

UEIL position

Opinion on the Regulatory Status of Metalworking Fluid Unintentional Reaction Products in the EU

The European Inventory of Existing Chemical Substances (EINECS) contains a number of criteria whereby substances are considered exempt from reporting (or notification). The relevant criteria have been transposed into the REACH Regulation which came into force on 1 June 2007, and which applies to notifiable substances under REACH from 1 June 2008. A transcript of the exemption criteria is presented in Addendum 1.

A thorough review of the criteria by regulatory experts in UKLA MWF PSG member companies has agreed that a number of the criteria are specifically relevant to the types of reaction products that can occur in water miscible metalworking fluids. Provided the metalworking fluid reaction products meet all the following criteria they are considered to be exempt from notification under the Dangerous Substances Directive (67/548/EEC) and under the REACH Regulation from 1 June 2008, according to the exemption criteria. If they do not meet all 4 criteria then they are potentially notifiable under the Directive/Regulation:

1. All the starting substances that form a reaction product must be present on the relevant inventory (or exempt from being present)
 - a) EINECS,
 - b) ELINCS
 - c) [REACH]
2. The reaction products should exist in an equilibrium state.
3. The reaction product formation is incidental to the use of the starting substances and is not intentional.
4. The reaction product remains part of the finished product mixture and is not isolated from the product.

Each fluid manufacturer/ importer is individually responsible for its own assessment for compliance against the criteria.

Addendum 1: text of exclusion criteria

ECOIN/EINECS

1. Substances already included in ECOIN should not be reported
2. Substances placed on the market before but not after 1 January 1971 or placed on the market for the first time after 18 September 1981 should not be reported.
3. Substances placed on the market exclusively for research, development and/or analytical purposes should not be reported.
4. Substances rendered radioactive by either natural or artificial nuclear transformation should not be reported.
5. 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 should not be reported
6. Substances which result from a chemical reaction that occurs incidental to storage of another substance, mixture or article should not be reported. For example, partially polymerised drying oils or other degradation products formed incidental to storage should not be reported.
7. Substances which result from a chemical reaction occurring upon end use of other substances, mixtures or articles (e.g. adhesives, paints, miscellaneous cleansers or housekeeping products, fuels, fuel additives, water softeners, photographic films batteries, matches) and which are not themselves placed on the market should not be reported. Only substances which are components of adhesives, paints, cleansers, etc. can be reported.
8. Substances which result from a chemical reaction that occurs when: (i) 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, flocculent, fire retardant, lubricant, chelating agent, or quality control reaction functions as intended, or (ii) a substance solely intended to impart a specific physico-chemical characteristic function as intended should not be reported.
9. Impurities should not be reported.
10. By-products should not be reported unless they are placed on the market. Substances such as reaction residues, sludges, fly ashes, dusts and slags, commonly termed as by-products, can be reported if they are placed on the market.
11. Medicinal products, cosmetic products and pesticide products, if placed on the market as intentional mixtures, should not be reported as such. The individual components, however, can be reported separately.

Annex V of REACH

EXEMPTIONS FROM THE OBLIGATION TO REGISTER IN ACCORDANCE WITH ARTICLE 2(7)(b)

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.
2. Substances which result from a chemical reaction that occurs incidental to storage of another substance, preparation or article
3. Substances which result from a chemical reaction occurring upon end use of other substances, preparations or articles and which are not manufactured, imported or placed on the market.
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, flocculent, fire retardant, lubricant, chelating agent, or quality control reaction functions as intended; or
 - (b) a substance solely intended to provide a specific physicochemical characteristic functions as intended.
5. By-products, unless they are imported or placed on the market themselves.
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
7. The following substances which occur in nature, if they are not chemically modified:

Minerals, ores, ore concentrates, cement clinker, natural gas, liquefied petroleum gas, natural gas condensate, process gases and components thereof, crude oil, coal, coke.
8. Substances occurring 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 Directive 67/548/EEC.
9. Basic elemental substances for which hazards and risks are already well known:

Hydrogen, oxygen, noble gases (argon, helium, neon, xenon), nitrogen