Industrial Chemicals Categorisation Guidelines

FINAL

Australian Industrial Chemicals Introduction Scheme (AICIS)

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1 About these Guidelines

These Guidelines are designed to help an introducer to categorise an industrial chemical introduction for the purposes of the *Industrial Chemicals Act 2019* and must be used in conjunction with the *Industrial Chemicals (General) Rules 2019* (the IC General Rules).

Part 2 of these Guidelines provides the meanings for certain terms from sections 5 and 6 of the IC General Rules. The terms in this part are those that require technical detail and description for their definitions. For example, the methods to work out the environment categorisation volume and human health categorisation volume are described in this part.

Parts 3 and 4 of these Guidelines provide meanings for terms that appear in Chapter 2 of the IC General Rules. These terms relate to the categorisation of introductions of industrial chemicals.

Part 5 of these Guidelines provides meanings for terms that appear in Chapter 4 of the IC General Rules. These terms relate to record keeping obligations for introductions of industrial chemicals.

Part 6 of these Guidelines provides meanings for terms that appear in Schedule 1 of the IC General Rules. These include definitions of human health hazard characteristics and environment hazard characteristics used for determining indicative human health risk and indicative environment risk. This section also provides definitions of certain terms that are used within section 6 of these Guidelines, such as 'suitable read across information' and 'acceptable test guideline'.

Part 7 of these Guidelines provides meanings for terms that appear in Schedule 2 of the IC General Rules.

The appendices provide further detail for certain definitions or concepts in these Guidelines:

- List of chemicals with high hazards for categorisation
- In silico information
- Suitable read across information
- Acceptable test guidelines

2 Definitions of terms in Chapter 1, Part 1 of the IC General Rules

2.1 Section 5 of the IC General Rules

2.1.1 Chemical identity holder

Chemical identity holder, in relation to an industrial chemical, means a person who knows the chemical identity of the industrial chemical, including its proper name and Chemical Abstracts Service Registry Number (CAS number), if assigned.

Chemical identity holder, in relation to a flavour or fragrance blend introduction, means a person who knows the chemical identity of the industrial chemicals in the flavour or fragrance blend, including the proper names and Chemical Abstracts Service Registry Numbers (CAS numbers), if assigned.

2.1.2 Environment categorisation volume

You use the environment categorisation volume (ECV) to determine the environment exposure band for your introduction. There are two methods for working out the ECV. You can use either method, and you must keep records to demonstrate how you worked out your ECV.

Method 1

The ECV is equal to the total volume of the industrial chemical that you will introduce in a registration year. It is the total introduction volume across all end uses.

Method 2

Work out the ECV by multiplying the introduction volume (IV) by the default release reduction factor (RRF) relevant for the intended end use scenario (refer to Table 1). That is,

Environment categorisation volume (ECV) = introduction volume (IV) x release reduction factor (RRF)

Where the industrial chemical will have a *single end use scenario*, the introduction volume you should use to calculate the ECV is the total volume that you will introduce in a registration year. The release reduction factor you should use is the relevant release reduction factor for your end use scenario.

Where the industrial chemical will have *multiple end use scenarios*, there are two options to calculate the ECV:

- Option 1: The simplest approach is to allocate the total introduction volume to the end use scenario that has the highest release reduction factor, and use the equation above.
- Option 2: If you know the introduction volume to be allocated to each end use scenario, you can calculate a separate environment categorisation volume for each end use scenario (using the introduction volumes allocated to each end use scenario and the relevant release reduction factors for each end use scenario), and then add these together to get a total ECV, using the equation:
  $$ECV = (IV_1 \times RRF_1) + (IV_2 \times RRF_2) + \ldots + (IV_n \times RRF_n)$$

The release reduction factors you need to calculate your introduction's ECV for each end use scenario are set out in Table 1. The end use scenarios are defined below the table.

Table 1: The release reduction factor you need to work out ECV, depending on end use scenario

If your introduction's end use scenario is...	The release reduction factor (RRF) you need to use is...
Chemical imported into Australia; import containers remain closed; then exported for end use overseas	0
Chemical imported into Australia; limited handling of the chemical (such that import containers are opened); then exported for end use overseas	0.05
Chemical manufactured in Australia; exported for end use overseas	0.05
Adhesive and sealant products (end use in Australia)	0.05
Apparel and footwear care products (end use in Australia)	0.05
Arts, crafts and hobby products (end use in Australia)	0.05
Explosive products (end use in Australia)	0.05
Fuel, oil, fuel oil additives and related products (end use in Australia)	0.05
Lubricant and grease products (end use in Australia)	0.05
Personal care products - limited environmental release (end use in Australia)	0.05
Tattoo ink products (end use in Australia)	0.05

If your introduction's end use scenario is...	The release reduction factor (RRF) you need to use is...
Paint and coating products (end use in Australia)	0.05
Plastic and polymer products (end use in Australia)	0.05
Construction products not covered by other end uses (end use in Australia)	0.2
Fabric, textile and leather products not covered by other end uses (end use in Australia)	0.4
Electronic products (end use in Australia)	0.5
Ink, toner and colourant products (end use in Australia)	0.8
Air care products (end use in Australia)	1
Anti-freeze and de-icing products (end use in Australia)	1
Automotive care products (end use in Australia)	1
Cleaning and furniture care products (end use in Australia)	1
Laundry and dishwashing products (end use in Australia)	1
Extractive products not covered by other end uses (end use in Australia)	1
Paper products (end use in Australia)	1
Personal care products not covered by other end use (end use in Australia)	1
Photographic products (end use in Australia)	1
Water treatment products (end use in Australia)	1
Personal vaporiser products (end use in Australia)	1
Any other end use not covered above (end use in Australia)	1

Adhesive and sealant products means an end use to fasten other materials together or stop the passage of liquid or gas. Examples include:

- glues
- binders
- adhesives
- pastes
- sealants
- fillers
- putties
- solder and caulking compounds

Apparel and footwear care products means an end use to care for apparel and footwear products intended for consumer and commercial use. Examples include:

- footwear polishes
- waxes and stains to waterproof and improve appearance and other desirable properties
- apparel surface treatment products for water, stain or flame resistance

Arts, crafts and hobby products means an end use in arts, crafts or hobbies. Examples include:

- crafting paints
- crafting glue
- adhesives (e.g. solder and hot-melt adhesives)
- fixatives
- finishing spray coatings and modelling clay

Explosive products means an end use for producing a sudden expansion, usually accompanied by production of heat and large changes in pressure. Examples include:

- pyrotechnics
- high explosives and propellants
- igniters
- primers
- initiatory
- illuminants
- smoke and decoy flares
- incendiaries

Fuel, oil, fuel oil additives and related products means an end use as:

- liquid fuel in containers used for cooking, heating or for power in vehicles or appliances, or
- a fuel additive to inhibit corrosion, provide lubrication, increase efficiency of use, or decrease production of undesirable by-products.

Examples of liquid fuels include:

- gasoline
- diesel fuels
- kerosene
- lamp oils

Examples of fuel oil additives include:

- stabilisers
- anti-knock agents
- corrosion inhibitors
- detergents
- fuel dyes
- oxygenates
- antioxidants
- odour agents

Lubricant and grease products means an end use in a liquid, paste or spray to reduce friction, heat generation and wear between solid surfaces. Examples include:

- engine oils
- transmission, brake and hydraulic fluids
- gear oils
- calcium, sodium, lithium, and silicone-based greases

Personal care products – limited environmental release means an end use in solid or hardening personal care products (including cosmetics) that are primarily disposed of to landfill. Examples include:

- baby wipes
- facial tissues
- nail care products including nail polish and remover

Tattoo ink products means an end use in a combination of industrial chemicals that contains one or more colouring agents and is applied to the dermal layer of the skin for the purposes of colouring the skin. Examples include:

- pigments
- dyes
- resins

Paint and coating products means an end use to paint or coat substrates intended for consumer or commercial use. Examples include:

- decorative coatings
- automotive coatings
- transportation coatings
- wood finishes
- powder coatings
- coil coatings

- packaging finishes
- general industrial coatings
- automotive refinish
- industrial maintenance and protective coatings
- marine coatings
- thinners
- removers

Plastic and polymer products means an end use in production of plastics or polymers. Examples include:

- monomers
- initiators
- additives

Construction products not covered by other end uses means an end use in construction materials, except where another scenario covers the end use. Examples include:

- additives in cements and dry mortar
- additives to bitumen for road repair
- internal release agents for thermo-set laminating resins
- resins in particle board manufacture
- wood substitutes used to make mouldings
- resins used in the production of composite materials

Fabric, textile and leather products not covered by other end uses means an end use to impart colour and other desirable properties onto fabric, textiles, and leather products that are intended for consumer or commercial use. These properties include:

- water/soil/stain repellence
- wrinkle resistance
- flame resistance

Examples of this type of product include:

- textile dyes
- textile finishing agents
- leather tanning products
- leather dyes
- leather finishing agents, leather conditioner and surface treatment products

Electronic products means an end use in the production of electronic components. Examples include:

- chemicals in vapour deposition
- electroless plating
- electroplating
- etching
- high vacuum evaporation/sputtering

- laminate processing
- soldering
- photolithography

Ink, toner and colourant products means an end use for:

- writing
- printing
- creating an image on paper and other substrates
- applying to substrates to change their colour or hide images

Examples of this type of product include:

- pigmented liquid
- toners or powders used in copy machines and toner/printer cartridges
- inks used in writing equipment
- inks for stamps and correction fluids and tapes

This category does **not** include pigments and colourants added to paints and coatings.

Air care products means an end use to odorise or deodorise indoor air in homes, offices, motor vehicles, and enclosed spaces and intended for consumer or commercial use. Examples include:

- aerosol sprays
- liquid/solid/gel diffusers
- air fresheners
- scented candles
- incense

Anti-freeze and de-icing products means an end use:

- as an additive to fluids, especially water, to reduce the freezing point of the mixture, or
- applied to surfaces to melt or prevent build-up of ice

Examples of this type of product include:

- anti-freeze liquids
- de-icing liquids (windshield de-icers, aircraft de-icers)
- de-icing solids (ice melting crystals)
- lock de-icers

Automotive care products means an end use (intended for consumer or commercial use) to clean and care for exterior and interior surfaces of automotive vehicles. Examples include:

- car waxes
- polishes
- waterproofing products for windshield or automotive window glass
- cleaners

- sealers
- car wash solutions
- vinyl/rubber/plastic protectants
- automotive carpet and upholstery cleaners
- wheel and tyre care products
- exterior trim protectants
- touch-up paint products

Cleaning and furniture care products means an end use (intended for consumer or commercial use) to:

- remove dirt, grease, stains, and foreign matter from furniture and furnishings
- cleanse, sanitise, bleach, scour, polish, protect, or improve the appearance of surfaces

Examples include:

- cleaners used on glass, floors, tub and tile, ovens and drains
- scouring powders
- dusting products
- waxes
- polishes
- stain repellent sprays

Laundry and dishwashing products means an end use in liquid, granular, gel or unit dose packets/tablets to:

- remove food residue from dishes
- remove dirt from textiles
- enhance properties of textiles
- remove stains from textiles

Examples include:

- dishwashing detergents and laundry detergents
- stain removers and fabric enhancers
- bleach
- rinse aids
- lime and rust removers
- dry cleaning products used in non-aqueous cleaning processes

Extractive products not covered by other end uses means an end use in:

- mining
- onshore drilling
- related activities such as extraction, cementing, hydraulic fracturing, refining

These scenarios do **not** include end use in offshore drilling. This end use is a *designated kind of release into the environment* (for which you do **not** calculate an ECV).

Paper products means an end use in paper production. Examples include:

- effluent treatment chemicals
- maintenance chemicals
- deposit and cleaning agents
- defoamers
- surfactants
- polymeric retention aids
- coagulants
- clay
- resins

Personal care products not covered by other end uses means an end use for cosmetic use, except those covered under the "personal care products - limited environmental release end use" scenario. Examples include:

- bath and shower products
- make-up products
- hair, oral and skin care products
- secondary sunscreen products
- deodorants
- perfumes

Photographic products means an end use (for consumer or commercial use) to take photographic images, develop and process film, and make photographic prints. Examples include:

- processing solutions (for developing, stopping, and fixing photos)
- chemicals used in the manufacture or processing of film or photographic paper

Water treatment products means an end use to treat water in cooling and heating systems (including industrial heat-exchanger systems) and potable water supplies. Examples include:

- chemicals used in pH buffers
- scale and corrosion inhibitors
- flocculating agents
- ion exchange resins

This scenario does not include end uses to treat municipal water supplies or other large-scale water supplies for human or animal consumptions or irrigation. These end uses involve a *designated kind of release into the environment* in accordance with the IC General Rules (for which you do **not** calculate an environment categorisation volume).

Personal vaporiser products means an end use in a device that is intended to produce a vapour or aerosol that is delivered into a person's body when the person inhales through the device. Examples include:

- e-cigarettes
- e-cigars

- e-hookah pens
- e-pens
- e-pipes
- vape pens

2.1.3 Human health categorisation volume

You use the human health categorisation volume (HHCV) to determine the human health exposure band for your introduction. There are two methods for working out the HHCV. You can use either method, and you must keep records to demonstrate how you worked out your HHCV.

Method 1

The HHCV is equal to the total volume of the industrial chemical that you will introduce in a registration year. It is the total introduction volume across all end uses.

Method 2

Work out the HHCV by multiplying the introduction volume (IV) by the default exposure reduction factor (ERF) relevant for the intended end use scenario (refer to Table 2). That is,

Human health categorisation volume (HHCV) = total introduction volume (IV) x exposure reduction factor (ERF)

Where the industrial chemical will have a *single end use scenario*, the introduction volume you should use to calculate the HHCV is the total volume of the industrial chemical that you will introduce in a registration year. The exposure reduction factor that you should use is the relevant exposure reduction factor for your end use scenario.

Where the industrial chemical will have *multiple end use scenarios*, there are two options to calculate the human health categorisation volume:

- Option 1: The simplest approach is to allocate the total introduction volume to the end use scenario that has the highest exposure reduction factor, and use the equation above.
- Option 2: If you know the introduction volume to be allocated to each end use scenario, you can calculate a separate human health categorisation volume for each end use scenario (using the introduction volumes allocated to each end use scenario and the relevant exposure reduction factors for each end use scenario), and then add these together to get a total HHCV, using the equation:
  $$\boldsymbol{HHCV = (IV_1 \times ERF_1) + (IV_2 \times ERF_2) + \ldots + (IV_n \times ERF_n)}$$

The exposure reduction factors you need to calculate your introduction's HHCV are set out in Table 2. The end use scenarios are defined below the table.

Table 2: The exposure reduction factor you need to work out HHCV, depending on end use scenario

If your introduction's end use scenario is...	The exposure reduction factor (ERF) you need to use is...
Chemical imported into Australia; import containers remain closed; then exported for end use overseas	0
Chemical imported into Australia; limited handling of the chemical (such that import containers are opened); then exported for end use overseas	0.05
Chemical manufactured in Australia; exported for end use overseas	0.05
Specified consumer products with end use in Australia	1
All other end uses in Australia	0.1

End use scenario definitions used in the above table:

Specified consumer products means the following products intended for end use by the public:

- cosmetics
- nasal sprays
- ear sprays
- intimate lubricants
- massage oils and gels
- products applied to the nails to harden, or deter the biting of, nails

Specified consumer products do **not** include tattoo inks and personal vaporisers. Tattoo inks and personal vaporiser end uses involve *designated kind of human exposure* in accordance with the IC General Rules (for which you do **not** need to calculate a human health categorisation volume).

2.1.4 Known environmental degradation products

Known environmental degradation products, in relation to an industrial chemical that is a polyhalogenated organic chemical, means the expected breakdown products of the chemical under environmentally relevant conditions that have been identified in information from scientific literature or studies, and the introducer is aware of this information.

2.1.5 Known hazard classification

Known hazard classification**,** for an industrial chemical, means hazard information that the introducer is aware of in the form of one or more of the following:

- A hazard class and category arising from classification under the 'Globally Harmonised System of Classification and Labelling of Chemicals' (GHS), Seventh revised edition, published by the United Nations, or
- A non-GHS hazard statement, assigned under the classification criteria in 'Guidance on the Classification of Hazardous Chemicals under the WHS Regulations' published by Safe Work Australia

except that it does **not** include any of the following hazard classes:

- flammable gases, category 2
- acute toxicity-oral, category 5
- acute toxicity-dermal, category 5
- acute toxicity-inhalation, category 5
- skin corrosion/irritation, category 3
- aspiration hazard, category 2

2.1.6 Persistent

Persistent means that any of the following apply to the industrial chemical:

- it has a degradation half-life ($T_{½}$) in air of $\geqslant$ 2 days, or
- it has a degradation half-life ($T_{½}$) in water of $\geqslant$ 2 months, or
- it has a degradation half-life ($T_{½}$) in soil of $\geqslant$ 6 months, or
- it has a degradation half-life ($T_{½}$) in sediment of $\geqslant$ 6 months.

To demonstrate that this definition does not apply to a polyhalogenated organic chemical, or its known environmental degradation products (for the purposes of table item 2, section 28 and table item 2, section 29 of the IC General Rules) the information required is at least one of the following:

- A study conducted on the industrial chemical following OECD test guideline 301 resulting in one of the following:
    - the pass levels being reached within the specified time period such that the industrial chemical is considered to be readily biodegradable, or
    - the pass levels being reached within the duration of the test, but not within the specified time period for the industrial chemical to be considered readily biodegradable, provided biodegradation has started within the specified time period, or
- A study conducted on the industrial chemical following OECD test guideline 308 resulting in both:
    - a degradation half-life in water of < 2 months, and
    - a degradation half-life in sediment of < 6 months.

2.2 Section 6 of the IC General Rules

2.2.1 International parallel process

For the purposes of table items 8 and 9 of subsection 6(3) of the IC General Rules, an **international parallel process** means a multilateral notification arrangement that has been undertaken in accordance with the 'Standard Operating Procedures (SOP) For The OECD Clearing House On New Chemicals Parallel Process' (ENV/JM/MONO(2012)26)[1]

3 Definition of terms in Chapter 2, Part 2 of the IC General Rules

3.1 High molecular weight polymer that has lung overloading potential

For the purposes of subsection 26(6) of the IC General Rules:

High molecular weight polymer that has lung overloading potential means that all of the following apply to the industrial chemical:

- it is a polymer, and
- it has a number average molecular weight that is >70,000 g/mol, and
- it has a solubility in water of < 0.1 mg/L, and
- it becomes aerosolised during end use.

4 Definition of terms in Chapter 2, Part 3 of the IC General Rules

4.1 Section 28 of the IC General Rules

4.1.1 Not soluble

For the purposes of table item 3(b) of section 28 of the IC General Rules, not soluble means at least one of the following applies:

[1] Published on the OECD website page http://www.oecd.org/chemicalsafety/risk-assessment/proceduresfornotificationofnewchemicals.htm

- the solubility of the chemical in water is <33.3 g/L, measured following an acceptable test guideline for water solubility, or
- the dissolution rate of the chemical is ≤ 70%.

4.1.2 The risks to human health from the introduction and use of the industrial chemical are no higher in Australia than in the overseas jurisdiction

For the purposes of table item 6(c) of section 28 of the IC General Rules:

To work out if the risks to human health from the introduction and use of the industrial chemical are no higher in Australia than in the overseas jurisdiction, all of the following must be considered:

- the mode of introduction of the chemical (import or manufacture) into Australia compared to the mode of introduction of the chemical into the overseas jurisdiction, and
- the concentration of the chemical when introduced into Australia compared to the concentration when introduced into the overseas jurisdiction, and
- the use of the chemical in Australia compared to the use of the chemical in the overseas jurisdiction - note that 'use' is broader than 'end use' (refer to the IC Act for definitions of these terms), and
- the concentration(s) of the chemical when used in Australia compared to the concentration(s) when used in the overseas jurisdiction - note that 'use' is broader than 'end use' so the concentration(s) during use may be different to the concentration during end use, and
- the route of any expected human exposure to the chemical during introduction and use (including end use) in Australia compared to the route of any expected human exposure in the overseas jurisdiction during introduction and use (including end use).

If any of these comparisons indicate a difference between Australia and the overseas jurisdiction, it must be considered whether this increases the risk to human health in Australia.

4.2 Section 29 of the IC General Rules

4.2.1 Not soluble

For the purposes of table item 3(b) of section 29 of the IC General Rules, not soluble means at least one of the following applies:

- the solubility of the chemical in water is <33.3 g/L, measured following an acceptable test guideline for water solubility, or
- the dissolution rate of the chemical is ≤ 70%.

4.2.2 The risks to the environment from the introduction and use of the industrial chemical are no higher in Australia than in the overseas jurisdiction

For the purposes of table item 9(c) of section 29 of the IC General Rules:

To work out if the risks to the environment from the introduction and use of the industrial chemical are no higher in Australia than in the overseas jurisdiction, all of the following must be considered:

- the mode of introduction of the chemical (import or manufacture) into Australia compared to the mode of introduction of the chemical into the overseas jurisdiction, and
- the use of the chemical in Australia compared to the use of the chemical in the overseas jurisdiction - note that 'use' is broader than 'end use' and includes release into the environment (such as waste disposal), and
- the environment risk assessment assumptions used by the international assessment body compared to the environment risk assessment assumptions that would be used in Australia.

If any of these comparisons indicate a difference between Australia and the overseas jurisdiction, it must be considered whether this increases the risk to the environment in Australia (for example, if the risk quotient (RQ) value would be higher in Australia).

The environment risk assessment assumptions that must be considered include:

- PBT (persistence, bioaccumulation and toxicity) criteria
- factors used to estimate environmental exposure
- size of the population
- dilution factors during disposal
- efficiency of sewage treatment plant (STP) removal.

5 Definitions of terms in Chapter 4, Part 4 of the IC General Rules

5.1 The potential for the industrial chemical to migrate to food

For the purposes of table item 4 of subsection 51(4), table item 4 of subsection 54(4), and table item 5 of subsection 57(3) of the IC General Rules:

The potential for the industrial chemical to migrate to food, in relation to the introduction of an industrial chemical that has an end use in an article with food contact, means quantitative information on the extent of the chemical's transfer from the article to food. This is **not** required if any of the following apply to the industrial chemical:

- it has an estimated dietary exposure value less than the threshold of toxicological concern (TTC) for the industrial chemical based on its structural class categorisation according to Cramer[2]

or

- its end use, concentration at the end use, and dietary concentration associated with the end use, as applicable, are consistent with one or more of the following:
    - the listing of the industrial chemical under Annexes I or II to Regulation (EC) No 10/2011 or Annex I to Regulation (EC) No 1935/2004 and any applicable restrictions, or
    - an adopted opinion on the industrial chemical by the European Food Safety Authority that is in favour of authorising the evaluated substance, or
    - use of the industrial chemical authorised under the United States Food and Drug Administration (US FDA) regulations, 21 CFR.170-199

or

- it is a permitted flavouring substance as defined by Standard 1.1.2 of the Food Standards Australia New Zealand Act 1991, with the dietary concentration associated with the end use of the industrial chemical in an article with food contact less than that associated with end use as a flavouring substance

or

- the extent of its migration was below the level of detection in a migration study conducted under conditions that simulated:
    - the food types that will be contacted at end use, and
    - the food contact conditions that are relevant for the end use

or

- the No Observed Adverse Effect Level (NOAEL) in an in vivo study on the industrial chemical or from suitable read-across information conducted following The Organisation for Economic Co-operation and Development (OECD) test guidelines was:
    - for OECD test guideline 407 ≥1000 mg/kg bw/day
    - for OECD test guideline 408 or 409 ≥300 mg/kg bw/day

5.2 The potential for the industrial chemical to be released into the mouth during end use or mouthing

For the purposes of table item 5 of subsection 51(4), table item 5 of subsection 54(4), and table item 6 of subsection 57(3) of the IC General Rules:

[2] EFSA (European Food Safety Authority), Guidance on the use of the Threshold of Toxicological Concern approach in food safety assessment, EFSA Journal 2019;17(6):5708

The potential for the industrial chemical to be released into the mouth during end use or mouthing, in relation to the introduction of an industrial chemical that has an end use in an article that is a children's toy or a children's care product, means quantitative information on the extent of the chemical's transfer from the article to the mouth.

5.3 Toxicokinetics information

For the purposes of table item 3 of subsection 54(4) and table item 4 of subsection 57(3) of the IC General Rules:

Toxicokinetics information, in relation to an industrial chemical that is a UV filter, means information (the full study report or the outcomes of the study and a written undertaking that the full study report will be provided to the Executive Director if requested) for both of the following:

- the bioavailability of the chemical by the dermal route, which may be determined using any of the following:
    - an in vitro study on the chemical conducted following OECD test guideline 428 (to predict skin absorption), or
    - an in vivo study on the chemical or suitable read-across information conducted following OECD test guideline 417, or
    - an in vivo study on the chemical or suitable read-across information conducted following OECD test guideline 427 (to predict skin absorption), or
    - an in vivo study on the chemical or suitable read-across information that tests for specific target organ toxicity following repeated dermal exposure in which toxicokinetic parameters are also measured

and

- any available information on the toxicokinetics of the chemical, which may include information on:
    - the absorption of the chemical into the body
    - the distribution of the chemical within the body
    - the metabolism of the chemical within the body
    - the excretion of the chemical from the body.

5.4 Photostability information

For the purposes of table item 3 of subsection 54(4) and table item 4 of subsection 57(3) of the IC General Rules:

Photostability information, in relation to an industrial chemical that is a UV filter, means information on the chemical to demonstrate its stability in light, including the degree to which it degrades after exposure to UV light.

6 Definitions of terms and concepts relating to Schedule 1 to the IC General Rules

6.1 Definitions of additional terms used within this Part of the Guidelines

GHS means the 'Globally Harmonized System of Classification and Labelling of Chemicals' (GHS), Seventh revised edition

List of chemicals with high hazards for categorisation means a list of chemicals that have hazard characteristics in human health hazard band C or environment hazard bands D or C based on at least one of the information sources shown in Appendix 8.1 of these Guidelines. This list is published on the AICIS website. It is used as a screening tool for categorisation.

Suitable in silico prediction means a prediction of the hazard characteristics of an industrial chemical using a computational approach (either a quantitative prediction or a prediction indicating the absence or presence of alerting groups) for which all of the following apply:

- the prediction is for the industrial chemical itself
- the in silico model used for the prediction is listed in Appendix 8.2 of these Guidelines as acceptable for the hazard characteristic
- the industrial chemical is within the chemical space for which the in silico model gives reliable predictions (the applicability domain) - the model applicability could be in relation to any of:
    - (sub)structures present in the training set
    - a range of molecular descriptors
    - metabolites/degradation products
    - mechanisms of action
- the guidelines, instructions and parameters for the in silico model have been followed in order to get the prediction
- the industrial chemical is not any of the following types of chemicals:
    - UVCB substance
    - polymer
    - surfactant
    - inorganic chemical
    - organometallic chemical
    - a chemical that is:
        - a solid or in a dispersion, and
        - consists of particles in an unbound state or as an aggregate or agglomerate, at least 50% (by number size distribution) of which have at least one external dimension in the nanoscale, and
        - is not soluble

Read across approach means an approach to predict the hazard characteristics of a chemical (target chemical) and fill information gaps by using information from one or more other chemicals (source chemicals). There are two read-across techniques:

- Analogue approach – a single chemical is used as the source chemical (this single chemical is then known as the 'analogue chemical')
- Category approach – a group of chemicals are used as the source chemicals.

Suitable read across information means that the read across approach is acceptable to fill an information gap for a hazard characteristic because all of the aspects outlined in Appendix 8.3 of these Guidelines have been considered, justified and documented.

Acceptable test guideline means a test guideline set out in Appendix 8.4 of these Guidelines for the hazard characteristic.

6.2 Use of animal test data for demonstrating the absence of hazard characteristics

Part 6 of these Guidelines sets out the information needed to demonstrate the absence of each hazard characteristic, for the purpose of section 30 of the IC General Rules.

For many hazard characteristics, there are options for the type of information that can be used, including both animal test data and non-animal test data.

The first step should be considering all existing information that is available to an introducer to determine whether it meets the requirements set out in Part 6 of these Guidelines. If it does not meet the requirements in this Part, information may need to be generated to demonstrate the absence of a hazard characteristic.

If new data needs to be generated, the options for non-animal test data should be considered first. The generation of new animal test data should be considered as a last resort.

6.3 Carcinogenicity – Human health hazard band C

6.3.1 Clause 2 of Part 1, Schedule 1 to the IC General Rules

For the purposes of table item 1 of Clause 2, Part 1, Schedule 1 to the IC General Rules:

Carcinogenicity means that any of the following apply to the industrial chemical:

- the chemical is a known, presumed or suspected human carcinogen, as described in chapter 3.6 of the GHS, with the chemical classified as carcinogenicity (category 1 or 2), or
- the chemical (or the chemical of which it is an ester or salt) is on the **list of chemicals with high hazards for categorisation** based on its carcinogenicity, or
- an in vivo study on the chemical conducted following an acceptable test guideline for carcinogenicity, chronic toxicity, subchronic oral toxicity, subchronic dermal toxicity or

subchronic inhalation toxicity results in the induction of cancer, or an increase in the incidence of cancer.

6.3.2 Section 30 of the IC General Rules - Information required to demonstrate the absence of hazard characteristics

For the purposes of paragraph 30(2)(b) and subparagraph 30(2)(c)(iv) of the IC General Rules, the information required to demonstrate that a chemical does not have the hazard characteristic, **carcinogenicity**, is confirmation that the chemical (or the chemical of which it is an ester or salt) is not on the **list of chemicals with high hazards for categorisation**, based on its carcinogenicity.

In addition, if the human health exposure band for the introduction is 4 and the chemical is a UV filter, information is required to justify why the chemical would not cause carcinogenicity mediated by exposure to UV light. This may include one or more of the following:

- the chemical has a molar extinction/absorption coefficient of less than 1,000$Lmol^{-1}cm^{-1}$ at wavelengths between 290 and 700nm (based on the results of a study following OECD test guideline 101), or
- results from in vitro phototoxicity studies, or
- results from in vivo carcinogenicity studies where the methods have been modified to include photoactivation.

6.4 Reproductive toxicity – Human health hazard band C

6.4.1 Clause 2 of Part 1, Schedule 1 to the IC General Rules

For the purposes of table item 2 of Clause 2, Part 1, Schedule 1 to the IC General Rules:

Reproductive toxicity means that any of the following apply to the industrial chemical:

- the chemical is known, presumed or suspected to produce adverse effects on sexual function and fertility, as described in chapter 3.7 of the GHS, with the chemical classified as toxic to reproduction (category 1 or 2), or
- the chemical (or the chemical of which it is an ester or salt) is on the **list of chemicals with high hazards for categorisation** based on its reproductive toxicity, or
- an in vivo study on the chemical conducted following an acceptable test guideline for reproductive toxicity, carcinogenicity, chronic toxicity, subchronic oral toxicity, subchronic dermal toxicity or subchronic inhalation toxicity results in adverse effects on sexual function and fertility, as described in chapter 3.7 of the GHS.

6.4.2 Section 30 of the IC General Rules - Information required to demonstrate the absence of hazard characteristics

For the purposes of paragraph 30(2)(b) and subparagraph 30(2)(c)(iv) of the IC General Rules, the information required to demonstrate that a chemical does not have the hazard characteristic, **reproductive toxicity**, is:

- if the chemical is a polyhalogenated organic chemical and the human health exposure band for the introduction is 4 -
    - an in vivo test result on the chemical or suitable read across information conducted following an acceptable test guideline for reproductive toxicity, which results in none of the adverse effects on sexual function or fertility described in chapter 3.7 of the GHS;
- otherwise –
    - confirmation that the chemical (or the chemical of which it is an ester or salt) is not on the **list of chemicals with high hazards for categorisation**, based on its reproductive toxicity.

6.5 Developmental toxicity – Human health hazard band C

6.5.1 Clause 2 of Part 1, Schedule 1 to the IC General Rules

For the purposes of table item 3 of Clause 2, Part 1, Schedule 1 to the IC General Rules:

Developmental toxicity means that any of the following apply to the industrial chemical:

- the chemical is known, presumed or suspected to produce adverse effects on the development of the offspring or effects on the offspring via lactation, as described in chapter 3.7 of the GHS, with the chemical classified as follows:
    - toxic to reproduction (category 1 or 2), or
    - effects on or via lactation, or
- the chemical (or the chemical of which it is an ester or salt) is on the **list of chemicals with high hazards for categorisation** based on its developmental toxicity, or
- an in vivo study on the chemical conducted following an acceptable test guideline for developmental toxicity or reproductive toxicity results in adverse effects on the development of the offspring or effects on the offspring via lactation, as described in chapter 3.7 of the GHS.

6.5.2 Section 30 of the IC General Rules - Information required to demonstrate the absence of hazard characteristics

For the purposes of paragraph 30(2)(b) and subparagraph 30(2)(c)(iv) of the IC General Rules, the information required to demonstrate that a chemical does not have the hazard characteristic, **developmental toxicity**, is:

- if the chemical is a polyhalogenated organic chemical and the human health exposure band for the introduction is 4 –

- an in vivo test result on the chemical or suitable read across information conducted following an acceptable test guideline for developmental toxicity or reproductive toxicity which results in none of the adverse effects on the development of the offspring or effects on the offspring via lactation, as described in chapter 3.7 of the GHS;

- otherwise –
  - confirmation that the chemical (or the chemical of which it is an ester or salt) is not on the **list of chemicals with high hazards for categorisation**, based on its developmental toxicity.

6.6 Adverse effects mediated by an endocrine mode of action – Human health hazard band C

6.6.1 Clause 2 of Part 1, Schedule 1 to the IC General Rules

For the purposes of table item 4 of Clause 2, Part 1, Schedule 1 to the IC General Rules:

Adverse effects mediated by an endocrine mode of action means that any of the following apply to the industrial chemical:

- the chemical meets all of the following:
  - it shows an adverse effect in an intact organism or its progeny, which is a change in the morphology, physiology, growth, development, reproduction or lifespan of an organism, system or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in the susceptibility to other influences, and
  - it has an endocrine activity, which is the capacity to alter the function(s) of the endocrine system, and
  - the adverse effect is a consequence of the endocrine activity

  or
- the chemical (or the chemical of which it is an ester or salt) is on the **list of chemicals with high hazards for categorisation**, based on its adverse effects mediated by an endocrine mode of action

  or
- the chemical meets all of the following:
  - information is available that is relevant to determining whether the chemical has the hazard characteristic, **adverse effects mediated by an endocrine mode of action**, and
  - the information has been considered in a weight of evidence analysis based on the following guidance documents:

        - the EU guidance for identifying endocrine disruptors[3], and
        - the guidance provided in OECD GD 150[4]; and
    - the weight of evidence analysis concludes that the chemical has the hazard characteristic, adverse effects mediated by an endocrine mode of action.

6.6.2 Section 30 of the IC General Rules - Information required to demonstrate the absence of hazard characteristics

For the purposes of paragraph 30(2)(b) and subparagraph 30(2)(c)(iv) of the IC General Rules:

- if the chemical has existing information relevant to determining whether it has the hazard characteristic, **adverse effects mediated by an endocrine mode of action**, information is required to demonstrate that the chemical does not have this hazard characteristic:
    - This must involve a documented weight of evidence analysis based on the EU guidance for identifying endocrine disruptors[2] and the guidance in OECD GD 150[3], and
    - The analysis must conclude that the chemical does not have the hazard characteristic, adverse effects mediated by an endocrine mode of action.
- Otherwise, the information required to demonstrate that a chemical does not have the hazard characteristic, adverse effects mediated by an endocrine mode of action, is confirmation that the chemical (or the chemical of which it is an ester or salt) is not on the **list of chemicals with high hazards for categorisation**, based on its adverse effects mediated by an endocrine mode of action.

6.7 Genetic toxicity – Human health hazard band C

6.7.1 Clause 2 of Part 1, Schedule 1 to the IC General Rules

For the purposes of table item 5 of Clause 2, Part 1, Schedule 1 to the IC General Rules:

Genetic toxicity means that any of the following apply to the industrial chemical:

- the chemical is known to induce or may induce mutations in the germ cells of humans, as described in chapter 3.5 of the GHS, with the chemical classified as germ cell mutagenicity (category 1 or 2), or
- the chemical (or the chemical of which it is an ester or salt) is on the **list of chemicals with high hazards for categorisation**, based on its genetic toxicity, or

[3] Guidance for the identification of endocrine disruptors in the context of 39 Regulations (EU) No 528/2012 and (EC) No 1107/2009, currently a 2017 consultation draft. Accessed here.
[4] ENV/JM/MONO(2012)22, OECD Series on Testing and Assessment, No. 150 - Guidance document on standardised test guidelines for evaluating chemicals for endocrine disruption. Accessed here.

- an in vitro study on the chemical:
    - conducted following an acceptable test guideline for gene mutation or chromosomal abnormalities results in the prediction of mutagenic or genotoxic effects, as described in chapter 3.5 of the GHS, and
    - the results of the study have not been negated by in vivo studies conducted on the chemical for gene mutation, chromosomal abnormalities or heritable germ cell mutagenicity, or
- an in vivo study on the chemical conducted following an acceptable test guideline for gene mutation, chromosomal abnormalities or heritable germ cell mutagenicity results in mutagenic or genotoxic effects, as described by chapter 3.5 of the GHS.

6.7.2 Section 30 of the IC General Rules - Information required to demonstrate the absence of hazard characteristics

For the purposes of paragraph 30(2)(b) and subparagraph 30(2)(c)(iv) of the IC General Rules, the information required to demonstrate that a chemical does not have the hazard characteristic, **genetic toxicity**, is:

- if the human health exposure band for the introduction is 4 - at least one of the following:
    - information to demonstrate that the chemical is included on the Select Committee on GRAS Substances (SCOGS) Database as a Type 1 conclusion, and that the human health exposure expected from the industrial use of the chemical is no higher than the human health exposure expected from food use, or
    - information to demonstrate that the chemical has been notified to the US FDA GRAS notification program and FDA had no questions about the notifier's conclusion of GRAS status, and that the human health exposure expected from the industrial use of the chemical is no higher than the human health exposure expected from food use, or
    - information that demonstrates that the chemical is a substance covered by Entry 9 of Annex V of the REACH Regulation, or
    - information to demonstrate that the chemical is a high molecular weight polymer, and if you are seeking to demonstrate that the introduction meets the criteria for very low risk (table item 14, section 28 of the IC General Rules) - test results from an in vitro study on the polymer or from suitable read across information conducted following an acceptable test guideline for gene mutation, which demonstrates the absence of mutagenic effects, or
    - test results that demonstrate the absence of mutagenic or genotoxic effects from both:
        - a study on the chemical or from suitable read across information conducted following an acceptable test guideline for gene mutation, and
        - a study on the chemical or from suitable read across information conducted following an acceptable test guideline for chromosomal abnormalities.

- if the human health exposure band for the introduction is 3, and you are seeking to demonstrate that the introduction meets the criteria for very low risk (table item 14, section 28 of the IC General Rules) - at least one of the following:
    - inclusion of the chemical in the Select Committee on GRAS Substances (SCOGS) Database as a Type 1 conclusion, as long as the human health exposure expected from the industrial use of the chemical is no higher than the human health exposure expected from food use, or
    - the chemical has been notified to the US FDA GRAS notification program and FDA had no questions about the notifier's conclusion of GRAS status, as long as the human health exposure expected from the industrial use of the chemical is no higher than the human health exposure expected from food use, or
    - information that demonstrates that the chemical is a substance covered by Entry 9 of Annex V of the REACH Regulation, or
    - if the polymer is a high molecular weight polymer, test results from an in vitro study on the polymer or from suitable read across information conducted following an acceptable test guideline for gene mutations, which demonstrates the absence of mutagenic effects, or
    - information that demonstrates the absence of mutagenic or genotoxic effects from both:
        - information on the chemical or from suitable read across information that addresses gene mutations - this could be:
            - a suitable in silico prediction, both with and without metabolic activation, or
            - test results from a study conducted following an acceptable test guideline for gene mutations; and
        - test results from a study on the chemical or from suitable read across information conducted following an acceptable test guideline for chromosomal abnormalities.
- otherwise, the information required to demonstrate that a chemical does not have the hazard characteristic, genetic toxicity, is confirmation that the chemical (or the chemical of which it is an ester or salt) is not on the **list of chemicals with high hazards for categorisation**, based on its genetic toxicity.
- in addition, if the human health exposure band for the introduction is 4 and the chemical is a UV filter, information is required to justify why the chemical would not cause genetic toxicity mediated by UV light. This may include one or more of the following:
    - the chemical has a molar extinction coefficient/absorption coefficient of less than 1,000Lmol^{-1}cm^{-1} at wavelengths between 290 and 700nm (based on the results of a study following OECD test guideline 101), or
    - results from in vitro phototoxicity studies, or
    - results from in vitro or in vivo genetic toxicity studies where the methods have been modified to include photoactivation.

6.8 High molecular weight polymer that is water absorbing – Human health hazard band B

6.8.1 Clause 2 of Part 1, Schedule 1 to the IC General Rules

For the purposes of table item 6 of Clause 2, Part 1, Schedule 1 to the IC General Rules:

High molecular weight polymer that is water absorbing means that all of the following apply to the industrial chemical:

- it is a high molecular weight polymer, and
- it has a number average molecular weight that is ≥10,000 g/mol, and
- it is capable of absorbing its own weight, or more, in water, and
- it contains particles with a particle size <10 micrometres (microns).

6.8.2 Section 30 of the IC General Rules - Information required to demonstrate the absence of hazard characteristics

For the purposes of subparagraph 30(2)(c)(iv) of the IC General Rules:

If the chemical is a high molecular weight polymer, the information required to demonstrate that it does not have the hazard characteristic, **high molecular weight polymer that is water absorbing**, is at least one of:

- molecular weight information that demonstrates the number average molecular weight (NAMW) is <10,000 g/mol, or
- information that demonstrates that the polymer is not introduced in a particulate form, or
- particle size information that demonstrates that the particle size is ≥ 10 micrometres (microns), or
- information that demonstrates that the polymer does not absorb its own weight or more in water, such as experiments that show that it does not form a gel in water, or that if it does, the gel dissolves upon addition of more water.

6.9 Respiratory sensitisation – Human health hazard band B

6.9.1 Clause 2 of Part 1, Schedule 1 to the IC General Rules

For the purposes of table item 7 of Clause 2, Part 1, Schedule 1 to the IC General Rules:

Respiratory sensitisation means that any of the following apply to the industrial chemical:

- the chemical is known or presumed to produce hypersensitivity of the airways in humans, as described in chapter 3.4 of the GHS, with the chemical classified as respiratory sensitisation (category 1), or
- the chemical is named:

    - on the EU SVHC Candidate list for authorisation, based on respiratory sensitising properties (https://echa.europa.eu/candidate-list-table), or
    - in the Danish EPA (Q)SAR Database as a predicted respiratory sensitiser (http://qsar.food.dtu.dk/), or
- the chemical is an enzyme, or
- the chemical is a polymer that contains one or more free isocyanate groups, or
- an in vivo study on the chemical indicates hypersensitivity of the airways, as discussed in chapter 3.4 of the GHS, or
- an in vitro study on the chemical:
    - indicates hypersensitivity of the airways, as discussed in chapter 3.4 of the GHS, and
    - the result of the study has not been negated by in vivo studies conducted on the chemical for hypersensitivity of the airways.

6.9.2 Section 30 of the IC General Rules - Information required to demonstrate the absence of hazard characteristics

For the purposes of subparagraph 30(2)(c)(iv) of the IC General Rules, there are no information requirements to demonstrate the absence of the hazard characteristic, **respiratory sensitisation**. If you do not have any information that demonstrates that the chemical has this hazard characteristic then you can assume it does not for the purposes of categorisation.

6.10 Corrosive to the respiratory tract – Human health hazard band B

6.10.1 Clause 2 of Part 1, Schedule 1 to the IC General Rules

For the purposes of table item 8 of Clause 2, Part 1, Schedule 1 to the IC General Rules:

Corrosive to the respiratory tract means that any of the following apply to the industrial chemical:

- the chemical is known to cause destruction of the respiratory tract tissue, as described in chapter 3.1 of the GHS, with the chemical classified as corrosive to the respiratory tract (AUH071 - non-GHS hazard statement), or
- an in vivo study on the chemical conducted following an acceptable test guideline for acute inhalation toxicity, subacute inhalation toxicity or subchronic inhalation toxicity results in destruction of the respiratory tract, as described in chapter 3.1 of the GHS.

6.10.2 Section 30 of the IC General Rules - Information required to demonstrate the absence of hazard characteristics

For the purposes of subparagraph 30(2)(c)(iv) of the IC General Rules there are no information requirements to demonstrate the absence of the hazard characteristic, **corrosive to the respiratory tract**. If you do not have any information that demonstrates that the

chemical has this hazard characteristic, then you can assume it does not for the purposes of categorisation.

6.11 Specific target organ toxicity after a single exposure (significant toxicity) – Human health hazard band B

6.11.1 Clause 2 of Part 1, Schedule 1 to the IC General Rules

For the purposes of table item 9 of Clause 2, Part 1, Schedule 1 of the IC General Rules:

Specific target organ toxicity after a single exposure (significant toxicity) means that any of the following apply to the industrial chemical:

- the chemical is known or presumed to produce significant toxicity in humans, as described in chapter 3.8 of the GHS, with the chemical classified as specific target organ toxicity – single exposure (category 1), or
- an in vivo study on the chemical**:**
    - conducted following an acceptable test guideline for acute oral toxicity results in significant toxic effects of relevance to human health, as discussed in chapter 3.8 of the GHS, at ≤300 mg/kg bw, or
    - conducted following an acceptable test guideline for acute dermal toxicity results in significant toxic effects of relevance to human health, as discussed in chapter 3.8 of the GHS, at ≤1,000 mg/kg bw, or
    - conducted following an acceptable test guideline for acute inhalation toxicity results in significant toxic effects of relevance to human health, as discussed in chapter 3.8 of the GHS:
        - for gases - ≤2,500 ppmV/4h, or
        - for vapours - ≤10 mg/L/4h, or
        - for dusts/mists/fumes - ≤1 mg/L/4h.

6.11.2 Section 30 of the IC General Rules - Information required to demonstrate the absence of hazard characteristics

For the purposes of subparagraph 30(2)(c)(iv) of the IC General Rules there are no information requirements to demonstrate the absence of the hazard characteristic, **specific target organ toxicity after a single exposure (significant toxicity)**. If you do not have any information that demonstrates that the chemical has this hazard characteristic, then you can assume it does not for the purposes of categorisation.

6.12 Skin corrosion – Human health hazard band B

6.12.1 Clause 2 of Part 1, Schedule 1 to the IC General Rules

For the purposes of table item 10 of Clause 2, Part 1, Schedule 1 to the IC General Rules:

Skin corrosion means that any of the following apply to the industrial chemical:

- the chemical is known to produce irreversible damage to the skin, as described in chapter 3.2 of the GHS, with the chemical classified as skin corrosion (category 1), or
- an in vitro study on the chemical conducted following an acceptable test guideline for skin corrosion results in the prediction of skin corrosion effects, or
- an in vivo study on the chemical conducted following an acceptable test guideline for skin irritation results in destruction of skin tissue, as described for skin corrosion in chapter 3.2 of the GHS, or
- the chemical is a pyrophoric liquid or a pyrophoric solid, as described in chapters 2.9 and 2.10 of the GHS respectively.

6.12.2 Section 30 of the IC General Rules - Information required to demonstrate the absence of hazard characteristics

For the purposes of subparagraph 30(2)(c)(iv) of the IC General Rules, the information required to demonstrate that a chemical does not have the hazard characteristic, **skin corrosion**, is at least one of the following:

- information that demonstrates that the chemical is a high molecular weight polymer that does not contain any of the following reactive functional groups:
    - anhydride, or
    - epoxide, or
    - sulfonic acid, or
    - amine, or
- information that demonstrates that the chemical is a high molecular weight polymer that contains any of the following reactive functional groups and the polymer has a combined functional group equivalent weight of ≥1,000 g/mol:
    - anhydride, or
    - epoxide, or
    - sulfonic acid, or
    - amine, or
- if the human health exposure band for the introduction is 3 - a suitable in silico prediction indicating that the chemical is not irritating to skin or has no alerting groups for skin irritation, or
- test results from an in vitro study on the chemical or from suitable read across information, conducted following an acceptable test guideline for skin corrosion, with a non-corrosive prediction, or

- test results from an in vitro study on the chemical or from suitable read across information, conducted following an acceptable test guideline for skin irritation, with a non-irritant prediction, or
- test results 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 in chapter 3.2 of the GHS.

6.13 Eye damage – Human health hazard band B

6.13.1 Clause 2 of Part 1, Schedule 1 to the IC General Rules

For the purposes of table item 11 of Clause 2, Part 1, Schedule 1 to the IC General Rules:

Eye damage means that any of the following apply to the industrial chemical:

- the chemical is known to produce serious eye damage, as described in chapter 3.3 of the GHS, with the chemical classified as eye damage (category 1), or
- an in vitro study on the chemical conducted following an acceptable test guideline for eye damage results in the prediction of serious eye damage effects, or
- an in vivo study on the chemical conducted following an acceptable test guideline for eye irritation results in effects on the eye, as described for serious eye damage in chapter 3.3 of the GHS, or
- the chemical is a pyrophoric liquid or a pyrophoric solid, as described in chapters 2.9 and 2.10 of the GHS, respectively.

6.13.2 Section 30 of the IC General Rules - Information required to demonstrate the absence of hazard characteristics

For the purposes of subparagraph 30(2)(c)(iv) of the IC General Rules, the information required to demonstrate that a chemical does not have the hazard characteristic, **eye damage**, is at least one of the following:

- information that demonstrates that the chemical is a high molecular weight polymer that does not contain any of the following reactive functional groups:
    - anhydride, or
    - epoxide, or
    - sulfonic acid, or
    - amine, or
- information that demonstrates that the chemical is a high molecular weight polymer that contains any of the following reactive functional groups with a combined functional group equivalent weight of ≥1,000 g/mol:
    - anhydride, or
    - epoxide, or
    - sulfonic acid, or

    - amine, or
- if the human health exposure band for the introduction is 3 - a suitable in silico prediction indicating that the chemical is not irritating to the eye, or
- test results from an in vitro study on the chemical or from suitable read across information, conducted following an acceptable test guideline for eye damage, which predicts the chemical would not induce serious eye damage
- test results from an in vivo study on the chemical or from suitable read across information, conducted following an acceptable test guideline for eye irritation, which does not result in effects on the eye, as described for eye damage in chapter 3.3 of the GHS.

6.14 Skin sensitisation – Human health hazard band B

6.14.1 Clause 2 of Part 1, Schedule 1 to the IC General Rules

For the purposes of table item 12 of Clause 2, Part 1, Schedule 1 to the IC General Rules:

Skin sensitisation means that any of the following apply to the industrial chemical:

- the chemical is known to cause an allergic response following skin contact, as described in chapter 3.4 of the GHS, with the chemical classified as skin sensitisation (category 1), or
- human testing or epidemiological studies on the chemical result in evidence of an allergic response, as described in chapter 3.4 of the GHS, or
- an in vitro study on the chemical**:**
    - conducted following an acceptable test guideline for skin sensitisation, results in the prediction of skin sensitisation effects, and
    - the results of the study have not been negated by in vivo studies conducted on the chemical for skin sensitisation, or
- an in chemico study on the chemical:
    - conducted following an acceptable test guideline for skin sensitisation, results in the prediction of skin sensitisation effects, and
    - the results of the study have not been negated by in vivo studies conducted on the chemical for skin sensitisation, or
- an in vivo study on the chemical conducted following an acceptable test guideline for skin sensitisation, results in the induction of an allergic response, as described in chapter 3.4 of the GHS.

6.14.2 Section 30 of the IC General Rules - Information required to demonstrate the absence of hazard characteristics

For the purposes of subparagraph 30(2)(c)(iv) of the IC General Rules:

- there are no information requirements to demonstrate the absence of the hazard characteristic, **skin sensitisation**, if the chemical is corrosive to the skin (GHS category 1) as the in vivo tests cannot be conducted

- otherwise, the information required to demonstrate that a chemical does not have the hazard characteristic, **skin sensitisation**, is at least one of the following:
    - information that demonstrates that the chemical is a high molecular weight polymer for which at least one of the following applies:
        - it contains only low concern reactive functional groups[5], or
        - it contains only low concern reactive functional groups[5] and unsubstituted positions ortho and para to phenolic hydroxyl groups, or
        - the only reactive functional groups it contains are unsubstituted positions ortho and para to phenolic hydroxyl groups, or
        - it contains only low[5] and moderate concern reactive functional groups[6], with a combined functional group equivalent weight of ≥ 1000 g/mol, or
        - it contains only moderate concern reactive functional groups[6], with a combined functional group equivalent weight of ≥ 1000 g/mol, or
        - it has a number average molecular weight that is greater than or equal to 10,000 g/mol and both:
            - less than 2% by mass of molecules with molecular weight that is less than 500 g/mol, and
            - less than 5% by mass of molecules with molecular weight that is less than 1,000 g/mol, or
    - information that demonstrates that the chemical is a substance covered by Entry 9 of Annex V, of the REACH Regulation, or
    - if the human health exposure band is 3 - all of the following:
        - a suitable in silico prediction indicating that the chemical and its metabolites (if any) do not cause skin sensitisation, and
        - test results from an in vitro study on the chemical or from suitable read across information, conducted following an acceptable test guideline for the 2nd key event in skin sensitisation, with a non-sensitising prediction, and
        - test results from an in vitro study on the chemical or from suitable read across information, conducted following an acceptable test guideline for the 3rd key event in skin sensitisation, with a non-sensitising prediction, or
    - all of the following:
        - test results from an in chemico test on the chemical or from suitable read-across information, conducted following an acceptable test guideline for the 1st key event in skin sensitisation, with a non-sensitising prediction, and

[5] Low concern reactive functional groups are listed in subclause 2(7) of Schedule 2, Part 1 of the IC General Rules

[6] Moderate concern reactive functional groups are listed in subclause 2(5) of Schedule 2, Part 1 of the IC General Rules

        - test results from an in vitro study on the chemical or from suitable read across information, conducted following an acceptable test guideline for the 2nd key event in skin sensitisation, with a non-sensitising prediction, and
        - test results from an in vitro study on the chemical or from suitable read across information, conducted following an acceptable test guideline for the 3rd key event in skin sensitisation, with a non-sensitising prediction
    - test results from an in vivo study on the chemical or from suitable read-across information, conducted following an acceptable test guideline for skin sensitisation, which does not result in induction of an allergic response, as described in chapter 3.4 of the GHS
- in addition, if the human health exposure band for the introduction is 4 and the chemical is a UV filter or is introduced for an end use in a tattoo ink, information is required to justify why the chemical would not cause skin sensitisation mediated by UV light. This may include one or more of the following :
    - the chemical has a molar extinction coefficient/absorption coefficient of less than or equal to 1,000Lmol^{-1}cm^{-1} at wavelengths between 290 and 700nm (based on the results of a study following OECD test guideline 101), or
    - results from in vitro phototoxicity studies, or
    - results from in vitro or in vivo skin sensitisation studies where the methods have been modified to include photoactivation.

6.15 Acute toxicity (fatal or toxic) – Human health hazard band B

6.15.1 Clause 2 of Part 1, Schedule 1 to the IC General Rules

For the purposes of table item 13 of Clause 2, Part 1, Schedule 1 to the IC General Rules:

Acute toxicity (fatal or toxic) means that any of the following apply to the industrial chemical:

- the chemical is known to exhibit acute toxicity effects, as described in chapter 3.1 of the GHS, with the chemical classified as acute toxicity (category 1 or 2 or 3), or
- an in vitro study on the chemical:
    - conducted following an acceptable test guideline for acute oral toxicity, results in a predicted acute oral toxicity LD50 value of ≤300 mg/kg bw, and
    - the results of the study have not been negated by in vivo studies conducted on the chemical for acute toxicity, or
- an in vivo study on the chemical:
    - conducted following an acceptable test guideline for acute oral toxicity results in an acute oral LD50 value of ≤300 mg/kg bw, or
    - conducted following an acceptable test guideline for acute dermal toxicity results in an acute dermal LD50 value of ≤1,000 mg/kg bw, or

- conducted following an acceptable test guideline for acute inhalation toxicity results in an acute inhalation LC50 value of:
  - for gases - ≤2,500 ppmV/4h, or
  - for vapours - ≤10 mg/L/4h, or
  - for dusts/mists/fumes - ≤1 mg/L/4h , or

- evidence in humans of systemic toxicity after eye contact, with the chemical classified with the non-GHS hazard statement – AUH070, or
- an in vivo study, conducted following an acceptable test guideline for eye irritation, results in overt signs of systemic toxicity or mortality, which is likely to be attributed to absorption of the chemical through the mucous membranes of the eye, with the chemical classified with the non-GHS hazard statement – AUH070.

6.15.2 Section 30 of the IC General Rules - Information required to demonstrate the absence of hazard characteristics

For the purposes of subparagraph 30(2)(c)(iv) of the IC General Rules:

- there are no information requirements to demonstrate the absence of the hazard characteristic, **acute toxicity (fatal or toxic)**, if the chemical is corrosive to the skin (GHS category 1), or likely to be corrosive to the skin (that is, the chemical is a strong acid (pH ≤ 2.0) or base (pH ≥ 11.5), and has high buffering capacity (if relevant)), as the in vivo tests cannot be conducted
- if the chemical is for end use in a personal vaporiser - the information required to demonstrate that the chemical does not have the hazard characteristic, **acute toxicity (fatal or toxic)**, is a test result from at least one in vivo study on the chemical or from suitable read-across information, conducted following an acceptable test guideline for acute inhalation toxicity with an LC50:
  - for gases - >2,500 ppmV/4h, or
  - for vapours - >10 mg/L/4h, or
  - for dusts/mists/fumes - >1 mg/L/4h, or
- otherwise, the information required to demonstrate that a chemical does not have the hazard characteristic, **acute toxicity (fatal or toxic)**, is at least one of the following:
  - if the human health exposure band for the introduction is 3 - both of the following:
    - a suitable in silico prediction for acute toxicity (LD50) of the chemical of >2,000 mg/kg bw/day, and
    - test results from an in vitro study on the chemical or from suitable read across information for acute toxicity (LD50), conducted following an acceptable test guideline for acute oral toxicity, of > 300 mg/kg bw, or
  - information that demonstrates that the chemical is a high molecular weight polymer that has:
    - < 5% by mass of molecules with molecular weight < 1,000 g/mol, and
    - < 2% by mass of molecules with molecular weight < 500 g/mol, or
  - inclusion of the chemical in the Select Committee on GRAS Substances (SCOGS) Database as a Type 1 conclusion, as long as the human health

exposure expected from the industrial use of the chemical is no higher than the human health exposure expected from food use, or

- the chemical has been notified to the US FDA GRAS notification program and FDA had no questions about the notifier's conclusion of GRAS status, as long as the human health exposure expected from the industrial use of the chemical is no higher than the human health exposure expected from food use, or
- the chemical is permitted to be used as a food additive according to Schedule 15 of the *Australia New Zealand Food Standards Code - Standard 1.3.1 - Food Additives*, as long as the human health exposure expected from the industrial use of the chemical is no higher than the human health exposure expected from food use, or
- information that demonstrates that the chemical is a substance covered by Entry 9 of Annex V of the REACH Regulation, or
- a test result from at least one in vivo study on the chemical or from suitable read across information, as detailed below, with the administration route dependent on the most relevant route of exposure (or the oral route if information on the most relevant route is not available):
  - conducted following an acceptable test guideline for acute oral toxicity with an LD50 >300 mg/kg bw, or
  - conducted following an acceptable test guideline for acute dermal toxicity with an LD50 >1,000 mg/kg bw, or
  - conducted following an acceptable test guideline for acute inhalation toxicity, with an LC50:
    - for gases - >2,500 ppmV/4h, or
    - for vapours - >10 mg/L/4h, or
    - for dusts/mists/fumes - >1 mg/L/4h, or
- test results from an in vivo study via the oral route on the chemical or from suitable read across information, conducted following an acceptable test guideline for subacute oral toxicity, with a NOAEL ≥ 1,000 mg/kg bw/day.

6.16 Specific target organ toxicity after repeated exposure – Human health hazard band B

6.16.1 Clause 2 of Part 1, Schedule 1 to the IC General Rules

For the purposes of table item 14 of Clause 2, Part 1, Schedule 1 of the IC General Rules:

Specific target organ toxicity after repeated exposure means that any of the following apply to the industrial chemical:

- the chemical is known to exhibit significant toxicity or be potentially harmful to human health following repeated exposure, as described in chapter 3.9 of the GHS, with the chemical classified as specific target organ toxicity – repeated exposure (category 1 or 2), or

- an in vivo study on the chemical:
    - conducted following an acceptable test guideline for subacute oral toxicity results in significant toxic effects of relevance to human health, as discussed in chapter 3.9 of the GHS, and a NOAEL (oral) value of <300 mg/kg bw/day, or
    - conducted following an acceptable test guideline for subchronic oral toxicity results in significant toxic effects of relevance to human health, as discussed in chapter 3.9 of the GHS, and a NOAEL (oral) of <100 mg/kg bw/day, or
    - conducted following an acceptable test guideline for subacute dermal toxicity results in significant toxic effects of relevance to human health, as discussed in chapter 3.9 of the GHS, and a NOAEL (dermal) value of <600 mg/kg bw/day, or
    - conducted following an acceptable test guideline for subchronic dermal toxicity results in significant toxic effects of relevance to human health, as discussed in chapter 3.9 of the GHS, and a NOAEL (dermal) of <200 mg/kg bw/day, or
    - conducted following an acceptable test guideline for subacute inhalation toxicity results in significant toxic effects of relevance to human health, as discussed in chapter 3.9 of the GHS, and a NOAEC (inhalation) of:
        - for gases - <750 ppmV/6 h/day, or
        - for vapours - <3 mg/L/6 h/day, or
        - for dusts/mists/fumes <0.6 mg/L/6 h/day, or
    - conducted following an acceptable test guideline for subchronic inhalation toxicity results in significant toxic effects of relevance to human health, as discussed in chapter 3.9 of the GHS, and a NOAEC (inhalation) of:
        - for gases - <250 ppmV/6 h/day, or
        - for vapours - <1 mg/L/6 h/day, or
        - for dusts/mists/fumes <0.2 mg/L/6 h/day.

6.16.2 Section 30 of the IC General Rules - Information required to demonstrate the absence of hazard characteristics

For the purposes of subparagraph 30(2)(c)(iv) of the IC General Rules, information is required to demonstrate the absence of the hazard characteristic, **specific target organ toxicity after repeated exposure**, if:

- the human health exposure band for the introduction is 4, and
- you are seeking to demonstrate that the introduction meets the criteria for low risk or very low risk,

and any of the following apply:

1. the human health categorisation volume for the introduction is >100 kg and the chemical is introduced for end use in any of the following types of articles:
    - food contact, or
    - children's toys that can be placed in the mouth, or
    - children's care products that can be placed in the mouth, or

2. the human health categorisation volume for the introduction is >1000 kg and the chemical is not introduced for end use in any of the following types of articles:
    - food contact, or
    - children's toys that can be placed in the mouth, or
    - children's care products that can be placed in the mouth, or

3. the chemical is for end use in a personal vaporiser.

If 1 or 2 apply, the information required to demonstrate that a chemical does not have the hazard characteristic, **specific target organ toxicity after repeated exposure**, is at least one of the following:

- inclusion of the chemical in the Select Committee on GRAS Substances (SCOGS) Database as a Type 1 conclusion, as long as the human health exposure expected from the industrial use of the chemical is no higher than the human health exposure expected from food use, or
- the chemical has been notified to the US FDA GRAS notification program and FDA had no questions about the notifier's conclusion of GRAS status, as long as the human health exposure expected from the industrial use of the chemical is no higher than the human health exposure expected from food use, or
- the chemical is permitted to be used as a food additive according to Schedule 15 of the *Australia New Zealand Food Standards Code - Standard 1.3.1 - Food Additives*, as long as the human health exposure expected from the industrial use of the chemical is no higher than the human health exposure expected from food use, or
- information that demonstrates that the chemical is a substance covered by Entry 9 of Annex V of the REACH Regulation, or
- information that demonstrates that the chemical is a high molecular weight polymer that does not have the hazard characteristic, **skin corrosion**, or
- a test result from at least one in vivo study on the chemical or from suitable read across information, as detailed below, with the administration route dependent on the most relevant route of exposure (or the oral route if information on the most relevant route is not available):
    - conducted following an acceptable test guideline for subacute oral toxicity, in which the NOAEL (oral) is ≥ 300 mg/kg bw/day or there were no significant toxic effects of relevance to human health (as described in chapter 3.9 of the GHS) produced, or
    - conducted following an acceptable test guideline for subchronic oral toxicity, in which the NOAEL (oral) is ≥100 mg/kg bw/day or there were no significant toxic effects of relevance to human health (as described in chapter 3.9 of the GHS) produced, or
    - conducted following an acceptable test guideline for subacute dermal toxicity, in which the NOAEL (dermal) is ≥600 mg/kg bw/day or there were no significant toxic effects of relevance to human health (as described in chapter 3.9 of the GHS) produced, or
    - conducted following an acceptable test guideline for subchronic dermal toxicity, in which the NOAEL (dermal) is ≥200 mg/kg bw/day or there were no

significant toxic effects of relevance to human health (as described in chapter 3.9 of the GHS) produced, or

- conducted following an acceptable test guideline for subacute inhalation toxicity, in which there were no significant toxic effects of relevance to human health (as described in chapter 3.9 of the GHS) produced, or the NOAEC (inhalation) is:
  - for gases - ≥ 750 ppmV/6 h/day, or
  - for vapours - ≥ 3 mg/L/6 h/day, or
  - for dusts/mists/fumes - ≥ 0.6 mg/L/6 h/day , or
- conducted following an acceptable test guideline for subchronic inhalation toxicity, in which there were no significant toxic effects of relevance to human health (as described in chapter 3.9 of the GHS) produced, or the NOAEC (inhalation) is:
  - for gases - ≥ 250 ppmV/6 h/day, or
  - for vapours - ≥ 1 mg/L/6 h/day, or
  - for dusts/mists/fumes - ≥ 0.2 mg/L/6 h/day.

If 3 applies (the chemical is for end use in a personal vaporiser), the information required to demonstrate that the chemical does not have the hazard characteristic, **specific target organ toxicity after repeated exposure**, is a test result from at least one in vivo study on the chemical or from suitable read across information, as detailed below:

- conducted following an acceptable test guideline for subacute inhalation toxicity, in which there were no significant toxic effects of relevance to human health, as discussed in chapter 3.9 of the GHS, or the NOAEC (inhalation) is:
  - for gases - ≥ 750 ppmV/6 h/day, or
  - for vapours - ≥ 3 mg/L/6 h/day, or
  - for dusts/mists/fumes - ≥ 0.6 mg/L/6 h/day, or
- conducted following an acceptable test guideline for subchronic inhalation toxicity, in which there were no significant toxic effects of relevance to human health, as discussed in chapter 3.9 of the GHS, or the NOAEC (inhalation) is:
  - for gases - ≥ 250 ppmV/6 h/day, or
  - for vapours - ≥ 1 mg/L/6 h/day, or
  - for dusts/mists/fumes - ≥ 0.2 mg/L/6 h/day.

There are **no** information requirements to demonstrate the absence of the hazard characteristic, **specific target organ toxicity after repeated exposure**, if:

- the human health exposure band for the introduction is 4, and
- you are seeking to demonstrate that the introduction meets the criteria for low risk or very low risk,

and any of the following apply:

- the human health categorisation volume for the introduction is ≤100 kg and the chemical is introduced for end use in any of the following types of articles:
  - food contact, or

        - children's toys that can be placed in the mouth, or
        - children's care products that can be placed in the mouth, or
- the human health categorisation volume for the introduction is ≤1,000 kg and the chemical is not introduced for end use in any of the following types of articles:
    - food contact, or
    - children's toys that can be placed in the mouth, or
    - children's care products that can be placed in the mouth

In these circumstances, if you do not have any information that demonstrates that the chemical has this hazard characteristic then you can assume it does not for the purposes of categorisation.

6.17 High molecular weight polymer that has lung overloading potential – Human health hazard band A

6.17.1 Clause 2 of Part 1, Schedule 1 to the IC General Rules

For the purposes of table item 15 of Clause 2, Part 1, Schedule 1 to the IC General Rules:

High molecular weight polymer that has lung overloading potential means that all of the following apply to the industrial chemical:

- it is a polymer, and
- it has a number average molecular weight that is >70,000 g/mol, and
- it has a solubility in water of < 0.1 mg/L, and
- it becomes aerosolised during end use.

6.17.2 Section 30 of the IC General Rules - Information required to demonstrate the absence of hazard characteristics

For the purposes of subparagraph 30(2)(c)(iv) of the IC General Rules:

If the chemical is a polymer, the information required to demonstrate that a chemical does not have the hazard characteristic, **high molecular weight polymer that has lung overloading potential**, is at least one of the following:

- molecular weight information that demonstrates that the number average molecular weight is ≤70,000 g/mol, or
- information that demonstrates that the polymer has a solubility in water that is ≥ 0.1 mg/L measured following an acceptable test guideline for water solubility, or
- information that demonstrates that the polymer does not become aerosolised during end use

6.18 Aspiration hazard – Human health hazard band A

6.18.1 Clause 2 of Part 1, Schedule 1 to the IC General Rules

For the purposes of table item 16 of Clause 2, Part 1, Schedule 1 of the IC General Rules:

Aspiration hazard means that any of the following apply to the industrial chemical:

- the chemical is known or presumed to cause aspiration toxicity, as described in chapter 3.10 of the GHS, with the chemical classified as may be fatal if swallowed and enters airways (category 1), or
- the chemical is a hydrocarbon that has a kinematic viscosity ≤20.5 mm^2/s, measured at 40°C.

6.18.2 Section 30 of the IC General Rules - Information required to demonstrate the absence of hazard characteristics

For the purposes of subparagraph 30(2)(c)(iv) of the IC General Rules:

- if the chemical is a hydrocarbon, the information required to demonstrate the absence of the hazard characteristic, **aspiration hazard**, is a measured kinematic viscosity >20.5 mm^2/s, at 40°C
- otherwise, there are no information requirements to demonstrate the absence of the hazard characteristic, **aspiration hazard**. If you do not have any information that demonstrates that the chemical has this hazard characteristic, then you can assume it does not for the purposes of categorisation.

6.19 Specific target organ toxicity after a single exposure (harmful or transient effects) – Human health hazard band A

6.19.1 Clause 2 of Part 1, Schedule 1 to the IC General Rules

For the purposes of table item 17 of Clause 2, Part 1, Schedule 1 to the IC General Rules:

Specific target organ toxicity after a single exposure (harmful or transient effects) means that any of the following apply to the industrial chemical:

- the chemical is known or presumed to be harmful to humans or to cause transient target organ effects, as described in chapter 3.8 of the GHS, with the chemical classified as specific target organ toxicity-single exposure (category 2 or 3), or
- an in vivo study on the chemical:
    - conducted following an acceptable test guideline for acute oral toxicity results in significant toxic effects of relevance to human health, as discussed in chapter 3.8 of the GHS, at >300 but ≤2,000 mg/kg bw, or

- conducted following an acceptable test guideline for acute dermal toxicity results in significant toxic effects of relevance to human health, as discussed in chapter 3.8 of the GHS, at >1,000 but ≤2,000 mg/kg bw, or
- conducted following an acceptable test guideline for acute inhalation toxicity results in significant toxic effects of relevance to human health, as discussed in chapter 3.8 of the GHS, at:
  - for gases - >2,500 but ≤20,000 ppmV/4h, or
  - for vapours - >10 but ≤20 mg/L/4h, or
  - for dusts/mists/fumes - >1 but ≤5 mg/L/4h.

6.19.2 Section 30 of the IC General Rules - Information required to demonstrate the absence of hazard characteristics

For the purposes of subparagraph 30(2)(c)(iv) of the IC General Rules, there are **no** information requirements to demonstrate the absence of the hazard characteristic, **specific target organ toxicity after a single exposure (harmful or transient effects)**. If you do not have any information that demonstrates that the chemical has this hazard characteristic, then you can assume it does not for the purposes of categorisation.

6.20 Skin irritation – Human health hazard band A

6.20.1 Clause 2 of Part 1, Schedule 1 to the IC General Rules

For the purposes of table item 18 of Clause 2, Part 1, Schedule 1 to the IC General Rules:

Skin irritation means that any of the following apply to the industrial chemical:

- the chemical is known to produce reversible damage to the skin, as described in chapter 3.2 of the GHS, with the chemical classified as skin irritation (category 2), or
- an in vitro study on the chemical conducted following an acceptable test guideline for skin irritation results in the prediction of skin irritation effects, or
- an in vivo study on the chemical conducted following an acceptable test guideline for skin irritation results in skin reactions, as described for skin irritation (category 2) in chapter 3.2 of the GHS.

6.20.2 Section 30 of the IC General Rules - Information required to demonstrate the absence of hazard characteristics

For the purposes of subparagraph 30(2)(c)(iv) of the IC General Rules, the information required to demonstrate that a chemical does not have the hazard characteristic, **skin irritation**, is at least one of the following:

- if the human health exposure band for the introduction is 3 - a suitable in silico prediction indicating that the chemical is not irritating to the skin, or
- test results from an in vitro study on the chemical or from suitable read across information, conducted following an acceptable test guideline for skin irritation, with a non-irritant prediction, or
- test results 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 skin reactions, as described for skin irritation in chapter 3.2 of the GHS, or
- test results from an in vivo study on the chemical or from suitable read across information conducted following an acceptable test guideline for acute dermal toxicity, that when tested at 2,000 mg/kg bw/day is not irritating to the skin.

In addition, if the chemical is introduced for an end use in a tattoo ink, information is required to justify why the chemical would not cause skin irritation mediated by UV light. This may include one or more of the following:

- the chemical has a molar extinction coefficient/absorption coefficient of less than 1,000Lmol^{-1}cm^{-1} at wavelengths between 290 and 700nm (based on the results of a study following OECD test guideline 101), or
- results from in vitro phototoxicity studies, or
- results from in vitro or in vivo irritation studies where the methods have been modified to include photoactivation.

6.21 Eye irritation – Human health hazard band A

6.21.1 Clause 2 of Part 1, Schedule 1 to the IC General Rules

For the purposes of table item 19 of Clause 2, Part 1, Schedule 1 to the IC General Rules:

Eye irritation means that any of the following apply to the industrial chemical:

- the chemical is known to produce changes in the eye, as described in chapter 3.3 of the GHS, with the chemical classified as eye irritation (category 2), or
- an in vitro study on the chemical conducted following an acceptable test guideline for eye irritation results in the prediction of eye irritation effects, or
- an in vivo study on the chemical conducted following an acceptable test guideline for eye irritation results in changes in the eye, as described for eye irritation in chapter 3.3 of the GHS.

6.21.2 Section 30 of the IC General Rules - Information required to demonstrate the absence of hazard characteristics

For the purposes of subparagraph 30(2)(c)(iv) of the IC General Rules, the information required to demonstrate that a chemical does not have the hazard characteristic, **eye irritation**, is at least one of the following:

- if the human health exposure band for the introduction is 3 - a suitable in silico prediction indicating that the chemical is not irritating to the eyes, or
- test results from an in vitro study on the chemical or from suitable read across information, conducted following an acceptable test guideline for eye damage or eye irritation with a non-irritant prediction, or
- test results from an in vivo study on the chemical or from suitable read across information, conducted following an acceptable test guideline for eye irritation, which does not result in changes in the eyes, as described for eye irritation (category 2) in chapter 3.3 of the GHS.

6.22 Acute toxicity (harmful) – Human health hazard band A

6.22.1 Clause 2 of Part 1, Schedule 1 to the IC General Rules

For the purposes of table item 20 of Clause 2, Part 1, Schedule 1 to the IC General Rules:

Acute toxicity (harmful) means that any of the following apply to the industrial chemical:

- the chemical is known to exhibit acute toxicity effects, as described in chapter 3.1 of the GHS, with the chemical classified as acute toxicity (category 4), or
- an in vitro study on the chemical:
    - conducted following an acceptable test guideline for acute oral toxicity, results in a predicted acute toxicity LD50 value of >300 but ≤2,000 mg/kg bw, and
    - the results of the study have not been negated by in vivo studies conducted on the chemical for acute toxicity, or
- an in vivo study on the chemical:
    - conducted following an acceptable test guideline for acute oral toxicity results in an acute oral LD50 value of >300 but ≤2,000 mg/kg bw, or
    - conducted following an acceptable test guideline for acute dermal toxicity results in an acute dermal LD50 value of >1,000 but ≤2,000 mg/kg bw, or
    - conducted following an acceptable test guideline for acute inhalation toxicity results in an acute inhalation LC50 value of:
        - for gases - >2500 but ≤20,000 ppmV/4h, or
        - for vapours - >10 but ≤20 mg/L/4h, or
        - for dusts/mists/fumes - >1 but ≤5 mg/L/4h.

6.22.2 Section 30 of the IC General Rules - Information required to demonstrate the absence of hazard characteristics

For the purposes of subparagraph 30(2)(c)(iv) of the IC General Rules:

- if the chemical is for end use in a personal vaporiser - the information required to demonstrate that the chemical does not have the hazard characteristic, **acute toxicity (harmful)**, is a test result from at least one in vivo study on the chemical or

from suitable read-across information, conducted following an acceptable test guideline for acute inhalation toxicity with an LC50 of:
    - for gases - >20,000 ppmV/4h, or
    - for vapours - >20 mg/L/4h, or
    - for dusts/mists/fumes - >5 mg/L/4h, or
- otherwise, the information required to demonstrate that a chemical does not have the hazard characteristic, **acute toxicity (harmful)**, is at least one of the following:
    - if the human health exposure band for the introduction is 3 - both of the following:
        - a suitable in silico prediction for acute toxicity (LD50) of the chemical of >2,000 mg/kg bw/day, and
        - test results from an in vitro study on the chemical or from suitable read across information, conducted following an acceptable test guideline for acute oral toxicity, with a predicted LD50 of > 2,000 mg/kg bw, or
    - information that demonstrates that the chemical is a high molecular weight polymer that has:
        - < 5% by mass of molecules with molecular weight < 1,000 g/mol, and
        - < 2% by mass of molecules with molecular weight < 500 g/mol
    - inclusion of the chemical in the Select Committee on GRAS Substances (SCOGS) Database as a Type 1 conclusion, as long as the human health exposure expected from the industrial use of the chemical is no higher than the human health exposure expected from food use, or
    - the chemical has been notified to the US FDA GRAS notification program and FDA had no questions about the notifier's conclusion of GRAS status, as long as the human health exposure expected from the industrial use of the chemical is no higher than the human health exposure expected from food use, or
    - the chemical is permitted to be used as a food additive according to Schedule 15 of the *Australia New Zealand Food Standards Code - Standard 1.3.1 - Food Additives*, as long as the human health exposure expected from the industrial use of the chemical is no higher than the human health exposure expected from food use, or
    - information that demonstrates that the chemical is a substance covered by Entry 9 of Annex V of the REACH Regulation, or
    - a test result from at least one in vivo study on the chemical or from suitable read across information, as detailed below, with the administration route dependent on the most relevant route of exposure (or the oral route if information on the most relevant route is not available):
        - conducted following an acceptable test guideline for acute oral toxicity with an LD50 >2,000 mg/kg bw, or
        - conducted following an acceptable test guideline for acute dermal toxicity with an LD50 >2,000 mg/kg bw, or
        - conducted following an acceptable test guideline for acute inhalation toxicity with an LC50:
            - for gases - >20,000 ppmV/4h, or
            - for vapours - >20 mg/L/4h, or

- for dusts/mists/fumes - >5 mg/L/4h, or
  - test results from an in vivo study on the chemical or from suitable read across information, conducted following an acceptable test guideline for subacute oral toxicity, with a NOAEL ≥ 1,000 mg/kg bw/day.

6.23 Ozone depleting chemical – Environment hazard band D

6.23.1 Clause 4 of Part 2, Schedule 1 to the IC General Rules

For the purposes of table item 2 of Clause 4, Part 2, Schedule 1 to the IC General Rules:

Ozone depleting chemical means that any of the following apply to the industrial chemical:

- the chemical is controlled under the *Ozone Protection and Synthetic Greenhouse Gas Management Act 1989*, or
- the chemical is controlled under the *Montreal Protocol on Substances that Deplete the Ozone Layer*.

6.24 Synthetic greenhouse gas – Environment hazard band D

6.24.1 Clause 4 of Part 2, Schedule 1 to the IC General Rules

For the purposes of table item 3 of Clause 4, Part 2, Schedule 1 to the IC General Rules:

Synthetic greenhouse gas means that any of the following apply to the industrial chemical:

- the chemical is controlled under the *Ozone Protection and Synthetic Greenhouse Gas Management Act 1989,* or
- the chemical is listed on the *Kyoto Protocol, Synthetic Greenhouse Gases* under Annex A, or
- the chemical is controlled under the *Montreal Protocol on Substances that Deplete the Ozone Layer*.

6.25 Adverse effects mediated by an endocrine mode of action – Environment hazard band D

6.25.1 Clause 4 of Part 2, Schedule 1 to the IC General Rules

For the purposes of table item 4 of Clause 4, Part 2, Schedule 1 to the IC General Rules:

Adverse effects mediated by an endocrine mode of action means that any of the following apply to the industrial chemical:

- the chemical meets all of the following:
    - it shows an adverse effect in an intact organism or its progeny, which is a change in the morphology, physiology, growth, development, reproduction or lifespan of an organism, system or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in the susceptibility to other influences, and
    - it has an endocrine activity, which is the capacity to alter the function(s) of the endocrine system, and
    - the adverse effect is a consequence of the endocrine activity

  or
- the chemical (or the chemical of which it is an ester or salt) is on the **list of chemicals with high hazards for categorisation**, based on its adverse effects mediated by an endocrine mode of action

  or
- the chemical meets all of the following:
    - information is available that is relevant to determining whether the chemical has the hazard characteristic, **adverse effects mediated by an endocrine mode of action**, and
    - the information has been considered in a weight of evidence analysis based on the following guidance documents:
        - the EU guidance for identifying endocrine disruptors[7], and
        - the guidance provided in OECD GD 150[8]; and
    - the weight of evidence analysis concludes that the chemical has the hazard characteristic, adverse effects mediated by an endocrine mode of action.

6.25.2 Section 30 of the IC General Rules - Information required to demonstrate the absence of hazard characteristics

For the purposes of paragraph 30(2)(b) and subparagraph30(2)(c)(iv) of the IC General Rules:

- if the chemical has existing information relevant to determining whether it has the hazard characteristic, **adverse effects mediated by an endocrine mode of action**, information is required to demonstrate that the chemical does not have this hazard characteristic:
    - This must involve a documented weight of evidence analysis based on the EU guidance for identifying endocrine disruptors[2] and the guidance in OECD GD 150[3], and
    - The analysis must conclude that the chemical does not have the hazard characteristic, **adverse effects mediated by an endocrine mode of action**.

[7] Guidance for the identification of endocrine disruptors in the context of 39 Regulations (EU) No 528/2012 and (EC) No 1107/2009, currently a 2017 consultation draft. Accessed here.
[8] ENV/JM/MONO(2012)22, OECD Series on Testing and Assessment, No. 150 - Guidance document on standardised test guidelines for evaluating chemicals for endocrine disruption. Accessed here.

- Otherwise, the information required to demonstrate that a chemical does not have the hazard characteristic, **adverse effects mediated by an endocrine mode of action**, is confirmation that the chemical (or the chemical of which it is an ester or salt) is not on the **list of chemicals with high hazards for categorisation**, based on its adverse effects mediated by an endocrine mode of action.

6.26 Persistent, bioaccumulative and toxic – Environment hazard band D

6.26.1 Clause 4 of Part 2, Schedule 1 to the IC General Rules

For the purposes of table item 5 of Clause 4, Part 2, Schedule 1 to the IC General Rules:

Persistent, bioaccumulative and toxic means that any of the following apply to the industrial chemical:

- the chemical (or the chemical of which it is an ester or salt) is on the **list of chemicals with high hazards for categorisation**, based on it being persistent, bioaccumulative and toxic, or
- all of the following apply:
    - the chemical is persistent (see part 2.1.6 of these Guidelines for the meaning), and
    - the chemical is bioaccumulative, and
    - the chemical has the hazard characteristic, very toxic to any aquatic life (see part 6.27.1 of these Guidelines for the meaning).

For the purposes of this hazard characteristic, bioaccumulative means any of the following apply to the chemical:

- it has a bioaccumulation factor (BAF) ≥ 2000 for the aquatic compartment, or
- it has a bioconcentration factor (BCF) ≥ 2000 for the aquatic compartment, or
- it has a measured log Kow ≥ 4.2 for the aquatic compartment (unless a measured BAF or BCF is <2000), or
- it has a log Koa > 6 and log Kow ≥ 2 for the terrestrial compartment, or
- it has a biomagnification factor (BMF) > 1.

6.26.2 Section 30 of the IC General Rules - Information required to demonstrate the absence of hazard characteristics

For the purposes of paragraph 30(2)(b) and subparagraph 30(2)(c)(iv) of the IC General Rules, the information required to demonstrate that a chemical does not have the hazard characteristic, **persistent, bioaccumulative and toxic**, is confirmation that the chemical (or the chemical of which it is an ester or salt) is not on the **list of chemicals with high hazards for categorisation** based on it being persistent, bioaccumulative and toxic.

In addition, if the environment exposure band for the introduction is 2 (and you are seeking to demonstrate that the introduction meets the criteria for very low risk in accordance with table item 16, section 29 of the IC General Rules), or 3, or 4, the information required to

demonstrate that a chemical does not have the hazard characteristic, **persistent, bioaccumulative and toxic**, is at least one of the following:

- information that demonstrates that the chemical is an inorganic chemical, or
- information to demonstrate that the chemical is a biological chemical, or
- information that demonstrates that the chemical has a molecular weight that is >1,000 g/mol, or
- information that demonstrates that the chemical is a high molecular weight polymer with:
    - < 25% low molecular weight oligomeric species <1,000g/mol, and
    - <10% low molecular weight oligomeric species <500g/mol, or
- information that demonstrates that the chemical has a solubility in water that is >5g/L, measured following an acceptable test guideline for water solubility, or
- information that demonstrates that the chemical is a gas that is not expected to partition to the aquatic compartment, or
- information that demonstrates that the chemical is a substance covered by Entry 9 of Annex V of the REACH Regulation, or
- a suitable in silico prediction for partition coefficient of the chemical itself of log Kow < 4.2 (that is not negated by a measured log Kow), or
- measured value from a study on the chemical or from suitable read-across information, conducted following an acceptable test guideline for partition coefficient, for which log Kow < 4.2, or
- if the chemical is not a highly branched organic chemical[9] – a test result from a study on the chemical or from suitable read across information, conducted following an acceptable test guideline for ready biodegradability, which meets at least one of the following degradation pass levels during the period specified in the test method:
    - tests based on dissolved organic carbon (DOC) - ≥ 70% DOC removal, or
    - tests based on carbon dioxide generation - ≥ 60% theoretical carbon dioxide, or
    - tests based on oxygen depletion - ≥ 60% theoretical oxygen demand, or
- a test result from a study on the chemical, conducted following an acceptable test guideline for ready biodegradability, which meets at least one of the following degradation pass levels during the period specified in the test method:
    - tests based on dissolved organic carbon (DOC) - ≥ 70% DOC removal, or
    - tests based on carbon dioxide generation - ≥ 60% theoretical carbon dioxide, or

[9] If the chemical *is* a highly branched organic chemical, in silico predictions and read across information cannot be used to demonstrate that the chemical does not have the persistence aspect of the persistent, bioaccumulative and toxic hazard characteristic – only studies on the chemical itself, as described in the next dot point, are acceptable

    - tests based on oxygen depletion - ≥ 60% theoretical oxygen demand, or
- if the chemical is not a highly branched organic chemical[10] – a test result from a study on the chemical or from suitable read across information, conducted following an acceptable test guideline for transformation in aquatic sediment systems, results in both:
    - a degradation half-life in water of < 2 months, and
    - a degradation half-life in sediment of < 6 months, or
- a test result from a study on the chemical, conducted following an acceptable test guideline for transformation in aquatic sediment systems, results in both:
    - a degradation half-life in water of < 2 months, and
    - a degradation half-life in sediment of < 6 months, or
- if the chemical is not a biocidal active and not a persistent, highly branched organic chemical[11] – information on aquatic toxicity for all three trophic levels (fish, invertebrates and algae), from suitable in silico predictions on the chemical or in vivo studies on the chemical or from suitable read-across information conducted following acceptable test guidelines for aquatic toxicity, with the following results for all three trophic levels:
    - acute aquatic toxicity > 1 mg/L (96h LC50 (fish), or 48h EC50 (invertebrates) or 72 or 96h ErC50 (algae)), or
    - chronic aquatic toxicity NOEC or EC_{10} > 0.1mg/L (for chemicals that are not readily biodegradable), or
- test results for all three trophic levels (fish, invertebrates and algae) from in vivo studies on the chemical or from suitable read-across information, conducted following acceptable test guidelines for chronic aquatic toxicity with a NOEC or EC_{10} > 0.1mg/L for all three trophic levels, or
- a test result from an in vivo study on the chemical or from suitable read-across information, conducted following an acceptable test guideline for bioconcentration, for which the BCF <2,000, or
- a test result from an in vivo study on the chemical or from suitable read-across information, conducted following an acceptable test guideline for bioaccumulation, for which the BAF <2,000.

6.27 Very toxic to any aquatic life – Environment hazard band C

[10] If the chemical *is* a highly branched organic chemical, in silico predictions and read across information cannot be used to demonstrate that the chemical does not have the persistence aspect of the persistent, bioaccumulative and toxic hazard characteristic – only studies on the chemical itself, as described in the next dot point, are acceptable

[11] If the chemical *is* a biocidal active or a persistent, highly branched organic chemical, in silico predictions cannot be used to demonstrate that the chemical does not have the toxicity aspect of the persistent, bioaccumulative and toxic hazard characteristic – only in vivo chronic aquatic toxicity studies, as described in the next dot point, are acceptable.

6.27.1 Clause 4 of Part 2, Schedule 1 to the IC General Rules

For the purposes of table item 6 of Clause 4, Part 2, Schedule 1 to the IC General Rules:

Very toxic to any aquatic life means that any of the following apply to the industrial chemical:

- the chemical is known to cause:
    - toxic injury to an organism following short term aquatic exposure as described in chapter 4.1 of the GHS, with the chemical classified as acute aquatic toxicity (category 1), or
    - adverse effects to an organism during aquatic exposures determined in relation to the life-cycle of the organism, as described in chapter 4.1 of the GHS, with the chemical classified as chronic aquatic toxicity (category 1), or
- the chemical (or the chemical of which it is an ester or salt) is on the **list of chemicals with high hazards for categorisation** based on it being very toxic to aquatic life, or
- an in vivo acute study on the chemical:
    - conducted following an acceptable test guideline for acute toxicity to fish results in a 96h LC50 ≤ 1mg/L, or
    - conducted following an acceptable test guideline for acute toxicity to invertebrates results in a 48h EC50 ≤ 1mg/L, or
    - conducted following an acceptable test guideline for acute toxicity to algae or other aquatic plants results in a 72 or 96h ErC50 ≤ 1mg/L, or
- an in vivo chronic study on the chemical conducted following an acceptable test guideline for chronic toxicity to fish, chronic toxicity to invertebrates, or chronic toxicity to algae or other aquatic plants results in a:
    - NOEC or EC_{10} ≤0.1mg/L (for chemicals that are **not** readily biodegradable), or
    - NOEC or EC_{10} ≤0.01mg/L (for chemicals that are readily biodegradable), or
- a suitable in silico prediction for acute aquatic toxicity results in a prediction of:
    - for fish - 96h LC50 ≤ 1mg/L, or
    - for invertebrates - 48h EC50 ≤ 1mg/L, or
    - for algae or other aquatic plants - 72 or 96h ErC50 ≤ 1mg/L

  and the predictions have not been negated by in vivo studies conducted on the chemical for aquatic toxicity.

6.27.2 Section 30 of the IC General Rules - Information required to demonstrate the absence of hazard characteristics

For the purposes of subparagraph 30(2)(c)(iv) of the IC General Rules, the information required to demonstrate that a chemical does not have the hazard characteristic, **very toxic to any aquatic life,** is:

- if the exposure band for the introduction is 1 - confirmation that the chemical (or the chemical of which it is an ester or salt) is not on the **list of chemicals with high hazards for categorisation** based on it being very toxic to any aquatic life
- if the environment exposure band for the introduction is 2, 3, or 4, - at least one of the following:

- information that demonstrates that the chemical has a molecular weight >1,000g/mol and has a low cationic density, or
- information that demonstrates that the chemical is a high molecular weight polymer that has a low cationic density, or
- information that demonstrates that the chemical is a substance covered by Entry 9 of Annex V of the REACH Regulation, or
- if the chemical is not a biocidal active and not a persistent, highly branched organic chemical[12] – information on aquatic toxicity for all three trophic levels (fish, invertebrates and algae), from suitable in silico predictions on the chemical or in vivo studies on the chemical or from suitable read-across information conducted following acceptable test guidelines for aquatic toxicity, with the following results for all three trophic levels:
  - acute aquatic toxicity >1 mg/L (LC50 (fish), or EC50 (invertebrates) or ErC50 (algae)), or
  - chronic aquatic toxicity NOEC or EC_{10} > 0.1mg/L (for chemicals that are not readily biodegradable), or
  - chronic aquatic toxicity NOEC or EC_{10} > 0.01mg/L (for chemicals that are readily biodegradable), or
- test results for all three trophic levels (fish, invertebrates and algae) from in vivo studies on the chemical or from suitable read-across information, conducted following acceptable test guidelines for chronic aquatic toxicity with the following results for all three trophic levels:
  - NOEC or EC_{10} > 0.1mg/L (for chemicals that are not readily biodegradable), or
  - NOEC or EC_{10} > 0.01mg/L (for chemicals that are readily biodegradable).

6.28 Persistent and bioaccumulative – Environment hazard band C

6.28.1 Clause 4 of Part 2, Schedule 1 to the IC General Rules

For the purposes of table item 7 of Clause 4, Part 2, Schedule 1 to the IC General Rules:

Persistent and bioaccumulative means that any of the following apply to the industrial chemical:

- the chemical (or the chemical of which it is an ester or salt) is on the list of chemicals with high hazards for categorisation, based on it being persistent and bioaccumulative, or

[12] If the chemical *is* a biocidal active or a persistent, highly branched organic chemical, in silico predictions cannot be used to demonstrate that the chemical does not have the very toxic to any aquatic life hazard characteristic – only in vivo chronic aquatic toxicity studies, as described in the next dot point, are acceptable

- both of the following apply:
    - the chemical is persistent (see section 2.1.6 for definition), and
    - the chemical is bioaccumulative.

For the purposes of this hazard characteristic, bioaccumulative means any of the following apply to the chemical:

- it has a bioaccumulation factor (BAF) ≥2000 for the aquatic compartment, or
- it has a bioconcentration factor (BCF) ≥2000 for the aquatic compartment, or
- it has a measured log Kow ≥4.2 for the aquatic compartment (unless a measured BCF or BAF is <2000), or
- it has a log Koa > 6 and log Kow ≥2 for the terrestrial compartment, or
- it has a biomagnification factor (BMF) >1.

6.28.2 Section 30 of the IC General Rules - Information required to demonstrate the absence of hazard characteristics

For the purposes of subparagraph 30(2)(c)(iv) of the IC General Rules, the information required to demonstrate that a chemical does not have the hazard characteristic, **persistent and bioaccumulative**, is confirmation that the chemical (or the chemical of which it is an ester or salt) is not on the **list of chemicals with high hazards for categorisation** based on it being persistent and bioaccumulative.

In addition, if the environment exposure band for the introduction is 2 (and you are seeking to demonstrate that the introduction meets the criteria for very low risk in accordance with table item 16, section 29 of the IC General Rules), or 3 or 4, at least one of the following:

- information that demonstrates that the chemical is an inorganic chemical, or
- information to demonstrate that the chemical is a biological chemical, or
- information that demonstrates that the chemical has a molecular weight that is >1,000 g/mol, or
- information that demonstrates that the chemical is a high molecular weight polymer with:
    - < 25% low molecular weight oligomeric species <1,000g/mol, and
    - < 10% low molecular weight oligomeric species <500g/mol, or
- information that demonstrates that the chemical has a solubility in water that is >5g/L, measured following an acceptable test guideline for water solubility, or
- information that demonstrates that the chemical is a gas that is not expected to partition to the aquatic compartment, or
- a suitable in silico prediction for partition coefficient of the chemical itself of log Kow <4.2 (that is not negated by a measured log Kow), or
- a measured value from a study on the chemical or from suitable read-across information, conducted following an acceptable test guideline for partition coefficient, for which log Kow <4.2, or

- if the chemical is not a highly branched organic chemical[13] – a test result from a study on the chemical or from suitable read across information, conducted following an acceptable test guideline for ready biodegradability, which meets at least one of the following degradation pass levels during the period specified in the test method:
    - tests based on dissolved organic carbon (DOC) - ≥ 70% DOC removal, or
    - tests based on carbon dioxide generation - ≥ 60% theoretical carbon dioxide, or
    - tests based on oxygen depletion - ≥ 60% theoretical oxygen demand, or
- a test result from a study on the chemical, conducted following an acceptable test guideline for ready biodegradability, which meets at least one of the following degradation pass levels during the period specified in the test method:
    - tests based on dissolved organic carbon (DOC) - ≥ 70% DOC removal, or
    - tests based on carbon dioxide generation - ≥ 60% theoretical carbon dioxide, or
    - tests based on oxygen depletion - ≥ 60% theoretical oxygen demand, or
- if the chemical is not a highly branched organic chemical[14] – a test result from a study on the chemical or from suitable read across information, conducted following an acceptable test guideline for transformation in aquatic sediment systems, results in both:
    - a degradation half-life in water of < 2 months, and
    - a degradation half-life in sediment of < 6 months, or
- a test result from the chemical, conducted following an acceptable test guideline for transformation in aquatic sediment systems, results in both:
    - a degradation half-life in water of < 2 months, and
    - a degradation half-life in sediment of < 6 months, or
- a test result from an in vivo study on the chemical or from suitable read-across information, conducted following an acceptable test guideline for bioconcentration, for which the BCF <2,000, or
- a test result from an in vivo study on the chemical or from suitable read-across information, conducted following an acceptable test guideline for bioaccumulation, for which the BAF <2,000.

[13] If the chemical *is* a highly branched organic chemical, in silico predictions and read across information cannot be used to demonstrate that the chemical does not have the persistence aspect of the persistent and bioaccumulative hazard characteristic – only studies on the chemical itself, as described in the next dot point, are acceptable

[14] If the chemical *is* a highly branched organic chemical, in silico predictions and read across information cannot be used to demonstrate that the chemical does not have the persistence aspect of the persistent and bioaccumulative hazard characteristic – only studies on the chemical itself, as described in the next dot point, are acceptable

6.29 Toxic to any aquatic life – Environment hazard band B

6.29.1 Clause 4 of Part 2, Schedule 1 to the IC General Rules

For the purposes of table item 8 of Clause 4, Part 2, Schedule 1 of the IC General Rules:

Toxic to any aquatic life means that any of the following apply to the industrial chemical:

- the chemical is known to cause:
    - toxic injury to an organism following short term aquatic exposure as described in chapter 4.1 of the GHS, with the chemical classified as acute aquatic toxicity (category 2), or
    - adverse effects to an organism during aquatic exposures determined in relation to the life-cycle of the organism, as described in chapter 4.1 of the GHS, with the chemical classified as chronic aquatic toxicity (category 2), or
- an in vivo acute study on the chemical:
    - conducted following an acceptable test guideline for acute toxicity to fish results in a 96h LC50 >1mg/L but ≤10mg/L, or
    - conducted following an acceptable test guideline for acute toxicity to invertebrates results in a 48h EC50 >1mg/L but ≤10mg/L, or
    - conducted following an acceptable test guideline for acute toxicity to algae or other aquatic plants results in a 72 or 96h ErC50 >1mg/L but ≤10mg/L, or
- an in vivo chronic study on the chemical conducted following an acceptable test guideline for chronic toxicity to fish, chronic toxicity to invertebrates, or chronic toxicity to algae or other aquatic plants results in a:
    - NOEC or EC_{10} >0.1mg/L but ≤1mg/L (for chemicals that are not readily biodegradable), or
    - NOEC or EC_{10} >0.01mg/L but ≤0.1mg/L (for chemicals that are readily biodegradable), or
- a suitable in silico prediction for acute aquatic toxicity results in a prediction of:
    - for fish - 96h LC50 >1mg/L but ≤10mg/L, or
    - for invertebrates - 48h EC50 >1mg/L but ≤10mg/L, or
    - for algae or other aquatic plants - 72 or 96h ErC50 >1mg/L but ≤10mg/L, or

  and the predictions have not been negated by in vivo studies conducted on the chemical for aquatic toxicity.

6.29.2 Section 30 of the IC General Rules - Information required to demonstrate the absence of hazard characteristics

For the purposes of subparagraph 30(2)(c)(iv) of the IC General Rules, the information required to demonstrate that a chemical does not have the hazard characteristic, **toxic to any aquatic life**, is at least one of the following:

- information that demonstrates that the chemical has a molecular weight >1,000g/mol and has a low cationic density, or
- information that demonstrates that the chemical is a high molecular weight polymer that has a low cationic density, or

- information that demonstrates that the chemical is a substance covered by Entry 9 of Annex V of the REACH Regulation, or
- if the chemical is not a biocidal active and not a persistent, highly branched organic chemical[15] – information on aquatic toxicity for all three trophic levels (fish, invertebrates and algae), from suitable in silico predictions on the chemical or in vivo studies on the chemical or from suitable read-across information conducted following acceptable test guidelines for aquatic toxicity, with the following results for all three trophic levels:
    - acute aquatic toxicity >10 mg/L (LC50 (fish), or EC50 (invertebrates) or ErC50 (algae)), or
    - chronic aquatic toxicity NOEC or EC_{10} >1mg/L (for chemicals that are not readily biodegradable), or
    - chronic aquatic toxicity NOEC or EC_{10} >0.1mg/L (for chemicals that are readily biodegradable), or
- test results for all three trophic levels (fish, invertebrates and algae) from in vivo studies on the chemical or from suitable read-across information, conducted following acceptable test guidelines for chronic aquatic toxicity with the following results for all three trophic levels:
    - NOEC or EC_{10} >1mg/L (for chemicals that are not readily biodegradable), or
    - NOEC or EC_{10} >0.1mg/L (for chemicals that are readily biodegradable).

6.30 Polymer that is not stable – Environment hazard band A

6.30.1 Clause 4 of Part 2, Schedule 1 to the IC General Rules

For the purposes of table item 11 of Clause 4, Part 2, Schedule 1 to the IC General Rules:

Polymer that is not stable means that all of the following apply to the industrial chemical:

- the chemical is a polymer, and
- the polymer substantially degrades, decomposes or depolymerises during use; that is, the polymer is considerably, meaningfully or to a significantly large extent, changed into simpler, smaller molecular weight chemicals as the result of processes including, but not limited to:
    - oxidation
    - hydrolysis
    - heat
    - sunlight
    - attack by solvents

[15] If the chemical *is* a biocidal active or a persistent, highly branched organic chemical, in silico predictions cannot be used to demonstrate that the chemical does not have the toxic to any aquatic life hazard characteristic – only in vivo chronic aquatic toxicity studies, as described in the next dot point, are acceptable

- microbial action.

6.30.2 Section 30 of the IC General Rules - Information required to demonstrate the absence of hazard characteristics

For the purposes of subparagraph 30(2)(c)(iv) of the IC General Rules, the information required to demonstrate that a chemical does not have the hazard characteristic, **polymer that is not stable**, is at least one of the following:

- information that demonstrates that the polymer is protected from degradation by being encapsulated during use, or
- information that demonstrates that all of the following applies to the polymer:
    - it is not designed to be pyrolysed or burnt, and
    - it is not designed or reasonably anticipated to substantially photodegrade, and
    - it is not designed or reasonably anticipated to substantially biodegrade, and
    - it is not explosive, and
    - it is hydrolytically stable (T½ ≥12 hours), and
    - it is not a biological polymer, and
    - it is not a polysaccharide, and
    - if it is a polymer that contains polyethylene glycol (PEG) functionalities and has a solubility in water of >200 mg/L - measured data demonstrates that the polymer does not substantially biodegrade, and
    - if it is a polymer that contains polypropylene glycol (PPG) functionalities and has a solubility in water of >200 mg/L - measured data demonstrates that the polymer does not substantially biodegrade.

6.31 Bioaccumulation potential – Environment hazard band A

6.31.1 Clause 4 of Part 2, Schedule 1 to the IC General Rules

For the purposes of table item 12 of Clause 4, Part 2, Schedule 1 to the IC General Rules:

Bioaccumulation potential means that at least one of the following applies to the industrial chemical:

- it has a bioconcentration factor (BCF) ≥500, or
- it has a bioaccumulation factor (BAF) ≥500, or
- it has a partition coefficient (log Kow) ≥4.0 (unless a measured BAF or BCF is <500).

6.31.2 Section 30 of the IC General Rules - Information required to demonstrate the absence of hazard characteristics

For the purposes of subparagraph 30(2)(c)(iv) of the IC General Rules, the information required to demonstrate that a chemical does not have the hazard characteristic, **bioaccumulation potential**, is at least one of the following:

- information that demonstrates that the chemical is an inorganic chemical, or
- information that demonstrates that the chemical has a high molecular weight, or
- information that demonstrates that the chemical is a high molecular weight polymer with:
    - < 25% low molecular weight oligomeric species <1,000g/mol
    - <10% low molecular weight oligomeric species <500g/mol, or
- information that demonstrates that the chemical has a solubility in water that is >5g/L, measured following an acceptable test guideline for water solubility, or
- information that demonstrates that the chemical is a gas that is not expected to partition to the aquatic compartment, or
- if the chemical is not a highly branched organic chemical[16] – a test result from a study on the chemical or suitable read across information, conducted following an acceptable test guideline for ready biodegradability, which meets at least one of the following degradation pass levels during the period specified in the test method:
    - tests based on dissolved organic carbon (DOC) - ≥ 70% DOC removal, or
    - tests based on carbon dioxide generation - ≥ 60% theoretical carbon dioxide, or
    - tests based on oxygen depletion - ≥ 60% theoretical oxygen demand, or
- a test result from a study on the chemical, conducted following an acceptable test guideline for ready biodegradability, which meets at least one of the following degradation pass levels during the period specified in the test method:
    - tests based on dissolved organic carbon (DOC) - ≥ 70% DOC removal, or
    - tests based on carbon dioxide generation - ≥ 60% theoretical carbon dioxide, or
    - tests based on oxygen depletion - ≥ 60% theoretical oxygen demand, or
- a measured value from a study on the chemical or from suitable read-across information, conducted following an acceptable test guideline for partition coefficient, for which log Kow <4.0, or
- a suitable in silico prediction for partition coefficient of the chemical using KOWWIN on the chemical for log Kow < 4.0 (that is not negated by a measured log Kow), or
- a test result from an in vivo study on the chemical or from suitable read-across information, conducted following an acceptable test guideline for bioconcentration, for which the BCF <500, or
- a test result from an in vivo study on the chemical or from suitable read-across information, conducted following an acceptable test guideline for bioaccumulation, for which the BAF <500.

[16] If the chemical *is* a highly branched organic chemical, in silico predictions and read across information cannot be used to demonstrate that the chemical does not have the bioaccumulation potential hazard characteristic – only studies on the chemical itself, as described in the next dot point, are acceptable.

6.32 Industrial chemical (other than a polymer) that does not meet the criteria for ready biodegradability – Environment hazard band A

6.32.1 Clause 4 of Part 2, Schedule 1 to the IC General Rules

For the purposes of table item 13 of Clause 4, Part 2, Schedule 1 to the IC General Rules:

Industrial chemical (other than a polymer) that does not meet the criteria for ready biodegradability, means that a study on the chemical, conducted following an acceptable test guideline for ready biodegradability, results in at least one of the following, as relevant to the test method used, and within the period specified in the test method:

- ≤70% dissolved organic carbon (DOC) removal, or
- ≤ 60% theoretical carbon dioxide, or
- ≤60% theoretical oxygen demand.

6.32.2 Section 30 of the IC General Rules - Information required to demonstrate the absence of hazard characteristics

For the purposes of subparagraph 30(2)(c)(iv) of the IC General Rules, the information required to demonstrate that a chemical does not have the hazard characteristic, **industrial chemical (other than a polymer) that does not meet the criteria for ready biodegradability**, is at least one of the following:

- information that demonstrates that the chemical is highly volatile and it is expected to predominately partition to the air compartment, or
- information that demonstrates that it is an inorganic chemical, or
- information that demonstrates that it is a biological chemical, or
- if the chemical is not a highly branched organic chemical[17] – a test result from a study on the chemical or suitable read across information, conducted following an acceptable test guideline for ready biodegradability, which meets at least one of the following degradation pass levels during the period specified in the test method:
    - tests based on dissolved organic carbon (DOC) - ≥70% DOC removal, or
    - tests based on carbon dioxide generation - ≥ 60% theoretical carbon dioxide
    - tests based on oxygen depletion -≥ 60% theoretical oxygen demand, or
- a test result from a study on the chemical, conducted following an acceptable test guideline for ready biodegradability, which meets at least one of the following degradation pass levels during the period specified in the test method:
    - tests based on dissolved organic carbon (DOC) - ≥70% DOC removal, or

[17] If the chemical *is* a highly branched organic chemical, in silico predictions and read across information cannot be used to demonstrate that the chemical does not have the hazard characteristic, industrial chemical (other than a polymer) that does not meet the criteria for ready biodegradability – only studies on the chemical itself, as described in the next dot point, are acceptable

- tests based on carbon dioxide generation - ≥60% theoretical carbon dioxide, or
- tests based on oxygen depletion - ≥60% theoretical oxygen demand.

6.33 Harmful to any aquatic life – Environment hazard band A

6.33.1 Clause 4 of Part 2, Schedule 1 to the IC General Rules

For the purposes of table item 14 of Clause 4, Part 2, Schedule 1 to the IC General Rules:

Harmful to any aquatic life means that any of the following apply to the industrial chemical:

- the chemical is known to cause:
  - toxic injury to an organism following short term aquatic exposure , as described in chapter 4.1 of the GHS, with the chemical classified as acute aquatic toxicity (category 3), or
  - adverse effects to an organism during aquatic exposures determined in relation to the life-cycle of the organism, as described in chapter 4.1 of the GHS, with the chemical classified as chronic aquatic toxicity (category 3 or 4), or
- an in vivo acute study on the chemical:
  - conducted following an acceptable test guideline for acute toxicity to fish results in a 96h LC50 >10mg/L but ≤100mg/L, or
  - conducted following an acceptable test guideline for acute toxicity to invertebrates results in a 48h EC50 >10mg/L but ≤100mg/L, or
  - conducted following an acceptable test guideline for acute toxicity to algae or other aquatic plants results in a 72 or 96h ErC50 >10mg/L but ≤100mg/L, or
- an in vivo chronic study on the chemical conducted following an acceptable test guideline for chronic toxicity to fish, chronic toxicity to invertebrates, or chronic toxicity to algae or other aquatic plants results in a:
  - NOEC or EC_{10} >0.1mg/L but ≤1mg/L (for chemicals that are readily biodegradable), or
- a suitable in silico prediction for acute aquatic toxicity results in a prediction of:
  - for fish - 96h LC50 >10mg/L but ≤100mg/L, or
  - for invertebrates - 48h EC50 >10mg/L but ≤100mg/L, or
  - for algae or other aquatic plants - 72 or 96h ErC50 >10mg/L but ≤100mg/L.

  and the predictions have not been negated by in vivo studies conducted on the chemical for aquatic toxicity.

6.33.2 Section 30 of the IC General Rules - Information required to demonstrate the absence of hazard characteristics

For the purposes of subparagraph 30(2)(c)(iv) of the IC General Rules, the information required to demonstrate that a chemical does not have the hazard characteristic, **harmful to any aquatic life**, is at least one of the following:

- information that demonstrates that the chemical has a molecular weight >1,000g/mol and has a low cationic density, or
- information that demonstrates that the chemical is a high molecular weight polymer that has a low cationic density, or
- information that demonstrates that the chemical is a substance covered by Entry 9 of Annex V of the REACH Regulation, or
- if the chemical is not a biocidal active and not a persistent, highly branched organic chemical[18] – information on aquatic toxicity for all three trophic levels (fish, invertebrates and algae), from suitable in silico predictions on the chemical or in vivo studies on the chemical or from suitable read-across information conducted following acceptable test guidelines for aquatic toxicity, with the following results for all three trophic levels:
    - acute aquatic toxicity >100 mg/L (LC50 (fish), or EC50 (invertebrates) or ErC50 (algae)), or
    - chronic aquatic toxicity NOEC or EC_{10} >1mg/L (for chemicals that are readily biodegradable), or
- test results for all three trophic levels (fish, invertebrates and algae) from in vivo studies on the chemical or from suitable read-across information, conducted following acceptable test guidelines for chronic aquatic toxicity with the following results for all three trophic levels:
    - NOEC or EC_{10} > 1mg/L (for chemicals that are readily biodegradable).

7 Definitions of terms in Schedule 2 to the IC General Rules

7.1 Clause 1 of Part 1, Schedule 2 to the IC General Rules

7.1.1 Polymer is stable

For the purposes of paragraph (d) of Clause 1, Part 1, Schedule 2 of the IC General Rules:

Polymer is stable means that all of the following apply to the industrial chemical:

- the chemical is a polymer, and
- the polymer does not substantially degrade, decompose or depolymerise during use; that is, the polymer is not considerably, meaningfully or to a significantly large extent,

[18] If the chemical *is* a biocidal active or a persistent, highly branched organic chemical, in silico predictions cannot be used to demonstrate that the chemical does not have the harmful to any aquatic life hazard characteristic – only in vivo chronic aquatic toxicity studies, as described in the next dot point, are acceptable

changed into simpler, smaller molecular weight chemicals as the result of processes including, but not limited to:

- oxidation
- hydrolysis
- heat
- sunlight
- attack by solvents
- microbial action.

8 Appendices

8.1 List of chemicals with high hazards for categorisation

The list of chemicals with high hazards for categorisation consists of chemicals that are present on the following information sources:

- Safe Work Australia's Hazardous Chemical Information System (HCIS) — list of substances classified for physical-chemical and (eco)toxicological hazards. Included substances 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. Included substances are those classified for CMR and PBT.
- European Union Substances of Very High Concern (EU SVHC) — list of CMR, PBT and vPvB substance, or substances with equivalent concern. Included substances are those that are identified as CMR, PBT, vPvB, or having endocrine disrupting properties.
- United States National Toxicology Program (US NTP) Report on Carcinogens — list of carcinogenic substances. Included substances are those that are known human carcinogens and reasonably anticipated to be human carcinogens.
- International Agency for Research on Cancer (IARC) Monographs — list of carcinogens. Included substances are carcinogens classified in Groups 1, 2A and 2B.
- European Commission Endocrine Disruptors Strategy — list of substances investigated for potential endocrine activity. Included substances are those listed in Category 1, identified as having endocrine activity in at least one animal study.
- United Nations Environment Programme scientific knowledge on endocrine disrupting chemicals — list of substances from a review of existing global initiatives on endocrine disrupting chemicals and potential endocrine disrupting chemicals. Included substances are those identified as having known or potential endocrine activity.
- Government of Canada Toxic Substances List (Schedule 1) — list of inorganic and organic chemicals with known health and/or environmental concerns. Included substances are those that are identified as having hazard characteristics in human health hazard band C or environment hazard bands D or C.
- Chemical Substances Control Law of Japan (CSCL) Class I and II Specified Chemical Substances — list of organic chemicals with known health and/or environmental concerns. Included substances are those identified as PBT (Class I) and those posing a concern for long-term toxicity in humans and the environment (Class II).

- European Chemicals Agency (ECHA) REACH Annex XIV Authorisation — list of inorganic and organic chemicals with known health and/or environmental concerns. Included substances are those identified as CMR, PBT or vPvB. Also included are substances with equivalent level of concern or having probable CMR, PBT or vPvB effects.

8.2 In silico information

Tables 1 and 2 provide an overview for which human health and environment hazard characteristics have in silico options, and which in silico models are appropriate.

Table 1 - In silico models for human health hazard characteristics

In silico model	Acute toxicity	Skin irritation / Skin corrosion	Eye damage / Eye irritation	Skin sensitisation	Respiratory sensitisation	Genetic toxicity
OECD QSAR Toolbox	Yes	Yes	Yes	Yes	Yes	Yes
VEGA QSAR	-	-	-	Yes	-	Yes
Danish EPA QSAR Database	Yes	Yes	-	Yes	Yes	Yes
T.E.S.T.	Yes	-	-	-	-	Yes

In silico model	Acute toxicity	Skin irritation / Skin corrosion	Eye damage / Eye irritation	Skin sensitisation	Respiratory sensitisation	Genetic toxicity
ToxTree	-	Yes	Yes	Yes	Yes (as protein binding alerts)	Yes
Derek Nexus	-	Yes	Yes	Yes	Yes	Yes
Sarah Nexus	-	-	-	-	-	Yes
OASIS-TIMES	Yes	Yes	Yes	Yes	-	Yes
Chemtunes	Yes	-	-	Yes	-	Yes
Case ULTRA	Yes	Yes	Yes	Yes	-	Yes
ADMET Predictor	-	-	-	Yes	Yes	Yes

In silico model	Acute toxicity	Skin irritation / Skin corrosion	Eye damage / Eye irritation	Skin sensitisation	Respiratory sensitisation	Genetic toxicity
Biovia Discovery Studio (TOPKAT)	Yes	Yes	Yes	Yes	-	Yes
ACD Percepta	Yes	Yes	Yes	-	-	Yes
Hazard Expert	-	-	-	-	-	Yes
Cheminformatics Tool Kit	Yes	Yes	Yes	Yes	-	Yes
Toxread	-	-	-	-	-	Yes
PaDEL-DDPredictor	-	Yes	Yes	-	-	-
Tox21	-	-	-	Yes	-	-

Table 2 - In silico models for environment hazard characteristics

In silico model	Acute aquatic toxicity	Chronic aquatic toxicity	Persistence (as a function of half-life)	Bioaccumulation (as a function of Log Kow)
ECOSAR	Yes	-	-	-
EPI Suite	-	-	Yes	-
KOWWIN	-	-	-	Yes

8.3 Suitable read across information

For your read across information to be considered suitable, you must consider the suitability of the source chemical/s for each of the hazard characteristics you are trying to predict. To do this you will need to look at the source chemical's areas of similarity to your chemical, outlined below. If you are using a category approach, then in addition to the following considerations, you may also need to consider that the chemical's properties may not be very similar. Rather, they may follow a regular trend, which allows you to predict the hazard characteristic for your chemical.

- **Similar structure**
  - Does the source chemical/s contain most, if not all, of the same structural features as your (target) chemical?
  - Are the relevant substructures for the hazard characteristic for which there is a data gap similar?
- **Similar physical-chemical properties**
  - Does the source chemical/s have similar physical-chemical properties to your chemical? This may influence bioavailability and environmental fate.
- **Similar metabolism/degradation**
  - Is metabolism/degradation important for the hazard characteristic you are predicting?
  - If so, does the source chemical/s produce similar breakdown products (metabolites or degradants) to your chemical?
- **Similar mode of action**
  - Do you know the relevant mode of action for the hazard characteristic you are predicting?
  - If so, does the source chemical/s have a similar mode of action to your chemical?
- **Similar reactivity/stability**
  - Does the source chemical/s have similar reactivity/stability to your chemical?

Not all of these will be relevant for every read-across justification. Regardless, you will still need to consider them all and document even if an area is not relevant.

UVCB substances (chemical substances of Unknown or Variable Composition, Complex reaction products and Biological materials) may need more justification to account for complexity of the composition and its impacts on the predictions of hazard characteristics.

8.4 Acceptable test guidelines

The acceptable test guidelines for each hazard characteristic and property are set out in the tables below. They include:

- current Organisation for Economic Cooperation and Development (OECD) test guidelines (and their adopted versions if the version shown in the table below is only a draft version)

- deleted and superseded OECD test guidelines if the study was done before the guideline was deleted or superseded
- US EPA OPPT (Office of Prevention, Pesticides and Toxic Substances) test guidelines
- US EPA OCSPP (Office of Chemical Safety and Pollution Prevention) Harmonised Test Guidelines
- test methods for EU REACH, set out in Council Regulation (EC) No 440/2008 (Test Methods Regulation).

8.4.1 Acceptable test guidelines for human health hazard characteristics

Hazard tested	OECD test guidelines	Equivalent test guidelines
Acute dermal toxicity – in vivo	402 or draft 434	EU Annex V test method B.3 OCSPP 870.1200, OPPT 798.110, OPP 81-2
Acute inhalation toxicity – in vivo	403 or 436 or draft 433	EU Annex V test methods B.2 or B.52 OCSPP 870.1300, OPPT 798.1150, OPP 81-3
Acute oral toxicity – in vivo	420, 423, 425 or deleted 401	EU Annex V test methods B.1, B.1 bis, B.1 tris OCSPP 870.1100, OPPT 798.1175, OPP 81-1
Acute oral toxicity – in vitro	129[19]	-
Carcinogenicity - in vivo	451	EU Annex V test method B.32 OCSPP 870.4200, OPPT 798.3300, OPP 83-2
	453	EU Annex V test method B.33 OCSPP 870.4300, OPPT 798.3320, OPP 83-5

[19] 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)

Hazard tested	OECD test guidelines	Equivalent test guidelines
Chromosomal abnormalities – in vivo	474	EU Annex V test method B.12 OCSPP 870.5395, OPPT 798.5395, OPP 84-2
	475	EU Annex V test method B.11 OCSPP 870.5385, OPPT 798.5385, OPP 84-2
Chromosomal abnormalities – in vitro	473	EU Annex V test method B.10 OCSPP 870.5375, OPPT 798.5375, OPP 84-2
	487	EU Annex V test method B.49
	490	-
Chronic toxicity – in vivo	452	EU Annex V test method B.30 OCSPP 870.4100, OPPT 798.3260, OPP 83-1
	453	EU Annex V test method B.33 OCSPP 870.4300, OPPT 798.3320, OPP 83-5
Developmental toxicity – in vivo	414	EU Annex V test method B.31 OCSPP 870.3700, OPPT 798.4900 or OPP 83-3
	426	OCSPP 870.6300, OPP 83-6
	422[20]	OCSPP 870.3650[10]
	437	EU Annex V test method B.47

[20] Only for the purposes of part 6.5.1 of these Guidelines

Hazard tested	OECD test guidelines	Equivalent test guidelines
Eye damage – in vitro		EURL ECVAM DB-ALM protocols No. 98 and 124
	438	EU Annex V test method B.48 EURL ECVAM DB-ALM protocol No. 80
	460	EURL ECVAM DB-ALM protocol No. 71
	491	-
	494	-
Eye irritation – in vitro	492	-
Eye irritation – in vivo	405	EU Annex V test methods B.5 OCSPP 870.2400, OPPT 798.4500 or OPP 81-4
Gene mutation – in vivo	486	EU Annex V test method B.39
	488	EU Annex V test method B.58
	489	-
Gene mutation – in vitro	471	EU Annex V test methods B.13 and B.14 OCSPP 870.5100, OPPT 798.5100, OPPT 798.5265, OPP 84-2
	476	EU Annex V test method B.17 OCSPP 870.5300, OPPT 798.5300, OPP 84-2
	478	EU Annex V test method B.22 OPPT 798.5450, 870.5450

Hazard tested	OECD test guidelines	Equivalent test guidelines
Heritable germ cell mutagenicity – in vivo	485	EU Annex V test method B.25 OPPT 798.5460, 870.5460
Reproductive toxicity – in vivo	421	OCSPP 870.3550
	422[21]	OCSPP 870.3650[11]
	443	EU Annex V test method B.56
	415	EU Annex V test method B.34
	416	EU Annex V test method B.35 OCSPP 870.3800, OPPT 798.4700 or OPP 83-4
Skin corrosion – in vitro	430	EU Annex V test method B.43 EURL ECVAM DB-ALM protocol No.115
	431	EU Annex V test method B.40 EURL ECVAM DB-ALM protocols No.118 and 119
	435	EURL ECVAM DB-ALM protocol No.116
Skin irritation – in vitro	439	EU Annex V test method B.46 EURL ECVAM DB-ALM protocols No.131, 135 and 138
Skin irritation – in vivo	404	EU Annex V test method B.4. OCSPP 870.2500, OPPT 798.4470, OPP 81-5

[21] Only for the purposes of part 6.4.1 of these Guidelines

Hazard tested	OECD test guidelines	Equivalent test guidelines
Skin sensitisation – in chemico (1st key event in skin sensitisation)	442C	EU Annex V test methods B.59 EURL ECVAM DB-ALM protocol No.154
Skin sensitisation – in vitro (2nd key event in skin sensitisation)	442D	EU Annex V test method B.60 EURL ECVAM DB-ALM protocol No.155
Skin sensitisation – in vitro (3rd key event in skin sensitisation)	442E	EURL ECVAM DB-ALM protocol No.158
Skin sensitisation – in vivo	406	EU Annex V test method B.6 OCSPP 870.2600, OPPT 798.4100 or OPP 81-6
	429	EU Annex V test method B.42
	442A	EU Annex V test method B.50
	442B	EU Annex V test method B.51
Subacute dermal toxicity - in vivo	410	EU Annex V test method B.9 OCSPP 870.3200 or OPP 82-2
Subacute inhalation toxicity – in vivo	412	EU Annex V test method B.8
Subacute oral toxicity – in vivo	407	EU Annex V test method B.7 OCSPP 870.3050

Hazard tested	OECD test guidelines	Equivalent test guidelines
Subchronic dermal toxicity – in vivo	411	EU Annex V test method B.28 OCSPP 870.3250, OPPT 798.2250, OPP 82-3
Subchronic inhalation toxicity – in vivo	413	EU Annex V test method B.29 OCSPP 870.3465, OPPT 798.2450, OPP 82-4
Subchronic oral toxicity – in vivo	408	EU Annex V test method B.26 OCSPP 870.3100, OPPT 798.2650, OPP 82-1
	409	EU Annex V test method B.27 OCSPP 870.3150, OPP 82-1

8.4.2 Acceptable test guidelines for environment hazard characteristics and properties

Hazard or property tested	OECD test guidelines	Equivalent test guidelines
Acute aquatic toxicity – in vivo (fish)	203	ISO 10229 EU Annex V test method C.1 OCSPP 850.1075, OPP 72-1, OPP 72-3
Acute aquatic toxicity – in vivo (invertebrates)	202	ISO 6341 EU Annex V test method C. 2 OCSPP 850.1010 or OPP 72-2
Acute aquatic toxicity – in vivo (algae or other aquatic plants)	201	EU Annex V test methods C.3 OCSPP 850.4550, OPPT 797.1050, OPP 122-2, OPP 123-2
Bioaccumulation	315	OCSPP 850.1710
	317	-
Bioconcentration	305	EU Annex V test methods C.13 OCSPP 850.1730 or OPP 72-6
Chronic aquatic toxicity – in vivo (fish)	210	OCSPP 850.1400 EU Annex V test method C.15
Chronic aquatic toxicity – in vivo (invertebrates)	211	OCSPP 850.1300 EU Annex V test method C.20
Chronic aquatic toxicity – in vivo (algae or other aquatic plants)	201	OCSPP 850.4550 OCSPP 850.4500 EU Annex V test method C.3

Hazard or property tested	OECD test guidelines	Equivalent test guidelines
Partition coefficient	107	EU Annex V test methods A.8 OCSPP 830.7550, OPPT 796.1550, OPP 63-11
	117	EU Annex V test methods A.8 OCSPP 830.7570, OPPT 796.1570, OPP 63-11
	123	EU Annex V test methods A.8
Ready biodegradability	301	EU Annex V test methods C.4 (A-F) OCSPP 835.3110, OPPT 796.3180, 796.3200, 796.3220, 796.3240, 796.3260
Transformation in aquatic sediment systems	308	-

8.4.3 Acceptable test guidelines for water solubility

Property tested	OECD test guidelines	Equivalent test guidelines
Water solubility – chemicals or polymers	105	OPPTS 830.7840 OPPTS 830.7860
Water solubility - polymers	120	-