

Record-keeping Checklist



Australian Government

Department of Health

Australian Industrial Chemicals Introduction Scheme

Reported introductions

Chemical is internationally assessed for the environment and is low or very low risk for human health

Use this checklist to make sure you have the records to prove your introduction is authorised as a **reported introduction — chemical is internationally assessed for the environment and is low or very low risk for human health**. 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 (including the name given in your pre-introduction report).
- The names of any products containing your chemical that you have imported into Australia.
- If it's a high molecular weight polymer and its human health exposure band is 4 — records to prove the:
 - number-average molecular weight
 - weight-average molecular weight
 - polydispersity index
 - percentage by mass of molecules with molecular weight that is < 1000g/mol
 - percentage by mass of molecules with molecular weight that is < 500g/molWe'll accept a GPC analysis report. If you **don't have** this information — a written undertaking from the supplier or manufacturer confirming it's a high molecular weight polymer. (They must provide records to prove the polymer molecular weight details if we ask for them.)

The introduction isn't medium to high risk

If you **don't know** the proper name — a written undertaking from the supplier or manufacturer confirming your introduction doesn't meet the criteria for medium to high risk. They must provide the following records 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 contravenedWe'll accept a signed and dated declaration that these checks took place.

- Fully fluorinated** — records to prove it **doesn't** contain a sequence of ≥ 4 and ≤ 20 fully fluorinated carbon atoms. We'll accept a signed and dated declaration that this check took place.
- Polyhalogenated** — records to prove one of the following:
 - it's **not** a polyhalogenated organic chemical. We'll accept a signed and dated declaration that this check took place.
 - the total volume introduced in a registration year is ≤ 100 kg. We'll accept shipping documents and any associated calculations.
 - your chemical and its known environmental degradation products is **not** persistent (see Guidelines). We'll accept a study report.
- Nanoscale** — records to prove one of the following:
 - it's **not** introduced as a solid or in a dispersion (if applicable). We'll accept an SDS or product information sheet that indicates the appearance.
 - it **doesn't** meet the definition of not soluble (see Guidelines). We'll accept a study report.
 - it **doesn't** consist of particles in an unbound state or as an aggregate or agglomerate, at least 50% of which (by number size distribution) have at least one external dimension in the nanoscale. We'll accept a study report.
 - the introduction of the nanoscale portion of the chemical is incidental to the non-nanoscale portion. We'll accept a justification for this.
- Gas** — records to prove one of the following:
 - it's **not** a gas. We'll accept an SDS or product information sheet that indicates the appearance.
 - the total volume introduced in a registration year is ≤ 100 kg. We'll accept shipping documents and any associated calculations.
 - it's **not** persistent (see Guidelines). We'll accept a study report.
- Organotin** — records to prove one of the following:
 - it's **not** an organotin chemical. We'll accept a signed and dated declaration that this check took place.
 - the total volume introduced in a registration year is ≤ 10 kg. We'll accept shipping documents and any associated calculations.

Introduction, use and exposure

- Records to prove the total volume of your chemical introduced in a registration year doesn't exceed that specified in your pre-introduction report. We'll accept shipping documents and any associated calculations.
- If the applicable human health exposure band criteria include a human health categorisation volume (HHCV) upper limit — a record of the HHCV for your chemical and records to prove the HHCV doesn't exceed that specified in the exposure band criteria. We'll accept shipping documents and any associated calculations.

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Hazard characteristics

- Records to prove any known hazard classification for the chemical. We'll accept an SDS.
- Detailed information, including full study reports, of the kind specified in the Guidelines to demonstrate the absence of certain human health hazard characteristics that would otherwise render the introduction medium to high risk.
 - If you **don't have** this information — a record of the outcomes of the information specified in the Guidelines, plus a written undertaking from the person who has the information that they'll give it to us if we ask for it.

Other records

- Records to prove how you're meeting any restrictions or conditions associated with the introduction or use of your chemical in the overseas jurisdiction. For example, use restriction — we'll accept copies of correspondence between you and your downstream users detailing the restrictions on use and their acknowledgement of the restrictions.
- Records to prove how you worked out that the risks to the environment are no higher in Australia than in the overseas jurisdiction (see Guidelines).

Specified classes of introduction

If your introduction is a specified class of introduction, you'll also need the following records.

- For **biochemicals** — a record of:
 - the concentration of any remaining viable cell or cellular components of the organisms used to produce the biochemical
 - any known adverse effects of any remaining viable cell or cellular components of the organisms used to produce the biochemicalWe'll accept a document from your supplier.
- For **GM products** — a record of:
 - the name of the genetically modified organism from which the GM product was derived or produced
 - details of any genetically modified organism that remains in the GM product as an impurityWe'll accept a document from your supplier.

- For **UV filters** (only required if the human health exposure band is 4) — a record of:
 - toxicokinetics information about the chemical (see Guidelines)
 - photostability information about the chemical (see Guidelines)We'll accept study reports.

- Where the **end use is in an article with food contact** — a record of:
 - any approval (if known) for the chemical for an end use in an article with food contact in another country by an agency or authority of that country
 - the potential for the chemical to migrate to food (see Guidelines). We'll accept study reports or other information.

- Where the **end use is in an article that's a children's toy or children's care product** — a record of:
 - whether the article can be placed in the mouth
 - if so, the potential for the chemical to be released into the mouth during end use or mouthing (see Guidelines). We'll accept quantitative information on the extent of the chemical's transfer to the mouth.