



Low-concern biological polymer

Use this checklist to make sure you have the records to prove your introduction is authorised as an **exempted introduction – low-concern biological polymer**. The records we'll accept indicate the type and level of information you must keep. You must give us the information in these records if we ask for them. Any declaration must be dated prior to your introduction.

Chemical identity

- If you know the CAS number** – written or electronic record of the CAS number and either the CAS name or INCI name for the chemical.
- If you don't know the CAS number** – you must have **either** A or B:
- A. Written or electronic record of the CAS name or IUPAC name. An INCI name can only be used if the chemical and its name meet all 4 criteria:
- the chemical does not have a CAS or IUPAC name
 - the chemical is a plant extract – examples are extracts of flowers, seeds, or leaves of trees, shrubs, herbs, grasses, ferns, and mosses
 - the name of the plant extract is an INCI name based on a proper botanical name – for example, 'Helianthus Annus Leaf/Stem Extract' is acceptable but 'Sunflower extract' is not acceptable
 - the plant extract cannot be chemically modified – for example, the chemical cannot be hydrolysed, acetylated or hydrogenated
- B. Written or electronic record of the names you use to refer to your chemical and a written undertaking from the supplier or manufacturer that they will give us the proper name (CAS or IUPAC) and CAS number (if assigned) if we ask for them.

Polymer criteria

If you don't know the proper name – a written undertaking from the supplier or manufacturer confirming each of the following items. They must provide records to prove each of the following items, if we ask for them.

- Records to prove your chemical is a biological chemical. We'll accept information that indicates the organism (for example, the plant, animal or micro-organism) from which your chemical is derived from or produced.
- Records to prove your chemical meets our definition of a polymer. We'll accept a GPC analysis report.

- Records to prove **either** A or B:
- A. the number average molecular weight (NAMW) of your polymer is greater than or equal to 10,000 g/mol **and** your polymer has:
- less than 2% (by mass) of molecules with molecular weight less than 500 g/mol; **and**
 - less than 5% (by mass) of molecules with molecular weight less than 1,000 g/mol.
- We'll accept a GPC analysis report.
- B. The NAMW of your polymer is greater than or equal to 1,000 g/mol and less than 10,000 g/mol **and** your polymer has:
- less than 10% (by mass) of molecules with molecular weight less than 500 g/mol; **and**
 - less than 25% (by mass) of molecules with molecular weight less than 1,000 g/mol; **and**
 - a combined (total) functional group equivalent weight (FGEW) of greater than or equal to 5,000 g/mol if the polymer includes high-concern reactive functional groups (taking into account all high concern reactive functional groups and any moderate concern functional groups included in the polymer), or a combined FGEW of greater than or equal to 1,000 g/mol if the polymer includes moderate-concern reactive functional groups and does not include high concern reactive functional groups (taking into account all moderate concern reactive functional groups included in the polymer).

We'll accept a GPC analysis report and associated calculations.

- Records to prove your polymer has a low cationic density. You'll need to prove one of the following:
- your polymer is not a cationic polymer or is not likely to become a cationic polymer in a natural aquatic environment ($4 < \text{pH} < 9$), if applicable. We'll accept a representative structural formula of your polymer.
 - the combined (total) FGEW of cationic, or potentially cationic, groups is at least 5,000 g/mol. We'll accept a GPC analysis report and associated calculations.

- your polymer is not soluble (less than 0.1 mg/L) or dispersible in water and will only be used in solid phase (for example, ion exchange beads). We'll accept a study report and information on how the polymer will be used.

Records to prove that your polymer contains approved elements only. We'll accept a representative structural formula of your polymer.

Records to prove your polymer does not have any known hazard classification. We'll accept an SDS.

If the NAMW for the polymer is greater than or equal to 10,000 g/mol – records to prove one of the following:

- your polymer is not introduced in a particulate form. We'll accept an SDS or product information sheet that indicates the appearance.
- the particle size of your polymer is greater than or equal to 10 micrometres (microns). We'll accept an SDS or product information sheet that indicates the appearance (for example, as pellets) or a study report.
- your polymer is not capable of absorbing its own weight in water. We'll accept a study report (for example, a study showing that the polymer does not form a gel in water or, if it does, that the gel dissolves upon adding more water).

Introduction requirements

If you don't know the proper name – a written undertaking from the supplier or manufacturer confirming each of the following items. They must provide records to prove each of the following items if we ask for them.

- Records to prove your polymer:
- isn't listed in Annex III of the Rotterdam Convention or Part 1 of Annex A, B or C of the Stockholm Convention on POPs (unless it is introduced solely for use in research or analysis and the amount that you introduce in a registration year does not exceed 100kg)
 - isn't listed on the Inventory with conditions of introduction or use that will be contravened.

We'll accept a signed and dated declaration that these checks took place.