

Proposed revisions to the Categorisation Guidelines in 2025

What's this about?

We propose to revise the Industrial Chemicals Categorisation Guidelines (the Guidelines) in **September 2025**.

The revisions mainly affect the <u>list of chemicals with high hazards for categorisation</u> (the list), which is a downloadable resource that some importers and manufacturers must use when working out their introduction category. We invite your comments on the proposed revisions.

This page contains 2 sections:

Consultation closes

5 December 2024

Have your say



<u>View the proposed updates and changes to the list of chemicals with high hazards for categorisation.</u>

Stay informed



<u>See editorial and minor changes that we propose to make to the Guidelines to fix errors and clarify requirements.</u>

Have your say by 5 December 2024:

Updating the Guidelines

The Guidelines (which include the list) were originally published in July 2020. They were updated on 24 April 2024 and 24 September 2024. We intend to update the Guidelines and list annually from here on, unless an urgent change is required.

- The updates would come into effect in September each year, to coincide with the start of the registration year.
- We propose to consult publicly on the changes in September/October of the preceding year.
- We would publish the final changes 6 months before they come into effect for changes that may have a regulatory impact.

This consultation and publication schedule provides stakeholders with certainty about the timing of public consultations and time to prepare for upcoming changes that may affect them.

Have your say

Do you agree with the proposal to update the Guidelines on an annual basis with the timeframes as described above?
○ Yes
○ No
O I don't have any comments about this
Your comments (optional)
Your business or organisation's name

Updates to the list

Adding chemicals to the list based on updates to external sources

In September 2025, we will add **116** entries to the list. These chemicals have been added to the external sources of the list since our last update. They have one or more hazard characteristics in human health hazard band C or environment hazard band C or D. Therefore, their introduction may **not** be able to be categorised as exempted or reported at steps 4 and 5 of the categorisation process.

Adding these entries will only affect a few importers or manufacturers, based on information we have received to date in pre-introduction reports and post-introduction declarations. We will contact these introducers before we add the entries to the list.

Adding AICIS-assessed chemicals to the list

We propose to add **4** AlCIS-assessed chemicals to the list. These chemicals have hazard characteristics in human health hazard band C or environment hazard bands D or C based on an AlCIS assessment of the chemical introduction.

We will contact potentially affected introducers before adding these chemicals to the list.

How do AICIS-assessed chemicals get onto the list?



In the April 2024 Guidelines update, we added a new source to appendix 8.1. This allows chemicals to be added to the list at the discretion of the AICIS Executive Director, if the chemical has been assessed or evaluated under the Industrial Chemicals Act 2019 or the Industrial Chemicals (Notification and Assessment) Act 1989 and identified as having hazard characteristics in human health hazard band C or environment hazard bands D or C.

Download

Proposed additions to the list [xlxs] [21KB]

Have your say

Do you agree with the proposal to add these AICIS-assessed chemicals to the list of chemicals with high hazards for categorisation?

\bigcirc) Yes

O No

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Hav Are t Guid chara Factor	We your say The chemical must be able to form salts and/or esters. The salt or ester of the chemical is likely to be introduced into Australia for industrial use. If the chemical is not added to part 6 of the Guidelines, it is possible for the introduction of its ester.

our comments (optional)					
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Changes to the text of sources in the list

I don't have any comments about this

We propose to revise the text in appendix 8.1 that describes each information source for the list. This will help to clarify which chemicals from the sources are included on the list by removing unnecessary information. **These changes will not add to or remove any chemicals from the list**.

Text deletions are indicated in strikethrough and additions are in **bold**.

- <u>Safe Work Australia's Hazardous Chemical Information System (HCIS)</u> list of substances classified for physical-chemical and (eco)toxicological hazards. Substances included on the list of chemicals with high hazards for categorisation are those classified for CMR and PBT.
- European Chemicals Agency (ECHA) Harmonised Classification and Labelling of Hazardous Substances (Annex VI to the CLP Regulation) list of substances classified for physical-chemical and (eco)toxicological hazards.
 Substances included on the list of chemicals with high hazards for categorisation are those classified for CMR and PBT.
- <u>European Union Substances of Very High Concern (EU SVHC)</u> <u>list of CMR, PBT and vPvB substance</u>.
 Substances included on the list of chemicals with high hazards for categorisation are those that are identified as CMR, PBT, vPvB, or having endocrine disrupting properties.
- <u>United States National Toxicology Program (US NTP) Report on Carcinogens</u> list of carcinogenic substances. Substances included on the list of chemicals with high hazards for categorisation are those that are known human carcinogens and those that are reasonably anticipated to be human carcinogens.
- <u>International Agency for Research on Cancer (IARC) Monographs</u> <u>list of carcinogens</u>. Substances included on the list of chemicals with high hazards for categorisation are carcinogens classified in Groups 1, 2A and 2B.
- <u>European Commission Endocrine Disruptors Strategy</u> <u>list of substances investigated for potential endocrine activity</u>. Substances included on the list of chemicals with high hazards for categorisation are those listed in Category 1, identified as having endocrine activity in at least one animal study.
- <u>United Nations Environment Programme scientific knowledge on endocrine disrupting chemicals</u> list of substances from a review of existing global initiatives on endocrine disrupting chemicals and potential endocrine disrupting chemicals. Substances included on the list of chemicals with high hazards for categorisation are those identified as having known or potential endocrine activity.

- <u>Chemical Substances Control Law of Japan</u> (CSCL) Class I Specified Chemical Substances list of organic chemicals with known health and/or environmental concerns. Substances included on the list of chemicals with high hazards for categorisation are those identified as PBT.
- <u>European Chemicals Agency (ECHA) REACH Annex XIV Authorisation</u> list of inorganic and organic chemicals with known health and/or environmental concerns. Substances included on the list of chemicals with high hazards for categorisation are those identified as CMR, PBT or vPvB, or having probable CMR, PBT or vPvB effectsendocrine-disrupting properties.

Note: We are not adding or changing substances on the list by inserting 'endocrine-disrupting properties' into this description. These substances are already on the list because they meet the criteria. This entry is a text correction and will not add any chemicals to the existing list.

• <u>European Commission Endocrine Disruptor List</u> – <u>list of substances identified as endocrine disruptors.</u>
Substances included on the list of chemicals with high hazards for categorisation are those on List I, identified as endocrine disruptors at EU level.

Cleaning up the entries on the list

We plan to tidy up entries on the list that still mention list sources or parts of list sources that were removed from appendix 8.1 as part of the April 2024 Guidelines update (version 2). This will mean that the downloadable spreadsheet of the list will only mention list sources that are currently in appendix 8.1. For example, we will remove the column for 'Government of Canada Toxic Substances List' because this source was removed. Cleaning up the entries on the list will not affect the categorisation process. This is only for the sake of clarity.

Stay informed: changes to clarify information or fix errors Footnotes

Some footnotes repeat on the same page. We will remove these duplicates but not alter the content of the footnotes.

Changes to improve the document's accessibility

We will update the document's formatting to make it accessible and consistent with other AICIS publications. We will not change the content of the document during this process.

Naming of the Categorisation Guidelines

- For future updates of the Guidelines, we will no longer include version numbers.
- Instead, the Guidelines will be identified by the date that they are in force from.
- This will reduce confusion with the 'Guide to categorising your chemical importation and manufacture' on the website, which is identified by version numbers.

Fixing or updating broken links to external sites

Updating the links will not change any categorisation outcomes.

Part	Description	New link
2.1.5	Globally Harmonised System of Classification and Labelling of Chemicals	https://unece.org/ghs-rev7-2017
2.2.1	Link to the Standard Operating Procedures (SOP) For The OECD Clearing House On New Chemicals Parallel Process' (ENV/JM/MONO(2012)26)1	https://one.oecd.org/document/ENV/JM/MONO(2012)26/en/pdf
5.1	Standard 1.1.2 of the Food Standards Australia New Zealand Act 1991	https://www.legislation.gov.au/F2015L00385/latest/text
6.1	Globally Harmonised System of Classification and Labelling of Chemicals	https://unece.org/ghs-rev7-2017
8.1	United States National Toxicology Program (US NTP) Report on Carcinogens	https://ntp.niehs.nih.gov/whatwestudy/assessments/cancer/roc
8.1	International Agency for Research on Cancer (IARC) Monographs	https://monographs.iarc.who.int/
8.1	United Nations Environment Programme scientific knowledge on endocrine disrupting chemicals	https://www.unep.org/topics/chemicals-and-pollution-action/pollution-and-health/endocrine-disrupting-chemicals
8.1	Chemical Substances Control Law of Japan	https://www.chem- info.nite.go.jp/en/chem/chrip/chrip_search/systemTop
8.2	T.E.S.T.	https://www.epa.gov/comptox-tools/toxicity-estimation-software- tool-test
8.2	Derek Nexus	https://www.lhasalimited.org/
8.2	Sarah Nexus	https://www.lhasalimited.org/
8.2	Chemtunes	https://mn-am.com/products/chemtunestoxgps/
8.2	Case ULTRA	https://multicase.com/case-ultra
8.2	Biovia Discovery Studio (TOPKAT)	https://www.3ds.com/products/biovia/discovery-studio
8.2	ACD Percepta	https://www.acdlabs.com/products/percepta-platform/
8.2	Cheminformatics Tool Kit	https://www.ul.com/
8.2	Tox21	https://ntp.niehs.nih.gov/whatwestudy/tox21/toolbox

Changes to other parts of the Guidelines

Part 6.12.2 - Skin corrosion

We propose to add the text shown below in **bold** to part 6.12.2 for clarity. This will **not** change any categorisation outcomes.

"test results⁸ from an in vivo study on the chemical or from suitable read-across information, conducted following an acceptable test guideline for skin irritation, which does not result in destruction of skin tissue, as described for skin corrosion (category 1) in chapter 3.2 of the GHS. "

Part 6.14.2 - Skin sensitisation

We propose to add the text shown in **bold** to part 6.14.2 to clarify that the functional group equivalent weight should be calculated using only the moderate concern reactive functional groups. This will **not** change any categorisation outcomes.

"it contains only low-14 and moderate-concern reactive functional groups 15, with a combined functional group equivalent weight **for the moderate-concern functional groups** of $\geq 1000 \, \text{g/mol}$, or"

Part 8.4.1 - Acceptable test guidelines for human health hazard characteristics

The table in part 8.4.1 for acceptable test guidelines for human health hazard characteristics incorrectly implies that OECD Environment, Health and Safety Publications Series on Testing and Assessment No. 129, Guidance Document on Using Cytotoxicity Tests To Estimate Starting Doses For Acute Oral Systemic Toxicity Tests (2010) is an OECD test quideline.

We propose to:

- delete the number '129' from the OECD test guidelines column to clarify that it is a guidance document rather than a test guideline and avoid any potential confusion
- delete the footnote
- put the details from the footnote into the 'Equivalent test guidelines' column of the table