Case study

Cosmetics - very low volume, no available hazard information

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

Cosmetics - very low volume

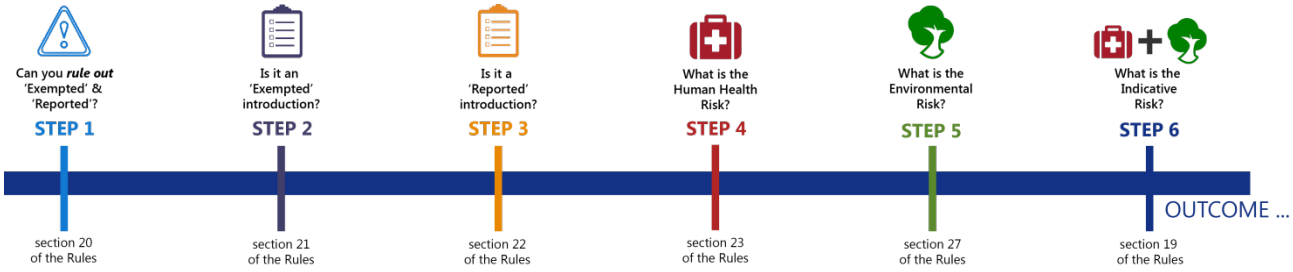
➔ No available hazard information

Case study introduction details	
Do you know the proper name for the chemical (including CAS or IUPAC name)? *(If 'no' you may need assistance from your supplier for categorisation)*	**No**
Is your chemical listed on the Inventory?	**No**
What is your chemical's end use?	**Fragrance ingredient in cosmetics**
What is your total introduction volume within a registration year?	**5 kg (or less)**
Is there information available detailing the hazards of the chemical? *(if "yes" see details on hazard information)*	**No**
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?	**0.05% (or less)**
What is the concentration of your chemical in end use products?	**0.05% (or less)**
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

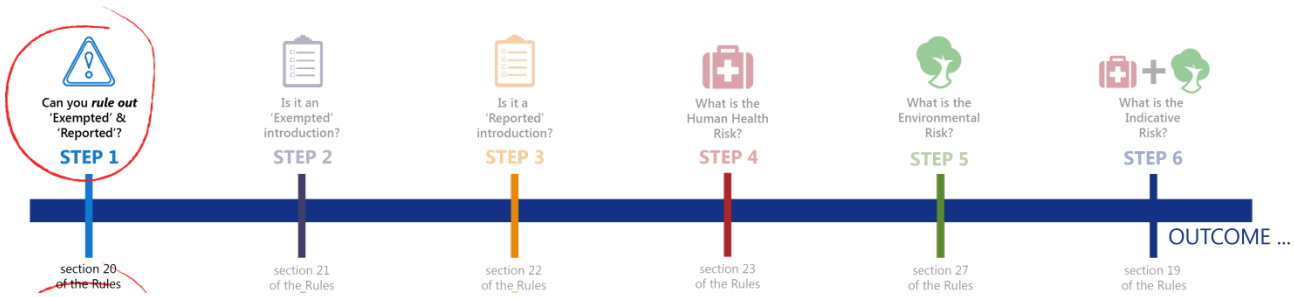
Steps to categorise your industrial chemical

Cosmetics, very low volume



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)	**very 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?	**very low risk**

Case study outcome → **It is an exempted introduction**



Step 1

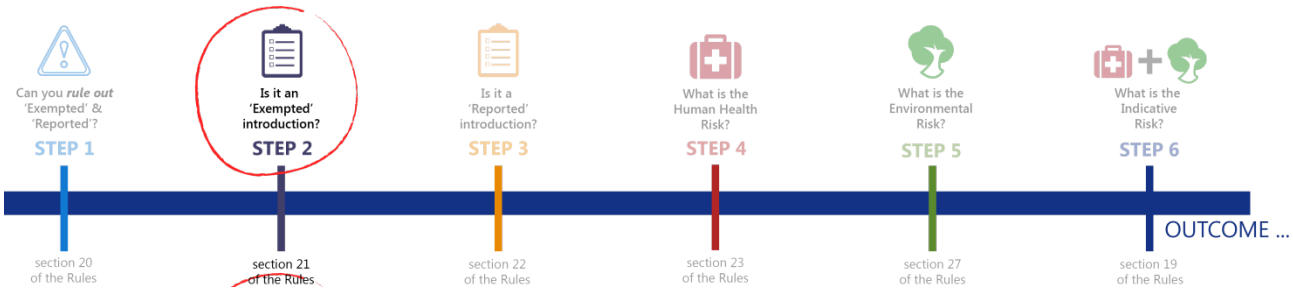
Is your introduction a type that can't be 'exempted' or 'reported'?

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

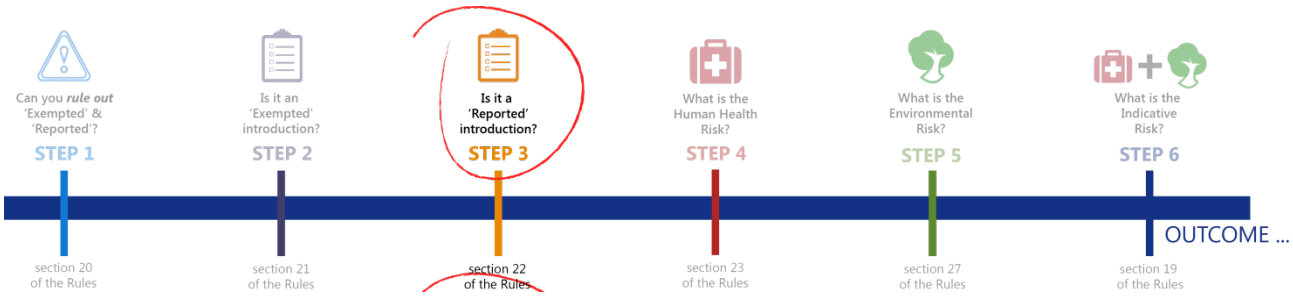
Is your introduction a type that is automatically 'exempted'?

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 at low volumes
- 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

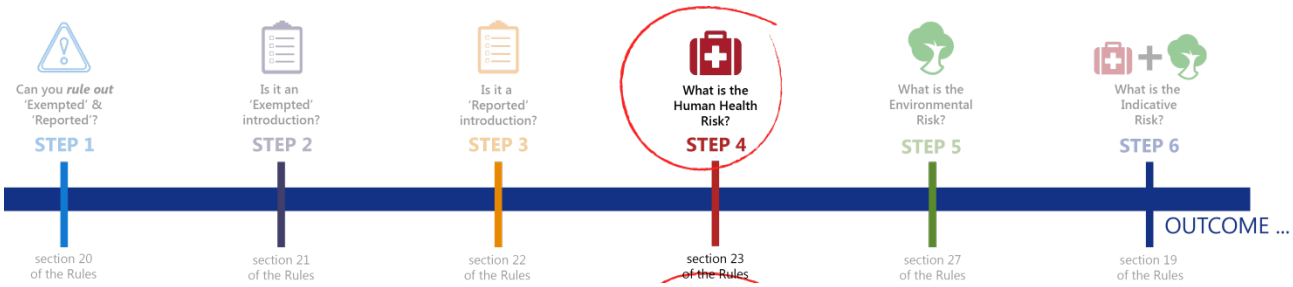
Is your introduction a type that is automatically 'reported'?

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

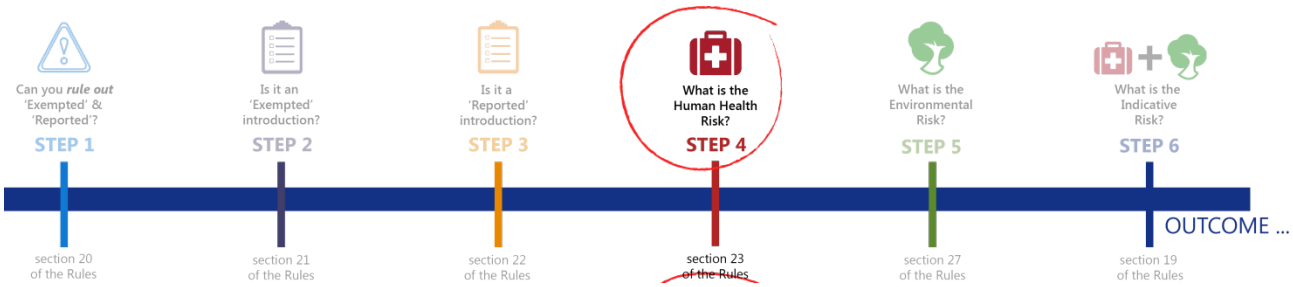
How to work out the indicative human health risk?

Refer to method statement from section 23 of the General Rules.

Summary of step 4 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 1 (table item 3)	Fits the exposure band scenario: - end use in cosmetics - total volume ≤ 10 kg/year - end use concentration < 0.1%

Questions?	Outcome	Reason
Q 3 – Which human health hazard bands do **not** apply to your chemical? (section 25 of General Rules)	human health hazard band C	Check Guidelines (Chapter 4 – human health exposure band 1). **Hazard band C** Your chemical is not on any of the identified lists for human health band C hazard characteristics: - carcinogenicity - mutagenicity or genotoxicity - reproductive toxicity - developmental toxicity - adverse effects mediated by an endocrine mode of action ⇨ No human health hazard band C characteristics
Q 4 – What is the indicative human health risk for your introduction? (section 26 of General Rules)	very low risk (section 26 table item 1)	Based on the results of Q 2 and Q 3



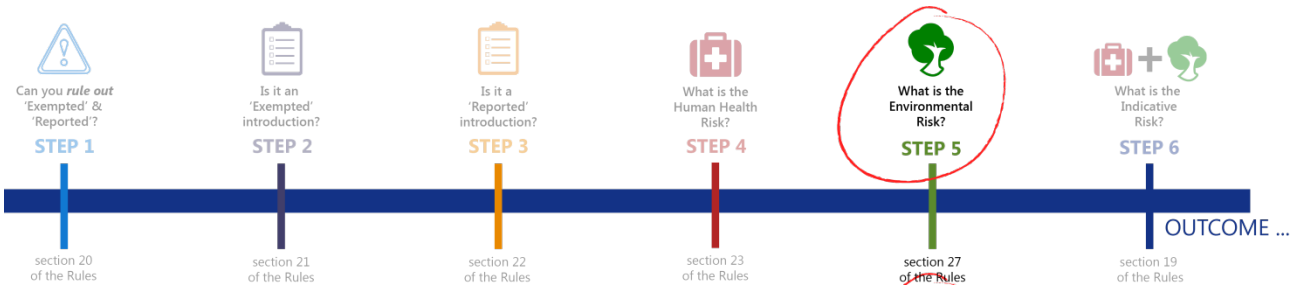
Step 4

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: VERY LOW RISK



Step 5

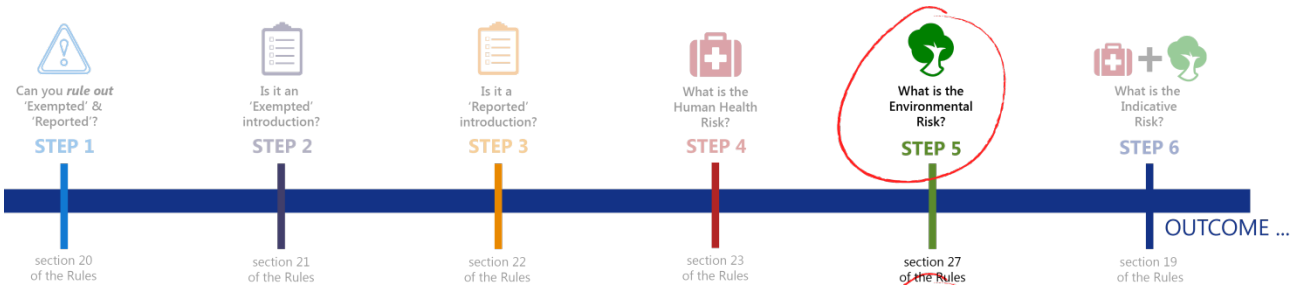
How to work out the indicative environment risk?

Refer to method statement from section 27 of the General Rules.

Summary of step 5 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 1 (Section 28 of General Rules table item 1)	Check Guidelines (Chapter 5, Determining the environment categorisation volume): - total introduction volume = 5 kg - reduction factor = 1 (personal care products not covered by other end uses) - environment categorisation volume = 5 kg x 1 = 5 kg Fits the exposure band scenario: - Does not involve a designated kind of release into the environment - Environment categorisation volume < 10 kg

Questions?	Outcome	Reason
Q 3 – Which environment hazard bands do **not** apply to your chemical? (section 29 of General Rules)	environment hazard bands D and C	Check Guidelines (Chapter 5, Environment exposure band 1 – very low risk). **Hazard band D** Your chemical is not on any of the identified lists for environment band D hazard characteristics: - Persistent, bioaccumulative and toxic - Adverse effects mediated by an endocrine mode of action These definitions do not apply to your chemical: - Ozone depleting - Synthetic greenhouse gas Your chemical does not contain arsenic, cadmium, lead or mercury ⇨ no environment hazard band D characteristics **Hazard band C** Your chemical is not on any of the identified lists for environment band C hazard characteristics: - Very toxic to any aquatic life - Persistent and bioaccumulative ⇨ no environment hazard band C characteristics
Q 4 – What is the indicative environment risk for your introduction? (section 30 of General Rules)	very low risk (section 30 of General Rules - table item 2)	Based on Q2 and Q3 results



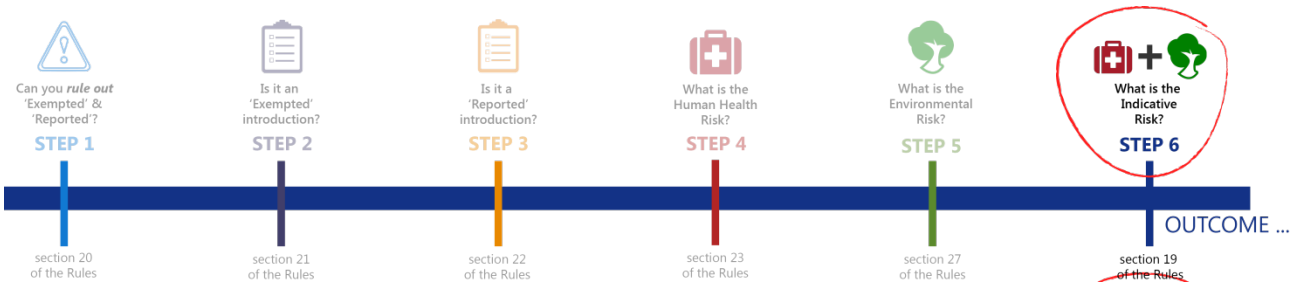
Step 5

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 categorised as EXEMPTED

What's next?

Annual declaration

See section 40 of the General Rules.

For exempted introductions the declaration will indicate if any introductions under this category occurred during the registration year. It will not involve provision of information on individual exempted introductions.

Record keeping

See section 43 and 44 of the General Rules.

Comparison with current legislation

Under current legislation, introduction of your chemical under the same circumstances would require a cosmetic ≤ 10kg/year no unreasonable risk exemption. This would involve:

- pre-introduction checks:
    - Determine whether the chemical is prohibited or restricted for use as a cosmetic or in cosmetic products in the European Union or the United States of America. If the chemical is prohibited or restricted it cannot be introduced under the exemption.
    - Determine whether the new chemical exceeds 1% and whether information is available for safe use by potentially high risk groups.
    - Determine whether the new chemical or product in use meets the requirements of relevant Commonwealth, S&T laws.
    - Determine whether chemical is being used as a preservative, colouring agent or ultraviolet filter (if yes, then it cannot be introduced under the exemption).
    - Determine whether it is a type of chemical NICNAS advises is unsuitable for exemption – chemicals classified as a carcinogen, mutagen or reprotoxin under the GHS; nanomaterials, perfluorinated chemicals
- pre-introduction risk assessment (by introducer) to establish that the introduction of the new chemical does not pose an unreasonable risk to occupational health and safety, public health or the environment.

  post-market reporting to NICNAS annually (minimum report is collective number of chemicals introduced up to 10kg each)