

Case study

High volume, lower hazard for non-cosmetic



Checklist 1 – Essential information requirements

- Chemical identity:** the proper name of the chemical
 - Inventory status:** whether your chemical is listed on the Inventory.
 - End use:** what the chemical will ultimately be used for.
 - Introduction volume:** the total quantity of chemical in kilograms that you will manufacture or import into Australia within a registration year (September- August).
 - Any available hazard information:** any existing hazard information on the chemical or from suitable read-across information. Note that more hazard information might be needed, depending on the exposure band for your introduction.
 - Chemical at the nanoscale:** whether your chemical is considered to be at the nanoscale and meets certain criteria
 - Specified class of introduction:** whether your introduction is a specified class of introduction
- ⇒ **If you don't have this information you may need to contact your supplier for more information, or assistance with categorisation.**

Check list 2 - Possible information requirements

- Introduction concentration:** the concentration (%) of your chemical when introduced into Australia. This might be needed when working out the exposure band
- End use concentration:** the final concentration (%) of your chemical in end use products. This might be needed when working out the exposure band
- Method of disposal:** needed for certain end uses
- Degradation products:** if you have information about the degradation products of the chemical in the environment, this might be needed for categorisation.

Check list 3 - Useful information

- High molecular weight polymer:** whether your chemical is a high molecular weight polymer.
- Internationally-assessed introductions:** whether your chemical has been previously assessed by an overseas assessment body for risks to human health or the environment and meets specified criteria

Case study scenario

High volume, lower hazard for non-cosmetic



Case study introduction details	
Do you know the proper name for the chemical (including CAS or IUPAC name)? <i>(If 'no' you may need assistance from your supplier for categorisation)</i>	Yes
Is your chemical listed on the Inventory?	No
What is your chemical's end use?	Automotive paints
What is your total introduction volume within a registration year?	25,000 kg
Is there information available detailing the hazards of the chemical? <i>(if "yes" see details on hazard information)</i>	Yes
Is your chemical considered to be at the nanoscale?	No
Is your introduction a specified class of introduction?	No
What is the concentration of your chemical when introduced into Australia?	5%
What is the concentration of your chemical in end use products?	5%
Do you have any information about the degradation products of the chemical in the environment?	No
Is it a high molecular weight polymer?	No
Is it an internationally-assessed introduction for human health or environment or both?	No

Case study

Known hazard information

High volume, lower hazard for non-cosmetic



Hazard information – environment

- An in domain in silico prediction (using KOWWIN) for the partition coefficient of 3.8
- In domain in silico predictions (using ECOSAR) that the chemical is not very toxic, toxic or harmful to fish, invertebrates, and algae
- The chemical degrades by >70% within a 28 day period (ready biodegradability study following OECD TG 301)

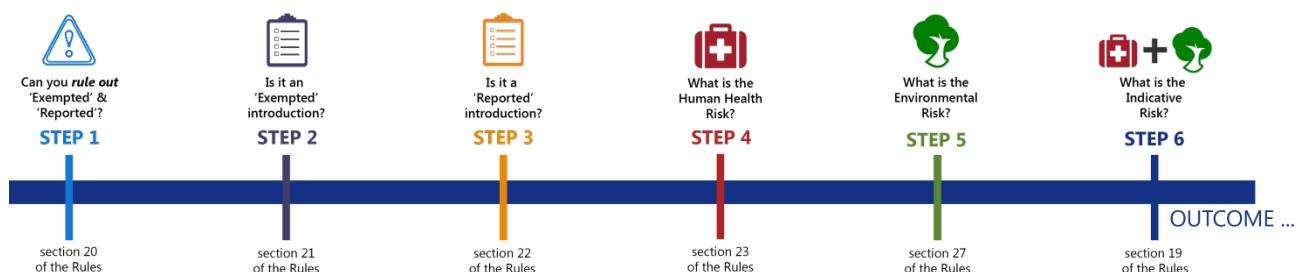








Hazard information - human health

- It is not mutagenic (based on an in vitro study following OECD TG 471 on the chemical that shows no point mutations in microbial systems)
- It is not genotoxic (based on an in vivo study following OECD TG 475 from suitable read-across information that shows no chromosome damage in mammalian cells)
- It is not acutely toxic (based on an oral in vivo study on the chemical following OECD TG 420)
- It does not cause specific target organ toxicity following repeated exposure (based on an in vivo study from a suitable analogue following OECD TG 407)
- It is not corrosive to the skin (based on an in vitro study from suitable read across information following OECD TG 430)
- It is not damaging to the eyes (based on an in vitro study from suitable read-across information following OECD TG 437)
- It is not sensitising to the skin (based on an in vivo study from suitable read-across information following OECD TG 429)

Case study

Steps to categorise your industrial chemical High volume, lower hazard for non-cosmetic

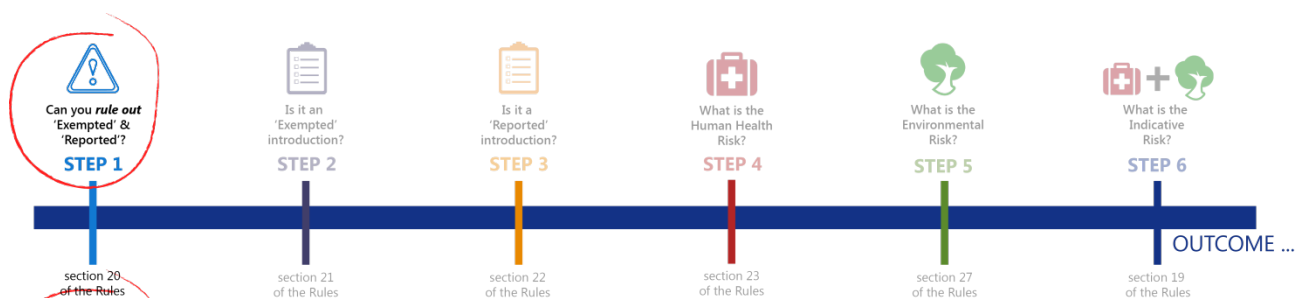


Steps	Questions?	Outcome
	Step 1: Is your introduction a type that can't be exempted or reported? (see section 20 of General Rules and below for details)	no
	Step 2: Is your introduction a type that is an exempted introduction? (see section 21 of General Rules and below for details)	no
	Step 3: Is your introduction a type that is a reported introduction? (see section 22 of General Rules and below for details)	no
	Step 4: What is the indicative human health risk for your introduction? (see section 23 of the General Rules and below for details)	low risk
	Step 5: What is the indicative environment risk for your introduction? (see section 27 of the General Rules and below for details)	very low risk
	Step 6: What is the highest indicative risk for your introduction?	low risk

Case study outcome



It is a reported introduction



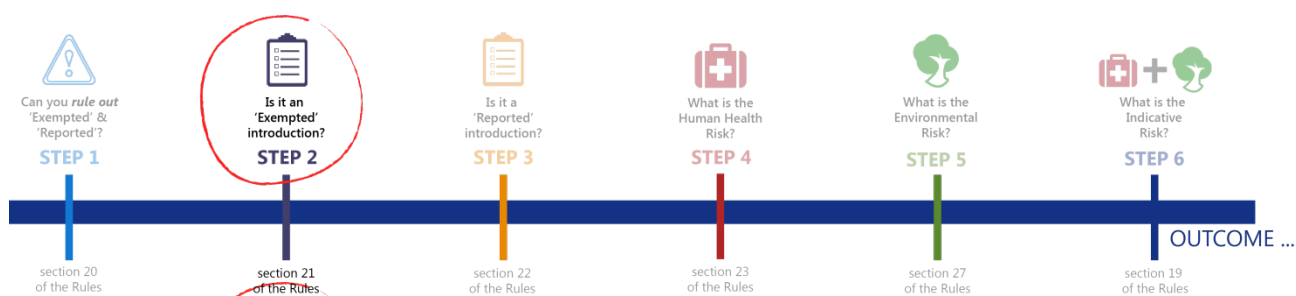
Step 1:

Is your introduction a type that can't be 'exempted' or 'reported'? Refer to section 20 of the General Rules.

If your introduction is any of the below types it can't be considered 'exempted' or 'reported'. **It would likely be an assessed introduction:**

- Introduction of an industrial chemical that is listed in Rotterdam or Stockholm Convention
- Introduction of certain industrial chemicals at the nanoscale
- Introduction of a persistent gas
- Introduction of certain fluorinated organic chemicals
- Introduction of a persistent polyhalogenated organic chemical
- Introduction of an industrial chemical that is listed on the Inventory with conditions

OUTCOME: Your introduction is not automatically *excluded* from exempted or reported



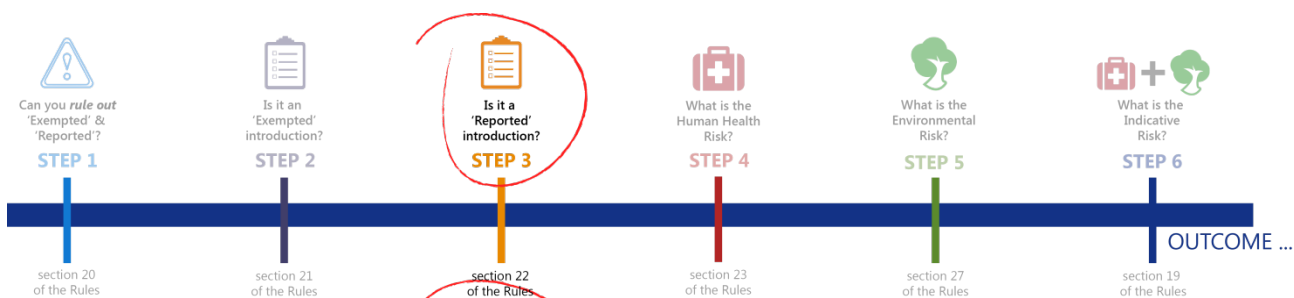
Step 2

Is your introduction a type that is automatically 'exempted'? Refer to section 21 of the General Rules.

If your introduction is one of the below types it is an **'exempted' introduction**:

- Introduction of an industrial chemical that is imported and subsequently exported
- Introduction of an industrial chemical that is solely for use in research and development
- Introduction of a polymer that is comparable to a polymer that is listed on the Inventory
- Introduction of an industrial chemical that is comparable to a listed industrial chemical
- Introduction of a polymer of low concern
- Introduction of a low concern biopolymer

OUTCOME: Your introduction cannot be *automatically* exempted



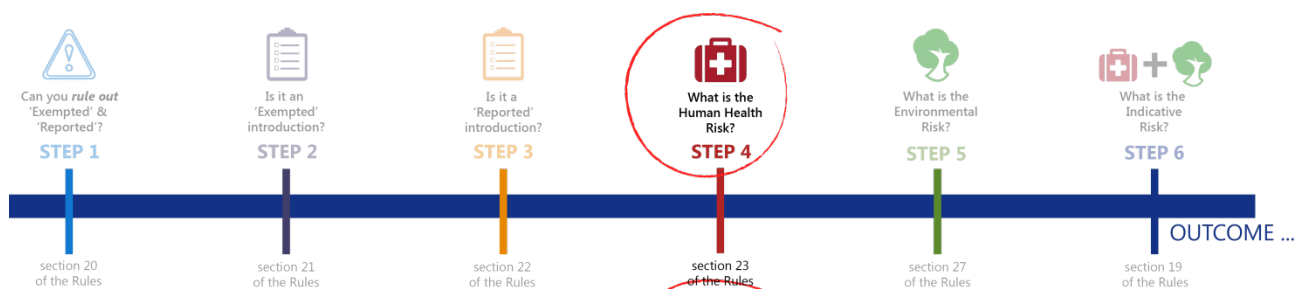
Step 3

Is your introduction a type that is automatically 'reported'? Refer to section 22 of the General Rules.

If your introduction is one of the below types it is a **'reported' introduction**:

- Introduction of an industrial chemical that is internationally-assessed for human health and the environment
- Introduction of an industrial chemical at the nanoscale that is solely for use in research and development

OUTCOME: Your introduction cannot be *automatically* reported



Step 4

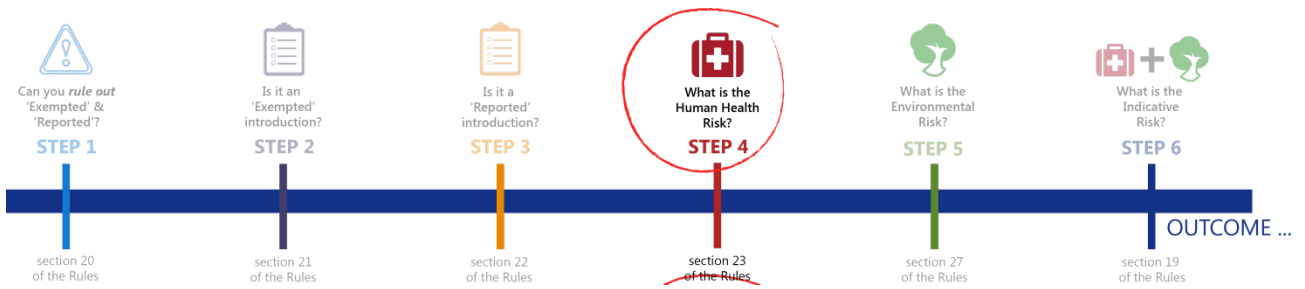
How to work out the indicative human health risk? Refer to method statement from section 23 of the General Rules.

Summary of process

Questions?	Outcome	Reason
Q 1 - Is your introduction internationally-assessed for human health? (subsection 6(1) of General Rules)	no	No international risk assessment available go to Q 2
Q 2 – What is the human health exposure band for your introduction? (section 24 of General Rules)	human health exposure band 3 (table item 9)	Fits the exposure band scenario: <ul style="list-style-type: none"> - end use other than cosmetics, tattoo ink or personal vaporisers - total introduction volume > 1,000 kg

Questions?	Outcome	Reason
<p>Q 3 – Which human health hazard bands do not apply to your chemical? (section 25 of General Rules)</p>	<p>human health hazard bands C and B</p>	<p>Check Guidelines (Chapter 4, human health exposure band 3 – low risk).</p> <p>Hazard band C Your chemical is not on any of the identified lists for human health band C hazard characteristics:</p> <ul style="list-style-type: none"> - carcinogenicity - mutagenicity or genotoxicity - reproductive toxicity - developmental toxicity - adverse effects mediated by an endocrine mode of action <p>Studies do not indicate mutagenicity or genotoxicity effects.</p> <p>⇒ No human health hazard band C characteristics</p> <p>Hazard band B Available information indicates that the chemical is:</p> <ul style="list-style-type: none"> - not an acute toxicant (fatal or harmful) - not a specific target organ toxicant following repeated exposure - not corrosive to skin - not damaging to the eyes - not sensitising to the skin <p>There is no information to indicate that the chemical causes:</p> <ul style="list-style-type: none"> - respiratory corrosion - respiratory sensitisation - specific target organ toxicity after single exposure <p>⇒ No human health hazard band B characteristics</p>

Questions?	Outcome	Reason
Q 4 – What is the indicative human health risk for your introduction? (section 26 of General Rules)	low risk	Based on the results of Q 2 and Q 3



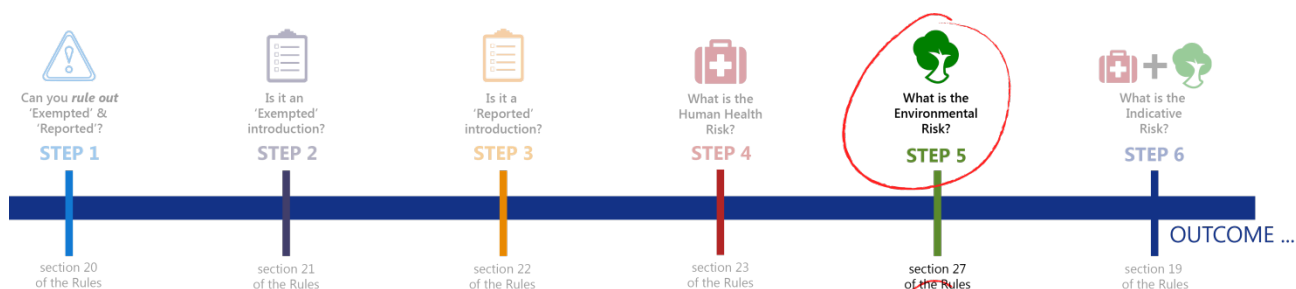
Step 4

Indicative human health risk

Human Health Matrix

Hazard Band	C	Medium to high risk	Medium to high risk	Medium to high risk
	B	Very low risk	Low risk	Medium to high risk
	A	Very low risk	Low risk	Low risk
	Not A, B or C	Very low risk	Very low risk	Very low risk
		1	2	3
		Exposure Band		

OUTCOME: The indicative human health risk is: LOW RISK



Step 5:

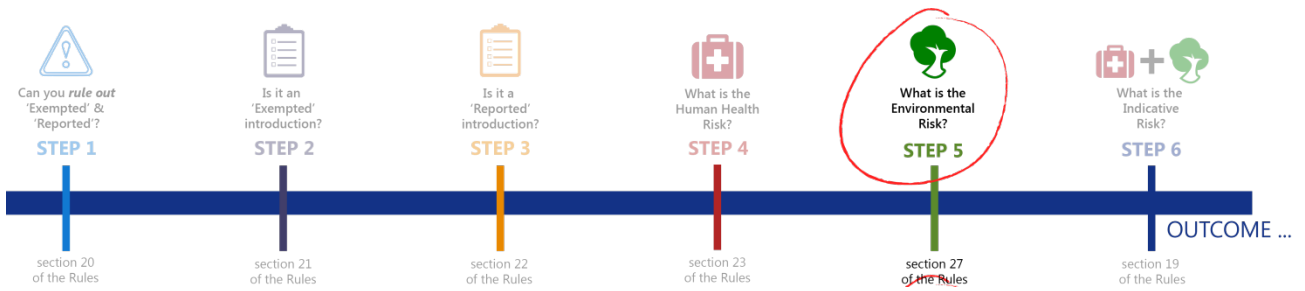
How to work out the indicative environment risk? Refer to method statement from section 27 of the General Rules.

Summary of process

Questions?	Outcome	Reason
Q 1 - Is your introduction internationally-assessed for environment? (subsection 6(2) of General Rules)	no	No international risk assessment available Go to Q2
Q 2 – What is the environment exposure band for your introduction? (section 28 of General Rules)	environment exposure band 3 (Section 28 of General Rules table item 3)	Check Guidelines (Chapter 5, Determining the environment categorisation volume): <ul style="list-style-type: none"> - total introduction volume = 25,000 kg - reduction factor = 0.05 (paints and coatings) - environment categorisation volume = 25,000 kg x 0.05 = 1250 kg Fits the exposure band scenario: <ul style="list-style-type: none"> - Does not involve a designated kind of release into the environment - Environment categorisation volume >1000 kg but ≤ 10,000 kg

Questions?	Outcome	Reason
<p>Q 3 – Which environment hazard bands do not apply to your chemical? (section 29 of General Rules)</p>	<p>environment hazard bands D, C, B and A</p>	<p>Check Guidelines (Chapter 5, Environment exposure band 3 – low risk).</p> <p>Hazard band D Your chemical is not on any of the identified lists for environment band D hazard characteristics:</p> <ul style="list-style-type: none"> - Persistent, bioaccumulative and toxic - Adverse effects mediated by an endocrine mode of action <p>These definitions do not apply to your chemical:</p> <ul style="list-style-type: none"> - Ozone depleting - Synthetic greenhouse gas <p>Your chemical does not contain arsenic, cadmium, lead or mercury.</p> <p>Available information indicates that your chemical is:</p> <ul style="list-style-type: none"> - not PBT as it is not bioaccumulative (based on log Kow prediction) <p><i>You only need to show one of not P, B or T, but the information also shows that the chemical is not very toxic to any aquatic life (based on in silico predictions of ecotoxicity), and not persistent (based on ready biodegradability study).</i></p> <p>⇒ no environment hazard band D characteristics</p> <p>Hazard band C Available information indicates that your chemical is:</p> <ul style="list-style-type: none"> - not very toxic to any aquatic life - not persistent and bioaccumulative (based

Questions?	Outcome	Reason
		<p>on in silico prediction of log Kow)</p> <p>⇒ no environment hazard band C characteristics</p> <p>Hazard band B Available information indicates that your chemical is not toxic to any aquatic life</p> <p>⇒ no environment hazard band B characteristics</p> <p>Hazard band A Available information indicates that your chemical:</p> <ul style="list-style-type: none"> - is not harmful to any aquatic life - does not have bioaccumulation potential (based on in silico prediction of log Kow) - meets the criteria for ready biodegradability <p>Your chemical does not contain aluminium, chromium, copper, nickel, silver, selenium or zinc.</p> <p>⇒ no environment hazard band A characteristics</p>
<p>Q 4 – What is the indicative environment risk for your introduction? (section 30 of General Rules)</p>	<p>Very low risk</p>	<p>Based on Q 2 and Q 3 results</p>



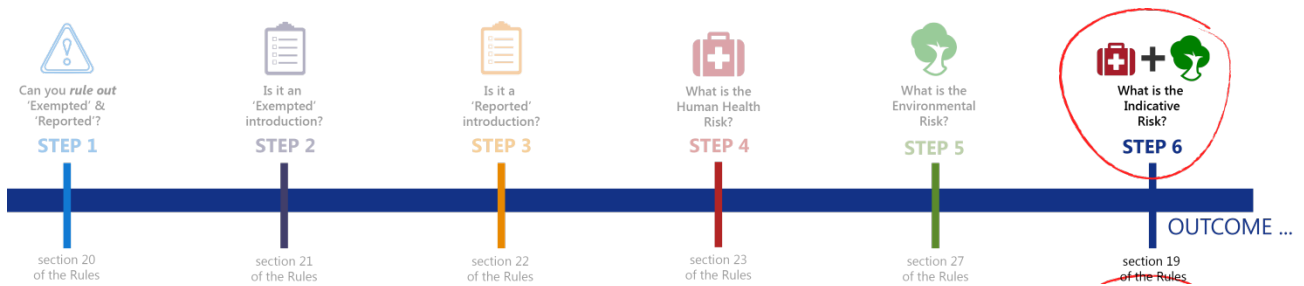
Step 5:

Indicative environment risk

Environment Matrix

Hazard Band	D	Medium to high risk	Medium to high risk	Medium to high risk	Medium to high risk
	C	Low risk	Low risk	Medium to high risk	Medium to high risk
	B	Very low risk	Low risk	Low risk	Medium to high risk
	A	Very low risk	Very low risk	Low risk	Low risk
	Not A, B, C or D	Very low risk	Very low risk	Very low risk	Very low risk
		1	2	3	4
		Exposure Band			

OUTCOME: The indicative environment risk is: VERY LOW RISK



+ Step 6



What is the highest indicative risk for your introduction?

Refer to Step 6 of the method statement from section 19 of the General Rules.

Use results from Step 4 (indicative human health risk) PLUS results from Step 5 (indicative environment risk).

What is your introduction category?



		 Your indicative human health risk		
		Very low	Low	Medium-high
Your indicative environment risk 	Very low	Exempted	Reported	Assessed (exceptions apply)
	Low	Reported	Reported	Assessed (exceptions apply)
	Medium-high	Assessed (exceptions apply)	Assessed (exceptions apply)	Assessed (exceptions apply)

FINAL OUTCOME: your introduction is REPORTED

What's next?

Pre-introduction report

See section 34 and 39 of the General Rules.

Annual declaration

See section 40 of the General Rules

For reported introductions the one declaration covers all introductions for that year and is a confirmation of continued compliance. It does not involve provision of information or separate declarations against each chemical introduction.

Record keeping

See section 46 and 51 of the General Rules

Comparison with current legislation

Under current legislation, introduction of your chemical under the same circumstances would require a Standard notification. This would involve:

- increased cost (minimum \$19,000 – Standard notification fee plus preparation costs)
- delay in time to market (minimum 90 days)
- greater information requirements (including skin and eye irritation, physical-chemical properties)
- chemical included on the Inventory (after 5 years or earlier at your request)