

Record-keeping Checklist



Australian Government

Department of Health

Australian Industrial Chemicals Introduction Scheme

Exempted introductions

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 these records if we ask for them. Any declaration must be dated prior to your introduction.

Chemical identity

- If you know the CAS number — a record of it, plus the CAS or INCI name.
- If you know the proper name (CAS or IUPAC) but no CAS number is assigned — a record of the proper name.
- If you don't know the proper name — a record of the name 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

You will need all of the following items. If you **don't know** the proper name, you will need 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 and information on the polymer constituents (including the weight percentage prior to polymerisation and any residual).

- Records to prove one of the following:
 - the number average molecular weight (NAMW) of your polymer is $\geq 10,000$ g/mol and your polymer has:
 - $< 2\%$ (by mass) of molecules with molecular weight < 500 g/mol; **and**
 - $< 5\%$ (by mass) of molecules with molecular weight $< 1,000$ g/mol.We'll accept a GPC analysis report.
 - the NAMW of your polymer is $\geq 1,000$ g/mol and $< 10,000$ g/mol and your polymer has:
 - $< 10\%$ (by mass) of molecules with molecular weight < 500 g/mol; **and**
 - $< 25\%$ (by mass) of molecules with molecular weight $< 1,000$ g/mol; **and**
 - a functional group equivalent weight (FGEW) of $\geq 5,000$ g/mol if the polymer includes high-concern reactive functional groups, or an FGEW of $\geq 1,000$ g/mol if the polymer includes moderate-concern reactive functional groups.We'll accept a GPC analysis report and associated calculations.
 - your polymer is a polyester manufactured solely from prescribed reactants. We'll accept chemical identity information on the polymer constituents.

- 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 chemical identity information on the polymer constituents and a representative structural formula of your polymer.
 - the combined (total) FGEW of cationic groups is at least 5000 g/mol. We'll accept a GPC analysis report and associated calculations.
 - your polymer is not soluble (< 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.

→ Continued overleaf

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Polymer criteria (continued)

- Records to prove that your polymer:
 - contains approved elements only; **and**
 - does not contain any difluoromethylene or trifluoromethyl groups.We'll accept chemical identity information on the polymer constituents and 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 $\geq 10,000$ 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 ≥ 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

You will need all of the following items. If you **don't know** the proper name, you will need 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:
 - isn't listed in Annex III of the Rotterdam Convention; Part 1 of Annex A, B or C of the Stockholm Convention on POPs; or section 71, 72 or 73 of the General Rules.
 - 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.