Polymers

Cefic Polymers' Working Group interpretation of specific polymers issues

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The Cefic Polymers Task Force has tried to formulate common interpretation of the REACH legislation and guidance documents.
In this paper they report their final conclusions on 6 specific issues.

1. Polymers formed from in-situ monomers

Certain reactions to produce polymers involve non-isolated monomers that are formed in-situ from non-monomeric species. If the monomers formed in this way are not isolated, then they are not subject to registration because they follow the rules for non-isolated intermediates. Companies should make the decision as to whether the starting materials used were themselves monomers or substances that were converted into monomeric units in the reaction vessel. Those starting materials produced or imported into the EU will of course be covered by the REACH regulation, however for non-EU produced polymers; the reactants along with the non-isolated in-situ monomers they produce do not require registration.

2. Polymers of unknown composition

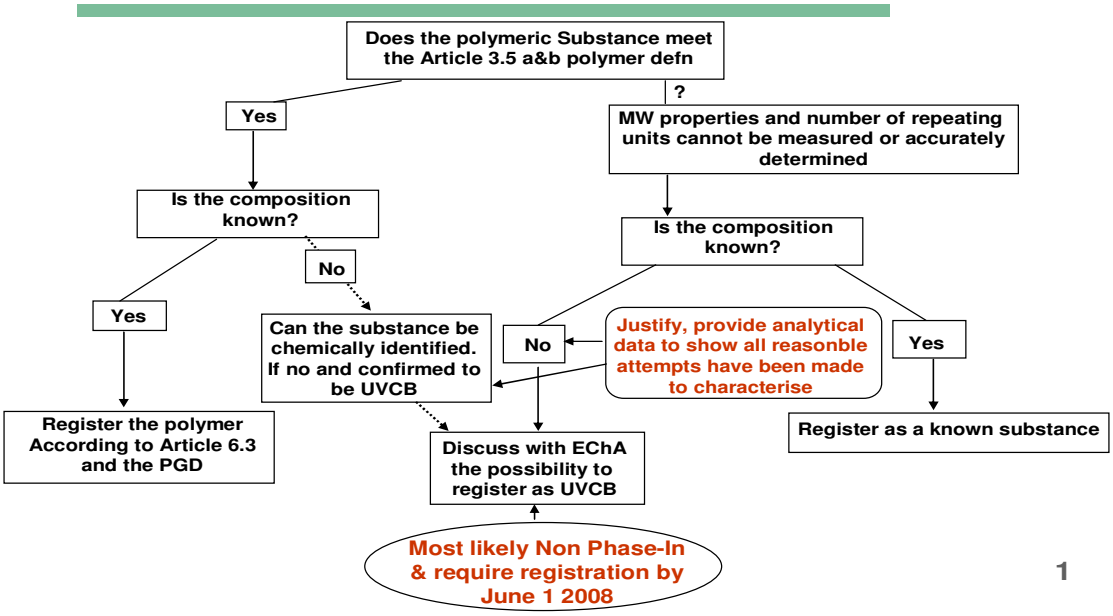
A UVCB substance is defined as a substance of Unknown or Variable composition, Complex reaction products or Biological material

Under REACH, it is essential that registrants have sufficient information on polymers to confirm:

- Conformance with the OECD polymer definition
- The identity and concentration of each monomer or other reactant the polymer contains in combined/reacted form

In those cases where this is not possible, the flow diagram below has been recognized as being appropriate to determine whether the substance in question can be treated and registered as a UVCB substance. If following the UVCB route is justified, pre-registration may be achieved, even if the substance does not have an EINECS number. The validity of such a pre-registration should be supported by a declaration from the non-EU manufacturer confirming its EINECS compliance which supports it having been previously placed on the EU market.

Polymers of Unknown Composition



Pre-registration could allow more information to be gathered to allow the monomers/other substances to be registered, but if not, the polymeric material could be registered as UVCB, at the appropriate time, as a Phase-In substance.

3. Post reacted Polymers

Manufacture of Polymer: Polymers may be synthesized in two ways:

1. by the polymerization of monomers
2. by chemical post-modification of a polymer

Examples of post-modification reactions include polymer end group modification, polymer functionalization via grafting, and controlled polymer degradation such as visbreaking. Polymer curing sometimes is a post reaction of polymers but often leads to articles. Certain kinds of substances are excluded from the monomer definition, i.e. catalysts, initiation, terminators. Post reactants and other types of substances that fall outside the definition of monomers (see Guidance for Monomers and Polymers[1] § 2.3), are also included under the "Other Reactant" descriptor. This interpretation is also in line with the EINECS reporting rules: *Polymers which have been post-reacted (undergone reactions after polymerization) should* not *be reported as such. Instead, the monomeric substances from which the polymer is manufactured and the post-treating reagent(s)* can be reported *separately.* An "other reactant" is defined in the Guidance for monomers and polymers as *a molecule that can be linked to one or more sequences of monomer units,*

[1] Guidance for monomers and polymers, version March 2008

but which cannot be regarded as a monomer under the relevant reaction conditions used for the polymer formation process.
This fits exactly the characteristics of a post-reactant.

Conclusion, a post-reactant is an "other reactant"

Question is how to treat an "other reactant". The REACH Regulations gives the answer in the definition of an intermediate. REACH article 3.15 defines an intermediate as *a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance*. This definition fits exactly with the characteristics of an "other reactant" and thus with that of a post-reactant.

Conclusion, a post-reactant is an "intermediate", and may be associated with the reduced testing outlined in Articles 17 & 18, provided that the post-reactant is not a monomeric unit, is manufactured and used under strictly controlled conditions and is rigorously contained by technical means during its whole lifecycle

In addition to this conclusion, section 3.1 of the Guidance for Monomers and Polymers clearly state that *Articles 17 and 18 apply for the other substances used in the manufacture of the polymer, provided those other substances meet the conditions of Articles 17 and 18*.

If the polymer consists of 2% weight by weight or more of the bound post-reactant
and
if the total quantity of the post-reactant makes up one ton or more per year
and
if the post-reactant hasn't already been registered by an actor up the supply chain, the manufacturer or importer shall submit a registration[2].

It always remains the responsibility of the manufacturer/importer to determine whether the post-reactant can be registered as an intermediate or not.

4. Polymers Notified under EU Directive 67/548/EEC

The Guidance for Monomers and Polymers (version March 2008) states *Polymer substances notified in accordance with Directive 67/548/EEC are regarded as registered by the manufacturer or importer who submitted the notification (Article 24(1)). The registration requirements under Title II are therefore covered by the notification in the tonnage band for which the notification was made. The registration of the monomers or other substances from which the notified polymers are derived is not required. As soon as the manufactured/imported quantity of polymer reaches the next tonnage threshold, the registration requirements (Title II of REACH) as described in this guidance should be followed for the monomer(s) or any other substance(s) meeting the conditions of Article 6(3).*

The Polymer Working Group accepts this approach for notified polymers and concludes from this position that the monomers or any other substance from which the notified polymers are derived, are exempted from registration under REACH, until the polymer reaches the next tonnage level for which the polymer was notified. Once a polymer reaches the next tonnage level and after the monomer(s) has (have) been registered,

[2] Based on REACH article 6.3.

the now registered monomer(s) will follow the REACH obligations as is applicable to any other monomer.

Even though registration of the monomers is not needed until a tonnage band is passed, it is advised by ECHA to pre-register the subjected monomer if the business plan indicates that the threshold for registration may be passed. This way the monomer will have phase-in status.

It should be noted that there is always the requirement under REACH Art 22, to update a dossier in case of any relevant new information.

As an observation, if a polymer has been notified under 67/548/EEC for a level of 1000 tpa or more, there is no *next tonnage threshold* and thus the monomer(s) will not need to be registered under REACH ever by the manufacturer or importer who submitted the notification.

5. Unbound monomers

Unbound monomers can be present in a polymer as impurities from incomplete reactions during the polymerization process. Monomers and other substances in both imported and EU manufactured polymers have to be treated in line with the requirements of Article 6.3

6. Naturally occurring polymers and their chemical modifications

Are there registration obligations for manufacturers and importers of natural polymers that have not been chemically modified?

Following Article 2(9) of the REACH Regulation, any polymer meeting the criteria of Article 3(5) of the Regulation does not have to be registered.

Monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s) in natural polymers can be treated as “non-isolated intermediates” and do not have to be registered.

Are there registration obligations for manufacturers and importers of natural polymers that have been chemically modified?

A natural polymer meeting the criteria of Article 3(5) of the REACH Regulation which is chemically modified (e.g. post-treatment of a natural polymer) does not have to be registered according to the provisions of Article 2(9) the Regulation.

Monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s) in the part of the natural polymer which is not affected by the chemical modification can be treated as “non-isolated intermediates” and do not have to be registered. The substances used to chemically modify the natural polymer and are chemically bound within the final polymer need to be registered according to the REACH requirements. Those meeting the definition of an intermediate (and being not regarded as monomers) they should be treated accordingly, and furthermore if they are used under strictly controlled conditions and rigorously contained by technical means

during their whole lifecycle they may be associated with the reduced testing outlined in Articles 17 & 18.