



Registration guidance for monomers and polymers

Polymers constitute the material of choice in a vast range of applications such as packaging, building and construction, transportation, electrical and electronic equipments, agriculture, as well as the medical and the sport sectors. However, polymers may still be subjected to authorization and restriction. Manufacturers and importers of polymers may also be required to register the monomers or other substances ending up as building blocks of the polymer, as these molecules are generally recognized as of higher concern than the polymer molecule itself.

Monomer

REACH defines a monomer (which can convert into a repeating unit of the polymer sequence) as a substance; and substances which exclusively involved in the catalysis, initiation or termination of the polymer reaction as an intermediate.

On the other hand, REACH defines any applications outside the scope of polymerization; the same substance is not regarded as a monomer. If it is used as an intermediate, it might fulfill the conditions of specific provisions for the registration of intermediates under REACH. Otherwise, it will have to follow all REACH requirements for a "normal substance" with registration requirements.

Polymer

A polymer is a substance consisting of molecules characterized by the sequence of one or more types of monomer units. In accordance with REACH (Article 3(5)), it is defined as a substance meeting the following criteria: (a) Over 50 percent of the weight for that substance consists of polymer molecules; and, (b) The amount of polymer molecules presenting the same molecular weight must be less than 50 weight percent of the substance.

In the context of this definition:

- A "polymer molecule" is a molecule that contains a sequence of **at least 3 monomer units**.
- A "monomer unit" means the reacted form of a monomer substance in a polymer.
- A "sequence" is a continuous string of monomer units within the molecule that are covalently bonded to one another and are uninterrupted by units other than monomer units.
- "Other reactant" refers to a molecule that can be linked to one or more sequences of monomer units but which cannot be regarded as a monomer under the relevant reaction conditions used for the polymer formation process.



Tasks and obligations: Manufacture/import of monomers

Manufacturers/importers of monomers have to register their monomers in accordance with the normal registration obligation laid down in REACH. Although monomers are by definition intermediates, these substances cannot be registered in accordance with the provisions, which normally apply to on-site or transported isolated intermediates.

If a natural or legal person manufactures or imports a substance to be used both as a monomer and as non-monomeric intermediate, he needs to submit **one “standard” registration dossier** according to Article 10. If part of the tonnage manufactured or imported is for a use as non-monomeric intermediate and is handled under strictly controlled conditions, this tonnage will not need to be taken into account for the information requirement of the registration dossier. Monomers are by definition intermediates cannot be subject to authorization under REACH for the use as monomers in polymerization reactions.

Tasks and obligations: Manufacture/import of polymers

1. Registration obligation – General situation

Polymers are exempted from the provisions on registration. The manufacturer/importer of a polymer is generally not required to provide to the Agency any information related to the intrinsic properties of the polymer itself. According to the regulation, the manufacturer/importer of a polymer must submit a registration to the Agency for the monomer substance(s) or any other substance(s), that have not already been registered by an actor up the supply chain, if both the following conditions are met: (a) the polymer consists of 2% weight by weight (w/w) or more of such monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s); (b) the total quantity of such monomer substance(s) or other substance(s), makes up 1 tonne or more per year. For manufacturers of polymers, registration of the monomer(s) and any other substance(s) by their supplier(s) will mostly be the standard situation.

For an importer of a polymer consisting of monomer(s) or other substance(s) fulfilling both conditions (a) and (b) depicted above, the monomer(s) or other substance(s) must be registered unless: (i) an only representative has been appointed by the non-Community polymer manufacturer to fulfill the obligations of the importer, or (ii) the monomer substances or any other substances used for the manufacture of the polymer have already been registered up the supply chain.

2. Classification and labelling

The importer or manufacturer of a polymer has to classify and label the polymer, and, if it is classified as dangerous and if the polymer is put on the market on its own or in a preparation above the concentration limits, he must notify the Agency. This notification has to be done by the 30th November 2010 if the polymer is already on the market or, from the 1st December 2010 onwards, as soon as the substance is put on the market. A manufacturer or importer of a polymer has to classify those monomer substances that he is registering, as part of the technical dossier.



3. Information down the supply chain

The manufacturer/importer of a polymer must provide his customer(s) with a safety data sheet (SDS) of the polymer if this substance meets the criteria for classification as dangerous, PBT or vPvB or if it is listed in the candidate list of substances to be subject to authorization. If the polymer is subject to either authorization or restriction, or if relevant information about the polymer necessary to enable appropriate risk management is available, the supplier must nonetheless provide that information to his customer(s).

Formulation/import of polymer preparation

In accordance with the REACH definition of a substance, any additive necessary to preserve the stability of a polymer substance is regarded as a constituent of that polymer. A polymer containing any unbound additive other than polymer stabilizers must however be treated as a preparation composed of the mixture of polymer substance and the additive substance. Polymer additives example include pigments, lubricants, thickeners, antistatic agents, compatibilisers, antifogging agents, nucleating agents, flame retardants, etc. There is the general obligation to register the additive substance manufactured or imported on its own or in the polymer preparation of at least 1 tonne per year.

Production/import of articles containing polymer substances

Polymers which are given a special shape are not systematically regarded as articles, For instance, thermoplastics are often extruded into pellets (pelletisation process) for the sole purpose of facilitating their further handlings. Pelletised polymer is therefore not regarded as an article. The producer or importer of an article containing a polymeric substance is under no circumstances required to register the polymer, as polymers are exempted from registration. The producer or importer of an article containing a polymeric substance has otherwise the same obligations under REACH as he would have for any other standard substance present in the article.