

Target audience and purpose

- Persons introducing industrial chemicals under certain NICNAS exemption provisions
 - non-cosmetic use (≤100 kg; no unreasonable risk)
 - cosmetic use (≤100 kg; no unreasonable risk)
 - cosmetic use (≤1%; non-hazardous chemical)
- Transitional arrangements introductions authorised until 31 August 2022
- Purpose make the categorisation process as simple as possible
- Chemicals are not listed on our Inventory
- Introductions in accordance with R&D NICNAS exemptions also authorised AICIS categorisation see our website https://www.industrialchemicals.gov.au/help-and-guides/extra-resources-help-you-categorise-your-introduction/categorisation-chemicals-introduced-research-and-development



Agenda

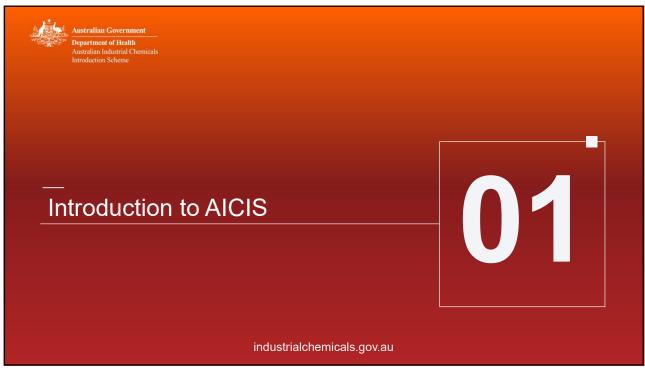
- Introduction to AICIS
- Assessed introductions
- The 6-step categorisation process
- Information you need to categorise
- Examples

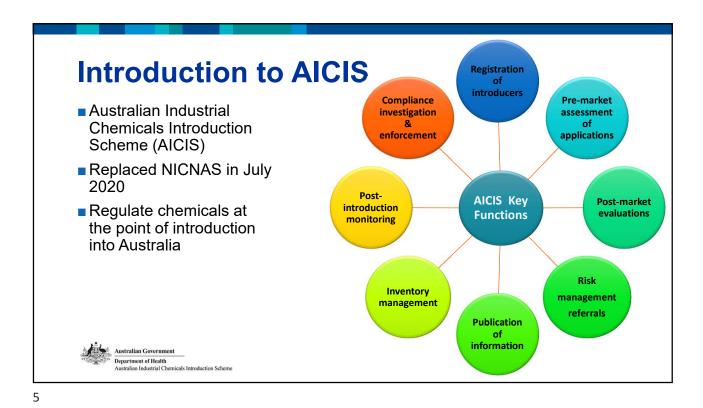
Examples

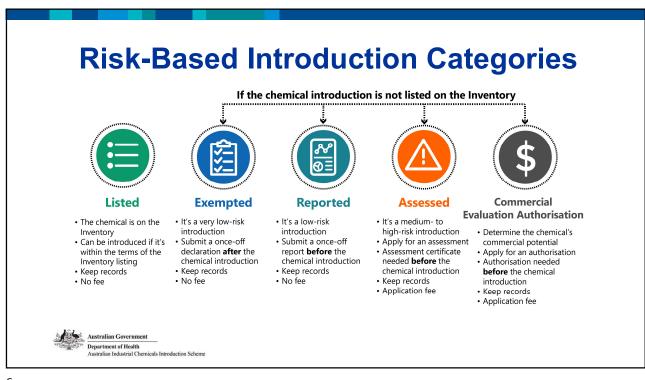
- 1. Chemical ≤100 kg/year
- Work through the 6-step process
- Obligations following categorisation
 - Submitting pre-introduction report
 - Records kept
- 2. Same chemical ≤1%
- 3. Same chemical ≤25 kg
- 4. Chemical ≤10 kg
- Work through the 6-step process
- Obligations following categorisation
 - Submitting post-introduction declaration
 - Records kept



3







Legislation/information to categorise

Key documents

- Industrial Chemicals Act 2019
- Industrial Chemicals (General) **Rules 2019**
- Industrial Chemicals Categorisation Guidelines

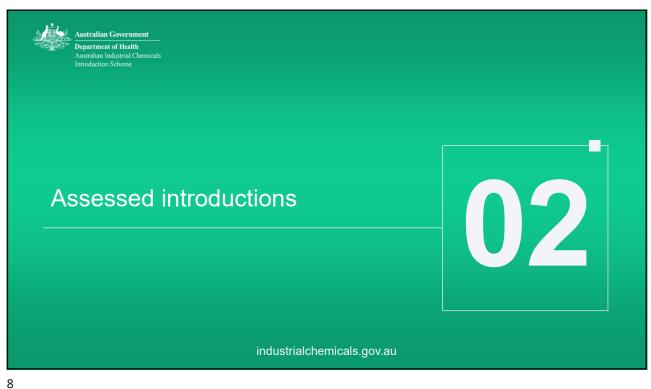
https://www.industrialchemicals.gov.au/ab out-us/industrial-chemicals-law-australia



Information on our website

- Categorisation Guide https://www.industrialchemicals.gov.au/helpand-guides/guide-categorising-your-chemicalimportation-and-manufacture
- Extra resources, e.g. categorisation of:
 - chemicals in cosmetics
 - polymers
 - chemicals in fragrance blends
 - polyhalogenated organic chemicals
 - etc.

https://www.industrialchemicals.gov.au/helpand-guides/extra-resources-help-youcategorise-your-introduction



Assessed introductions

Some introductions will likely be categorised as assessed

- Chemicals with a sequence of 4 to 20 fully fluorinated carbon atoms
- Persistent polyhalogenated organic chemicals >100 kg/year
- Certain chemicals at the nanoscale
- Persistent gases >100 kg/year
- Organotin chemicals >10 kg/year
- Chemicals with hazard characteristics in human health hazard band C*
- Chemicals with hazard characteristics in environment hazard band D
- Chemicals with certain end uses: tattoo inks, personal vaporisers, offshore, firefighting, intentional release (e.g. town water treatment, soil conditioner)**



9

Applications for assessment

- An application for an assessment certificate must be submitted for introductions of chemicals categorised as assessed
- Introduction of the chemical must be in accordance with the terms of the issued certificate
- Timeframe: generally 70 working days
- Fee applies

https://www.industrialchemicals.gov.au/business/apply-assessment-certificate#timeframes-and-assessment-process

Applications can also be submitted for introductions otherwise categorised as exempted/reported (e.g. to have the chemical added to our Inventory)





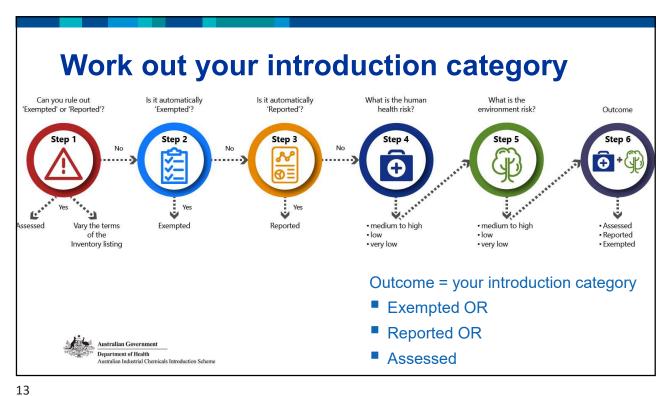
Work out your introduction category

- Categorisation for exempted and reported is a 6-step process – you may not need all 6 steps
- The category for the majority of introductions meeting the NICNAS exemption criteria will be determined using all 6 steps
- We have video guides available on our website to step you through it:

https://www.industrialchemicals.gov.au/help-and-guides/video-guides-learn-about-aicis-and-your-obligations/video-series-categorising-your-introduction

Important:

If a chemical was introduced under the NICNAS exemptions, it does NOT mean that it is an exempted introduction under AICIS - the criteria are NOT the same.



Work out the indicative risk

Steps 4 and 5

		Human health exposure band			
		1	2	3	4
Human health hazard band	С	Low risk	Medium to high risk	Medium to high risk	Medium to high risk
	В	Very low risk	Very low risk	Low risk	Medium to high risk
	Α	Very low risk	Very low risk	Low risk	Low risk
Huma	Not A, B, or C	Very low risk	Very low risk	Very low risk	Very low risk

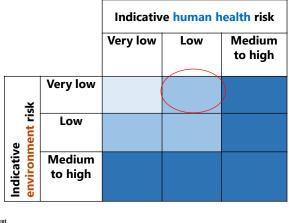
		1	2	3	4
d band	D	Medium to high risk	Medium to high risk	Medium to high risk	Medium to high risk
	С	Low risk	Low risk	Medium to high risk	Medium to high risk
Environment hazard band	В	Very low risk	Low risk	Low risk	Medium to high risk
onme	Α	Very low risk	Very low risk	Low risk	Low risk
Envir	Not A, B, C or D	Very low risk	Very low risk	Very low risk	Very low risk

Environment exposure band

Australian Government Department of Health Australian Industrial Chemicals Introduction Scheme

Work out your introduction category

Step 6 – use the results from steps 4 and 5



Australian Government

Department of Health
Australian Industrial Chemicals Introduction Scheme

15

Tips for faster categorisation

Are you aiming for an exempted or reported introduction?

- 1. Working out exposure bands (step 4.3 and 5.3)
 - need human health categorisation volume (HHCV) and environment categorisation volume (ECV)
 - quick option: don't apply exposure and release reduction factors
 - HHCV and ECV = introduction volume
 Example: introduction volume ≤100 kg regardless of use HHCV ≤100 kg



		Human health exposure band				
		1	2 (3 ≤100 kg) 4	
Human health hazard band	С	Low risk	Medium to high risk	Medium to high risk	Medium to high risk	
	В	Very low risk	Very low risk	Low risk	Medium to high risk	
ın hea	Α	Very low risk	Very low risk	Low risk	Low risk	
Huma	Not A, B, or C					

Tips for faster categorisation

Are you aiming for an exempted or reported introduction?

2. Working out hazard characteristics (step 4.4 and 5.4)

 higher exposure bands = more hazard characteristics to consider and need more information to be a very low risk introduction

Example: human health exposure band 3

 low risk – absence of characteristics in hazard band C

 very low risk – absence of characteristics in hazard bands C, B and A

quick option: aim for low risk

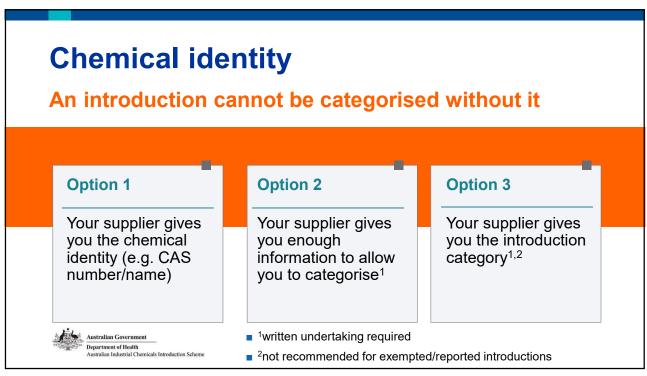


		1	2	3 ≤100 kg	4	
d band	С	Low risk	Medium to high risk	Medium to high risk	Medium to high risk	
Human health hazard band	В	Very low risk	Very low risk	Low risk	Medium to high risk	
ın hea	A	Very low risk	Very low risk	Low risk	Low risk	
Huma	Not A, B, or C	Very low risk	Very low risk	Very low risk	Very low risk	

Human health exposure band

17





Written undertakings

The supplier holds certain information

- If you rely on information held by someone else (e.g. the overseas supplier or manufacturer) to categorise your introduction, you must keep a written undertaking from that person
- Information in the undertaking varies and depends on
 - the introduction category
 - the information held by that person
- More than 1 undertaking may need to be held for the same introduction
- Undertakings must confirm that the information can be provided if we ask for it



You don't know the chemical identity

Option 2 - Supplier gives you enough information to categorise

- You need the categorisation elements that require the identity, e.g. whether the chemical:
 - is listed on our Inventory
 - is listed in the Rotterdam or Stockholm convention
 - meets the polymer of low concern (PLC) criteria
 - is polyhalogenated
 - contains certain elements (e.g. tin, arsenic, cadmium, lead or mercury)
 - has any known hazard characteristics
 - is on 'The list of chemicals with high hazards for categorisation'
 - is a specified class of introduction



21

Other information you'll likely need

- Maximum introduction volume
- End use
- Introduction and end use concentration (≤1%?)*
- 'certain chemicals at the nanoscale'?
- Specified class of introduction?

https://www.industrialchemicals.gov.au/glossary/specified-class-introduction

Hazard information:

- Known hazard characteristics of the chemical
- Information that is available to demonstrate the absence of human health and environment hazard characteristics

Other information

Demonstrating the absence of hazard characteristics

- Information needed to demonstrate the absence of hazard characteristics is set out in our Categorisation Guidelines
- HH EB3 extensive hazard information to demonstrate low risk is not required
- Chemical must not be:
 - Known to have certain hazard characteristics
 - On 'The list of chemicals with high hazards for categorisation'



		Human health exposure band			
		1	2	3 ≤100 kg ≤1%	4
Human health hazard band	С	Low risk	Medium to high risk	Medium to high risk	Medium to high risk
	В	Very low risk	Very low risk	Low risk	Medium to high risk
	Α	Very low risk	Very low risk	Low risk	Low risk
Huma	Not A, B, or C	Very low risk	Very low risk	Very low risk	Very low risk

23

Summary

- Introductions under the NICNAS exemption provisions must be categorised under AICIS for introduction to be authorised beyond 31 August 2022
- Introductions may be categorised as exempted, reported or assessed
- There is a 6-step process to work out if your introduction can be exempted or reported
- You need to know certain information about the chemical you are introducing to be able to categorise the introduction



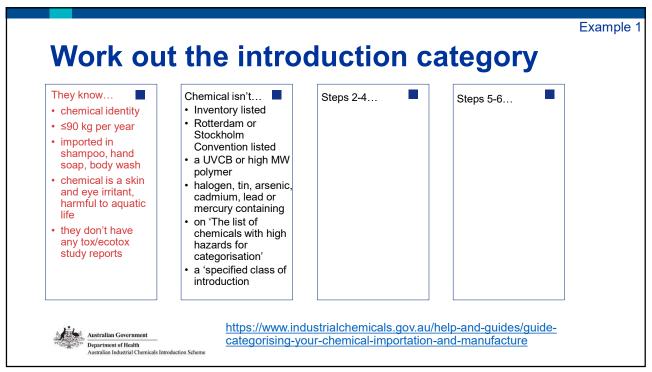


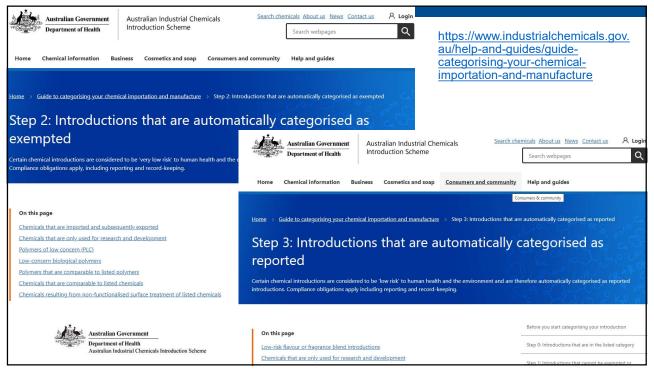
Example 1: scenario

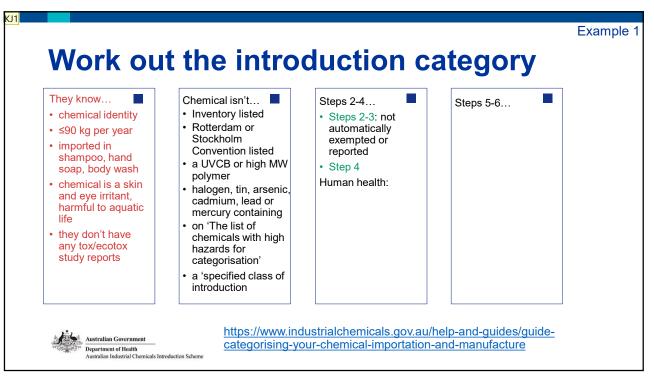
- Chemical is currently being introduced into Australia in accordance with the NICNAS exemption criteria
- cosmetic use (≤100 kg; no unreasonable risk)
- Introducer needs to categorise the introduction under AICIS

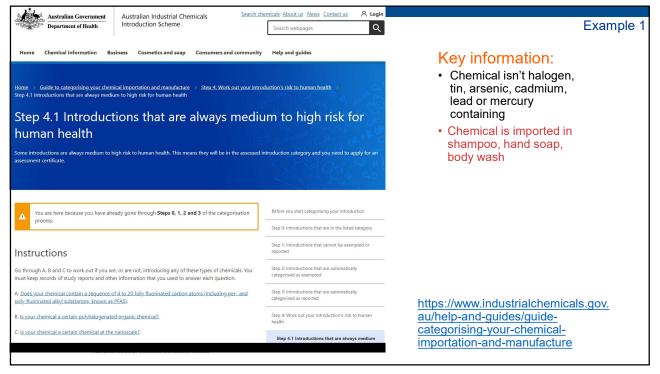
They know:

- chemical identity
- ■≤90 kg per year
- imported in shampoo, hand soap, body wash
- chemical is a skin and eye irritant, harmful to aquatic life
- they don't have any tox/ecotox study reports





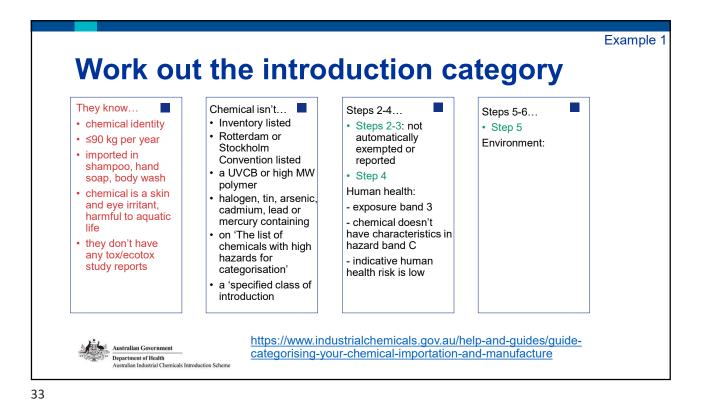


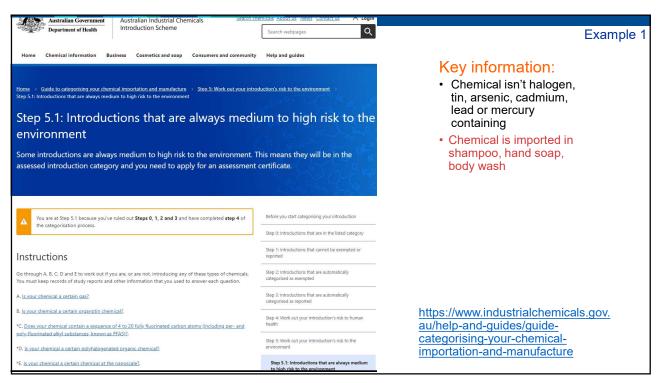


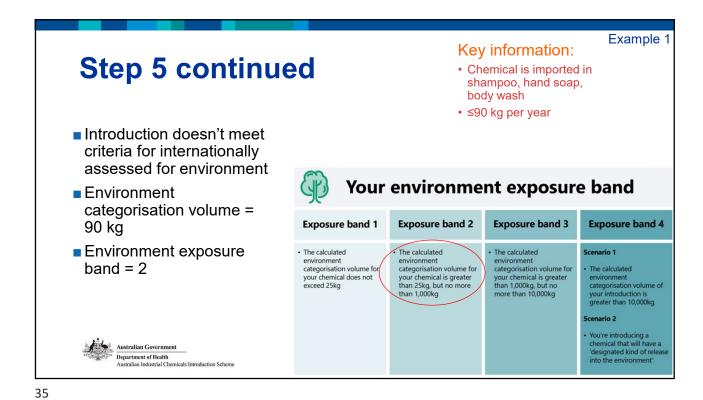
Example 1 **Key information: Step 4 continued** · Chemical is imported in shampoo, hand soap, body wash • ≤90 kg per year Introduction doesn't meet Your human health exposure band criteria for internationally assessed for human **Exposure band 2 Exposure band 3 Exposure band 4 Exposure band 1** health Human health The concentration of your chemical at introduction is less than 0.1 % and The concentration is less than 0.1 % across all your introduction's end uses The calculated human health categorisation volume for your chemical is greater than 100kg categorisation volume = The calculated human health categorisation volume for your chemical does not exceed 100kg The calculated human health categorisation volume for your chemic does not exceed 25kg 90 kg Human health exposure The introduction is not for Scenario 2 Scenario 2 Scenario 2 The concentration of your chemical at introduction is less than 0.1 % and The concentration is less than 0.1 % across all your introduction's end uses band = 3 The concentration of your chemical at introduction is less than or equal to 1% Your introduction has an end use in tattoo inks or The concentration is less than or equal to 1% across all your introduction's end The concentration is less than or equal to 1% across all your introduction's end The concentration is less than or equal to 1% across than or equal to 1% and The introduction has at Australian Government least 1 consumer end use Department of Health Australian Industrial Chemicals Introduction Scheme

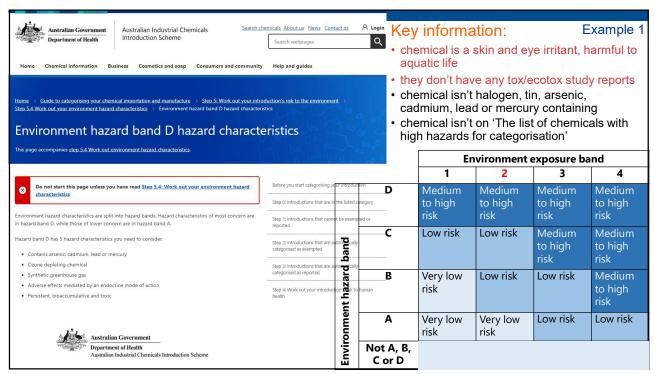
Example 1 Search chemicals About us News Contact us Key information: Department of Health · chemical is a skin and eye irritant, harmful Chemical information Business Cosmetics and soap Consumers and community Help and guides to aquatic life they don't have any tox/ecotox study Home > Guide to categorising your chemical importation and manufacture > Step 4: Work out your introduction's risk to human health Step 4.4 Work out your human health hazard characteristics > Human health hazard band C hazard characteristics · chemical isn't on 'The list of chemicals with high hazards for categorisation' Human health hazard band C hazard characteristics Human health exposure band Do not start this page unless you have read Step 4.4 Work out your human health hazard 2 Step 0: Introductions that are in the listed category Human health hazard characteristics are split into hazard bands. Hazard characteristics of most concern a n hazard band C, while those of lower concern are in hazard band A. c Low risk Medium Medium Medium to high to high to high Hazard band C has 5 hazard characteristics you need to consider hazard В Very low Medium Very low Low risk reproductive toxicity Step 3: Introductions that are auto categorised as reported developmental toxicity to high adverse effects mediated by an endocrine mode of action Human health risk genetic toxicity Low risk Very low Very low Low risk risk risk Australian Government Very low Not A, Very low Very low Very low Department of Health Australian Industrial Chemicals Introduction Scheme B, or C

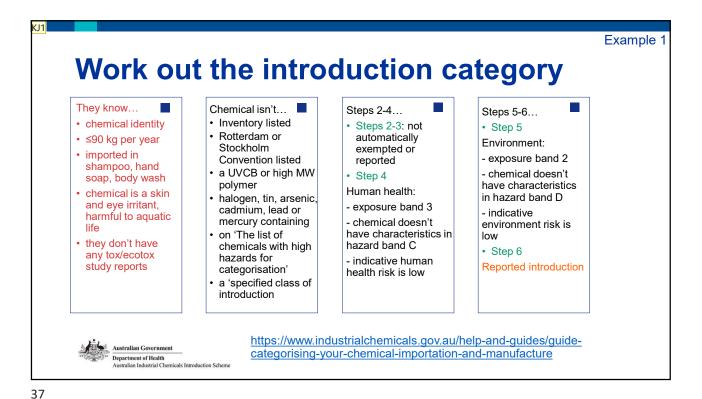
32











Work out your introduction category Step 6 - use the results from steps 4 and 5 Indicative human health risk Very low Medium Low to high Very low Exempted Reported **Assessed** environment risk Low Reported/ Reported Assessed ndicative Medium Assessed **Assessed** Assessed to high Australian Government Department of Health Australian Industrial Chemicals Introduction Scheme

Example 1: Following categorisation...

Before they introduce:

Submit a pre-introduction report (PIR)

https://www.industrialchemicals.gov.au/business/reporting-and-record-keeping-obligations/pre-introduction-reports-reported-category

 Make sure they can meet their record keeping obligations

https://www.industrialchemicals.gov.au/business/reporting-and-record-keeping-obligations/record-keeping-obligations-reported-introductions

After they introduce:

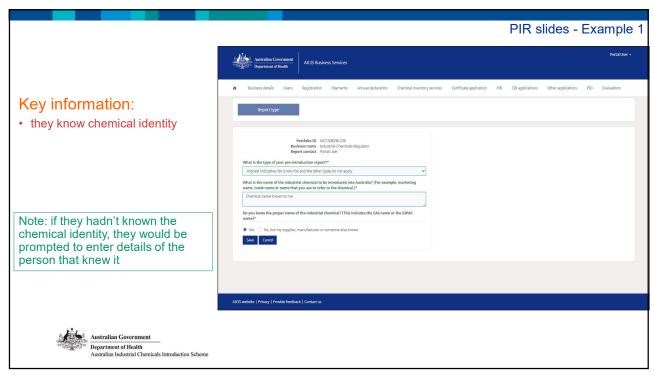
- Introduce chemical in accordance with the PIR terms
- If the introduction circumstances change, vary the PIR*
- Keep records about the introduction
- Indicate that they are introducing chemicals in the reported category in their annual declaration

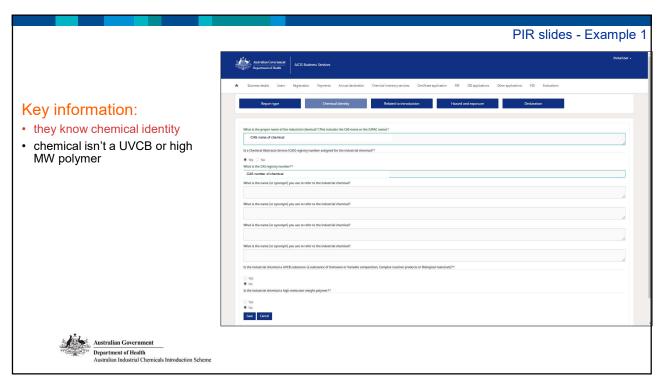
39

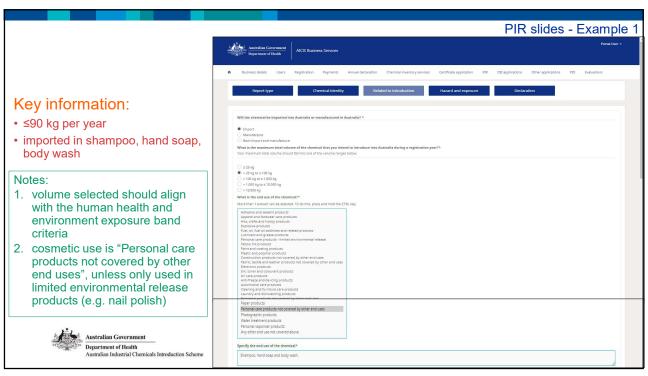
Pre-introduction report (PIR)

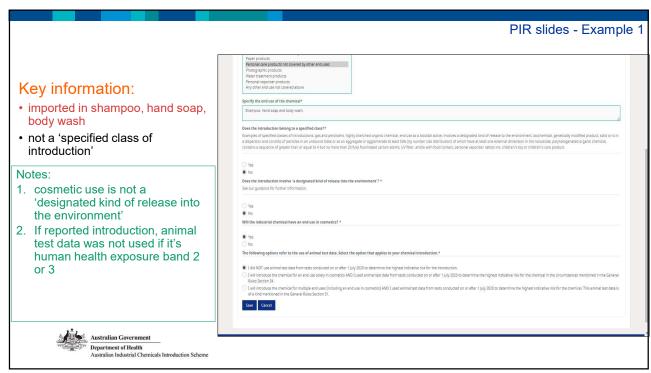
- The Australian introducer (or an agent) must submit a pre-introduction report (PIR) for reported introductions
- Submission is via our business portal
- The contents of the PIR differs depending on the type of introduction
- Main type: 'highest indicative risk is low risk and the other types do not apply'
 - Chemical identity information is required
 - This can be provided securely by overseas suppliers they need to be enrolled in and then login to our portal
- Step-by-step guide to complete/submit the report: https://www.industrialchemicals.gov.au/business/reporting-and-record-keepingobligations/pre-introduction-reports-reported-category/pre-introduction-report-highestindicative-risk-low-risk

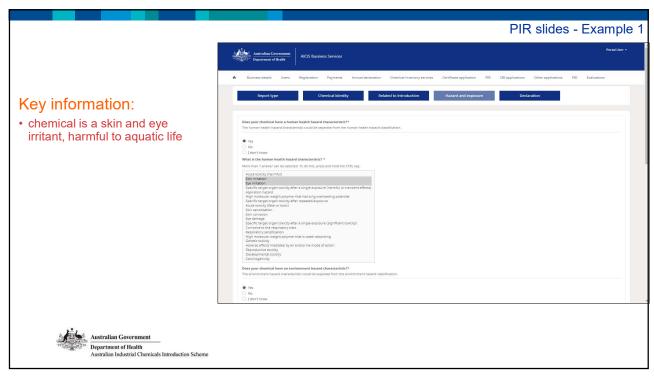


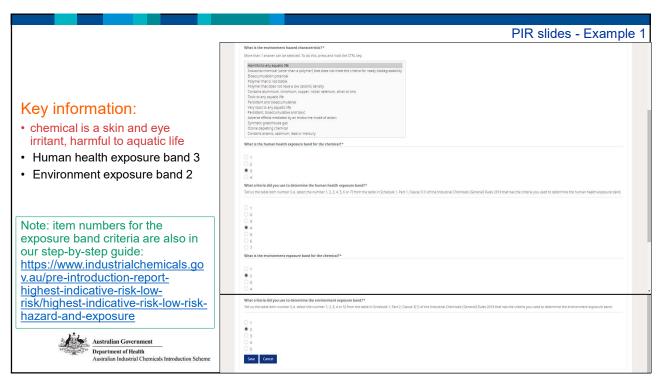


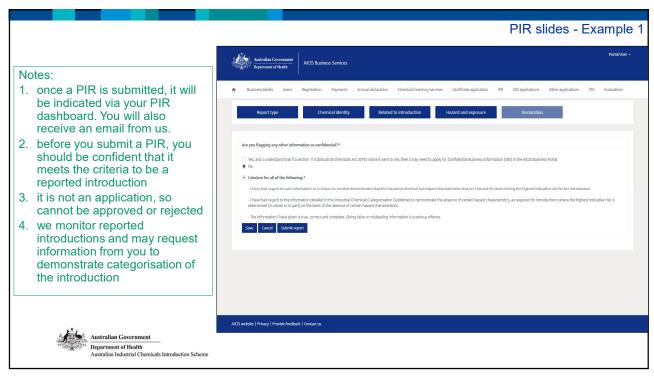














We may request information



· Introducers must keep records about their introductions



We may ask you for information related to the introduction of your chemicals



 If you hold a written undertaking from a supplier - ask them to provide the information that they hold to us



Information given to us (by you and your supplier, if applicable)



· We will review the information to confirm that the introduction is authorised



49

Example 1 - records kept

A document

- Signed and dated at the time of categorisation, indicating the CAS number/name of the chemical and that it isn't:
 - Inventory listed
 - Rotterdam or Stockholm Convention listed
 - a UVCB or high MW polymer
 - halogen, tin, arsenic, cadmium, lead or mercury containing
 - on 'The list of chemicals with high hazards for categorisation'
 - a specified class of introduction



Other items

- Product information sheets containing information on end use (and supporting that it's imported in liquid form)
- Shipping documents and concentration of chemical to support the introduction volume (and names of products imported)
- Information from the supplier, indicating the chemical is a skin and eye irritant and harmful to aquatic life

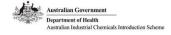
https://www.industrialchemicals.gov.au/business/reporting-and-record-keeping-obligations/record-keeping-obligations-reported-introductions/record-keeping-reported-introductions-highest-indicative-risk-low-risk

Example 2: cosmetic use (≤1%)

Comparison with example 1 (cosmetic; ≤100 kg)

	Same	Different or possibly different
Categorisation	Process (steps 1-6 of Categorisation guide) – step 4.3 – both in human health exposure band 3	Step 5.3 – environment exposure band – environment categorisation volume may be >100 kg
Pre-introduction report*	Report type: 'highest indicative risk is low risk and the other types do not apply' – same type of information	Specific information provided, e.g. select human health exposure band criteria (item 5 not 4, as shown for example 1)
Record keeping*	Same type of information	Additional requirement – a record of the maximum concentration of the chemical at introduction and end use

^{*}assuming introduction categorised as reported



51

Example 3: introducing ≤25 kg

Introduction may be able to be reported or exempted

		Human health exposure band			
		1	2 ≤25 kg	3 ≤100 kg	4
rd band	С	Low risk	Medium to high risk	Medium to high risk	Medium to high risk
Human health hazard band	В	Very low risk	Very low risk	Low risk \	Medium to high risk
ın he	Α	Very low risk	Very low \risk	Low risk	Low risk
Humi	Not A, B, or C	Very low risk	Very low risk	Very low risk	Very low risk

14	Australian Government
and the same	Department of Health Australian Industrial Chemicals Introduction Scheme

		En	Environment exposure band			
		1 ≤25 kg	2 ≤1000 kg	3	4	
	D	Medium to high risk	Medium to high risk	Medium to high risk	Medium to high risk	
band	С	Low risk	Low risk	Medium to high risk	Medium to high risk	
Environment hazard band	В	Very low risk	Low risk	Low risk	Medium to high risk	
onme	Α	Very low risk	Very low risk	Low risk	Low risk	
Envir	Not A, B, C or D	Very low risk	Very low risk	Very low risk	Very low risk	

Example 3

Introducing ≤25 kg – which category?

 If criteria to be exempted met - consider whether reported/exempted category best suits your business/introduction circumstances

Reported (PIR) ≤100 kg

- 1. PIR then introduce
- 2. No fee to submit PIR
- 3. Less volume monitoring
- 4. Keep records (↓)
- 5. Chem ID required PIR1



Exempted (PID) ≤25 kg

- 1. Introduce then PID
- 2. No fee to submit PID
- 3. Monitor volume
- 4. Keep records (↑)
- 5. Chem ID required PID1

Exempted (PID) ≤10 kg

- 1. Introduce then PID
- 2. No fee to submit PID
- 3. Monitor volume
- 4. Keep records (↑)
- 5. Chem ID required $PID^{1,2}$

¹If identity not known – written undertaking needed for records

²If identity not known – chem ID not required in PID

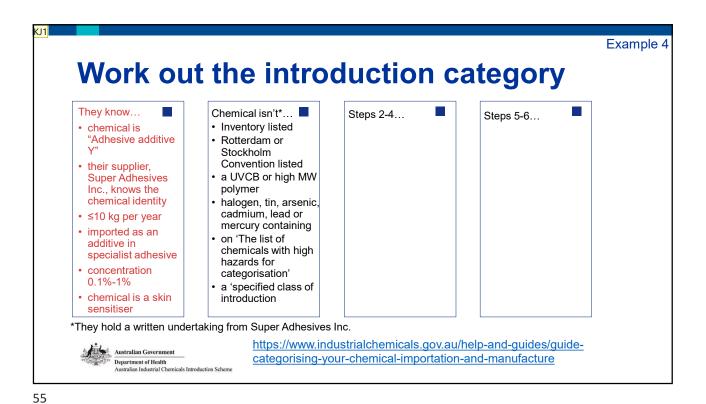
53

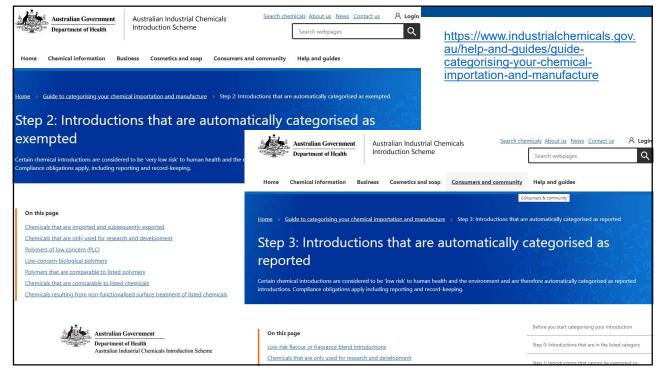
Example 4: scenario

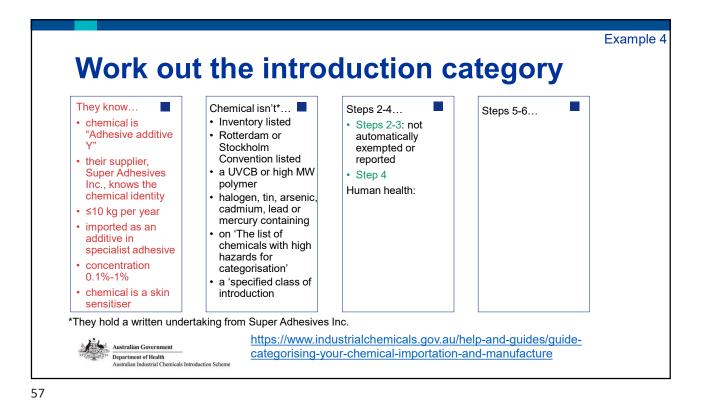
- Chemical is currently being introduced into Australia in accordance with the NICNAS exemption criteria
- non-cosmetic use (≤100 kg; no unreasonable risk)
- Introducer needs to categorise the introduction under AICIS

They know:

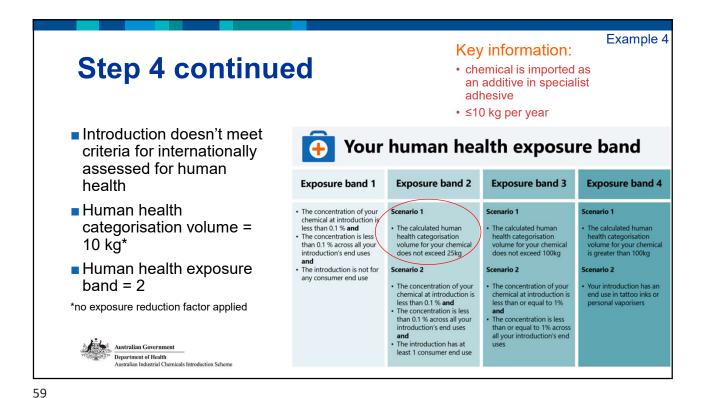
- chemical is "Adhesive additive Y"
- their supplier, Super Adhesives Inc., knows the chemical identity
- ■≤10 kg per year
- imported as an additive in specialist adhesive
- concentration 0.1%-1%
- chemical is a skin sensitiser
- Super Adhesives Inc. will provide a written undertaking



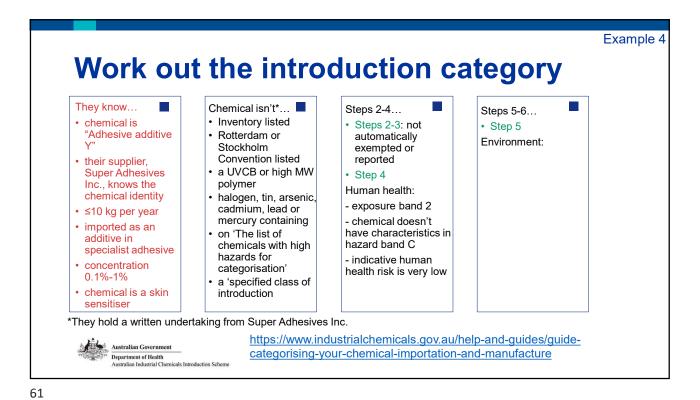


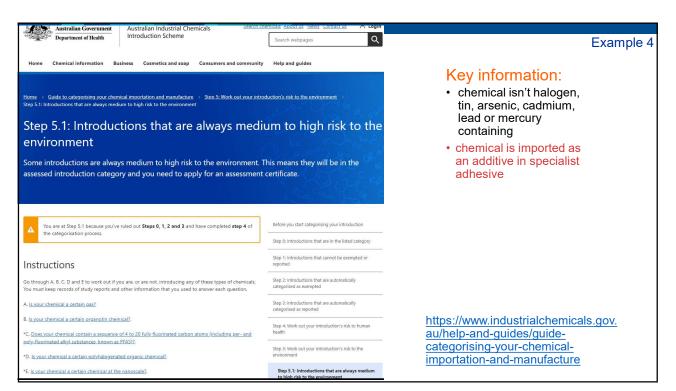


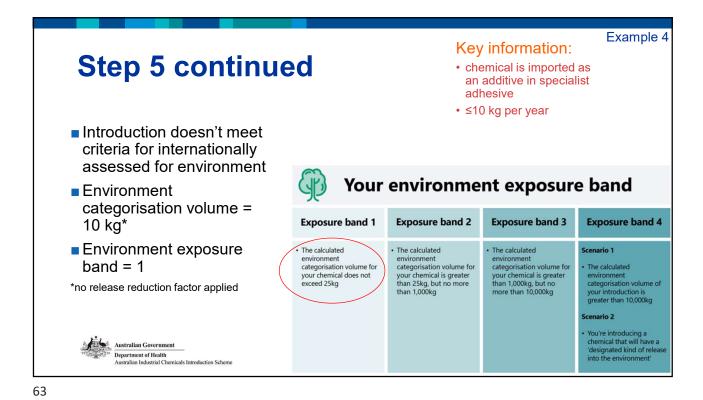
Search chemicals About us News Contact us A Login Australian Industrial Chemicals Introduction Scheme Australian Government Example 4 Chemical information Business Cosmetics and soap Consumers and community Key information: · chemical isn't halogen, Home > Guide to categorising your chemical importation and manufacture > Step 4: Work out your introduction's risk to human health
Step 4.1 Introductions that are always medium to bigh risk for human health tin, arsenic, cadmium, lead or mercury containing Step 4.1 Introductions that are always medium to high risk for chemical is imported as human health an additive in specialist adhesive You are here because you have already gone through **Steps 0, 1, 2 and 3** of the categorisation process. Step 0: Introductions that are in the listed category Instructions Step 2: Introductions that are automatically categorised as exempted A. Does your chemical contain a sequence of 4 to 20 fully fluorinated carbon atoms (including per- and poly-fluorinated alkyl substances, known as PFAS). Step 3: Introductions that are automatically categorised as reported https://www.industrialchemicals.gov. Step 4: Work out your introduction's risk to human au/help-and-guides/guide-B. Is your chemical a certain polyhalogenated organic chemical? categorising-your-chemical-C. Is your chemical a certain chemical at the nanoscale?. importation-and-manufacture



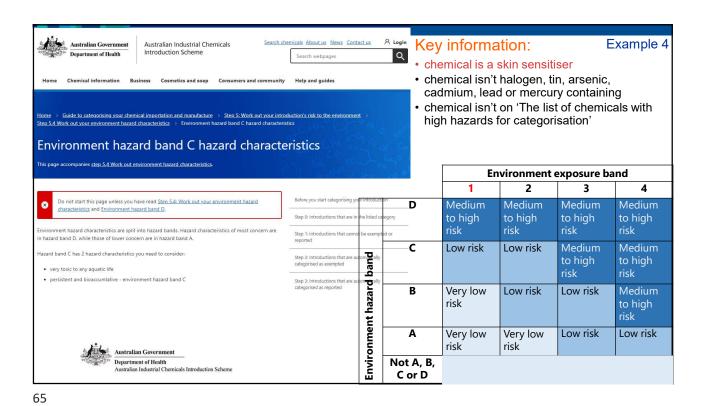
Search chemicals About us News Contact us Example 4 Department of Health Key information: Chemical information Business Cosmetics and soap Consumers and community Help and guides · chemical is a skin sensitiser · chemical isn't on 'The list of Home > Guide to categorising your chemical importation and manufacture > Step 4: Work out your introduction's risk to human health Step 4.4 Work out your human health hazard characteristics > Human health hazard band C hazard characteristics chemicals with high hazards for categorisation' Human health hazard band C hazard characteristics Human health exposure band Do not start this page unless you have read Step 4.4 Work out your human health hazard Step 0: Introductions that are in the listed category Human health hazard characteristics are split into hazard bands. Hazard characteristics of most concern a n hazard band C, while those of lower concern are in hazard band A. C Low risk Medium Medium Medium to high to high to high Hazard band C has 5 hazard characteristics you need to consider hazard В Very low Medium Very low Low risk reproductive toxicity Step 3: Introductions that are auto categorised as reported developmental toxicity to high adverse effects mediated by an endocrine mode of action Human health risk genetic toxicity Low risk Very low Very low Low risk risk risk Australian Government Very low Not A, Very low Very low Very low Department of Health Australian Industrial Chemicals Introduction Scheme B, or C







cals About us News Contact us Australian Government Example 4 Australian Industrial Chemicals **Key information:** Department of Health Introduction Scheme · chemical is a skin sensitiser · chemical isn't halogen, tin, arsenic, cadmium, lead or mercury containing chemical isn't on 'The list of chemicals with Home > Guide to categorising your chemical importation and manufacture > Step 5: Work out your introduction's risk to the environment Step 5.4 Work out your environment hazard characteristics > Environment hazard band D hazard characteristics high hazards for categorisation' Environment hazard band D hazard characteristics This page accompanies step 5.4 Work out environment hazard characteristics **Environment exposure band** 2 3 4 Do not start this page unless you have read Step 5.4: Work out your environment hazard Medium Medium Medium Medium Step 0: Introductions that are to high to high to high to high Environment hazard characteristics are split into hazard bands. Hazard characteristics of most cor in hazard band D, while those of lower concern are in hazard band A. C Low risk Low risk Medium Medium Hazard band D has 5 hazard characteristics you need to consider to high to high Contains arsenic, cadmium, lead or mercury risk risk Ozone depleting chemical Medium Very low Low risk Low risk Adverse effects mediated by an endocrine mode of action to high risk · Persistent, bioaccumulative and toxic Environment Very low Very low Low risk Low risk risk risk Australian Government Department of Health Australian Industrial Chemicals Introduction Scheme Not A, B, C or D



Example 4 Work out the introduction category They know... Chemical isn't*... Steps 2-4... Steps 5-6... · Inventory listed chemical is Steps 2-3: not Step 5 "Adhesive additive Rotterdam or automatically Environment: Stockholm exempted or Convention listed - exposure band 1 their supplier, reported Super Adhesives a UVCB or high MW - chemical doesn't • Step 4 Inc., knows the polymer have characteristics in Human health: chemical identity hazard band D or C halogen, tin, arsenic, - exposure band 2 cadmium, lead or ≤10 kg per year indicative mercury containing - chemical doesn't environment risk is imported as an have characteristics in on 'The list of very low additive in chemicals with high hazard band C specialist adhesive Step 6 hazards for - indicative human concentration **Exempted introduction** categorisation' health risk is very low 0.1%-1% a 'specified class of chemical is a skin introduction sensitiser *They hold a written undertaking from Super Adhesives Inc. https://www.industrialchemicals.gov.au/help-and-guides/guide-Australian Government categorising-your-chemical-importation-and-manufacture Department of Health Australian Industrial Chemicals Introduction Scheme

Example 4: Following categorisation...

Before they introduce:

 Make sure they can meet their record keeping obligations

https://www.industrialchemicals.gov.au/business/reporting-and-record-keeping-obligations/record-keeping-obligations-exempted-introductions

After they introduce:

- Keep records about the introduction
- Submit a once-off post-introduction declaration (PID) at the end of the registration year (by 30 November)

https://www.industrialchemicals.gov.au/business/reporting-and-record-keeping-obligations/exempted-introduction-declarations

 Indicate that they are introducing chemicals in the exempted category in their annual declaration

67

Example 4 - records kept

Written undertaking

- A written undertaking from Super Adhesives Inc.
 - Information to categorise their introduction
 - Confirmation that they will provide information (including CAS number/name) to us, if requested

https://www.industrialchemicals.gov.au/business/reporting-and-record-keeping-obligations/record-keeping-obligations-exempted-introductions/record-keeping-exempted-introductions-highest-indicative-risk-very-low



Other items

- Document containing categorisation steps/outcomes (including exposure band criteria)
- Product information sheets containing information on end use (and supporting that it's imported in liquid form)
- Shipping documents to support the introduction volume (and names of products imported)
- The SDS for the chemical, which indicates that it's a skin sensitiser

Post-introduction declaration (PID)

- The introducer (or an agent) must submit a post-introduction declaration (PID) for exempted introductions
- Submission is via our business portal
- The contents of the PID differs depending on the type of introduction
- Main type: 'highest indicative risk is very low risk'
 - Chemical identity information is required
 - Introduction volume ≤10 kg details of chemical identity holder



69

