COMPLIANCE

Tests for EU compliance

Minimum analysis required for oils and cosmetic products

GUIDE

ABioSA GUIDE

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THE ABS CAPACITY DEVELOPMENT INITIATIVE

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Contents

This guide is part of a series of knowledge products produced by ABioSA. These knowledge products and other biotrade resources can be found at www.abs-biotrade.info/projects/abiosa/resources

A glossary of biotrade terms can be found at www.abs-biotrade.info/resources

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Glossary

- **CLP** - Classification, Labelling and Packaging (defined by EC Regulation 1272/2008)
- **ECHA** - European Chemicals Agency
- **EC** - European Council
- **EEA** - European Economic Area
- **EU** - European Union
- **Not Chemically Modified** - This is the chemical structure of a substance that remains unchanged, even after it has undergone a chemical process/treatment, or a physical mineralogical transformation to remove impurities
- **SIP** - Substance Identification Profile
- **REACH** - Registration, Evaluation, Authorisation and Restriction of Chemicals
- **REACH IT** - Central IT system that supports Industry, EU Member State authorities and the European Chemicals Agency (ECHA) to securely submit, process and manage data and dossiers for REACH purposes

Introduction

This ABioSA best practice guide is designed to help small businesses to understand what tests and analyses are required in order for vegetable, seed and essential oils, and cosmetic products, to comply with EU CLP, REACH and cosmetics regulations.

It is based on the regulatory requirements for Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), and Classification, Labelling and Packaging (CLP) and cosmetic products.

The document details the minimum and additional analyses required by regulatory guidelines.

The tests required for a REACH registration are dependent on the amount of a substance being manufactured or imported per year into the EU market.

Each part of EC Regulation 1907/2006 applies to a specific manufacturing or import volume:

Tonnage per year (manufactured/imported)	Standard information required by REACH
1 to < 10	Annex VII
10 to < 100	Annex VII - VIII
100 to < 1000	Annex VII - IX
1000 or more	Annex VII - X

Table 1: *Legal requirements per tonnage band*

Does my substance need to be registered?

You need to check whether your substance needs to be registered or is exempt from registration. This can easily be done on the **website** of the European Chemicals Agency (ECHA), where you can search by CAS number, EC number or chemical name.

If your substance is not registered, this could mean it is exempted. The diagram below shows three main steps to assess if it is exempt.

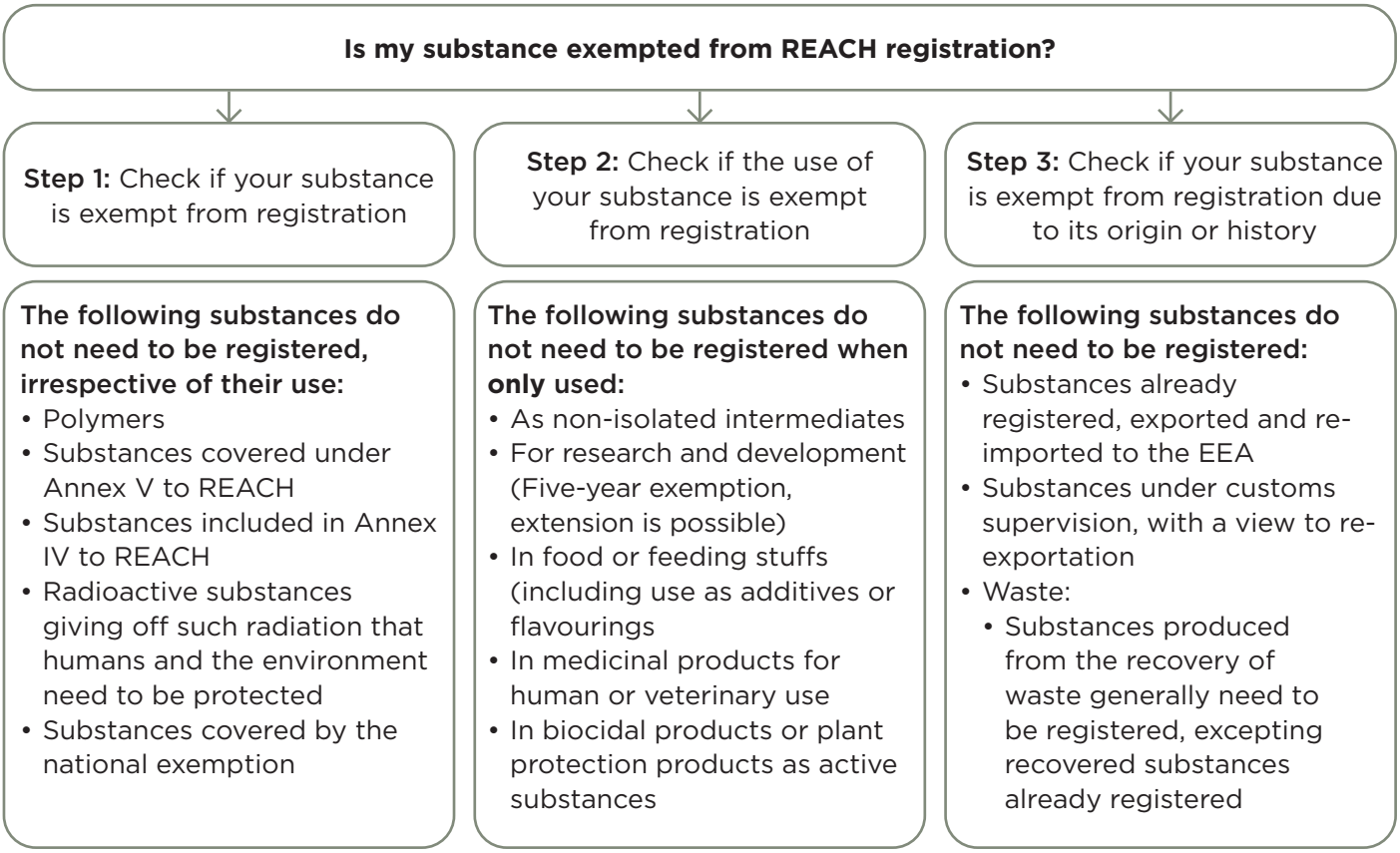


Figure 1: *Overview of substances exempted from REACH – adapted from ECHA (ECHA, n.d.)*

Quick overview assessment of exemption of a substance

If your substance does not meet the requirements of Annex V, and is not exempt from REACH, an inquiry should be submitted to ECHA. The agency will then inform the applicant if there are pre-registered substances or if the substance has already been registered, in which case ECHA will share the Lead Registrant's details in order for the applicant to contact them and share information.

The figure below shows a brief overview of the REACH processes. This guide focuses on tests required for the evaluation of the substance.

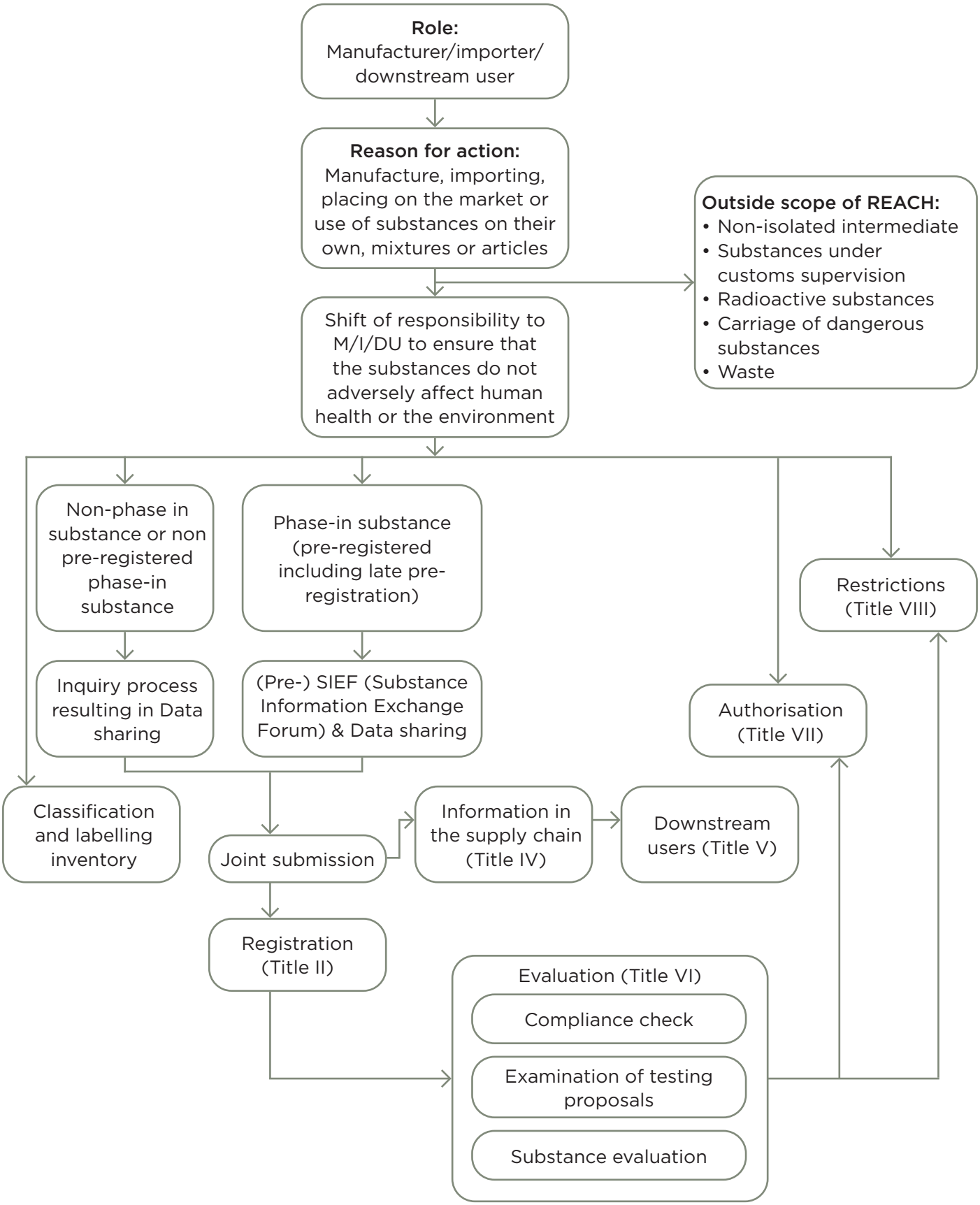


Figure 2: *General overview of REACH processes and scope of this ABioSA guide*

Minimum physical and chemical analyses needed for REACH and CLP

Vegetable oils
Naturally sourced vegetable fats, oils and waxes, and animal fats, oil and waxes, are exempt from REACH, provided they are not chemically modified and are not classified as hazardous. This is according to the EC Regulation 1272/2002 (CLP).

The exception is substances classified as flammable or which irritate the skin or eyes. Substances that are considered persistent, bio-accumulative or toxic (PBTs) according to EC Regulation 1907/2006 are not exempt.

Proof of exemption must be provided by the manufacturer or importer who wishes to use this exemption. An absence of information on the properties of the substance cannot equate to the absence of hazardous properties. To secure an exemption for substances obtained from natural sources based on insufficient information about their hazards would undermine the aims of REACH.

The exemption does not apply to synthetic materials or hydrogenated fats and oils, as they have undergone chemical modification.

EC Regulation 1907/2006 states that a naturally occurring substance should be processed only by manual, mechanical or gravitational means, dissolution in water, flotation, extraction with water, steam distillation or by heating for the purposes of removing water, or the extraction by air. It defines a "not chemically modified substance" as a substance whose chemical structure remains unchanged even after chemical processing/treatment or mineralogical transformation to remove impurities.

The table below indicates the necessary tests needed to prove exemption for vegetable or seed oils.

Vegetable oils			
Test parameters	**Test method/s**	**1-10 tonnes**	**10-100 tonnes**
GC analysis C6-C24, and review of potassium, sodium, calcium, and magnesium salts levels	Suitable gas chromatographic (GC) profile	x	x
PBT/vPvB assessment Seeds - criteria Annex XIII	Existing toxicological data for individual chemical components or use QSAR software to read across	x	x

Table 2: *Basic tests required to prove exemption of vegetable/seed oils*

Below is a process flow to prove exemption for vegetable/seed oils:

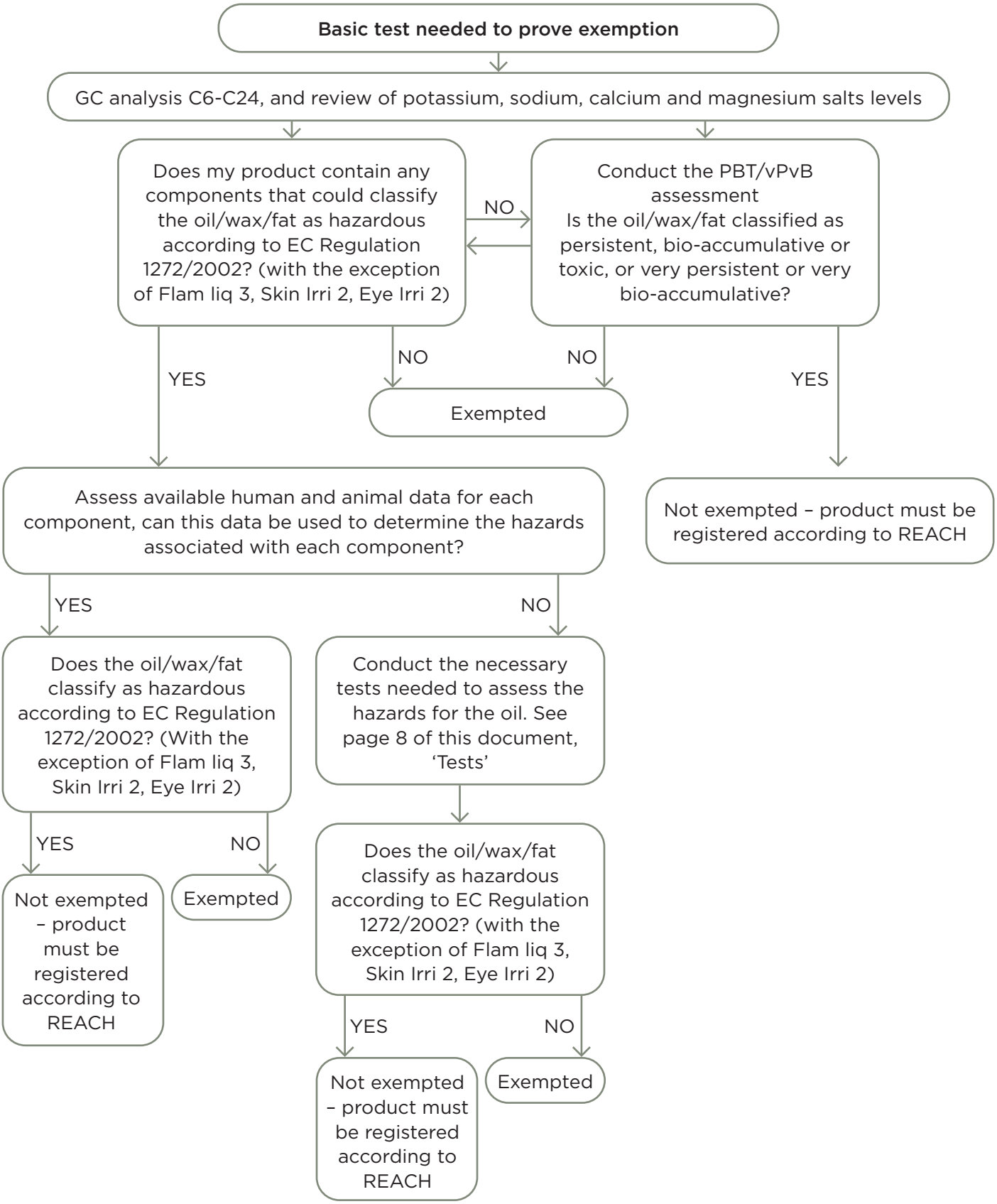


Figure 3: *Process flow to prove exemption of vegetable/seed oils*

Essential oils
The exemption in EC Regulation 1907/2006 does not apply to essential oils as they are hydrophobic liquids with complex compositions, and are derived from parts of plants containing volatile organic compounds, including alcohols, ketones, phenols, esters, aldehydes, etc.

Essential oils are commonly known as a UVCB substance (substance of unknown or variable composition, complex reaction products or biological materials), and may be registered as a single substance under REACH.

Tests

Physical and chemical tests
The diagrams below indicate the necessary and additional physical/chemical tests that may be required for the oil. These are the typical analyses for REACH and CLP.

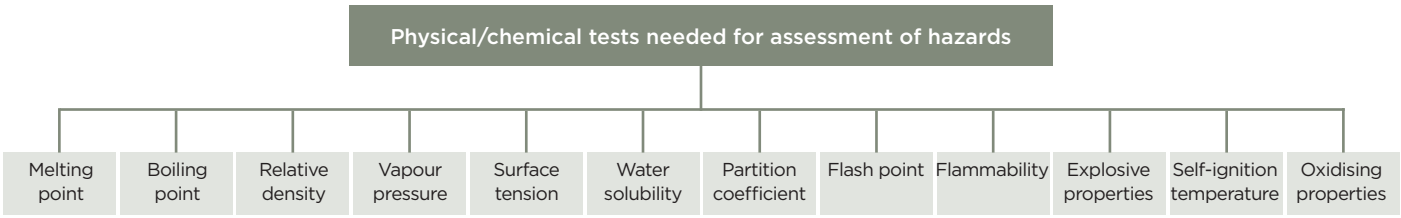


Figure 4: *Overview of physical/chemical tests required for assessment of hazards*

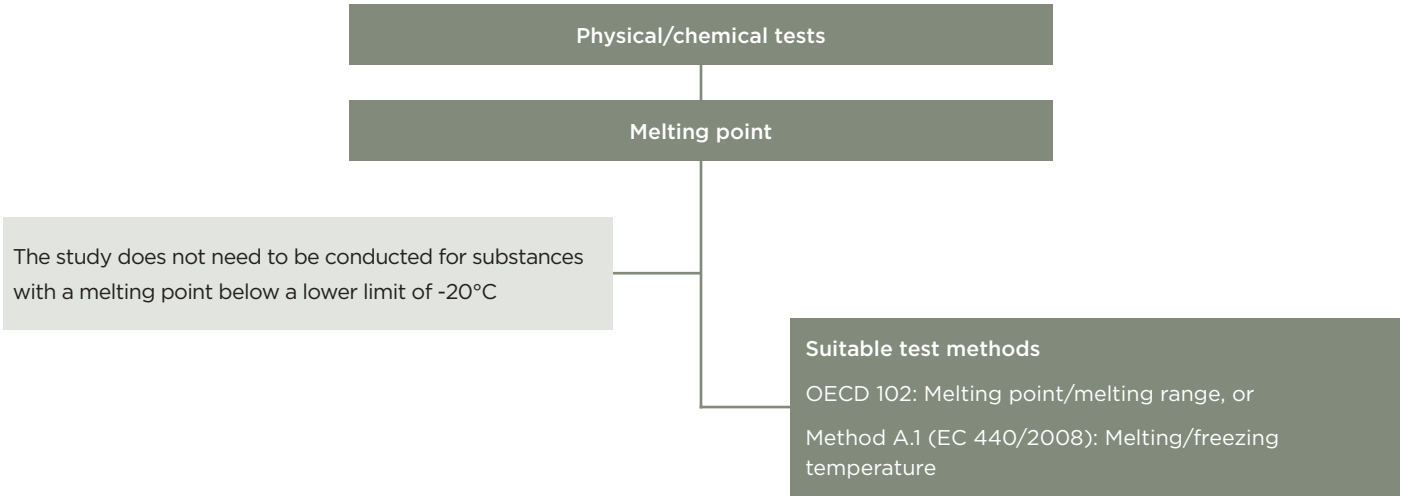


Figure 5: *Physical/chemical tests: Melting point*

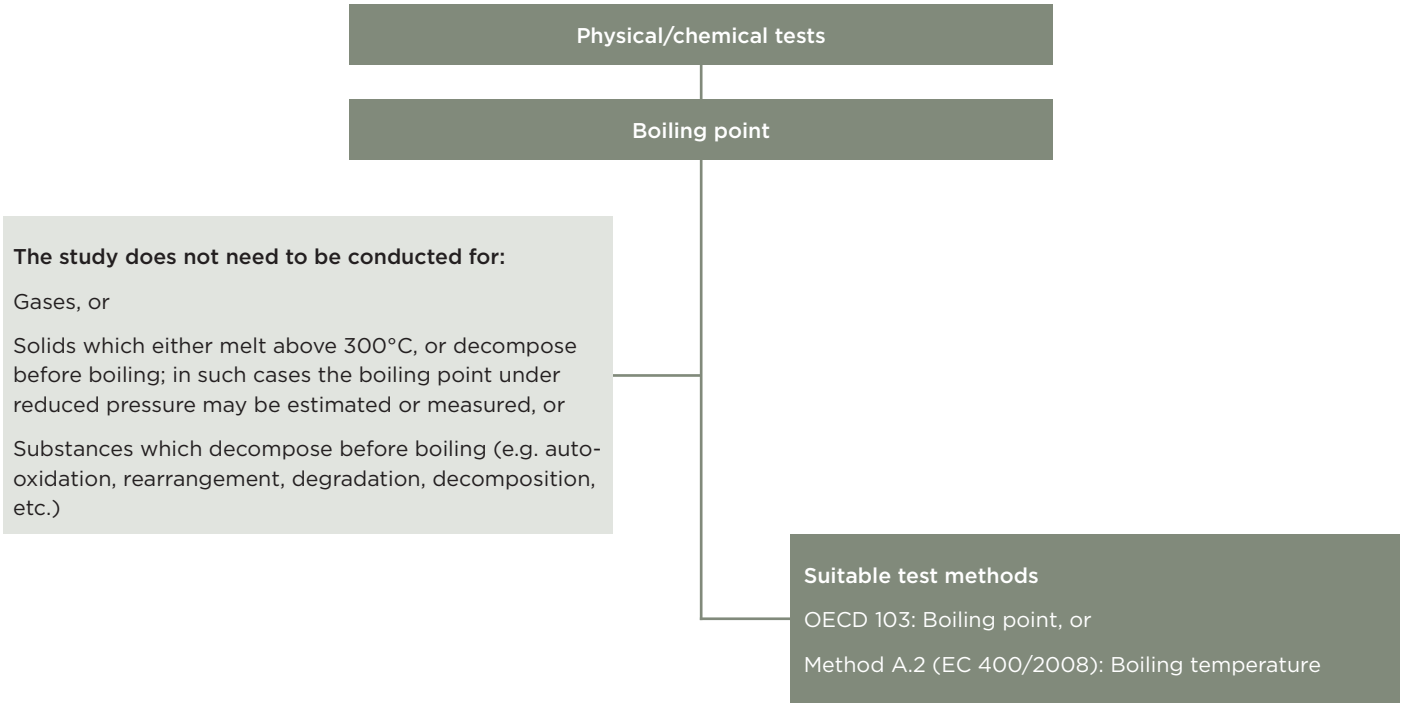


Figure 6: *Physical/chemical tests: Boiling point*

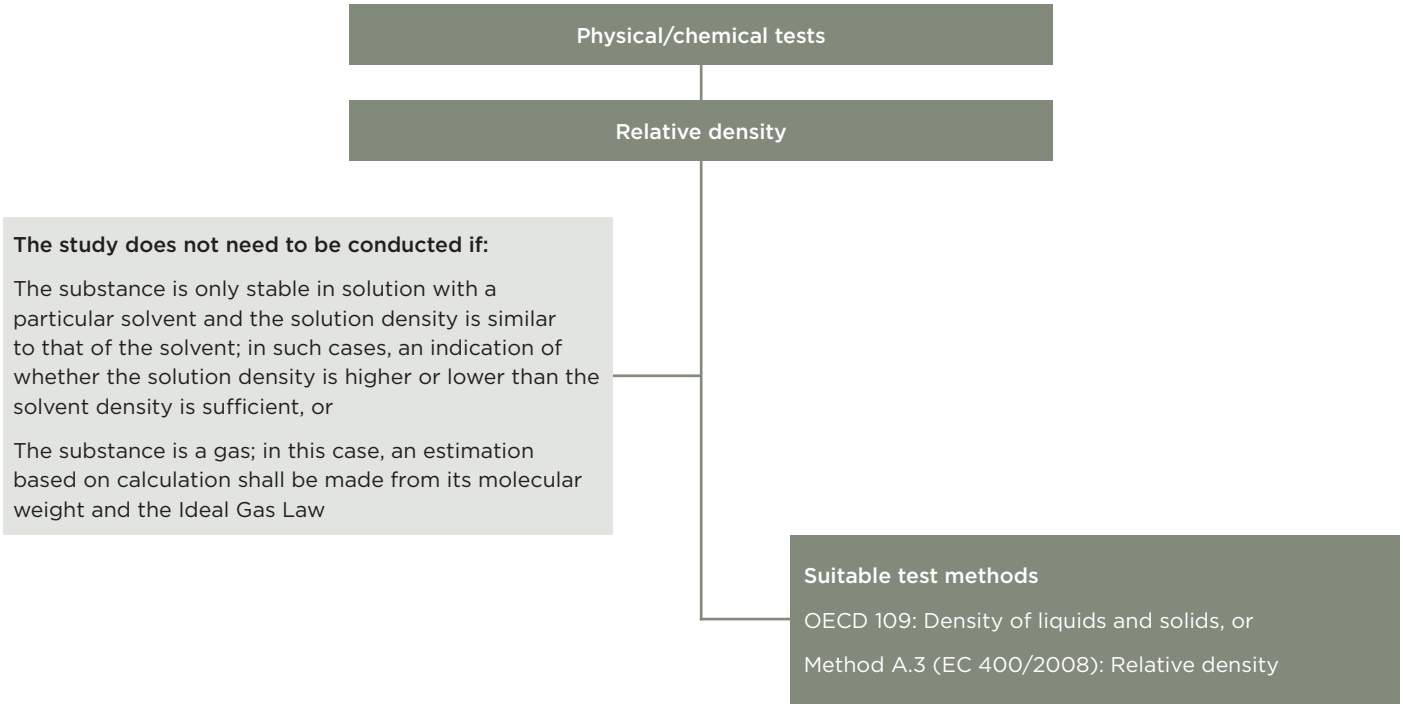


Figure 7: *Physical/chemical tests: Relative density*

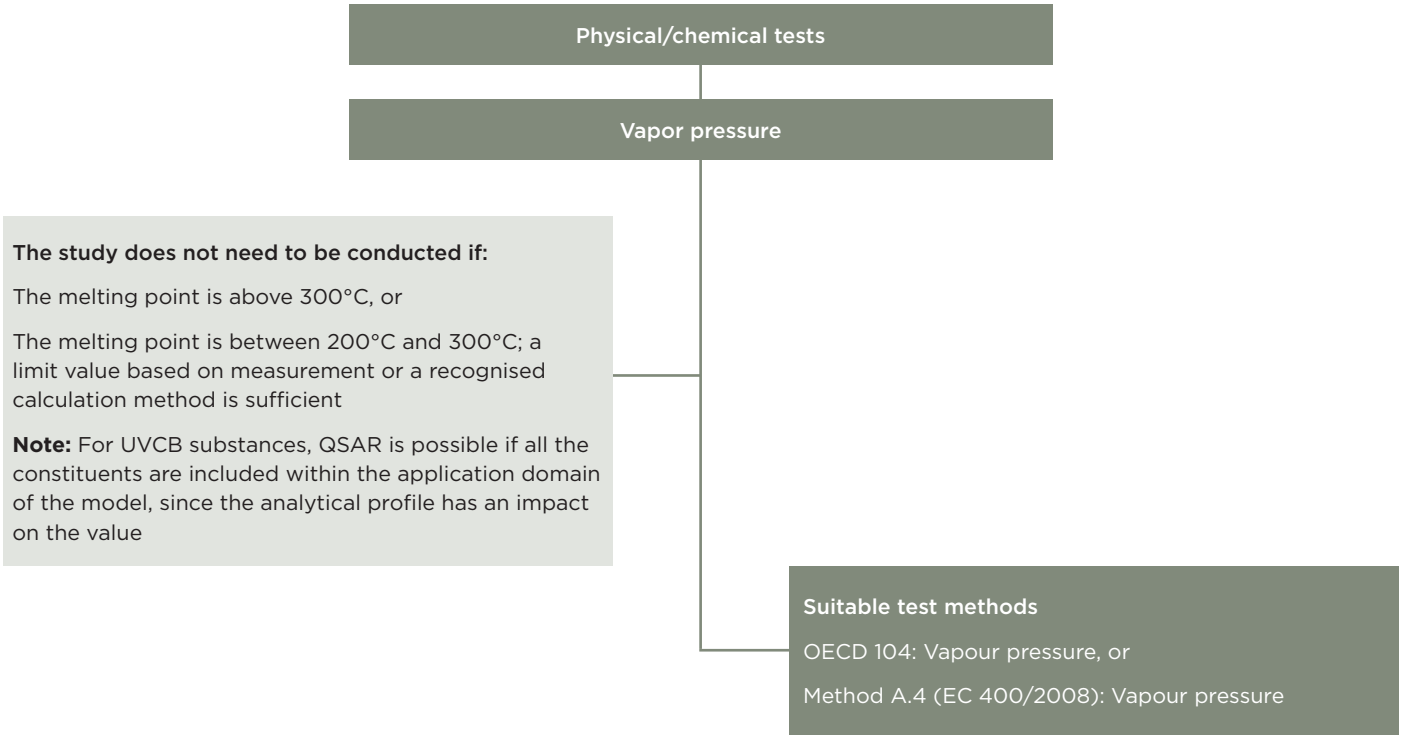


Figure 8: *Physical/chemical tests: Vapour pressure*

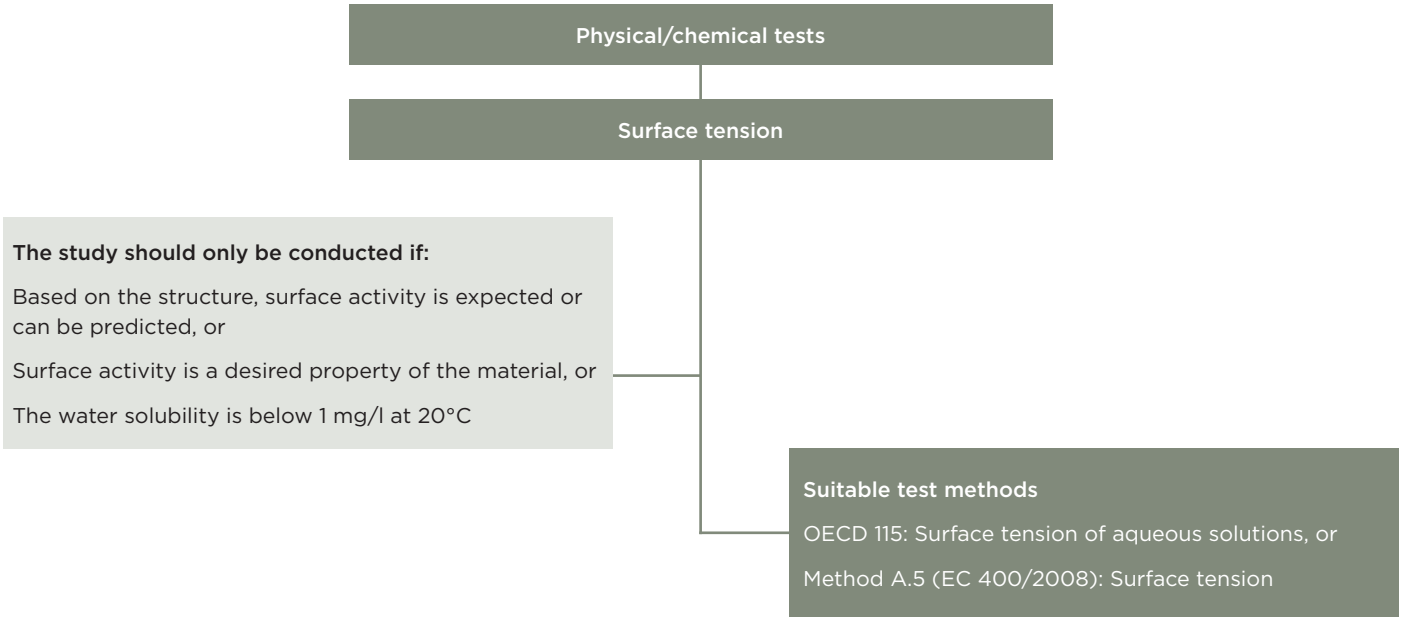


Figure 9: *Physical/chemical tests: Surface tension*

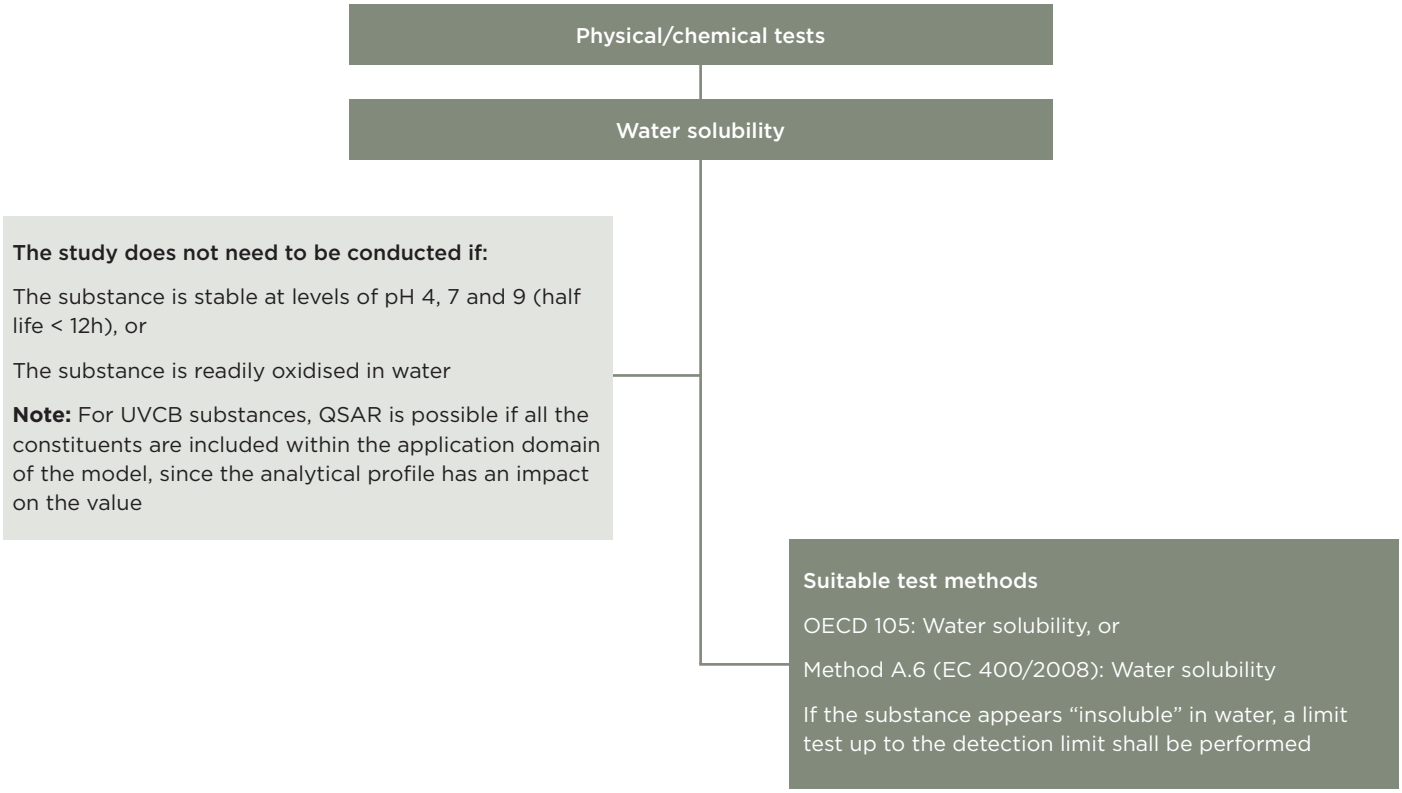


Figure 10: *Physical/chemical tests: Water solubility*

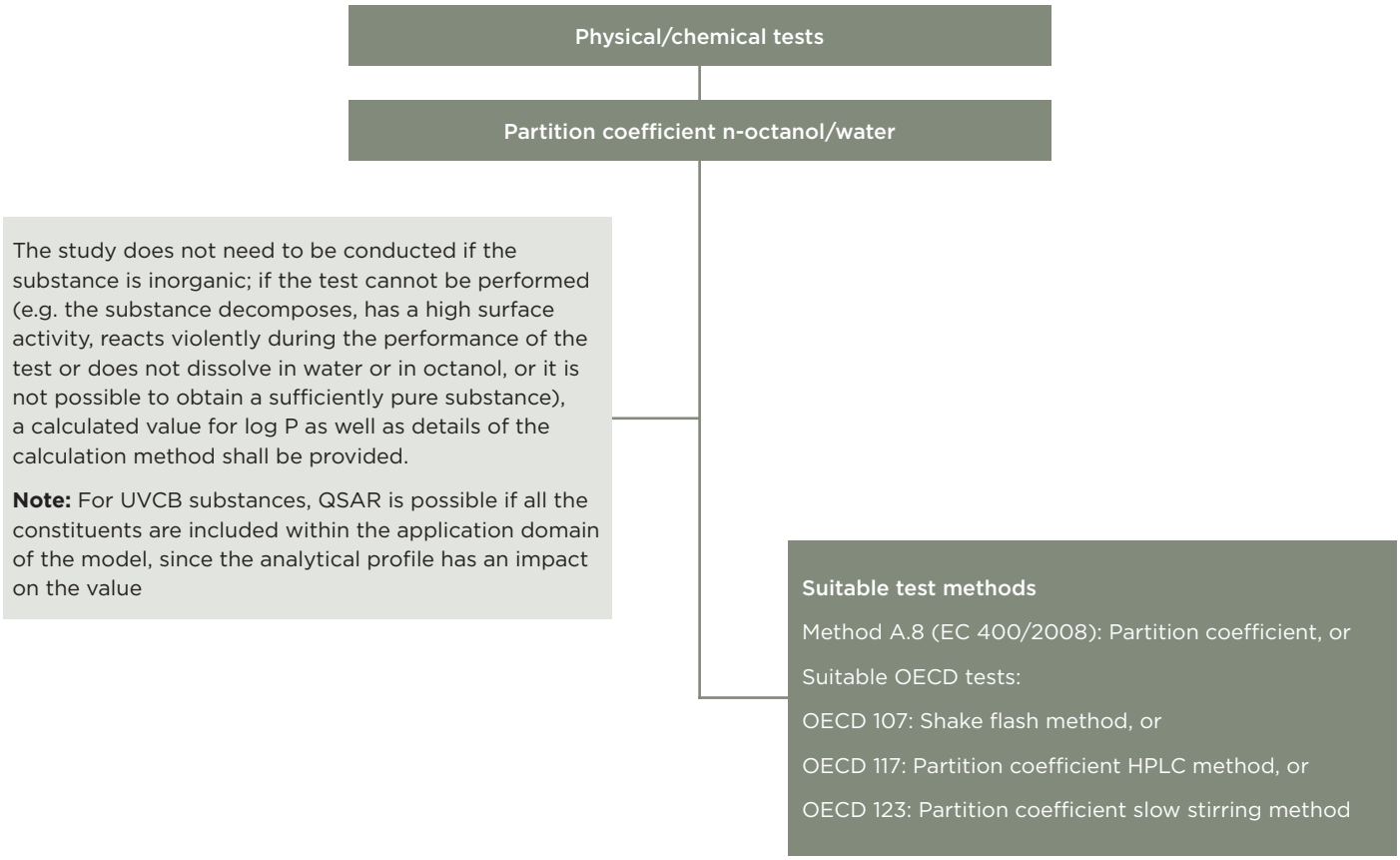


Figure 11: *Physical/chemical tests: Partition coefficient n-octanol/water*

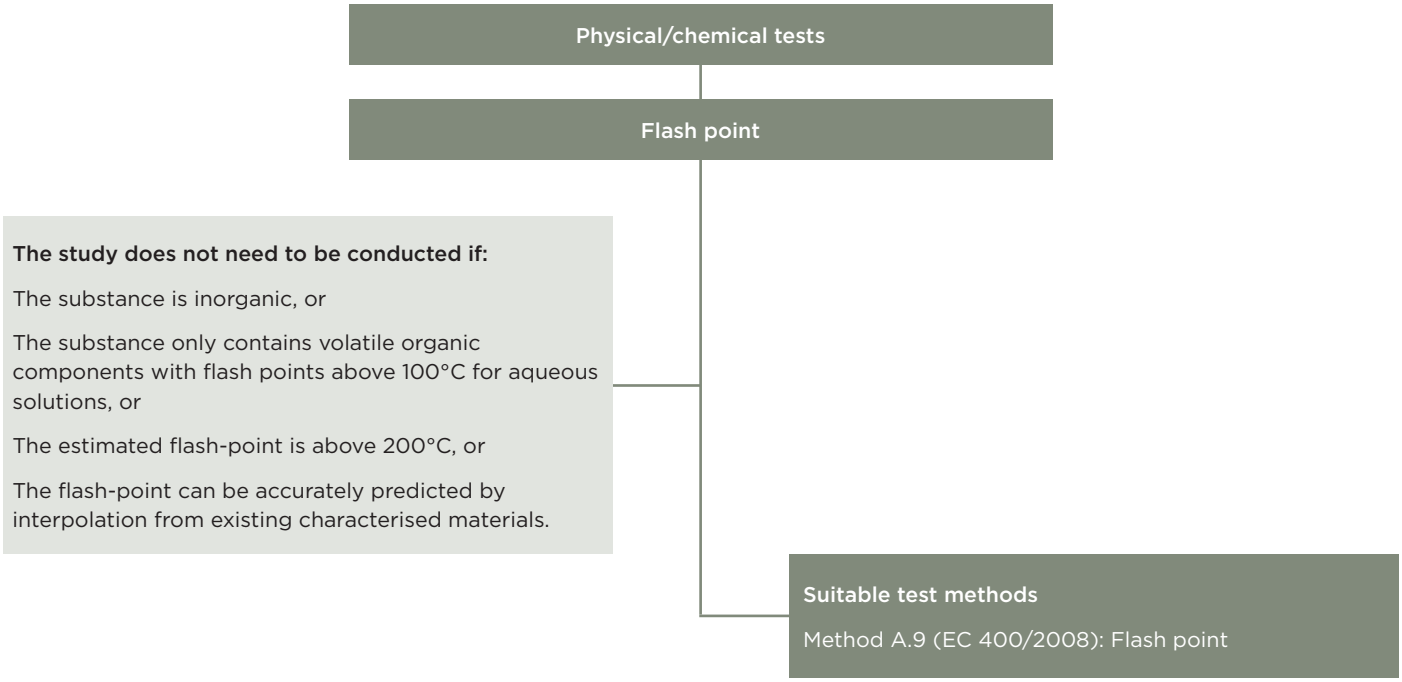


Figure 12: *Physical/chemical tests: Flash point*

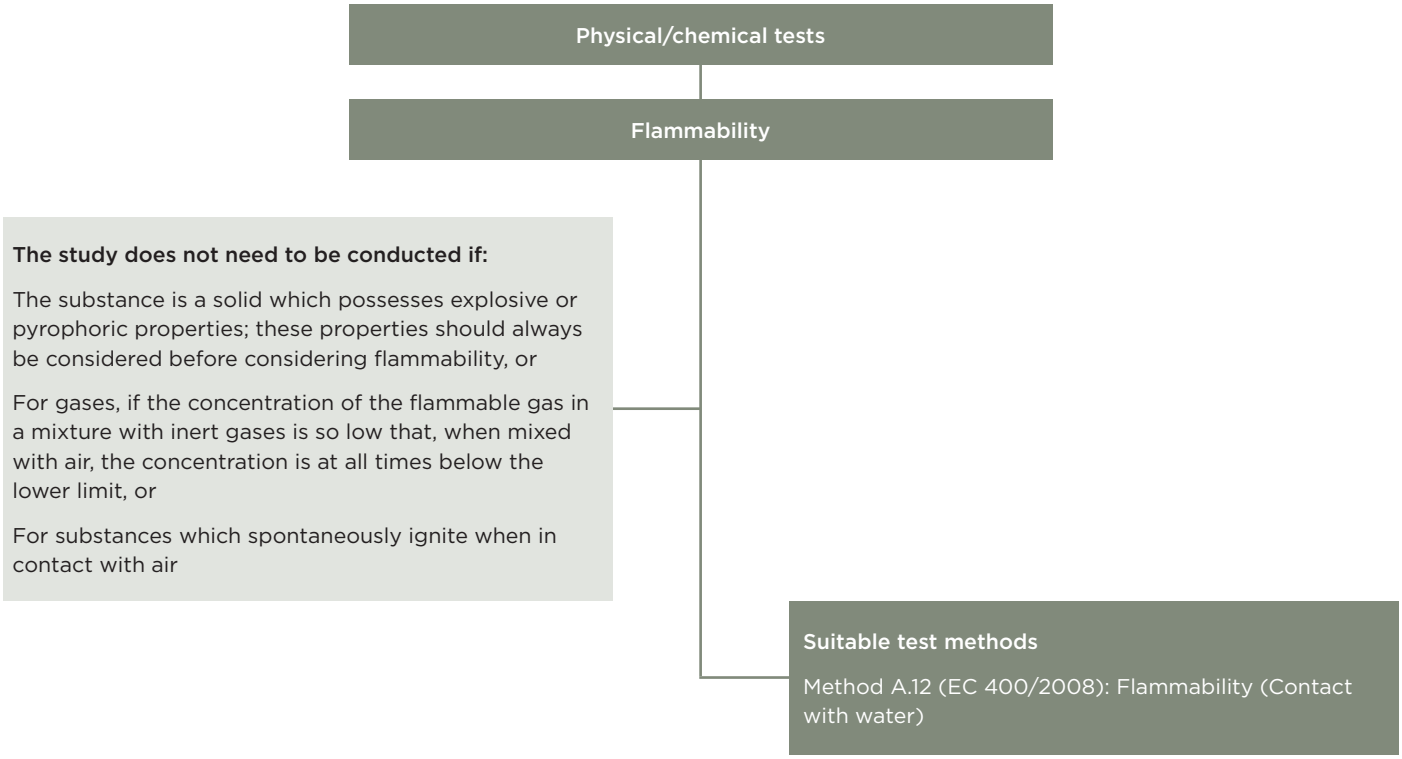


Figure 13: *Physical/chemical tests: Flammability*

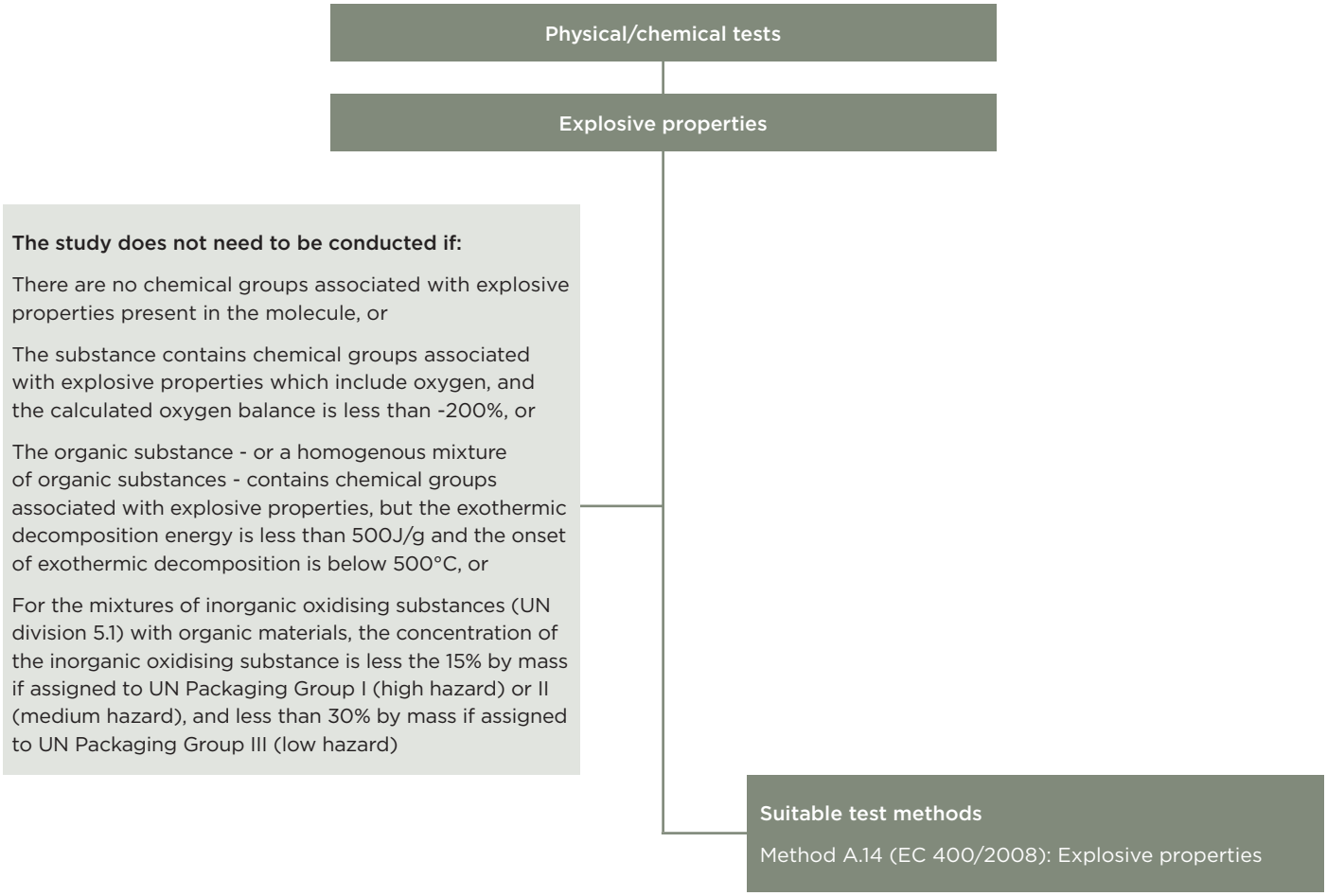


Figure 14: *Physical/chemical tests: Explosive properties*

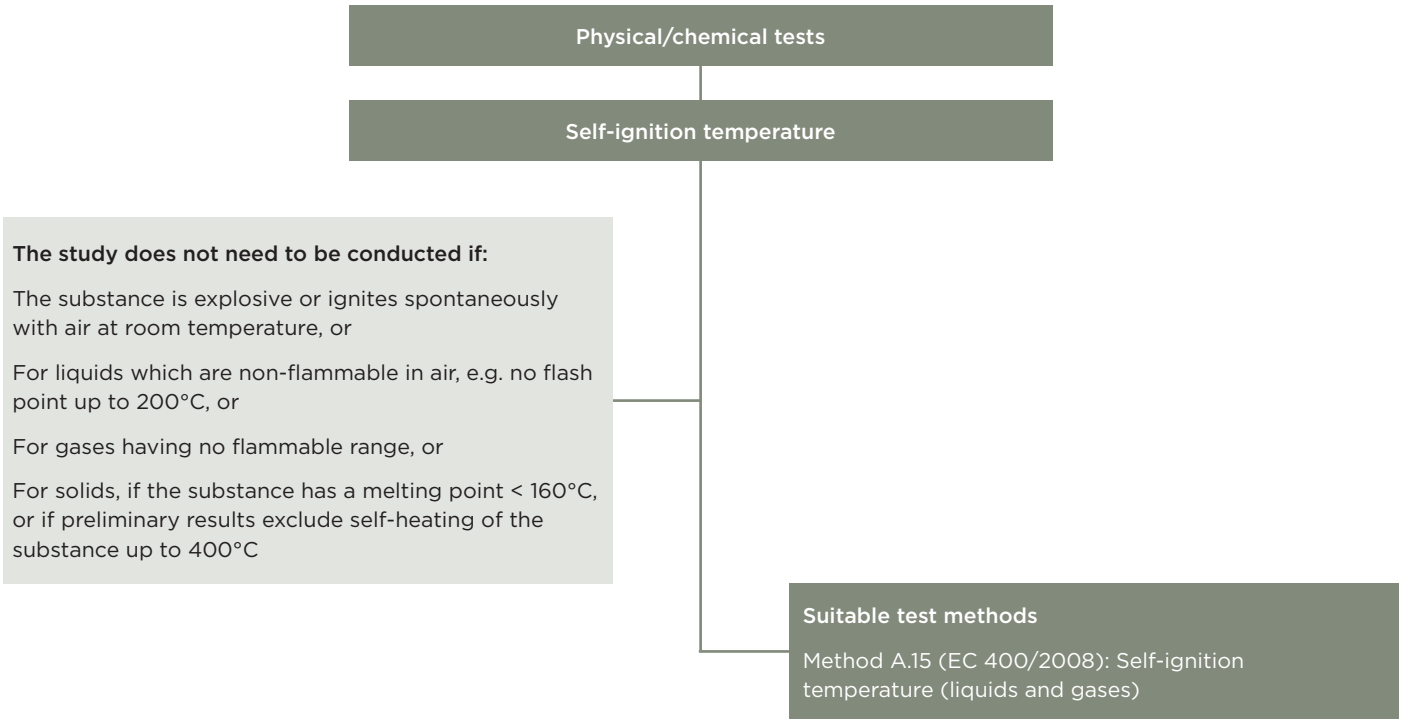


Figure 15: *Physical/chemical tests: Self-ignition temperature*

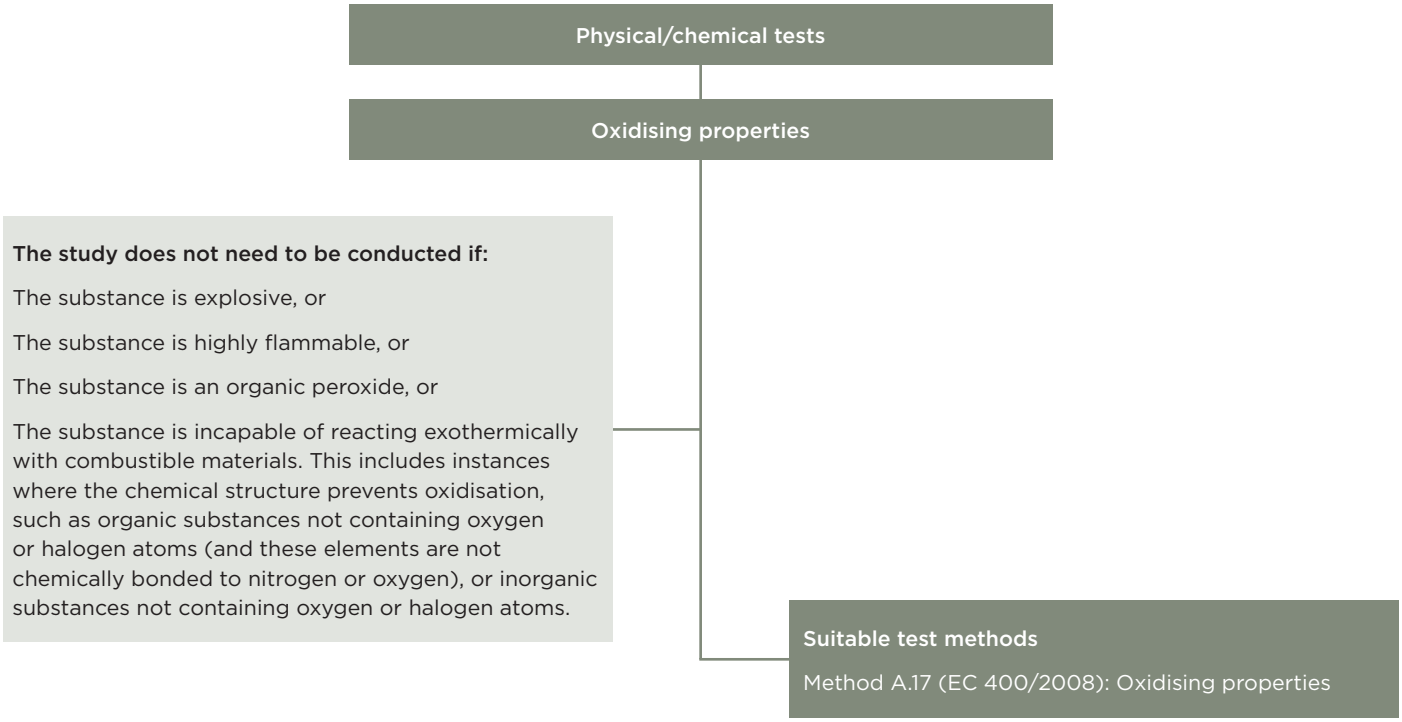


Figure 16: *Physical/chemical tests: Oxidising properties*

EC Regulation 1907/2006 states other methods can be used to obtain data without testing. These methods include:

- Use of existing data
- Weight of evidence
- Qualitative or quantitative structure-activity relationship (QSAR)
- In-vitro methods
- Grouping of substances and read-across approach

The flow diagram below shows the flow of activities that should be followed when the substance is to be tested for REACH registration. Some tests can be avoided if there is sufficient information on each component.

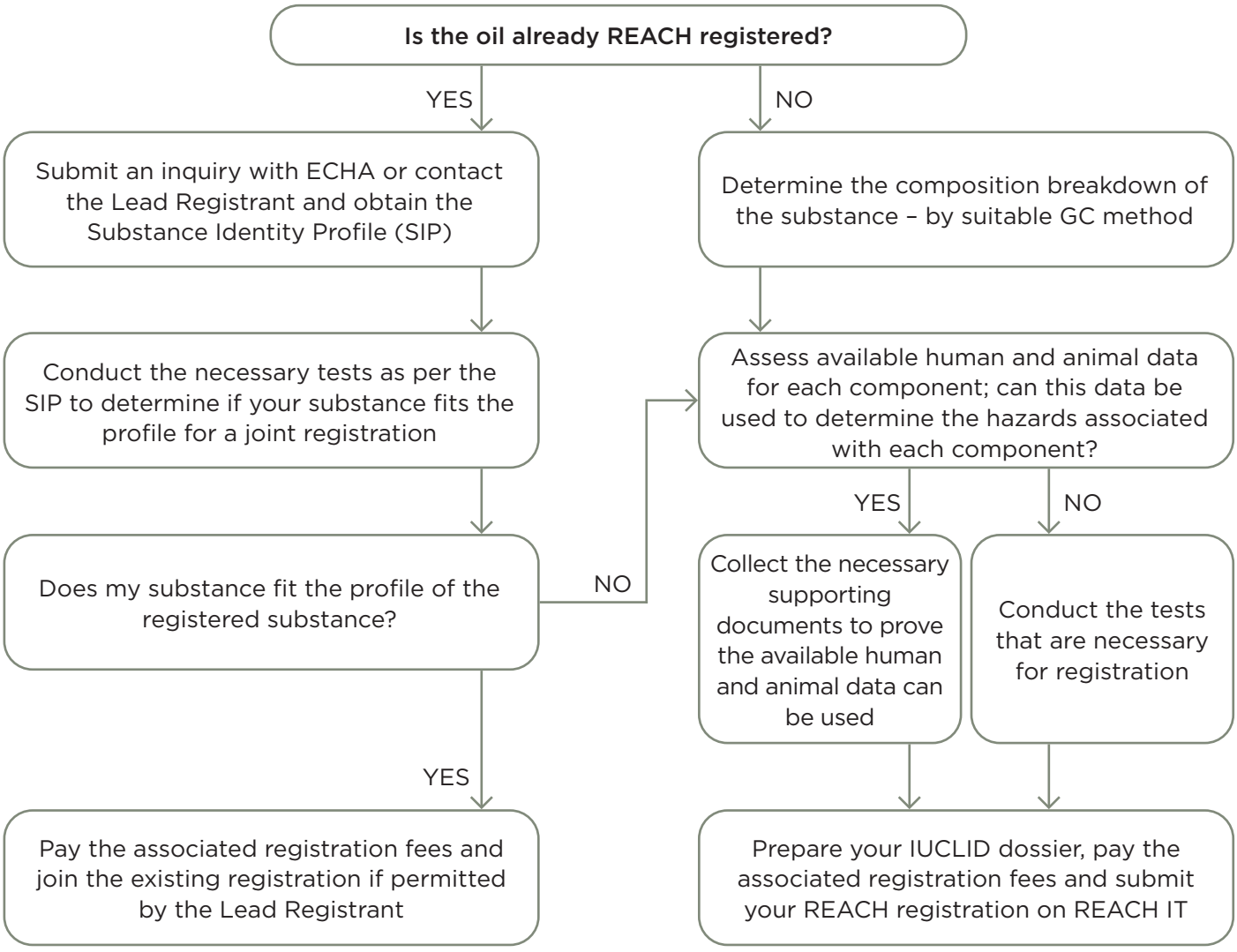


Figure 17: *Flow of activities that should be followed when the substance is to be tested for REACH registration*

Toxicological tests required for substances > 1 tonne

The diagrams below indicate the necessary and additional toxicological tests for substances > 1 tonne that may be required for the oil. These are the typical analyses for REACH and CLP.

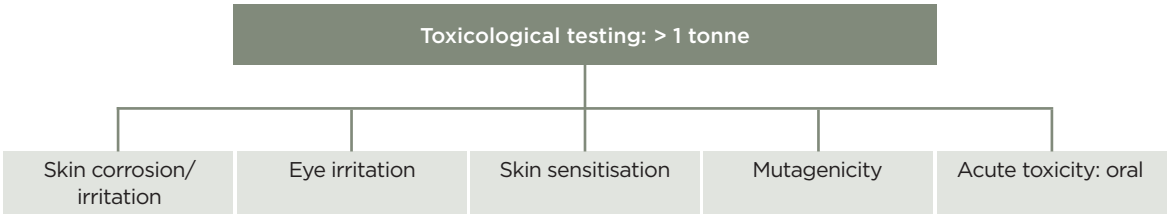
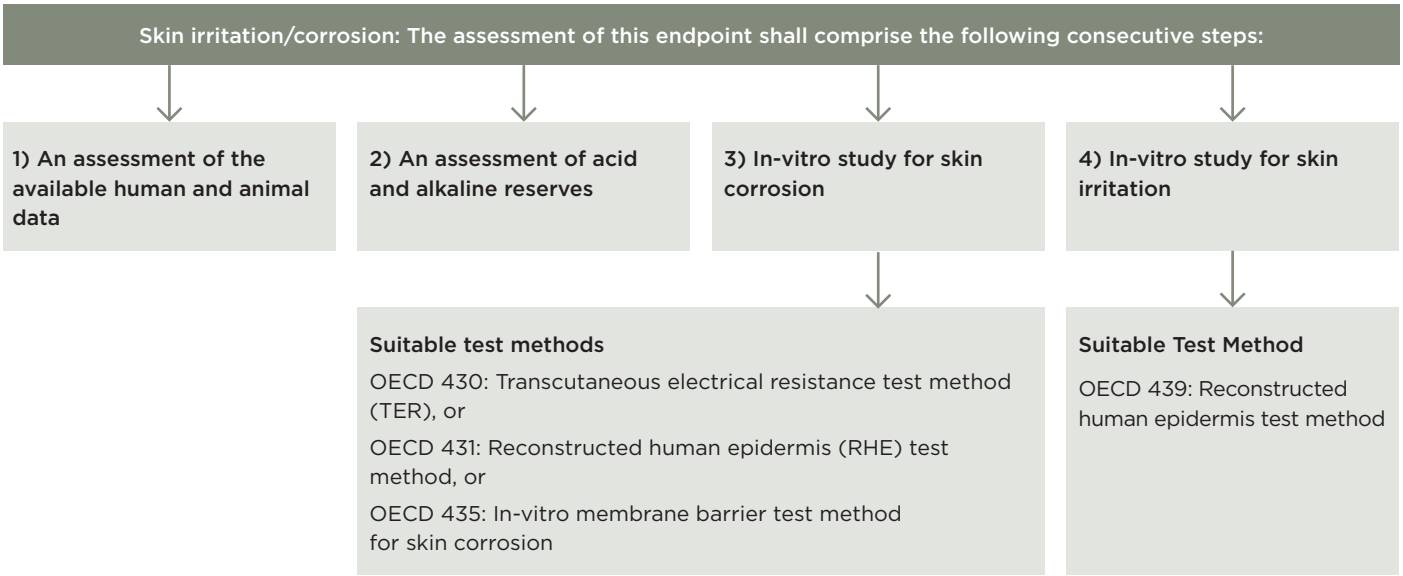


Figure 18: *Overview of toxicological tests required for substances > 1 tonne*



Steps 3 and 4 do not need to be conducted if:

Available human and animal data indicates that the criteria are met for classification as corrosive to the skin or irritating to the eyes, or

The substance is flammable when exposed to air at room temperature, or

The substance is strongly acidic (pH < 2.0) or strongly basic (pH > 11.5), or

The substance is classified as very toxic in contact with skin, or

An acute toxicity study by the dermal route does not indicate skin irritation up to the limit dose level (2,000 mg/kg bw).

Note: For essential oils, in some cases it is possible to fulfil the endpoint based on calculation rules for mixtures of the CLP, considering all the constituents of the essential oil, if there is available data.

Figure 19: *Toxicological test (> 1 tonne): Skin irritation/corrosion*

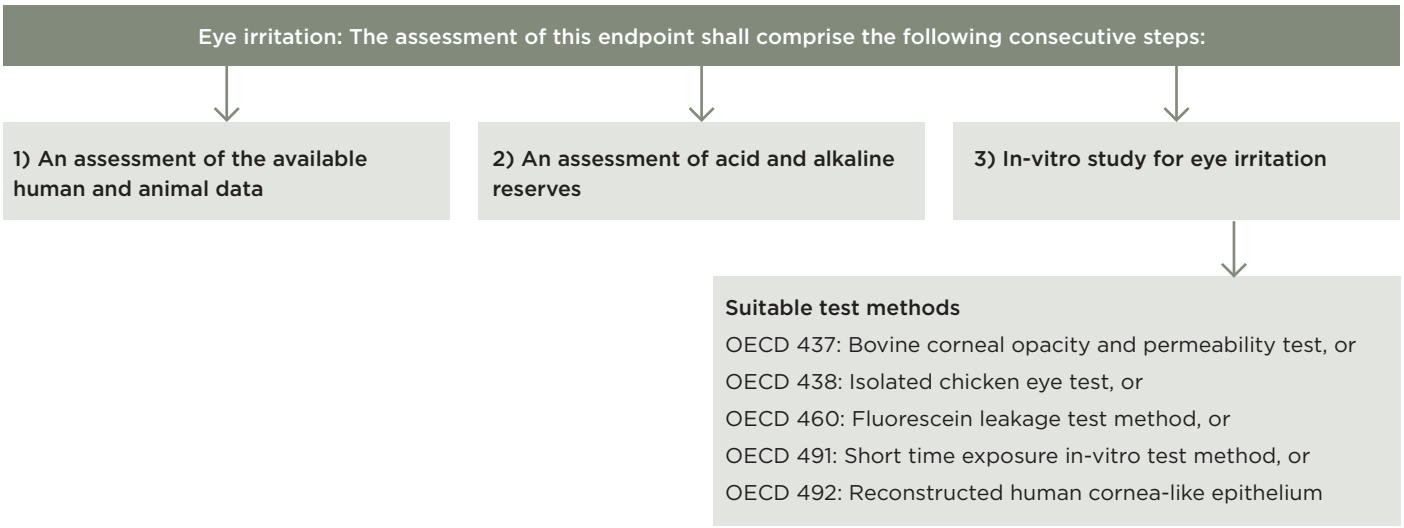


Figure 20: *Toxicological test (> 1 tonne): Eye irritation*

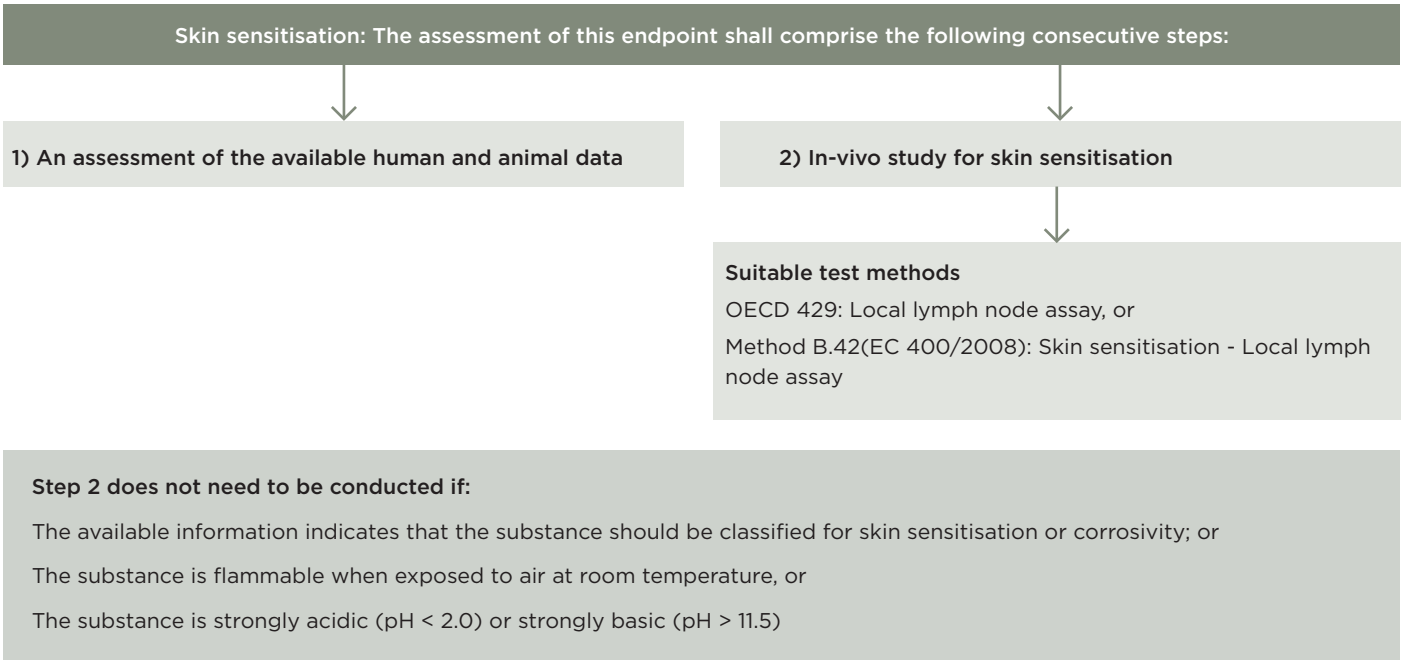


Figure 21: *Toxicological test (> 1 tonne): Skin sensitisation*

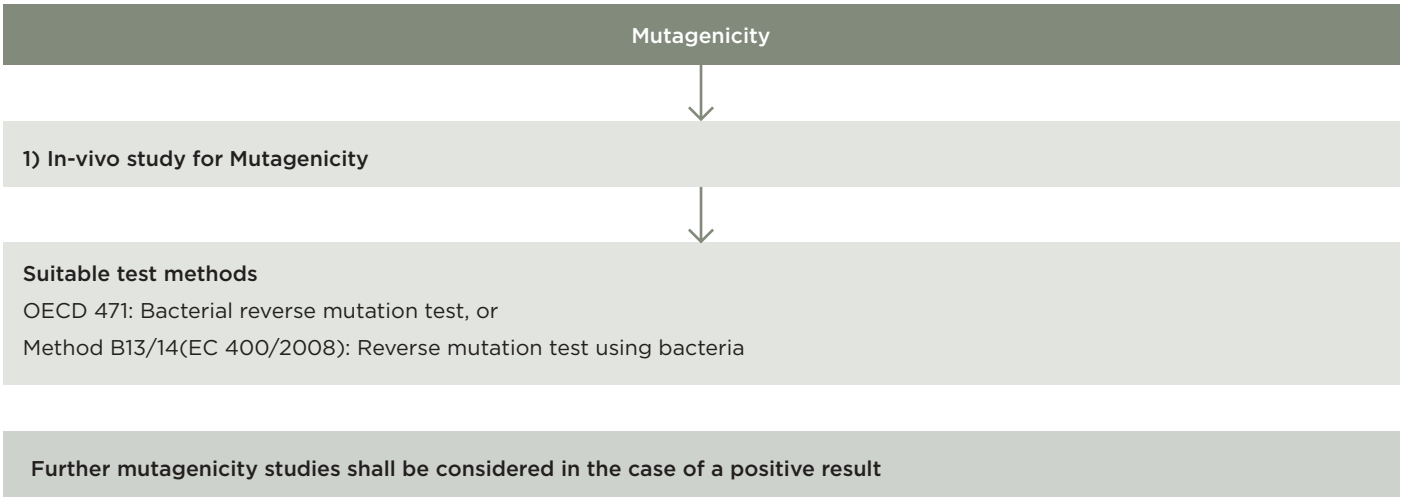


Figure 22: *Toxicological test (> 1 tonne): Mutagenicity*

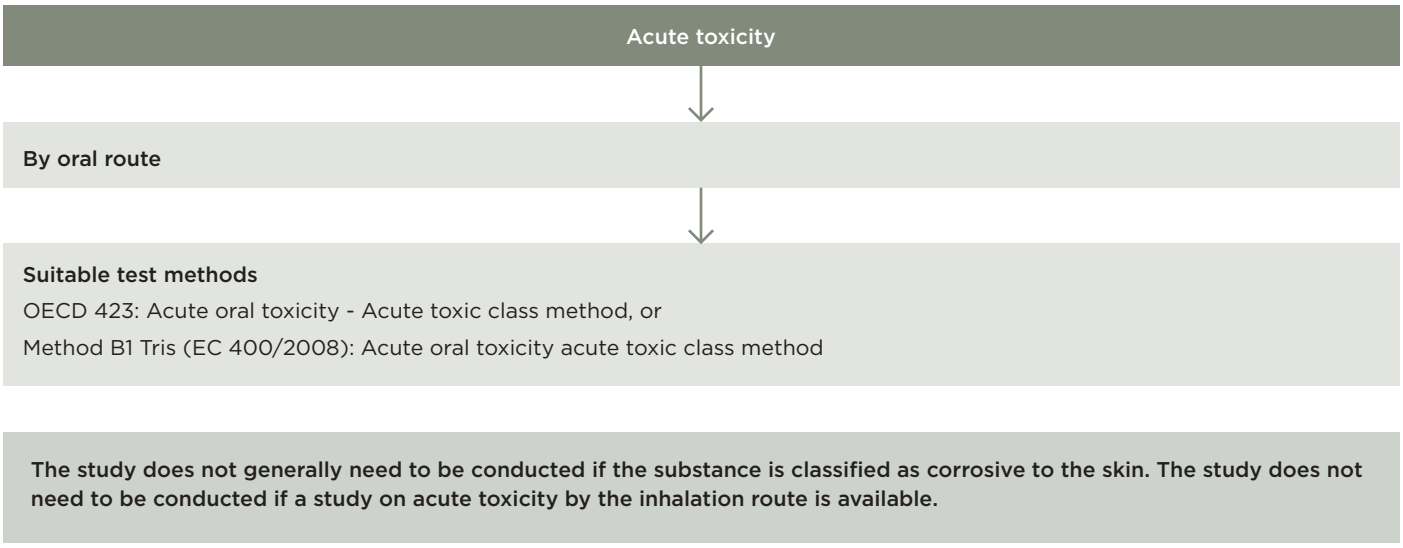


Figure 23: *Toxicological test (> 1 tonne): Acute toxicity - oral*

Ecotoxicological tests required for substances > 1 tonne

The diagrams below indicate the necessary and additional ecotoxicological tests for substances > 1 tonne that may be required for the oil. These are the typical analyses for REACH and CLP.

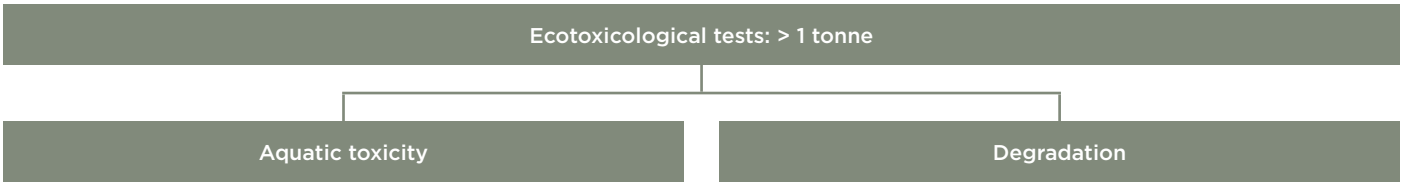


Figure 24: *Overview of ecotoxicological tests required for substances > 1 tonne*

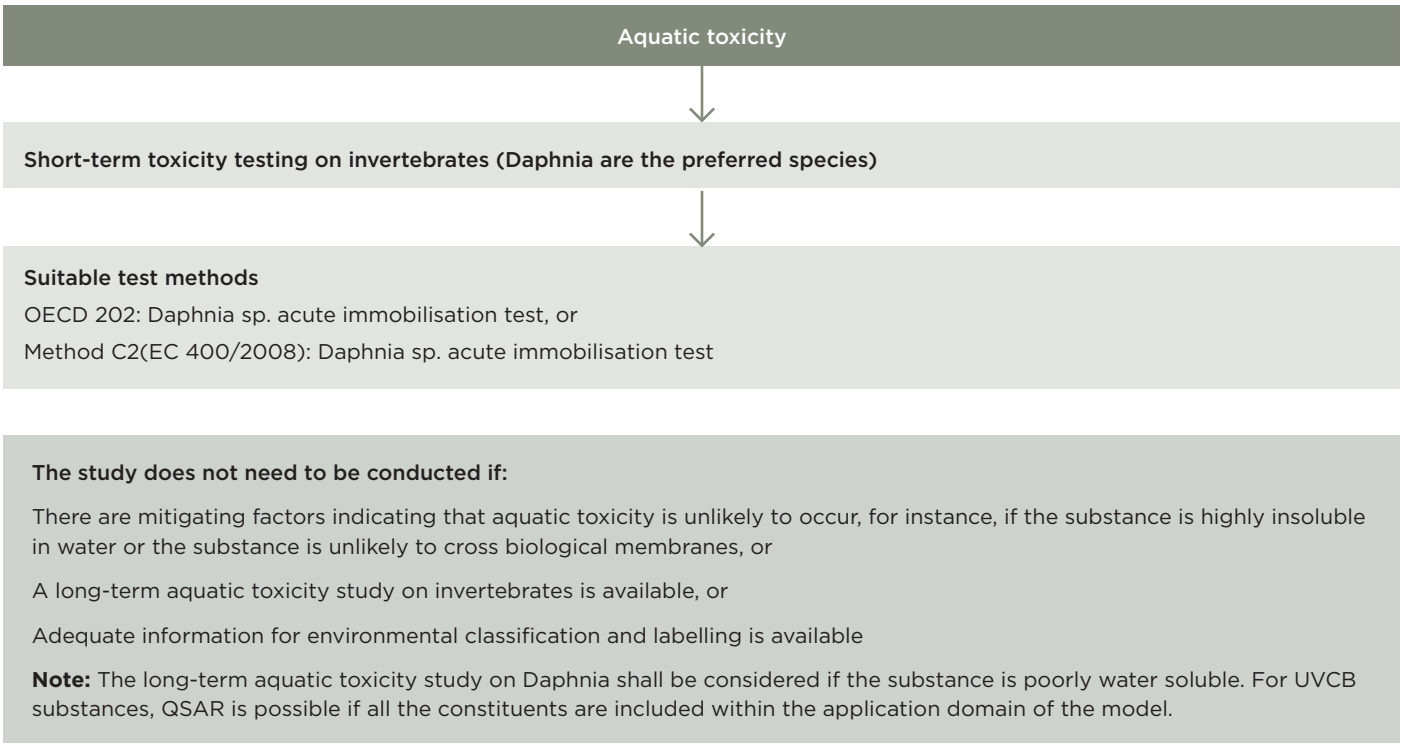


Figure 25: *Ecotoxicological test (> 1 tonne): Acute toxicity - short-term*

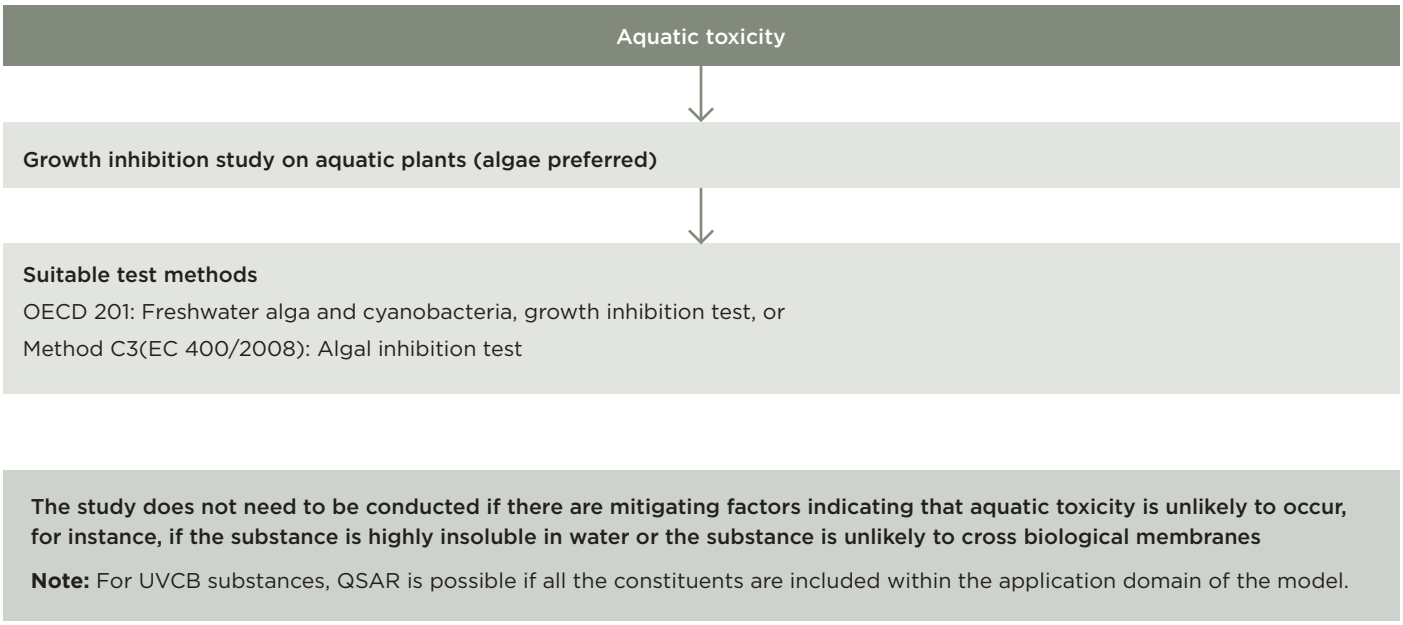


Figure 26: *Ecotoxicological test (> 1 tonne): Acute toxicity - growth inhibition*

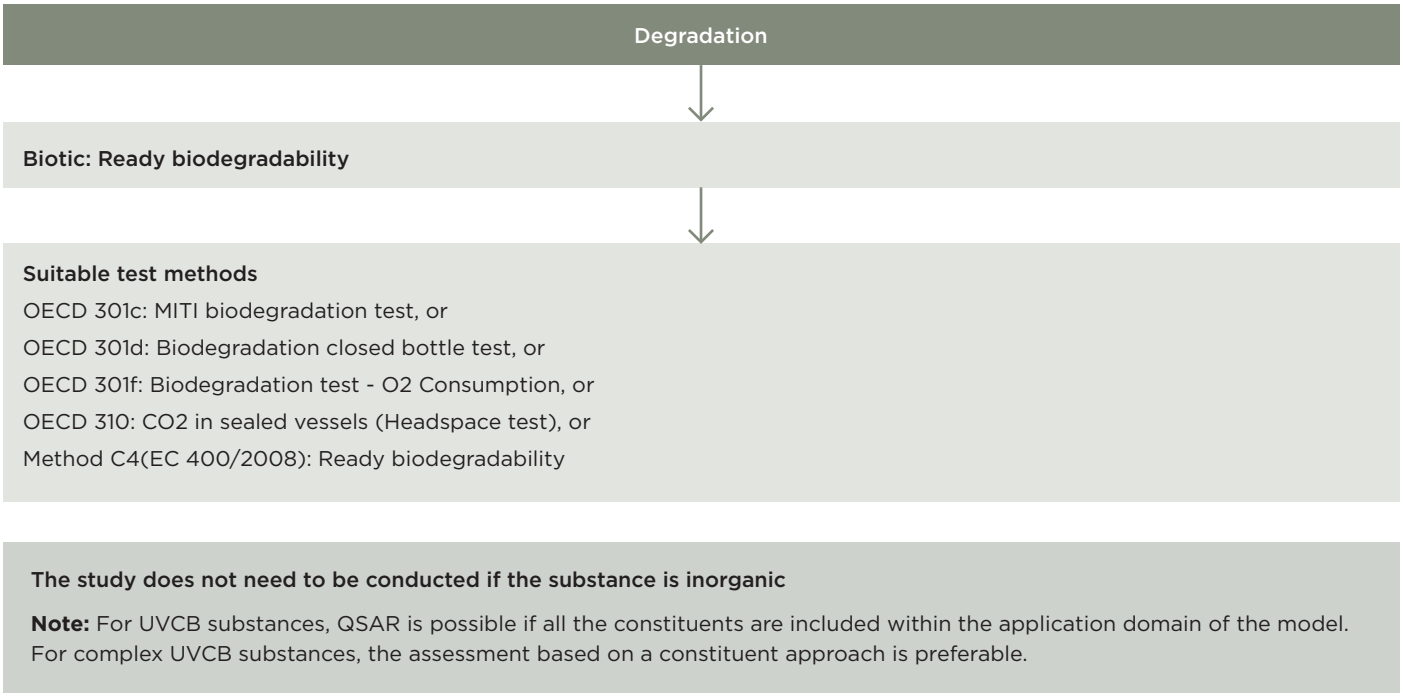


Figure 27: *Ecotoxicological test (> 1 tonne): Degradation*

Toxicological tests required for substances > 10 tonnes

The diagrams below indicate the necessary and additional toxicological tests for substances > 10 tonnes that may be required for the oil. These are the typical analyses for REACH and CLP.

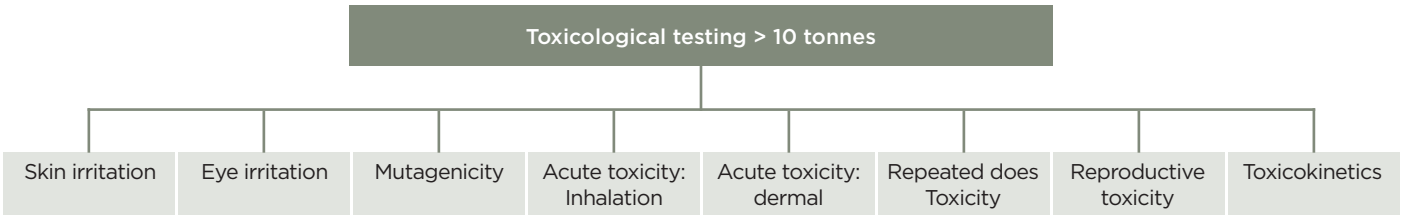


Figure 28: *Overview of toxicological tests required for substances > 10 tonnes*

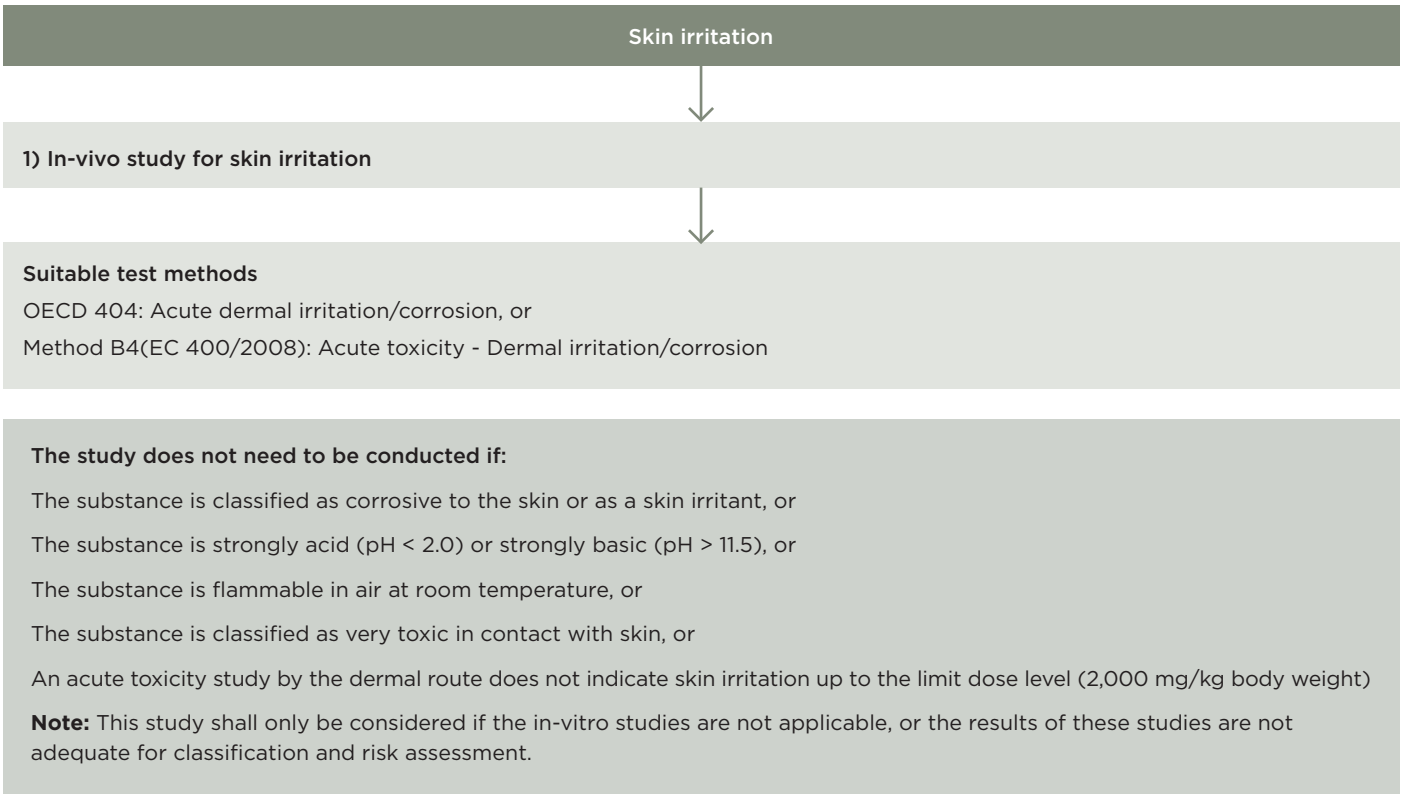


Figure 29: *Toxicological test (>10 tonnes): Skin irritation*

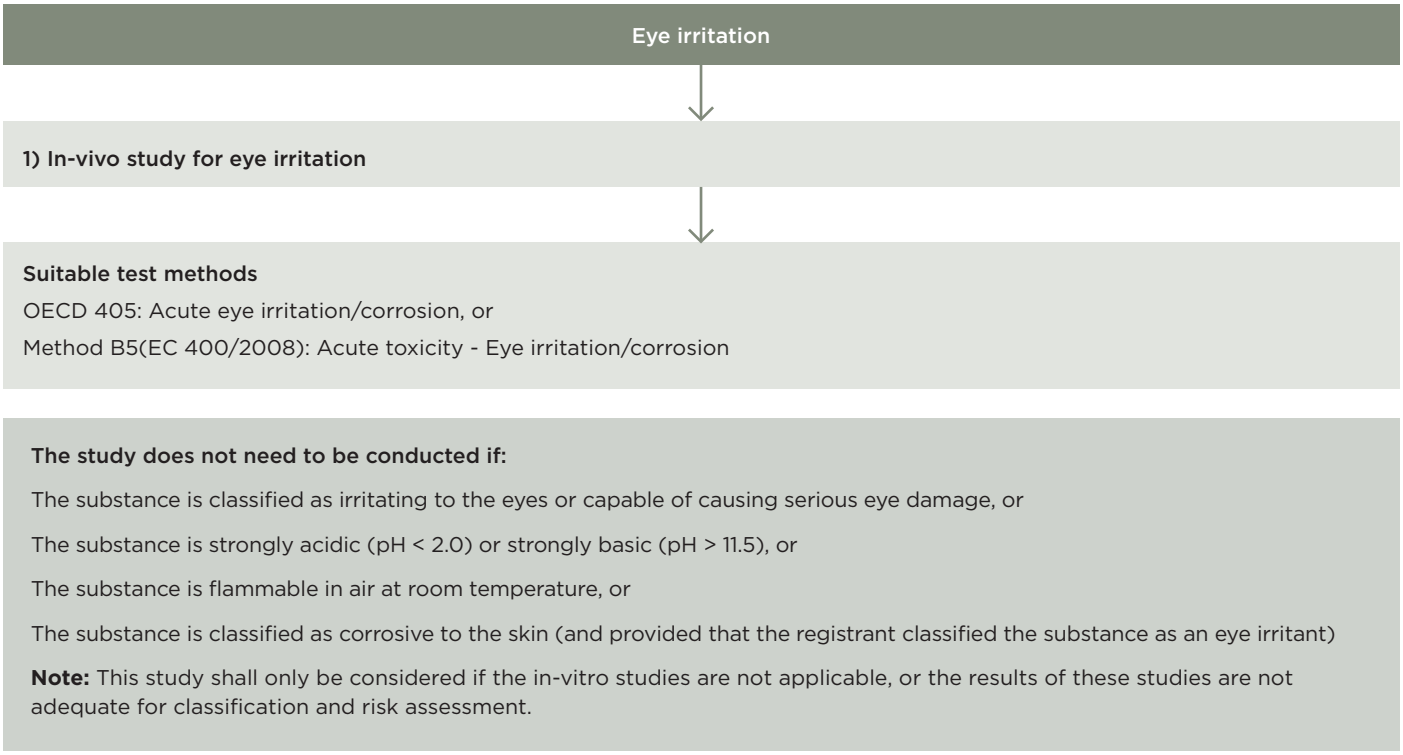


Figure 30: *Toxicological test (> 10 tonnes): Eye irritation*

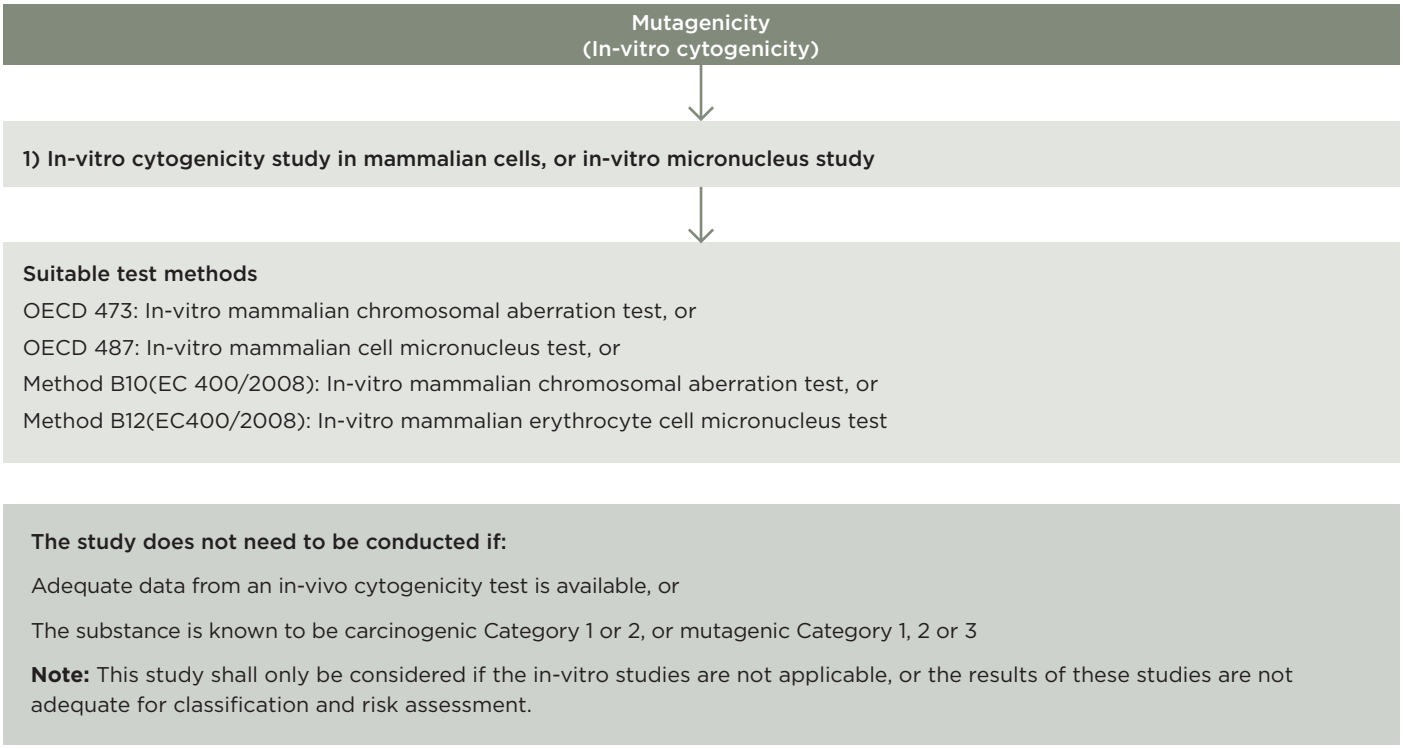


Figure 31: *Toxicological test (> 10 tonnes): Mutagenicity – in-vitro cytogenicity*

Mutagenicity (In-vitro gene mutation)

2) In-vitro gene mutation study in mammalian cells, if negative results for OECD tests 471 and 473, or OECD 487, are received

Suitable test methods

OECD 490: In-vitro mammalian cell gene mutation tests using the thymidine kinase gene

OECD 476: In-vitro mammalian cell gene mutation tests using the HPRT and XPRT genes

Method B17(EC 400/2008): In-vitro mammalian cell gene mutation

The study does not usually need to be conducted if adequate data from a reliable in-vivo mammalian gene mutation test is available

Note: Appropriate in-vivo mutagenicity studies shall be considered in the case of a positive result in any of the genotoxicity studies.

Figure 32: *Toxicological test (> 10 tonnes): Mutagenicity – in-vitro gene mutation*

Acute toxicity: Inhalation

The choice of the second route* will depend on the nature of the substance and the likely route of exposure to humans. If there is only one route of exposure then information for the route needs to be provided.

Suitable test methods

OECD 403: Acute Inhalation Toxicity; or

Method B2(EC 400/2008): Acute Inhalation Toxicity

Note: Testing by the inhalation route is appropriate if exposure of humans via inhalation is likely taking into account the vapour pressure of the substance and/or the possibility of exposure to aerosols, particles or droplets of an inhalable size.

*There are four routes of exposure: inhalation; ingestion; contact with skin and eyes, or; injection

Figure 33: *Toxicological test (> 10 tonnes): Acute toxicity - inhalation*

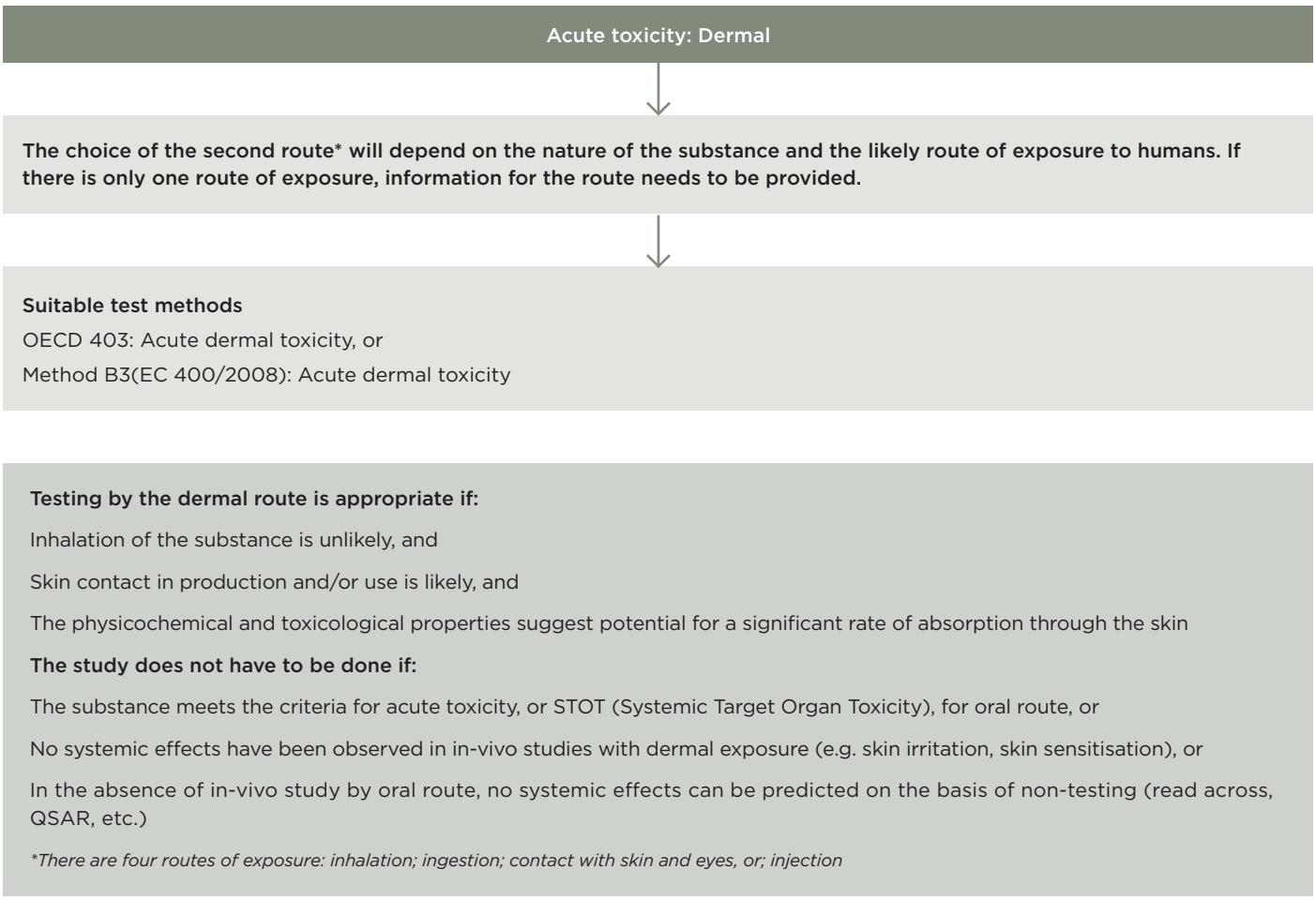


Figure 34: *Toxicological test (> 10 tonnes): Acute toxicity – dermal*

Dermal testing is appropriate if:

- Inhalation of the substance is unlikely
- Skin contact in production and/or use is likely
- The physicochemical and toxicological properties suggest potential for a significant rate of absorption through the skin

Testing by inhalation is appropriate if exposure to humans via inhalation is likely. The vapour pressure of the substance and/or the possibility of exposure to aerosols, particles or droplets of an inhalable size, should be considered.

The registrant can propose to conduct a sub-chronic toxicity study (90 days) if the frequency and duration of human exposure indicates that a longer-term study is appropriate; and one of the following conditions is met:

- Other available data indicates that the substance may have a dangerous property that cannot be detected in a short-term toxicity study, or
- Appropriately designed toxicokinetic studies reveal accumulation of the substance or its metabolites in certain tissues or organs which would possibly remain undetected in a short-term toxicity study, but which are liable to result in adverse effects after prolonged exposure

According to Annex VIII of EC regulation 1907/2006:
Further studies shall be proposed by the registrant, or may be required by ECHA, where:

- There is a failure to identify a NOAEL (no-observed-adverse-effect-level) in the 28- or the 90-day study, unless the reason for the failure to identify a NOAEL is the absence of adverse toxic effects, or
- Toxicity being of particular concern (e.g. serious/severe effects), or
- There are indications of an effect for which the available evidence is inadequate for toxicological and/or risk characterisation; in such cases it may also be more appropriate to perform specific toxicological studies that are designed to investigate these effects (e.g. immunotoxicity, neurotoxicity), or
- The route of exposure used in the initial repeated dose study was inappropriate in relation to the expected route of human exposure, and route-to-route extrapolation cannot be made, or
- There is a particular concern regarding exposure (e.g. use in consumer products leading to exposure levels which are close to the dose levels at which toxicity to humans may be expected), or
- The effects shown in substances with a clear relationship in molecular structure with the substance being studied were not detected in the 28- or the 90-day study (EC, 2006)

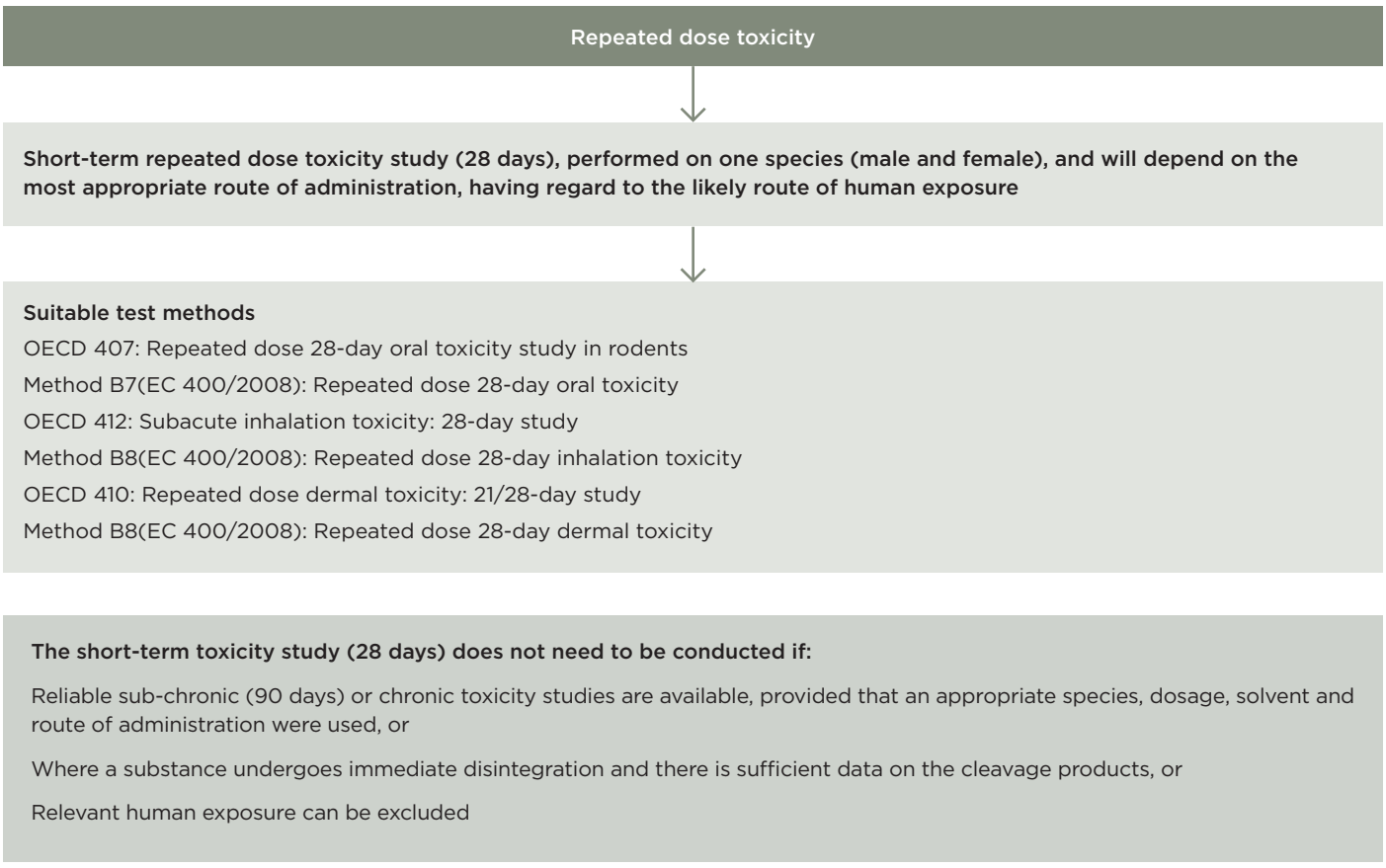


Figure 35: *Toxicological test (> 10 tonnes): Repeated dose toxicity*

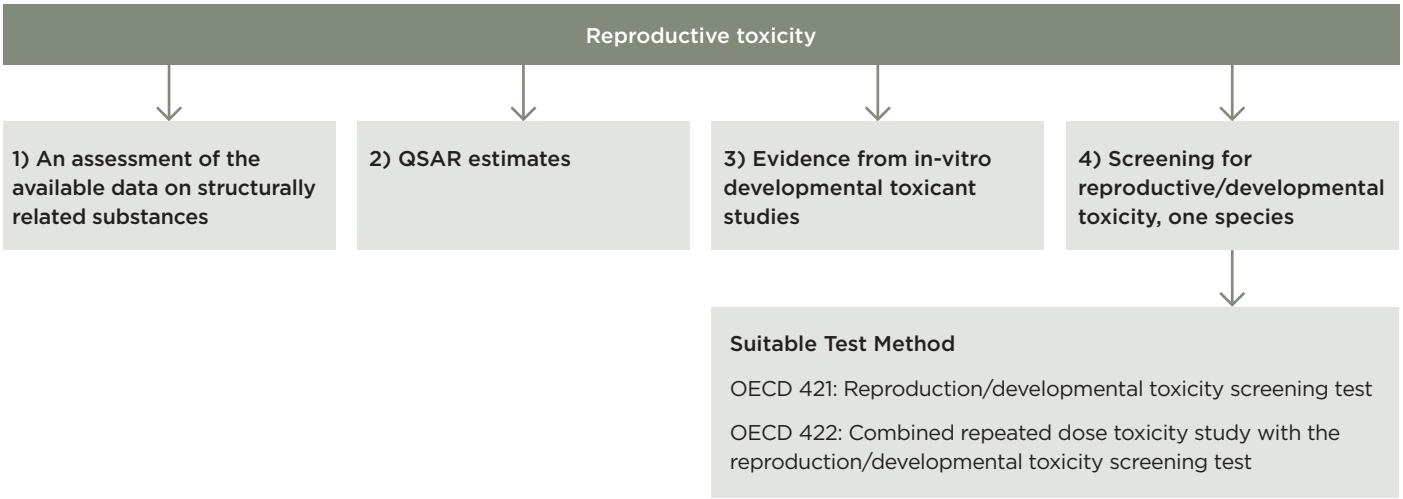


Figure 36: *Toxicological test (> 10 tonnes): Reproductive toxicity*

If a substance is known to have an adverse effect on fertility, meeting the criteria for classification (as Repr. Cat 1 or 2: R60), and the available data is adequate to support a robust risk assessment, then no further testing for fertility will be necessary. However, testing for development toxicity must be considered.

In cases where there are serious concerns about the potential for adverse effects on fertility or development, either a pre-natal developmental toxicity or a two-generation reproductive toxicity study may be proposed by the registrant instead of the screening study.

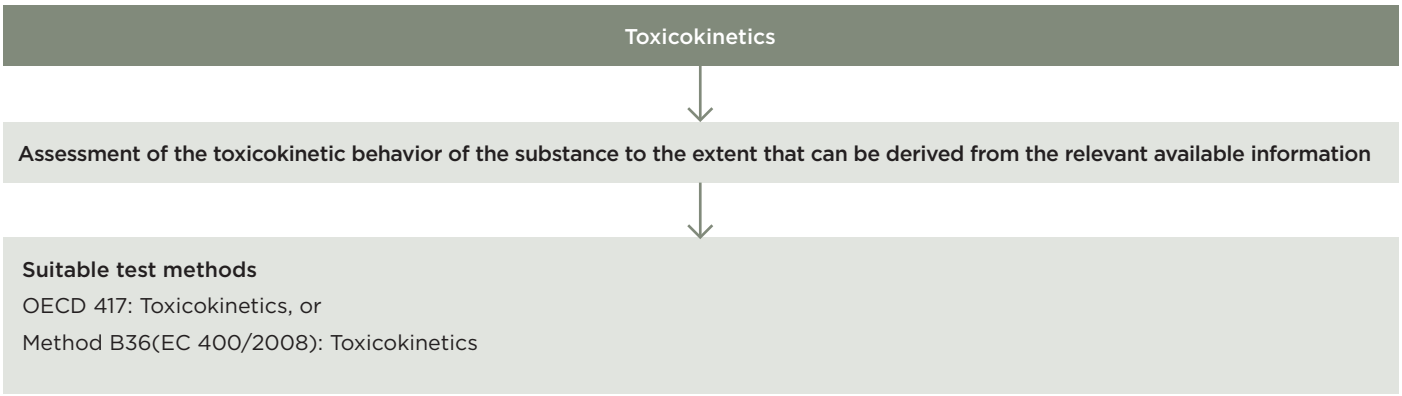


Figure 37: *Toxicological test (> 10 tonnes): Toxicokinetics*

Ecotoxicological tests for substances > 10 tonnes

The diagrams below indicate the necessary and additional ecotoxicological tests for substances > 10 tonnes that may be required for the oil. These are the typical analyses for REACH and CLP.

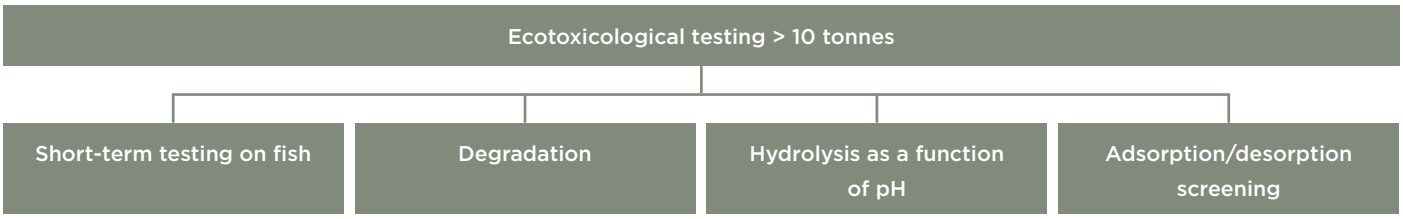


Figure 38: *Overview of ecotoxicological tests required for substances > 10 tonnes*

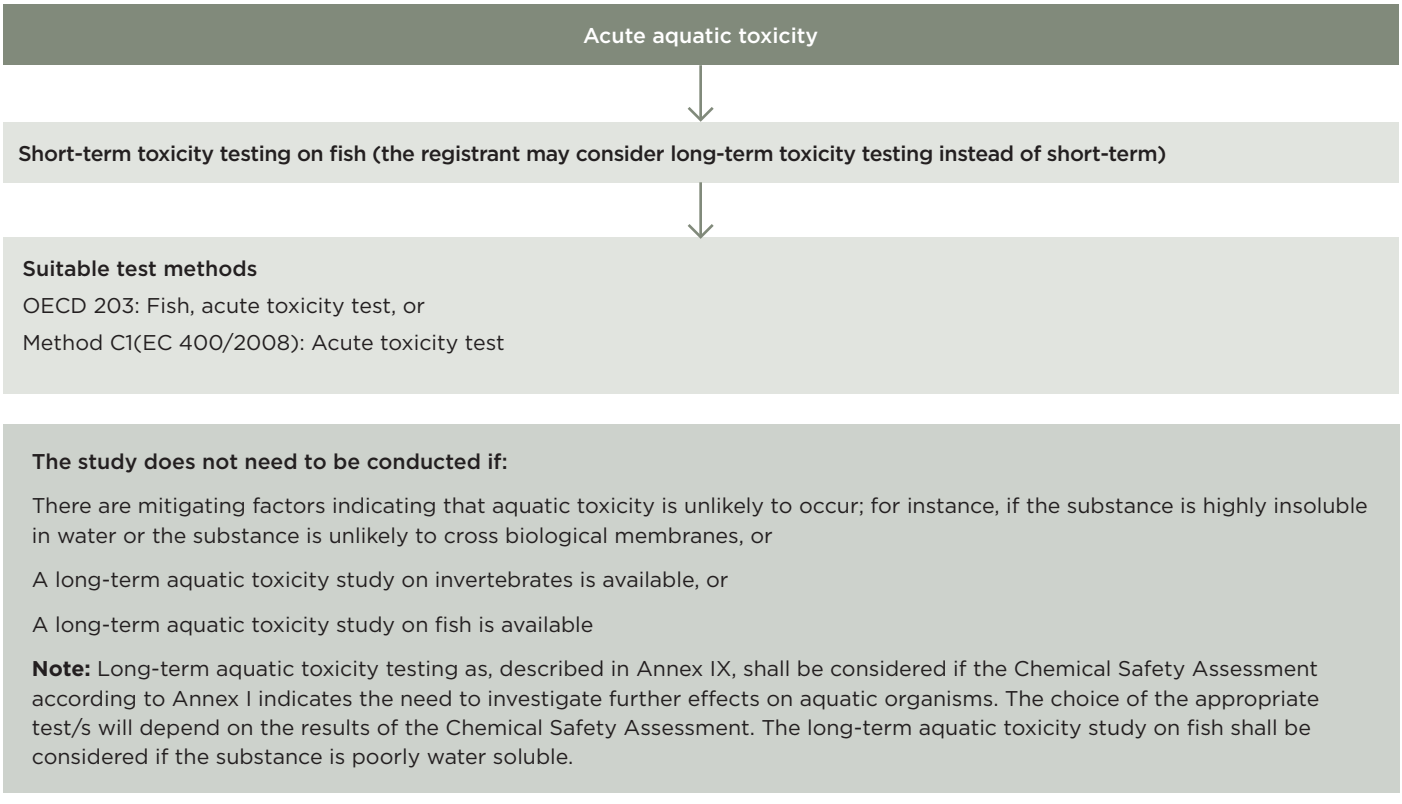


Figure 39: *Ecotoxicological tests (> 10 tonnes): Acute aquatic toxicity*

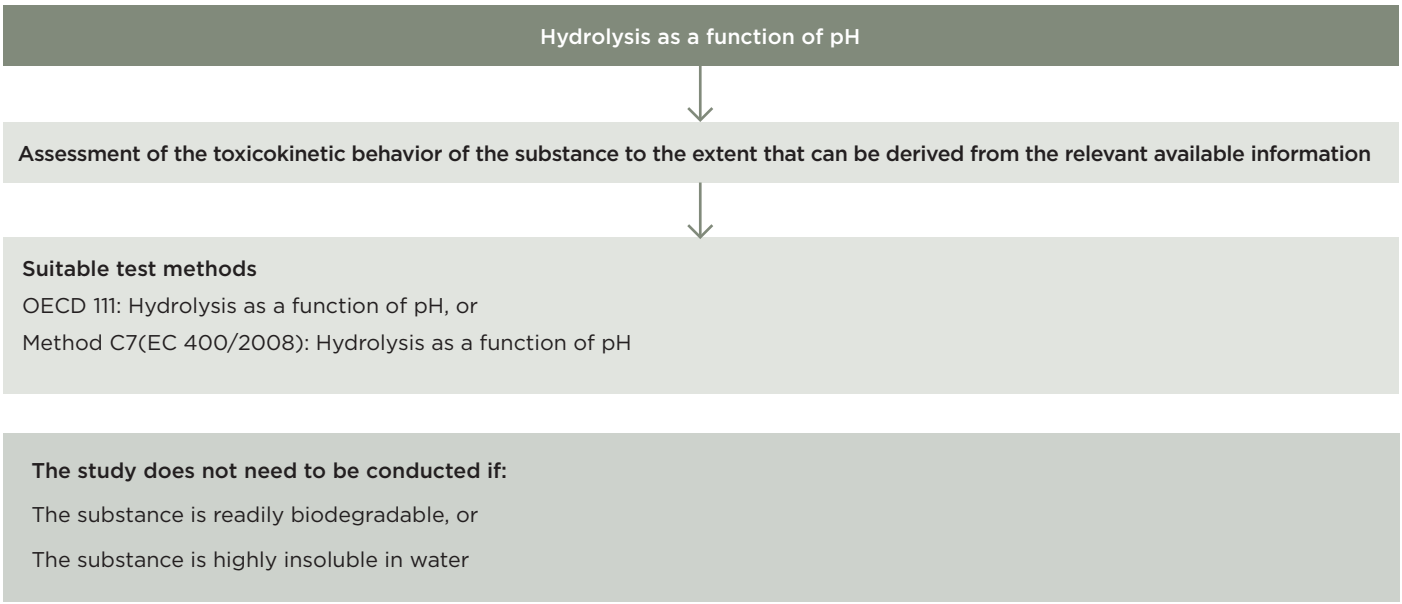


Figure 40: *Ecotoxicological tests (> 10 tonnes): Hydrolysis as a function of pH*

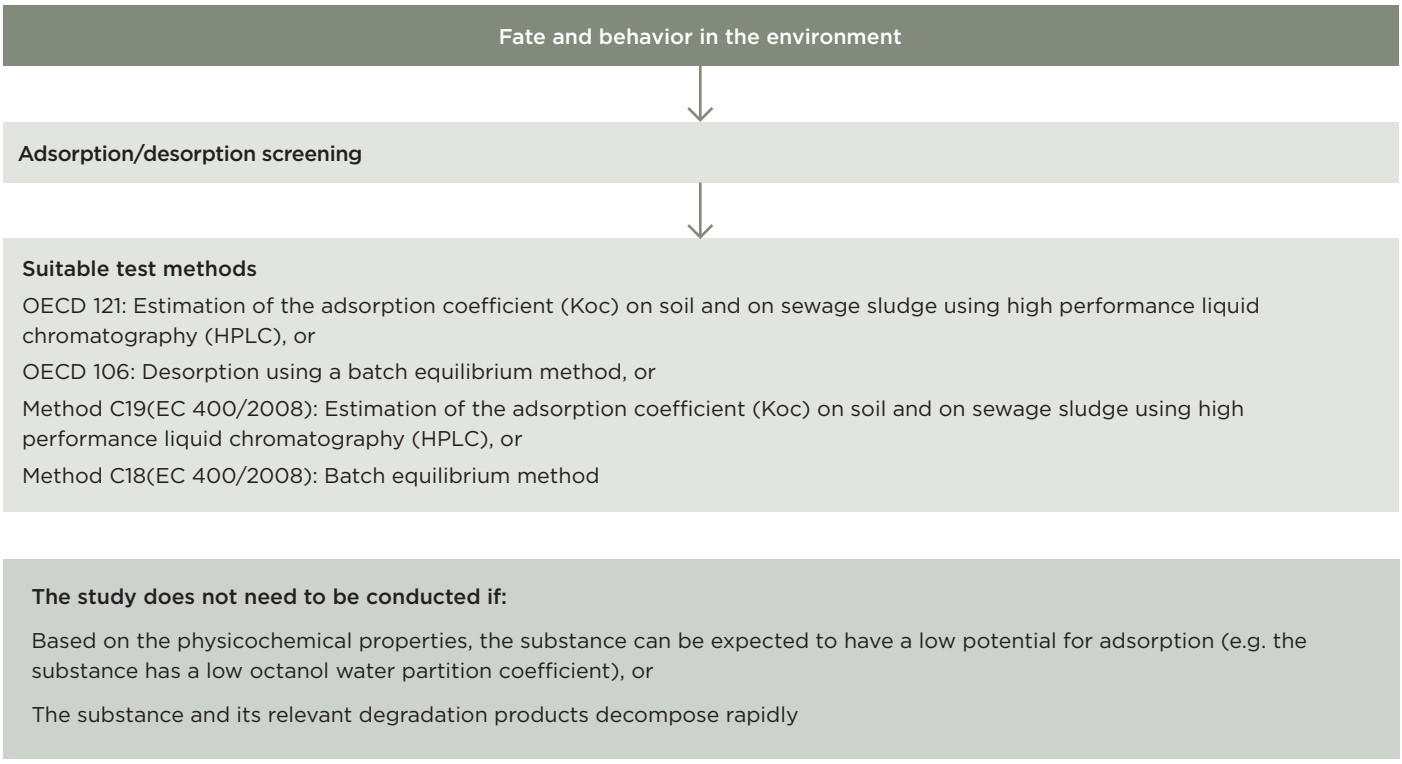


Figure 41: *Ecotoxicological tests (> 10 tonnes): Fate and behaviour in the environment*

Oils sold as cosmetic products or used as cosmetic raw materials

The necessary tests listed below are based on the Cosmetics Regulation (EC 1223/2009) and the Scientific Committee on Consumer Safety notes of guidance. For further information on the advised process flow of creating a cosmetic product and the associated tests, refer to the **ABioSA guide** titled 'Order of analyses for cosmetic products: Ensuring safety and compliance in the EU market'.

Minimum tests required for cosmetic raw material
The table below shows the minimum tests needed for oils used as a cosmetic raw material.

Test parameters	Test method/s	Vegetable oil	Essential oil
Peroxide Value and/or Acid Value	EU Pharmacopoeia or other suitable method	x	x
Refractive index	NF ISO 592	x	x
Pesticide residue	Liquid chromatography–mass spectrometry (LCMS)	x	x
Heavy metals	Inductively Coupled Plasma (ICP)	x	x
Iodine Value	EU Pharmacopoeia or other suitable method	x	x
Saponification Value	EU Pharmacopoeia or other suitable method	x	x
Foreign esters	EU Pharmacopoeia or other suitable method		
Shelf life/stability	See guidance document	x	x
Microbiology:			
Total Plate Count (TPC)	Food/cosmetic suitable method	x	x
Total Viable Count (TVC)	Food/cosmetic suitable method	x	x
Total Yeast	Food/cosmetic suitable method	x	x
Total Fungi (Mould)	Food/cosmetic suitable method	x	x
Escherichia coli	Food/cosmetic suitable method	x	x
Staphylococcus aureus (S. aures)	Food/cosmetic suitable method	x	x
Pseudomonas aeruginosa	Food/cosmetic suitable method	x	x
Candida albicans	Food/cosmetic suitable method	x	x
Mycotoxins:			
Aflatoxins	Food/cosmetic suitable method	x	
Fumotoxins	Food/cosmetic suitable method	x	
Ochratoxins	Food/cosmetic suitable method	x	
Zearlaleone	Food/cosmetic suitable method	x	

Table 3: *Minimum tests needed for oils used as a cosmetic raw material*

Minimum tests needed for oils used as a cosmetic product
The table below indicates the minimum tests needed for oils used as a cosmetic product.

Test parameters	Test method/s
Peroxide Value and/or Acid Value	EU Pharmacopoeia or other suitable method
Refractive index	NF ISO 592
Pesticide residue	Liquid chromatography–mass spectrometry (LCMS)
Heavy metals	Inductively Coupled Plasma (ICP)
Shelf life	Guidance document method
Challenge Testing (preservative efficacy)	International Standard ISO 11930 European Pharmacopoeia (EP) Chapters 5.1.3
Claim support	Test method depends on the test parameter needed
Microbiology:	
Total Plate Count (TPC)	Any suitable test method
Total Viable Count (TVC)	Any suitable test method
Total Yeast and mould	ISO 16212
Total Fungi(Mould)	Any suitable test method
Escherichia coli	ISO 21150: 2006
Staphylococcus aureus (S. aures)	ISO 22718: 2006
Pseudomonas aeruginosa	ISO 22717: 2006
Candida albicans	ISO 18416: 2007

Table 4: *Minimum tests needed for oils used as a cosmetic product*

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