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## Steps to gather information for low tonnage substances

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## 1. Introduction

In this document, we illustrate the steps to follow to make sure that you gather all relevant and reliable information before you register your substance under REACH.

For this example, we consider that your substance is a solid organic substance and a mono-constituent. You manufacture the substance less than 10 tonnes per year.

Therefore, the information requirements from Annex VII are relevant.



REACH requires that you to always submit every all relevant information in your possession and not just the ones required.

## General information on your substance

### Identity of the substance

To correctly identify your substance, you need to submit the following data:

- IUPAC or other international name.
- Other names (e.g. trade name).
- EINECS or ELINCS number.
- CAS name and number.
- Other identity code (if available).
- Molecular and structural formula.
- Optical activity and ratio of (stereo) isomers.
- Molecular weight (or range).
- Degree of purity.
- Nature of impurities.
- Percentage of (significant) main impurities.
- Nature and magnitude of additives.
- Appropriate spectral data.
- Appropriate chromatogram.
- Analytical methods and references used for the identification of the substance.

For more information on identifying your substance, see [Guidance for identification and naming of substances under REACH and CLP](#).

### Manufacture and use of the substance

Submit the following information:

- Quantity produced and imported.
- Brief description of the manufacturing process.
- Tonnage used for own (internal) use.
- Form/physical state of the substance as made available to downstream users.
- Concentration (range) in mixtures made available to downstream users.
- General description of uses.
- Waste quantities.
- Uses advised against.

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Use the 'use descriptors' to describe manufacture and use, next to a brief description.

You should indicate all uses of your substance. If you do not know all of them, you should find out from your supply chain.

### Hazard classification of the substance

If there is no harmonised classification for your substance, submit a self-classification and labelling, if applicable. This self-classification should be based on all your data and assessments.

Note: You must already have notified your substance to the Classification and Labelling Inventory under the CLP Regulation.



If your substance has a [harmonised classification](#), you always need to use that.

### Guidance on safe use

You should base this guidance on all available knowledge. You should already have a safety data sheet if you supply your substance to industrial or professional users.

Submit the following information:

- Elements that are under headings 4 to 8, 10, 13 and 14 of the safety data sheet of your substance.
- Information on recycling.

## 2. Information gathering for physico-chemical properties



A full set of physico-chemical data must always be provided. However, some data may be omitted because of the substance properties.

1. You have reliable information for the following physico-chemical properties:

- Melting point.
- Relative density.
- Surface tension.
- Flash point.
- Flammability
- Explosive properties.
- Self-ignition temperature.
- Oxidising properties.
- Granulometry

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2. You compare the information that you have to the list in Annex VII to REACH. You notice that to fulfil the physico-chemical information requirements for your substance, you are missing data on the following:
  - Boiling point.
  - Vapour pressure.
  - Water solubility.
  - Partition coefficient n-octanol/water.
3. You check whether some of the information could be omitted based on column 2 in Annex VII. You notice that the boiling point is not required for solid substances that melt above 300°C. As the melting point of your substance is 350°C, you can omit this information from your dossier.
4. Similarly, you notice that the vapour pressure does not need to be determined when the melting point is >300°C.
5. You consult the other SIEF members and make an inventory of all data available in the SIEF. You find out that data is needed for the remaining two properties (water solubility and partition coefficient n-octanol/water)
6. You also consult open literature such as handbooks or databases and publicly available study reports. You find some information on water solubility of your substance in handbooks.
7. You carefully assess all the information that you have: is it reliable and does it provide a relevant value for assessing your substance? You conclude that the data you found for water solubility is reliable, relevant and adequate to fulfil the REACH requirement.
8. Very often, data from handbooks or other secondary sources do not provide the information on how the data has been obtained. Therefore, information from handbooks or other secondary sources need to be used in a weight of evidence (WoE) approach. This means that you need to provide information from several independent data sources. Consult the [Practical guide: How to use alternatives to animal testing to fulfil your information requirements for REACH registration](#).
9. For partition coefficient n-octanol/water, you need to consider how to fill in the data gap. You consult ECHA's [Practical Guide for SME Managers and REACH Coordinators](#). There are three standard tests to find out this property. You conclude with the experts that you consult, that the shake flask method is the most appropriate for your substance, because your substance is a pure, water-soluble substance, which does not dissociate or associate, and it is not surface active.
10. You order the test to be done to complete your information gathering for physico-chemical properties.

**Tips:**

- ! If you want to use information from a handbook or database, you have to check carefully whether the tested substance is the same as the one you want to register (with regard to purity/impurities) and whether that data was derived with a reliable test method. The same applies to old reports from studies that were performed before test

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methods were standardised.

- ! An overview of accepted handbooks and databases and the requirements for such data to be used can be found in the [Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.7a](#).
- ! Information from handbooks or other secondary sources need to be used in a weight of evidence (WoE) approach. This means that you need to provide information from several independent data sources.
- ! New testing of physico-chemical properties, which may determine physical hazard classification (according to the CLP Regulation), need to be performed in compliance with good laboratory practice (GLP). Already existing data that has not been performed according to GLP may be acceptable.

### 3. Information gathering for environmental and human health properties

1. You have reliable information for:
  - Physico-chemical properties – they do not lead to classification.
  - From experience on the use of the substance, you know that contact with the skin causes severe damage. In other words, it is a corrosive substance.
  - The results of the ready biodegradability test.
2. You compare the information that you have to the list in Annex VII to REACH.
3. You check whether some of the information could be omitted based on column 2 in Annex VII. You notice that because your substance is corrosive to the skin, the tests for determining eye irritation potential, skin sensitisation potential and acute oral toxicity do not need to be performed. You can waive these three tests and choose a valid justification why these tests do not need to be performed.
4. You notice that to fulfil the information requirements for your substance, you are missing data on the following:
  - Short-term toxicity testing on invertebrates.
  - Growth inhibition study on aquatic plants.
  - *In vitro* gene mutation test in bacteria.
5. You check the open literature such as handbooks or databases and publicly available study reports and also consult the SIEF members to ask whether they have this data.
6. You agree in the SIEF to order the test to complete the information gathering. New tests for human health and environmental endpoints need to be performed according to the applicable guideline and in compliance with GLP.

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**Tips:**

- ! If you exceed the 10-tonne threshold, you will also need to comply with the information requirements in Annex VIII to REACH and provide a chemical safety assessment and a chemical safety report in your registration dossier.
  
- ! Consult the practical guides available on ECHA's website, especially:
  - [Practical guide for SME managers and REACH coordinators](#)
  - [How to use alternatives to animal testing to fulfil your information requirements for REACH registration](#)

## 4. Can I benefit from reduced information requirements?

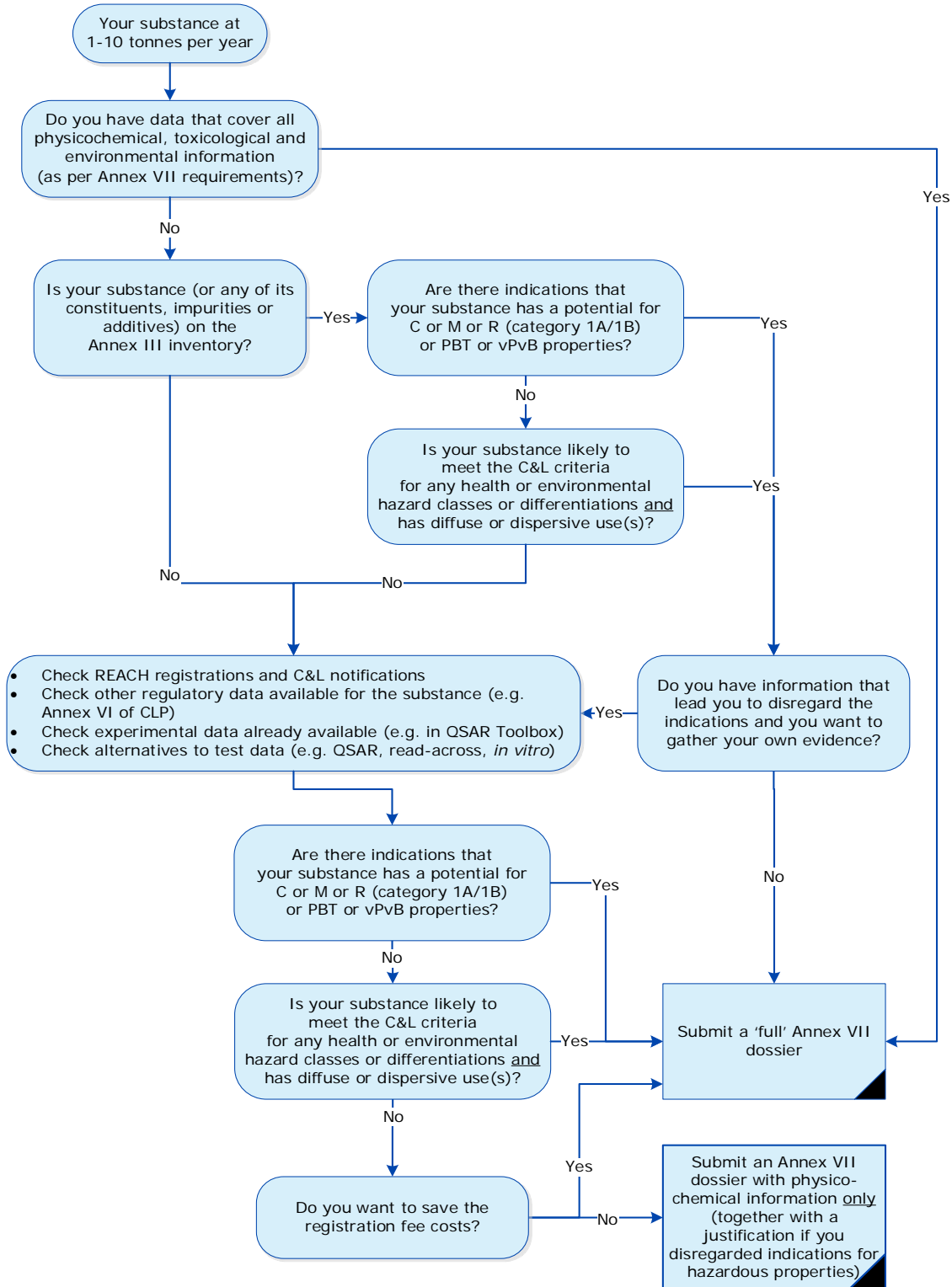
If your substance fulfils the criteria defined in Annex III to REACH, you must submit all the information listed in Annex VII to REACH. These are the physico-chemical information and also data on toxicological and ecotoxicological properties.

If your substance does not fulfil the criteria defined in Annex III to REACH, you must submit all information that is available to you and, in any case, physico-chemical information listed in Annex VII to REACH. To help you decide, ECHA has published an inventory of substances for which there are indications that a full Annex VII dataset would be required.

You can find it on [ECHA's website](#).

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**Decision scheme to decide whether you need a full set of information.**



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## 5. Scenarios justifying submission of a reduced data set

### What you need to do to benefit from the reduced information requirements for 1-10 tonnes registration:

- Submit the full set of physicochemical information as indicated in Annex VII to REACH because the physico-chemical data always need to be provided.
- Submit environmental and human health data that you already have available.
- Document all your considerations in IUCLID, Section 14 "Annex III criteria".



If you conclude that you do not need to submit the full information set for your substance, you must clearly document your argumentation and keep it for inspection by the authorities.

Write down what information is available, what checks you have done and what considerations have led you to your conclusion.

You also need to include all relevant justification in Section 14 of your IUCLID dossier.

### Scenario 1

#### What you know

- Your substance is not on the [Annex III inventory](#), published by ECHA, of substances that are likely to fulfil, either the criterion of Annex III(a), or both criteria of Annex III(b) to REACH.
- Your substance is used in a consumer product, in a hobby glue.
- The information you have gathered (search in ECHA's chemicals database, C&L Inventory, search for experimental data or other information such as (Q)SAR predictions) does not indicate the need for a classification or hint towards persistent or bioaccumulative properties.

#### Your conclusion

- Your substance fulfils only one of the two criteria mentioned in Annex III(b) to REACH.
- Therefore, your registration can benefit from the reduced information requirements.
- You have to submit a full set of physico-chemical information as indicated in Annex VII because the physico-chemical data always needs to be provided.



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## Scenario 2

### What you know

- Your substance is on ECHA's [Annex III inventory](#) and is likely to fulfil the criterion of Annex III(a): there are indications that it is a possible carcinogen.
- You have data that shows your substance does not have carcinogenic properties.
- You have data that shows your substance does not have any persistent, bioaccumulative and toxic (PBT) or very persistent, very bioaccumulative (vPvB) properties.
- There are no dispersive or diffuse uses for your substance, such as:
  - consumer uses;
  - uses by professional workers (i.e. uses by professionals outside industrial sites);
  - uses in articles, unless these are only limited to industrial sites;
  - uses at industrial sites (including uses of articles), if not limited to a few sites only and carried out under rigorous containment (with minimised environmental emissions).
- The information you gathered (search in ECHA's chemicals database, C&L Inventory, search for experimental data or other information such as (Q)SAR predictions) does not indicate the need for a classification or hint towards persistent or bioaccumulative properties.

### Your conclusion

- Although there were indications that the substance is carcinogenic, your data shows this is not the case for your substance. Therefore, it does not fulfil the criterion of Annex III(a).
- It is also not a classifiable substance with wide dispersive, diffuse or consumer use. It therefore also does not fulfil both criteria of Annex III(b).
- Therefore, your registration can benefit from the reduced information requirements.
- You have to submit a full set of physico-chemical information as indicated in Annex VII because the physico-chemical data always needs to be provided.

## Scenario 3

### What you know

- Your substance has been used for many years by only two industrial companies in their processes. They do not sell it to consumers or put it in consumer articles.
- There have never been any indications of human health effects such as irritation of the skin or of effects in the environment around the manufacturing site of your biggest customer or elsewhere.
- You have checked the [Annex III inventory](#) published by ECHA and your substance does not appear on that inventory.
- You have checked REACH registrations and notifications in the C&L Inventory and found no indication for human health or environmental classification of your substance.

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- You have checked other regulatory data available for the substance and, found, e.g. on [ECHA's information on chemicals portal](#) that there is no harmonised classification for your substance.
- You have checked available experimental data (e.g. through the eChemPortal) and found no indication for human health or environmental classification of your substance.
- Your substance is not similar to any other substance for which you know that there are negative effects.
- Relevant (Q)SARs (e.g. from the Danish (Q)SAR database) do not indicate the need for any human health or environmental classification of your substance.
- All-in-all, it appears that your substance is mostly harmless.

### Your conclusion

- Your substance does not fulfil either of the two criteria mentioned in Annex III to REACH.
- Therefore, your registration can benefit from the reduced information requirements.
- You have to submit a full set of physico-chemical information as indicated in Annex VII because the physico-chemical data always needs to be provided.

## Scenario 4

### What you know

- You have checked ECHA's [Annex III inventory](#) and your substance is not there.
- There is no indication in any information you know that your substance has negative effects on the environment or on humans and several similar substances you produce in higher amounts are not classified either.
- You have a negative skin irritation/corrosion test result.
- Your customer, an industrial company, uses the substance as a pigment in a coating on a consumer article.
- You have checked REACH registrations and notifications in the C&L Inventory and found no indication for human health or environmental classification of your substance.
- You have checked other regulatory data available for the substance (e.g. harmonised classification) and found no entry on [ECHA's information on chemicals portal](#).
- You have checked available experimental data (e.g. through the eChemPortal) and found no indication for human health or environmental classification of your substance.
- Relevant (Q)SARs (e.g. from the Danish (Q)SAR database) do not indicate the need for a human health or environmental classification of your substance.

### Your conclusion

- You have to submit a full set of physico-chemical information as indicated in Annex VII because the physico-chemical data always needs to be provided.
- You have to submit the results of the skin irritation/corrosion test, because you have to provide all available data.
- You do not have to provide any other information on environmental properties or human health, because:
  - you have no such information;
  - testing is not required, since there are no indications of effects or a necessary classification;

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- o the fact that the substance will be in a consumer article only fulfils the first criterion of Annex III(b) to REACH. You only have to submit the full dataset according to Annex VII, if both criteria are fulfilled.

## 6. Scenarios justifying submission of a full data set for 1-10 tonnes registration

### Scenario 5

#### What you know

- Your substance is not on the [Annex III inventory](#) of substances that are likely to fulfil either the criterion of Annex III(a), or both criteria of Annex III(b) to REACH.
- From experience of using the substance or by comparing with another substance, your substance may need to be classified for either human health properties or environmental properties (or both)
- Your substance is used in a consumer article.

#### Your conclusion

- Your substance fulfils both criteria of Annex III(b): indications for a possible need for classification for a human health or environmental property, and possible use (in an article) by consumers.
- Therefore, you will have to submit (i) information on all elements mentioned in Annex VII to REACH and (ii) any other relevant information you have available.

### Scenario 6

#### What you know

- Substance is not on the [Annex III inventory](#) of substances that are likely to fulfil either the criterion of Annex III(a), or both criteria of Annex III(b) to REACH.
- Your substance is used by many professionals.
- A publication indicates that your substance has unwanted effects on the environment.

#### Your conclusion

- Because of the widespread use of your substance, in combination with evidence from the publication, your substance fulfils both criteria of Annex III(b) to REACH.
- Therefore, you will have to submit (i) information on all elements mentioned in Annex VII to REACH and (ii) any other relevant information you have available.

### Scenario 7

#### What you know

- Your substance is on the [Annex III inventory](#) , and is likely to fulfil the criterion of Annex III(a): there are indications that it is a possible carcinogen.
- You have data that shows your substance has to be classified as a carcinogen.

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### Your conclusion

- Your substance fulfils the criterion of Annex III(a); therefore, you have to submit all data according to Annex VII to REACH.
- **Note:** you also have to submit the information that shows your substance is a carcinogen and make sure your substance is labelled according to your classification.

### Scenario 8

#### What you know

- Substance is on the [Annex III inventory](#), and likely to fulfil the criterion of Annex III(a): there are indications that it is a possible carcinogen.
- You do have data that shows your substance does not have carcinogenic properties.
- There is a consumer use.
- You expect that your substance needs to be classified for an environmental effect.

#### Your conclusion

- Although there were indications that the substance is carcinogenic, your data shows this is not the case for your substance. Therefore, it does not fulfil the criterion of Annex III(a).
- However, it does fulfil both criteria of Annex III(b).
- Therefore, you have to fulfil the full set of information requirements of Annex VII.
- **Note:** You also have to submit the information that shows that your substance is hazardous to the environment. Make sure your substance is labelled according to your classification.

### Scenario 9

#### What you know

- You have checked the [Annex III inventory](#) and your substance is not on that inventory.
- You know that there is a substance with a very similar structure and some very similar properties and you expect that your substance may have the same effects as that substance. That similar substance is on the Annex III inventory which indicates a classification as carcinogenic, mutagenic and/or reproduction toxic effects.
- **Note:** The Annex III inventory is not searchable by using chemical structures. Therefore, you have to have a good understanding of chemical names to find a structurally similar substance on that list. This will probably require advanced scientific expertise.

#### Your conclusion

- You have to submit a full set of physico-chemical information as indicated in Annex VII because the physico-chemical data always needs to be provided.
- You also decide to submit a full set of environmental and human health data as indicated in Annex VII, because you expect that your substance has similar CMR effects as a substance that is on the Annex III inventory.
- **Note:** If you already manufactured or imported this substance before, and if you were already aware of the potential that your substance has carcinogenic, mutagenic or toxic to reproduction properties, you should already have registered your substance before the first REACH deadline in 2010!

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## Scenario 10

### What you know

- Your substance is not soluble in water.
- You have checked the Annex III inventory and your substance is not on that inventory.
- Your customers have complained about red skin of workers if they handle the substance without gloves.
- You sell the substance to a distributor for use (in small quantities) in a professional use.

### Your conclusion

- You have to submit a full set of physico-chemical information as indicated in Annex VII because the physico-chemical data always need to be provided.
- You also have to submit a full set of environmental and human health, because complaints of red skin are an indication of skin effects of your substance and because the substance has a widespread use. The substance, therefore, fulfils both criteria of Annex III(b).
- **Note:** You need to investigate the skin irritation effects of your substance.
- **Note:** You may not need to submit some data, because the substance is not soluble in water.

## Scenario 11

### What you know

- You have checked the [Annex III inventory](#) and your substance is not on that inventory.
- There is a publication that shows that your substance has been tested for acute toxicity to water organisms and that there were negative effects at concentrations that require classification. The study is, however, not well reported.
- Your substance will become part of a polymer product intended for consumers.

### Your conclusion

- You have to submit a full set of physico-chemical information as indicated in Annex VII because the physico-chemical data always need to be provided.
- You also have to provide a full set of environmental and human health data because the effects in an environmental study, although not well reported, are an indicator that the substance may need to be classified for environmental effects.
- Furthermore, there is a use in consumer articles.
- The substance, therefore, fulfils both criteria of Annex III(b).