty acids differ in number and position of double bonds and in configuration (i.e. cis- or trans-isomers). Odd-numbered fatty acids do occur but are usually present in small quantities for example, undecanoic acid ($C_{11}$) has been found in butter fat and heptadecanoic acid (margaric acid ($C_{17}$)) has been found in the milk and body fat of ruminants). Other fatty acids with more unusual structures, such as branching or different side groups can be found in lower life forms such as algae or bacteria. Fatty acids from $C_6$ to $C_{24}$ and their potassium, sodium, calcium and magnesium salts covered by this exemption must be obtained from natural sources.
Separation of the single fatty acids by distillation of the crude fatty acids originated from e.g. fats or oils are also covered by this exemption provided that no chemical modification of the individual fatty acids occurs. Hence their individual structures remain unchanged.

The exemption includes:

(a) groups of fatty acids which are saturated and/or unsaturated fatty acid having a range from $C_6$ to $C_{24}$ and their potassium, sodium, calcium and magnesium salts

(b) single fatty acids which are saturated and/or unsaturated fatty acid ranging from $C_6$ to $C_{24}$ and their potassium, sodium, calcium and magnesium salts

**Examples:**

(a) fatty acids, olive oils; fatty acids, palm oil; fatty acids, sunflower oil; etc. and fatty acids, $C_{8-16}$; fatty acids, $C_{10-14}$; fatty acids, $C_{8-18}$ and $C_{18}$-unsatd.; calcium salts; fatty acids, tallow, sodium salts.

(b) hexanoic acid, octanoic acid, decanoic acid, and so on, up to tetracosanoic acid. It also includes hydroxyl-fatty acids obtained from natural sources, e.g. 12-hydroxy-9-cis-octadecanoic acid obtained from castor oil.

## Glycerol

Glycerol, which is also commonly called glycerine or propane-1,2,3-triol, forms the backbone of triglycerides bound to a number of fatty acids.

Note: This exemption refers to glycerol which is obtained from natural sources as described above. Glycerol manufactured synthetically needs to be registered.

# ENTRY 10

**The following substances if they are not chemically modified: Liquefied petroleum gas, natural gas condensate, process gases and components thereof, coke, cement clinker, magnesia.**

This exemption comprises a number of substances that are exempted unless they are chemically modified[16]:

## Liquefied petroleum gas (LPG)

In general, liquefied petroleum gas comprises the hydrocarbons propane, propene, butane, butene, isobutane and combinations thereof. These combinations of gases can be liquefied by cooling, compression, or a combination of both processes. Liquefied petroleum gas is extracted from crude oil and natural gas streams. It can also be obtained by processing of crude oil in refineries and in some instances as a by-product from chemical plants. The composition of LPG depends on the manufacturing process applied. For example, butane and propane combinations supplied commercially for use as fuel would fall under this category.

For information, the EINECS lists LPG under the following entry; however, the LPG exemption is not limited to this definition:

EINECS number: 270-704-2, CAS number: 68476-85-7

*Petroleum gases, liquefied*

*A complex combination of hydrocarbons produced by the distillation of crude oil. It consists of hydrocarbons having carbon numbers predominantly in the range of C3 through C7 and boiling in the range of approximately -40°C to 80°C (-40°F to 176°F).*

## Natural gas condensate

Natural gas condensate is a low-density combination of hydrocarbon liquids that are present as gaseous components in the raw natural gas. It condenses out of the raw natural gas if the temperature is reduced below the hydrocarbon dew point temperature of the raw natural gas. Natural gas condensate is regarded as a by-product of the processing of the natural gas. Depending on the processes used to isolate it, natural gas condensate may be regarded as a substance which occurs in nature and falling under entry iv of Annex V(7).

[16] The notion of the term 'not chemically modified substance' is explained under point 7 and 8 of this guidance

For information, the EINECS lists natural gas condensate under the following entry[17]:

EINECS number 272-896-3, CAS number 68919-39-1

*Natural gas condensates*

*A complex combination of hydrocarbons separated and/or condensed from natural gas during transportation and collected at the wellhead and/or from the production, gathering, transmission, and distribution pipelines in deeps, scrubbers, etc. It consists predominantly of hydrocarbons having carbon numbers predominantly in the range of C2 through C8.*

## Process gases and components thereof

Process gases are not naturally occurring substances. The expression 'process gas' can be regarded as an umbrella term for all kinds of gases produced during certain technical processes. Any risks from the process gas should be covered in the Chemical Safety Assessment of the substances involved in the process itself. An example of a 'process gas' is blast furnace gas. This gas is produced during the reduction of iron ores and sinter with coke in blast furnaces in the iron and steel industry. It is recovered and used as a fuel partly within the plant and partly in other steel industry processes or in power stations equipped to burn it.

## Cement clinker

Cement clinker is a component of cement. Cement is regarded as a preparation composed of cement clinker, gypsum and other constituents depending on the cement type. Cement clinker is manufactured from the raw materials limestone, clay, bauxite, iron ore and quartz, grounded to a fine powder which is heated under oxidising conditions up to around 1400°-1450° C, at which temperature partial melting (sintering) takes place, resulting in drab granules. This process warrants that chemical bonds in the raw material cease to exist and new bonds are irregularly formed through material melting, producing the granules containing mainly tricalcium silicate, dicalcium silicate, dicalcium aluminate ferrite, tricalcium aluminate and calcium oxide. The melted material is rapidly cooled (quenched) to preserve its reactive mineral constituents.

Cement clinker does not have an EINECS number but it is very close in composition to "Cement, portland, chemicals" and/or "Cement, alumina, chemicals". Both of these substances have entries in EINECS and are included below for reference:

[17] Please note that the natural gas condensate exemption is not limited to this definition.

1. EINECS number 266-043-4, CAS number 65997-15-1

*Cement, portland, chemicals*

*Portland cement is a mixture of chemical substances produced by burning or sintering at high temperatures (greater than 1200°C (2192°F)) raw materials which are predominantly calcium carbonate, aluminium oxide, silica, and iron oxide. The chemical substances which are manufactured are confined in a crystalline mass. This category includes all of the chemical substances specified below when they are intentionally manufactured in the production of Portland cement. The primary members of the category are Ca2SiO4 and Ca3SiO5. Other compounds listed below may also be included in combination with these primary substances.*

| | | |
|---|---|---|
| $CaAl_2O_4$ | $Ca_2Al_2SiO_7$ | $CaO$ |
| $CaAl_4O_7$ | $Ca_4Al_6SO_{16}$ | $Ca_6Al_4Fe_2O_{15}$ |
| $CaAl_{12}O_{19}$ | $Ca_{12}Al_{14}Cl_2O_{32}$ | $Ca_2Fe_2O_5$ |
| $Ca_3Al_2O_6$ | $Ca_{12}Al_{14}F_2O_{32}$ | |
| $Ca_{12}Al_{14}O_{33}$ | $Ca_4Al_2Fe_2O_{10}$ | |

2. EINECS number: 266-045-5, CAS number: 65997-16-2

*Cement, alumina, chemicals*

*High-Alumina cement is a mixture of chemical substances produced by burning or sintering at high temperature (greater than 1200°C (2192°F)) raw materials which are predominantly calcium carbonate, aluminium oxide, silica, and iron oxide. The chemical substances which are manufactured are confined in a crystalline mass.*

*This category includes all of the chemical substances specified below when they are intentionally manufactured in the production of high-alumina cement. The primary members of this category are CaAl2O4, Ca4Al2Fe2O10, Ca12Al14O33, and Ca2SiO4. Other compounds listed below may also be included in the combination with these primary substances.*

| | | |
|---|---|---|
| $CaAl_4O_7$ | $Ca_2Al_2SiO_7$ | $Ca_3SiO_5$ |
| $CaAl_{12}O_{19}$ | $Ca_4Al_6SO_{16}$ | $Ca_6Al_4Fe_2O_{15}$ |
| $Ca_3Al_2O_6$ | $Ca_{12}Al_{14}Cl_2O_{32}$ | $Ca_2Fe_2O_5$ |
| $CaO$ | $Ca_{12}Al_{14}F_2O_{32}$ | |

## Magnesia

Magnesia, (MgO, magnesium oxide) rarely occurs as a natural mineral (also known as periclase). It is mostly manufactured from natural magnesite ($MgCO_3$), seawater and natural and synthetic brines.

There are several forms of magnesia covered by this exemption. These include dead-burned magnesia, caustic-calcinated (light-burned magnesia), hard-burned magnesia and fused magnesia.

The EINECS is listing magnesium oxide under the following entry:

EINECS number 215-171-9, CAS number 1309-48-4

*Magnesium oxide*

## Coke

Coke is a black, combustible residue of the coking (respectively carbonizing or baking) processes, predominantly consisting of carbon. All types of coke are exempted regardless of the starting materials from which they are obtained. Coking is a general term for high temperature treatment of substances such as coal or the residues from the petroleum refinery processes. The conditions of the processes depend on the starting materials used (e.g. coking of coal involves heating up to 1100ºC in the absence of oxygen). The typical coking process is a thermal process which takes place either in a liquid or in a solid phase.

Examples of different types of coke on EINECS are listed as follows:

EINECS number 310-221-7, CAS number 140203-12-9

*coke (coal tar), high-temperature pitch*

*The carbon containing residue from the carbonization coking of pitch from high temperature (>700°C or >1272°F) coal tar. Consists primarily of carbon. Also contains small amounts of sulfur and ash.*

EINECS number 266-010-4, CAS number 65996-77-2

*Coke (coal)*

*The cellular carbonaceous mass resulting from the high temperature (greater than 700°C (1292°F)) destructive distillation of coal. Composed primarily of carbon. May contain varying amounts of sulfur and ash.*

EINECS number 265-080-3, CAS number 64741-79-3

*Coke (petroleum)*

*A solid material resulting from high temperature treatment of petroleum fractions. It consists of carbonaceous material and contains some hydrocarbons having a high carbon-to-hydrogen ratio.*

# ENTRY 11

**The following substances unless they meet the criteria for classification as dangerous according to Directive 67/548/EEC[18] and provided that they do not contain constituents meeting the criteria as dangerous in accordance with Directive 67/548/EEC present in concentrations above the lowest of the applicable concentration limits set out in Directive 1999/45/EC[19] or concentration limit set out in Annex I to Directive 67/548/EEC, unless conclusive scientific experimental data show that these constituents are not available throughout the life-cycle of the substance and those data have been ascertained to be adequate and reliable: Glass, ceramic frits.**

According to the scientific literature glass is the state of a substance rather than a substance as such. For legislative purposes, it can best be defined through its starting materials and production process, similar to many other UVCB substances. EINECS has several entries for glasses as follows:

Glass, nonoxide, chemicals (EC: 295-731-7); glass, oxide, calcium magnesium potassium sodium phosphosilicate (EC: 305-415-3); glass, oxide, calcium magnesium sodium phosphosilicate (EC: 305-416-9); and glass, oxide, chemicals (EC: 266-046-0)[20];

According to available scientific information frits are a ground glass or glassy substance used for example in ceramic tiles and in pottery.

EINECS lists frits under the following entry:

*Frits, chemicals (EC: 266-047-6).*

The glass and frits substances are very similar in composition and manufacturing process.

Only those types of glass and ceramic frits are exempted which do not have any significant hazard properties:

- Firstly, glass or ceramic frits are only to be exempted if they (as substances as such) do not meet the criteria for classification as dangerous according to Directive 67/548/EEC. There are two possibilities to assess this criterion: look at the glass or frit itself or look at the starting materials.

[18] Directive 67/548/EEC will be fully repealed by Regulation (EC) No 1272/2008 with effect from 1 June 2015.
[19] Directive 1999/45/EEC will be fully repealed by Regulation (EC) No 1272/2008 with effect from 1 June 2015.
[20] Please note that the description following the heading in the EINECS listing of these substances is part of the substance entry and in most cases it is most decisive for substance identification.

- Secondly, they are not exempted if the substance contains constituents meeting the criteria as dangerous in accordance with Directive 67/548/EEC that are present in concentrations above the lowest of the applicable concentration limits set out in Directive 1999/45/EC or concentration limit set out in Annex I to Directive 67/548/EEC, unless conclusive scientific experimental data show that these constituents are not available throughout the life-cycle of the substance and those data have been ascertained to be adequate and reliable. In this case, industry has to look at the constituents after the production of the glass (constituents could be different than the starting materials) to see if they meet the criteria as dangerous in accordance with Directive 67/548/EEC and are present above the relevant concentration limit. If this is the case then they are not exempted unless the constituent is not available throughout the life-cycle of the substance[21].

It is the responsibility of manufacturers or importers to assess and document the conclusive scientific data to demonstrate their substance(s) fulfil these criteria.

Man Made Vitreous Fibres (MMVF) included in Annex I to Directive 67/548/EEC are not covered by this exemption as they meet the criteria in Annex VI of that Directive. In addition, MMVF, which are not listed in Annex I to Directive 67/548/EEC, but that meet the criteria for classification as dangerous according to Annex VI of Directive 67/548/EEC are also not to be exempted.

[21] Consistency needs to be ensured with guidance on Article 7(3) and Annex XI of the REACH Regulation. ECHA may provide additional guidance on this issue if new information becomes available.

# ENTRY 12

**Compost and biogas**

This exemption covers compost when it is potentially subject to registration, i.e. when it is no longer waste according to Directive 2008/98/CE, and is understood as being applicable to substances consisting of solid particulate material that has been sanitised and stabilised through the action of micro-organisms and that result from the composting treatment.

This explanation is without prejudice to discussions and decisions to be taken under Community waste legislation on the status, nature, characteristics and potential definition[22] of compost, and may need to be updated in the future.

Biogas is gas produced by the biological breakdown of organic matter in the absence of oxygen and consists of mainly methane.

# ENTRY 13

**Hydrogen and oxygen**

This exemption covers two substances, hydrogen (EC Number 215-605-7) and oxygen (EC Number 231-956-9).

[22] The definition of compost should be seen in the context of this guidance and not pre-empt the outcome of the discussion on the end-of-waste criteria for compost under the Waste Framework Directive and not pre-empt the current definition under national/regional legislation.

# ATTACHMENT 1: IONIC MIXTURES[23]

In order to provide a specific physicochemical characteristic, water is added to mixtures of ionic substances (salts, acids and bases). The ionic pairs in equilibrium in the aqueous solution are then the result of the water functioning as intended and would consequently not be considered to be themselves manufactured, imported or placed on the market and may under well defined conditions qualify for an exemption under entries 3, 4(a) or 4(b) of Annex V as explained hereafter.

In order for this exemption to be applicable, the following conditions must be fulfilled:

1. All starting substances (salts, acids and bases) of the aqueous solution must be registered;

2. None of the salts in the aqueous solution is isolated from the solution; and

3. The salts remain in their ionic form in the solution.

These three conditions equally apply to imported solutions. In particular, this requires that all starting substances of the imported solution must be known and registered in the EU; otherwise the exemption does not apply.

The latter two conditions must also be fulfilled by any customer down the supply chain. If a customer removes any salt from the solution his/her role as downstream user is ending here and he/she becomes a manufacturer which must register the isolated substances.

For solutions of salts in water no registration is required of ionic pairs as long as the combinations of ions co-exist with their different equilibria in the solution and no salts are isolated. In this context, it might be useful to clarify that

(1) whenever ionic pairs exist only as a part of the chemical equilibrium in the aqueous solution, they are not themselves considered to be manufactured, imported or placed on the market and thus do not require registration.

(2) whenever a salt is isolated from the solution, it is manufactured and needs to be registered.

[23] Substances ionised in water, CARACAL/05/2009 first Meeting of the Competent Authorities for REACH and CLP (CARACAL), 16-17 March 2009, Centre A. Borschette Rue Froissart 36, 1040 Brussels, Belgium.

(3) deliberate neutralisation of acids or bases to form the corresponding salts, including neutralisation during formulation, is usually a manufacturing process and is not covered by this exemption.

It should be noted that although the registration of substances ionised in water as described above is deemed inappropriate and is therefore exempted, the potential risks associated with the substances ionised in water must be taken into account in the chemical safety assessment of the starting materials (i.e. salts, acids or bases introduced in the aqueous solution), where applicable.

In some cases, there are water solutions that are manufactured by mixing many different kinds of substances (e.g. salts, acids, bases) in water. One example of this can be a detergent used as all-purpose cleaner. A formulation of such a product can contain the following substances (First list):

- Sodium lauryl ether sulphate
- (Linear) alkylbenzene sulphonic acid
- Oleic acid
- Nitrilotriacetic acid (NTA)
- Phosphoric acid
- Citric acid
- Sodium hydroxide
- Potassium hydroxide
- Non-ionic surfactant, preservative, dyes, fragrance: do not participate to acid/base equilibria

In this case, some salts, acids and basis are mixed in different proportions in order to achieve a product with a certain surfactant properties. As a consequence of the dissolution of the different substances, the different cations and anions find an equilibrium state forming pairs of ions. In the example shown above, it is theoretically possible to identify 12 anions and 2 cations. In this case, more than 40 substances may theoretically coexist in solution. Some of them may be the same as the precursor substances. A non-exhaustive list of potential substances in solution (based on acid-base reactions/equilibria achieved via the protolytic reactions with water) that could be formed in addition of the above-mentioned ingredients (and identified only if water is removed) is shown below (Second list):

- Sodium alkylbenzene sulphonate
- Potassium alkylbenzene sulphonate
- Trisodium citrate
- Disodium citrate
- Monosodium citrate
- Tripotassium citrate
- Dipotassium citrate

- Monopotassium citrate
- Monosodium, monopotassium citrate
- Sodium oleate
- Potassium oleate
- Sodium phosphates
- Potassium phosphates
- Potassium lauryl ether sulphate
- Potassium salt of NTA

Adding one more base (e.g. ammonia) to the formulation would lead to an even greater number of potential ion pairs in solution.

As long as the salts in solution remain stable in their ionic form in the solution and are not isolated from it, it is only necessary to register the precursors (first list) but not the potential substances that may be formed in a solution (second list).

# ATTACHMENT 2: YEAST[24]

## 1. Background:

The issue of the status of yeasts under REACH had been discussed in the realm of REHCORN. In this context, answers had been provided for this issue, indicating that yeast extract was subject to registration. NL decided to bring this issue up to the attention of Competent Authorities in December 2008, by circulating a paper on the status of yeast extract and vinasses and requesting the opinion of the GRIP.

NL communicated its view that yeast extract and vinasses should be considered as parts of naturally occurring substances and are exempted from the REACH registration requirements. A number of Member States supported this view, but DE was of the opinion that yeast extract and vinasses should be considered as substances which are produced in manufacturing processes including biotechnological processes, and were therefore not exempted from the REACH registration requirements.

NL developed a document for review by GRIP. Three comments were received not showing a unanimous opinion. Based on these comments a GRIP paper was finalised with the intention to bring this issue forward to the CARACAL meeting on 16 and 17 March 2009. The Commission has been asked to express its views on the issue.

## 2. Commission views on the issue of yeast extract

*Yeasts under REACH*

Yeast is a microorganism and consequently, as a living or dead organism it is not considered a substance, a mixture or an article under the REACH Regulation (see draft guidance on Annex V(7) and Annex V(8). In this context, it is not relevant whether yeast has been grown in nature or via a man-made cultivation.

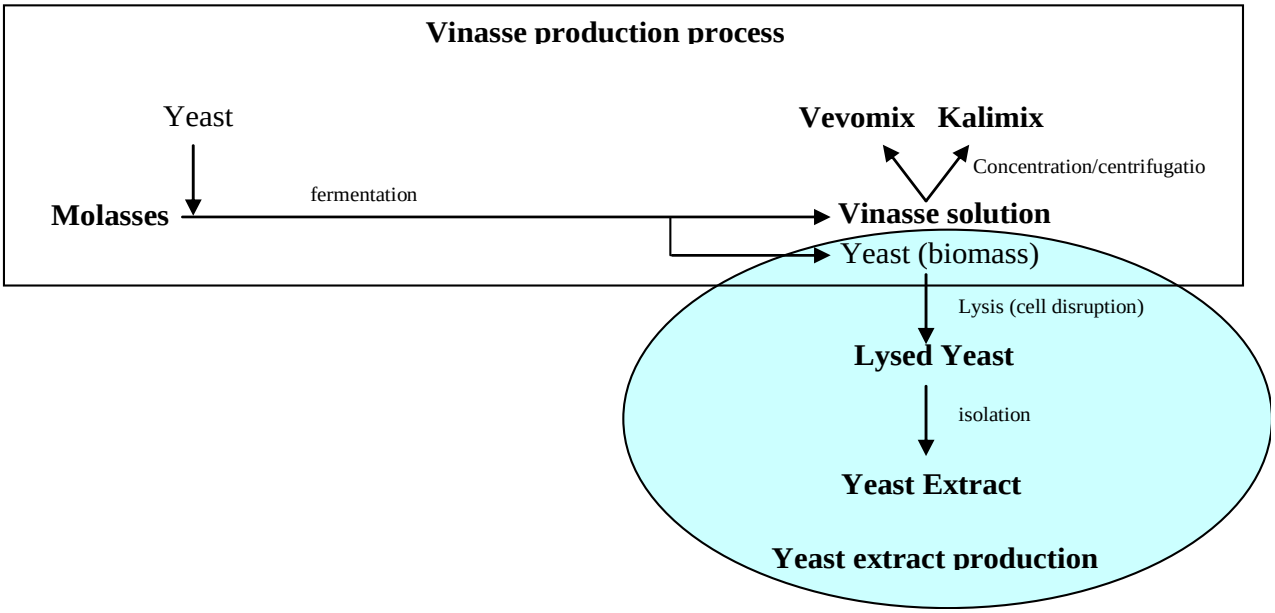
At the end of life, dead yeast cells and their content undergo degradation upon an action of enzymes released from dead cells. This process is called autolysis.

*Yeast extract under REACH*

Yeast extract is different from yeast as it results from the chemical modification of dead yeast biomass through a two step process: (i) lysis of yeast cells due to action of its own

[24] Unsolved interpretation questions - yeast CA/39/2009, 2nd Meeting of the Competent Authorities for REACH and CLP (CARACAL), 15-16 June 2009, Centre A. Borschette Rue Froissart 36, 1040 Brussels, Belgium.

enzymes, which may or may not be enhanced and followed by application of physical, chemical and/or enzymatic inducers (which results in lysed yeast) and (ii) isolation of yeast extract from the lysed yeast cells using processes such as centrifugation. After its isolation, the yeast extract could be further treated (e.g. pasteurised) for its further use or placing on the market.




Yeast extract could be considered a naturally occurring substance if, following lysis of yeast cells by mechanical processing, it is isolated by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water (see Article 3(39)). Naturally occurring lysed yeast and naturally occurring yeast extract benefit from the exemption under Annex V(8) if they comply with the conditions of the exemption, namely:

- not being chemically modified (in accordance with Article 3(40))
- not meeting the criteria for classification as dangerous
- not being a PBT or a vPvB
- not having been identified in the candidate list for authorisation at least two years previously as a substance of equivalent level of concern under Article 57(f).

However, to the Commission's knowledge yeast extract is generally obtained through a process by which the rupture of the yeast cells (lysis) is not the result of a mechanical process or any other process listed in Article 3(39), but of the chemical lysis of the yeast by other means than those of Article 3(39), either by the yeast's own enzymes or man-enhanced for example (but not exclusively) by adding salt or enzymes, and followed by isolation (typically involving centrifugation). Under these circumstances, the yeast extract is not a naturally occurring substance within the scope of Article 3(39) definition, as the substance cannot be considered unprocessed or processed only by means enumerated in Article 3(39), as it has been generated by a chemical modification of biomass by other means than those of Article 3(39) under the influence (action) of the yeast own enzymes,

and possibly (but not necessarily) also enhanced, and with further isolation. Additionally, this type of yeast extract is not the result of any of the processes mentioned under Annex V(1), Annex V(2), Annex V(3) or Annex V(4) and therefore not exempted under any of these sections of Annex V.

The above applies irrespective of whether the natural yeast extract has the same chemical identity and properties as a yeast extract resulting from a chemical modification of biomass by other means than those of Article 3(39).

Finally, the application of Annex V(9) to yeast extract was tackled in the GRIP document, as it was argued that the process to obtain the yeast extract is similar to the hydrolysis process used to obtain fatty acids. In this context, it is important to note that the list of substances exempted through Annex V(9) is a closed list, and only those substances listed therein could benefit from this exemption (when meeting the conditions of the exemption).

The idea of amending Annex V(9) of REACH to read "substances *such as* the ones listed" is not acceptable to the Commission, as it will open the door to the exemption for registration, evaluation and downstream user provisions to an unknown number of substances and processes. Such an approach was not favoured during the recent review of Annexes IV and V[25], when entry 9 was added to Annex V in the form of an exhaustive list with strict conditions, as it reads after the amendment.

### 3. Commission views on vinasses solution, vevomix and kalimix

The GRIP paper argues that vinasses solution comply with the definition of naturally occurring substance in accordance with Article 3(39), as they are obtained by centrifugation of fermentation mass out of bakers yeast grown by fermentation. Vevomix and kalimix are obtained by further concentration by evaporation and centrifugation of vinasses solution. The GRIP paper bases its conclusion on the fact that none of the processing steps involve chemical modifications, while concentration and centrifugation are covered by Article 3(39) as processes that do not alter the status of naturally occurring substances.

The Commission notes that the first step in determining whether vinasse, vevomix and kalimix benefit from the Annex V (8) exemption, is to identify the status of the substance which results from fermentation i.e. whether the 'fermentation mass' (as presented in the GRIP paper) or the substance that results from fermentation of molasses by bakers yeast is a naturally occurring substance. Should that be the case, indeed the step of centrifugation that follows the fermentation is one of the processes covered by Article 3(39) and the exemption would be open to these substances.

[25] COMMISSION REGULATION (EC) No 987/2008 of 8 October 2008 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annexes IV and V.

It is the Commission's understanding that the production of vinasses is a man-made fermentation process of molasses by yeast. During this process, molasses (more particularly, sugars contained therein) are chemically transformed by yeast into other substances, for example one or more alcohols (components of vinasses). In this process yeast is acting as a biocatalyst during the chemical transformation and after it has fulfilled its biocatalyst function it can further be processed, for example, into yeast extract (see figure in page 2).

Article 3(39) contains a closed lists of activities which can be considered to process naturally occurring substances without altering such status. The nature of this list as a limited enumeration of processes is confirmed by the use of the term 'only' *("[…] or processed only by […]").* Since fermentation is not specifically listed in Article 3(39), it cannot be understood as one of the operations allowed for the sake of keeping within the definition of processed substances which occur in nature. Furthermore, due to the controlled (bio)chemical transformation taking place, 'fermentation mass' cannot be understood as an 'unprocessed' substance in accordance with Article 3(39).

On the basis of the explanation given above and in the GRIP paper, the Commission is of the opinion that the substance resulting from a man-made fermentation of molasses by bakers yeast is not naturally occurring, but the result of a chemical transformation of molasses through a man-made fermentation process by yeast. Consequently, the exemption in Annex V(8) is neither applicable to vinasses nor to the derived products vevomix and kalimix.

## 4. Conclusion

The Commission believes that yeast extract can be considered a naturally occurring substance if the lysis of yeast cells is a result of a mechanical process or if it is only processed by any processes listed in Article 3(39). In the case at hand, as presented in the GRIP paper, in which yeast extract is obtained in a process of chemical lysis of the yeast by other means than those of Article 3(39), either by the yeast's own enzymes or man-enhanced for example (but not exclusively) by adding salt or enzymes, and followed by isolation (typically involving centrifugation), the Commission believes that yeast extract is not a naturally occurring substance and thus cannot benefit from the exemption under Annex V(8).

Additionally, the Commission believes that yeast extract cannot benefit from the exemption under Annex V(9), as it is not one of the substances listed. The Commission is not considering amending Annex V(9) of REACH to change the nature of the list of exempted substances from a closed list to an open one.

The Commission believes that vinasses solution, vevomix and kalimix cannot benefit from the exemption in Annex V(8) of REACH, as they are not the result of processing that is allowed under Article 3(39) for a naturally occurring substance.

These conclusions are without prejudice to the fact that to the extent yeast extract or vinasse is used in food or feedingstuffs in accordance with Regulation (EC) No 178/2002, it is exempted from Titles II, IV, V, VI and VII in line with Articles 2(5)(b) and 2(6)(d) of REACH.

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