Case study

High volume surfactant - cosmetics

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:

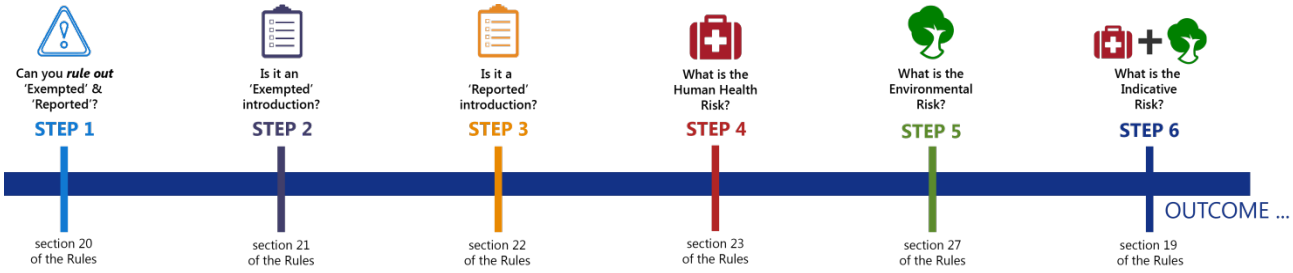
High volume surfactant - cosmetics

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)*	**Yes**
Is your chemical listed on the Inventory?	**No**
What is your chemical's end use?	**Surfactant in rinse-off cosmetics**
What is your total introduction volume within a registration year?	**5000kg**
Is there information available detailing the hazards of the chemical? *(if "yes" see details on hazard information)*	**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?	**<80%**
What is the concentration of your chemical in end use products?	**25%**
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

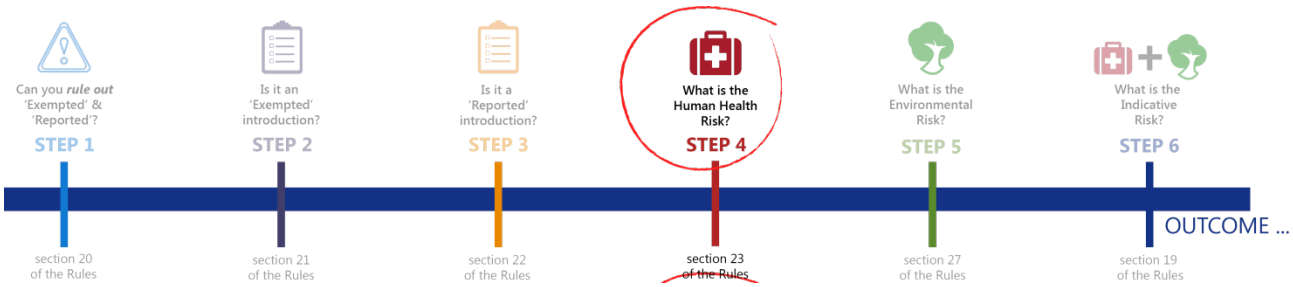
High volume surfactant - cosmetics



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 and Step 5

This case study is focusing on Step 4 and Step 5 of the categorisation process.



Step 4

How to work out the indicative human health risk?

Refer to section 23 of the General Rules.

Summary of step 4 process

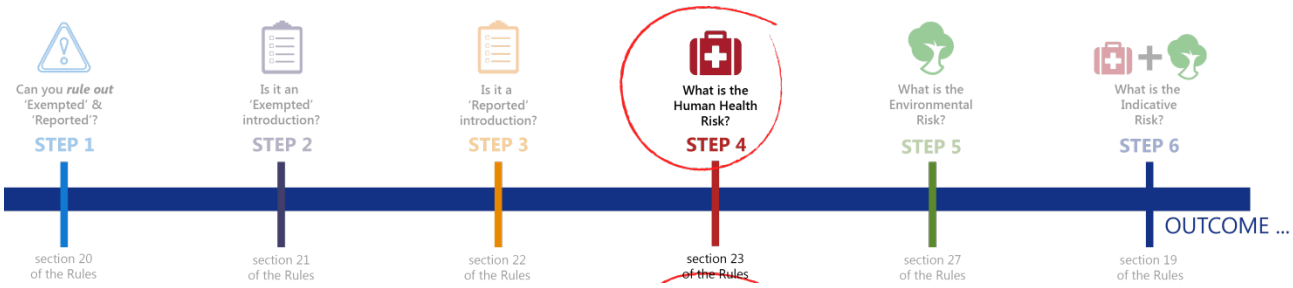
Questions?	Outcome	Reason
Q 2 – What is the human health exposure band for your introduction? (section 24 of General Rules)	human health exposure band 3 (table item 10)	Fits the exposure band scenario: - end use in cosmetics - total volume > 100 kg/year

What hazard information would you need in order to categorise this high volume surfactant chemical introduction as low risk for human health?

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		

In this exposure band you would need information to demonstrate that human health hazard bands C and B do not apply to the chemical.



Step 4

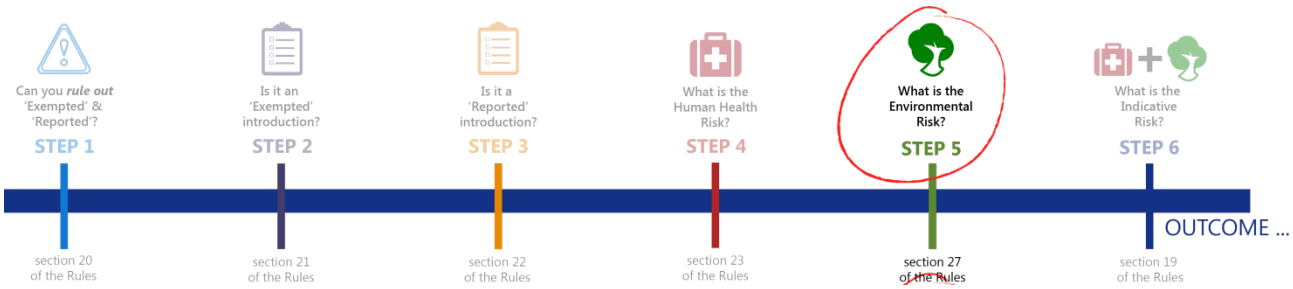
Case study: Human health hazard information for low risk in Exposure Band 3 (EB3) High volume surfactant - cosmetics

Minimum hazard information needed for low risk	Example
Hazard Band C	
Carcinogenicity: • not on a specified list	-
Reproductive and developmental toxicity: • not on a specified list	-
Adverse effects known to be mediated by an endocrine mode of action • not on a specified list	-
Mutagenicity/genotoxicity: • not on a specified list AND • in vitro or in vivo study - point mutations in microbial systems – do not indicate mutagenic/genotoxic effects AND	• In vitro study on chemical – OECD TG 471 AND • In vitro study using suitable read-across information – OECD 473

Minimum hazard information needed for low risk	Example
• in vitro or in vivo study – chromosome damage in mammalian cells - do not indicate mutagenic/genotoxic effects	
Hazard band B	
Acute toxicity (fatal or toxic): • in vivo result – acute oral toxicity LD50 > 300 mg/kg bw OR • in vivo result – acute dermal toxicity LD50 > 1000 mg/kg bw OR • in vivo result – acute inhalation toxicity LC50 > 2500ppmV (gases), or > 10 mg/L (vapours), or > 1 mg/L (dusts/mists/fumes)	• In vivo acute oral toxicity study using suitable read-across information – OECD TG 420
Specific target organ toxicity after a single exposure (significant toxicity): • Not required	-
Specific target organ toxicity after repeated exposure: • in vivo result – 28 day oral toxicity: NOAEL ≥ 300 mg/kg bw/day, or no significant toxic effects relevant to humans OR • in vivo result – 90 day oral toxicity: NOAEL ≥ 100 mg/kg bw/day, or no significant toxic effects relevant to humans OR • in vivo result – 21/28 day dermal toxicity: NOAEL ≥ 600 mg/kg bw/day, or no significant toxic effects relevant	• In vivo 28 day oral toxicity study using suitable read-across information – OECD TG 407

Minimum hazard information needed for low risk	Example
to humans OR • in vivo result – 90 day dermal toxicity: NOAEL ≥ 200 mg/kg bw/day, or no significant toxic effects relevant to humans OR • in vivo result – 28 day inhalation toxicity: NOAEC ≥ 750ppmV/6h/day (gases), or ≥ 3mg/L/6h/day (vapours), or ≥ 0.6mg/L/6h/day (dusts/mists), or no significant toxicity effects relevant to humans OR • in vivo result – 90 day inhalation toxicity: NOAEC ≥ 250ppmV/6h/day (gases), or ≥ 1mg/L/6h/day (vapours), or ≥ 0.2mg/L/6h/day (dusts/mists), or no significant toxicity effects relevant to humans	
Skin corrosion: • in vitro result for skin corrosion – non-corrosive prediction OR • in vitro result for skin irritation – non-irritant prediction OR • in vivo result for skin corrosion – no indication of tissue destruction	• In vitro study on chemical – OECD TG 430
Eye damage: • in silico prediction indicates does not cause serious eye damage OR • in vitro result predicts does not induce serious eye damage OR • in vivo result indicates does not cause effects on the eye	• In vitro study using suitable read-across information – OECD TG 437

Minimum hazard information needed for low risk	Example
Skin sensitisation: • in vivo study that does not result in induction of an allergic response OR • ALL OF THE FOLLOWING: - In silico prediction indicates does not cause skin sensitisation AND - In chemico result (OECD TG 442C) with a non-sensitising prediction AND - In vitro result (OECD TG 442D) with a non-sensitising prediction AND - In vitro result (OECD TG 442E) with a non-sensitising prediction	• In vivo study using suitable read-across information – OECD TG 429
Respiratory sensitisation: • Not required	-
Respiratory corrosion: • Not required	-



Step 5

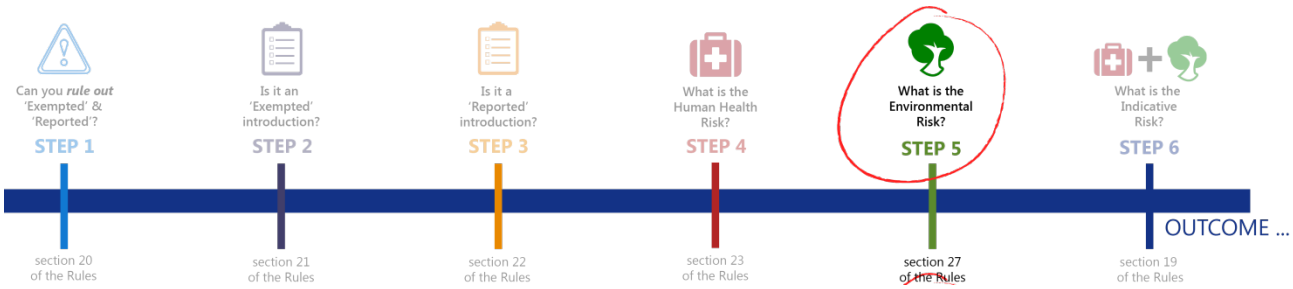
How to work out the indicative environment risk?

Refer to section 27 of the General Rules.

Summary of step 5 process

Questions?	Outcome	Reason
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): - total introduction volume = 5000kg - reduction factor = 1 (personal care products not covered by other end uses) - environment categorisation volume = 5000kg x 1 = 5000kg Fits the exposure band scenario: - Does not involve a designated kind of release into the environment - Environment categorisation volume >1,000kg but ≤ 10,000kg

What hazard information would you need in order to categorise this high volume surfactant chemical introduction as low risk for environment?



Step 5

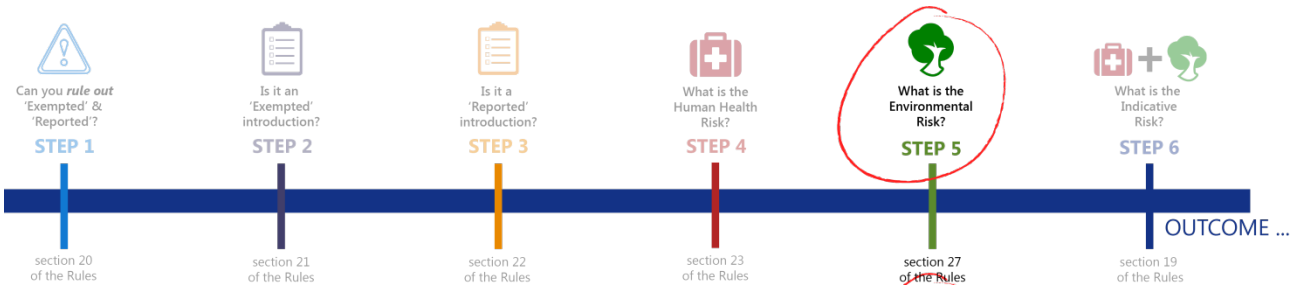
How to work out the indicative environment risk?

Refer to section 27 of the General Rules.

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			

In this exposure band you would need information to demonstrate that environment hazard bands D and C do not apply to the chemical.



Step 5

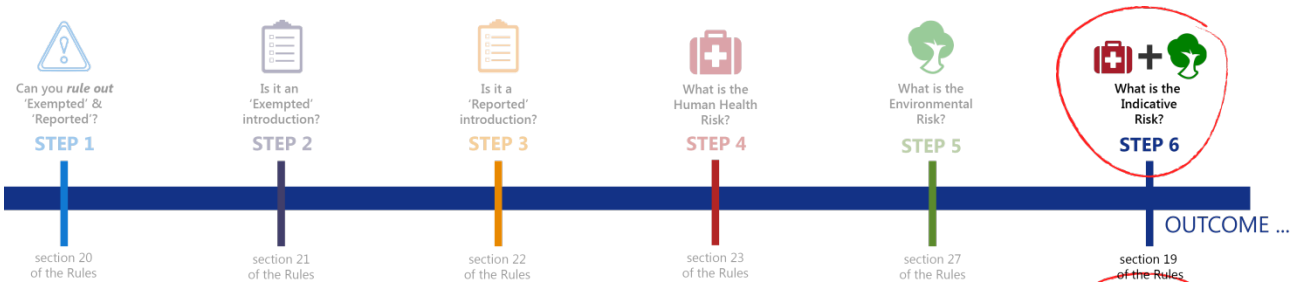
Case study: Environment hazard information for low risk in Exposure Band 3 (EB3)

High volume surfactant - cosmetics

Minimum hazard information needed for low risk	Example
Hazard band D	
PBT: • not on a specified list AND • Show that not P, not B or not T: - not P: - measured ready biodegradability showing it degrades by > 70% within 28 days, or the BOD/COD ratio is ≥0.5 OR - not B: - measured partition coefficient of < 4.2 OR - measured bioconcentration factor of < 2000 OR - measured bioaccumulation factor of	• Ready biodegradability test – OECD TG 301 – shows chemical is readily biodegradable (so not PBT)

Minimum hazard information needed for low risk	Example
< 2000 OR - not T: - in vivo acute test result on fish, invertebrates and algae of >1mg/L OR - in vivo chronic test result of NOEC or ECx of: - > 0.1mg/L (for chemicals that are not readily biodegradable) - > 0.01mg/L (for chemicals that are readily biodegradable)	
Ozone depleting chemicals: • definition does not apply to chemical	-
Synthetic greenhouse gas: • definition does not apply to chemical	-
Contains arsenic, cadmium, lead or mercury: • identity of chemical	-
Adverse effects known to be mediated by an endocrine mode of action • not on a specified list	-
Hazard band C	
Very toxic to any aquatic life: • in vivo acute toxicity test results for fish, invertebrates and algae • in vivo chronic toxicity test results for fish, invertebrates and algae	• In vivo acute fish toxicity study using suitable read-across information – LC50 = 5mg/L (OECD TG 203) AND • In vivo acute daphnia toxicity study on chemical – EC50 = 3mg/L (OECD TG 202) AND • In vivo acute algae toxicity study on chemical – ErC50 = 7mg/L (OECD TG 201)

Minimum hazard information needed for low risk	Example
Persistent and bioaccumulative: • Show that chemical is not P, or not B: - not P: - measured ready biodegradability showing it degrades by > 70% within 28 days, or the BOD/COD ratio is ≥0.5 - not B: - measured partition coefficient of < 4.2 OR - measured bioconcentration factor of < 2000 OR - measured bioaccumulation factor of < 2000	• Ready biodegradability test – OECD TG 301 – shows chemical is readily biodegradable (so not P)



Step 6

What is the highest indicative risk for your introduction?

Refer to 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)