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How to gather information to register an inorganic mono-constituent substance (including the chemical safety assessment)

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1. Introduction

The substance is a metal salt, a solid inorganic substance.

The company that wants to register the substance produces the substance in a volume equal to or more than 10 tonnes per year, but less than 100 tonnes per year. Therefore, the registrant(s) must provide the standard information required in Column 1 of the REACH Annexes VII and VIII. Similarly, registrants have the obligation to perform a chemical safety assessment (CSA) and submit a chemical safety report (CSR) as part of the registration dossier.

This example will mainly illustrate:

- analytical methods and identification of inorganic substances;
- information-gathering programmes for human health and environmental information;
- use mapping;
- gathering data on conditions of use;
- exposure assessment and risk characterisation.

Within the example, there are multiple scenarios where existing information will lead to different routes of further data gathering. Not all the routes will be completely described. For some routes, only a limited description of next steps and relevant issues will be provided.

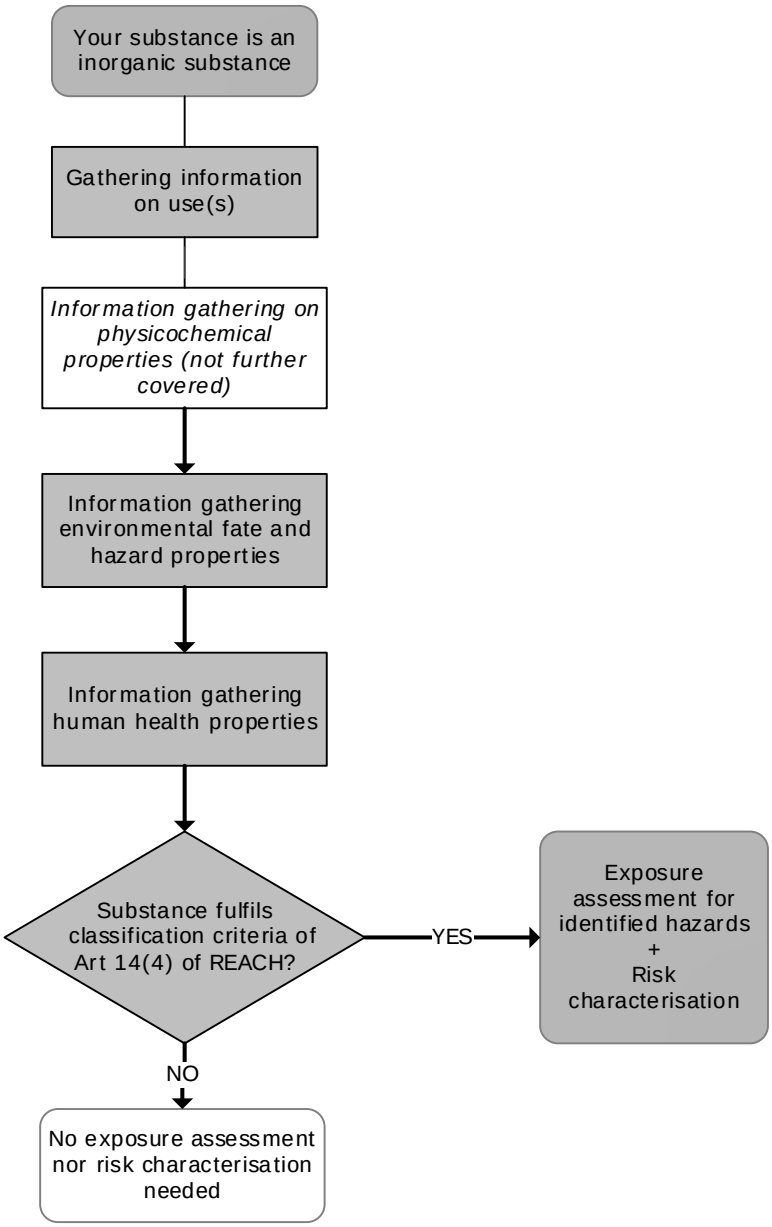
We assume that all required physicochemical information is available and therefore the corresponding information-gathering programme is mentioned only partly.

More information is provided in chapters I and II of the Practical guide for SME managers and REACH coordinators – How to fulfil your information requirements at tonnages 1-10 and 10-100 tonnes per year.

All the Guidance documents referred to in this document are on ECHA's website.

Figure 1 illustrates the flow chart of this example.

Figure 1: Steps to consider for the preparation of the chemical safety assessment



2. Analytical methods and identification of inorganic substances

First, you need to provide the spectral and analytical information together with the description of the analytical methods for the identification of your substance.

Table 1: Steps to gather spectral and analytical data for substance identification

Table 1 What you know	What you need to do	Remark
Your technical people tell you that the substance is a coloured inorganic substance and that there are no spectral and analytical data available.	You need to provide adequate information to establish the chemical structure of the salt, the purity and the impurity profile. The standard spectral and chromatographic techniques applied for organic substances in general are not appropriate for inorganic substances. For inorganic substances, you need to gather at least one of the following spectral and analytical data types: • X-ray diffraction screening • X-ray fluorescence screening • inductively coupled plasma optical emission spectrometry • ion chromatography • infrared (IR) spectroscopy may be useful too, e.g. if the substance contains a carbonate. Sometimes more than one type is necessary to properly identify the substance. For coloured substances, the following spectral data should also be considered: • ultraviolet and visible absorption spectroscopy.	It requires scientific expertise to decide which analytical methods are appropriate for your substance. Therefore, the analyses need to be carried out by a competent person. **NB:** The spectral and analytical data do not have to be obtained in compliance with the principles of good laboratory practice (GLP). The description of the analytical methods need to be in such detail that the methods can be reproduced.
From the spectral and analytical data you now know that your substance is a metal salt with a purity of 99.9% and containing 0.1 % of an unspecified impurity.	This information has to be used to name your substance and to determine the further strategy for registration of your substance.	Naming your substance might require scientific expertise. Please see Guidance for identification and naming of substances under REACH and CLP for more information.

3. Physicochemical information and risk characterisation

For metal salts, it is important that you know whether the substance is soluble in water, and what is its particle size.

Table 2 describes scenarios where you have some physicochemical information and these affect the risk characterisation.

Table 2: How physicochemical information on your metal salt affects your conclusions / further actions

Table 2 What you know	What you need to do	Remark
Scenario 1: Your substance is soluble in water (it dissolves / dissociates)		
You do not have a test on water solubility of your substance. You have other required physicochemical data already available.	As a first step, you can search the publicly available literature, such as handbooks, to see if there is any information regarding your substance. If you cannot find useful information in public literature, you have to consider performing some tests to find out how your substance behaves in water: • perform a water solubility test.	**NB:** For a dissolved salt, ions of the metal may be relevant for environmental risk characterisation, while for human health risk characterisation of the full salt may be relevant.
The water solubility is known from publicly available literature.	To be able to use the publicly available literature, you must: • make sure that the substance described in literature is the same substance as your substance; • make sure that the method used, the results and the conclusions are described with enough detail, so that you can understand what was tested and that the results are reliable.	If you find more than one publication describing dissociation/solubility, these publications may not be used on their own to draw a conclusion, whereas they may be considered in combination: this approach is called 'weight of evidence' and requires scientific expertise. **NB:** To confirm the reliability of publications, you usually need more than one source of information.
Scenario 2: Your substance is of very low solubility in water (it is not soluble)		

Table 2 What you know	What you need to do	Remark
From the physicochemical tests you performed, you know that your metal salt has a very low solubility in water.	You still have to gather physicochemical, environmental and human health information.	Some of the required physico-chemical, human health and environmental endpoints may be 'waived' or are scientifically unjustified based on the substance's very low solubility in water. See chapters I and II of the Practical guide for SME managers and REACH coordinators.
You know that your substance is an inorganic solid.	If your substance is a solid, you have to determine the particle size distribution (for more information, see Chapter I.1.13 of the Practical guide for SME managers and REACH coordinators)	Knowing the particle size distribution of your substance is important for the risk characterisation, because it can tell you if humans can be exposed to your substance by inhaling it.

4. Information gathering for environmental and human health information

Once you have information regarding the identity and the physicochemical properties of your substance, you have to gather the information on environmental fate and hazards and the human health information that is prescribed in Annexes VII and VIII.

!	Information gathering is a joint activity of the substance information exchange forum (SIEF) and should be organised together with your co-registrants. New tests on animals are the last option! First search and compile all existing information, to avoid unnecessary animal testing.

4.1. Indicative steps to gather (some of) the environmental fate and hazard information

What you know:

From a search on ECHA's web page 'Information on Chemicals' you know that full REACH registration dossiers for more than 1000 tonnes per year are available for two metal salts that, according to your technical people, are similar to your metal salt (i.e. contain at least either the same cation or same anion).

What you need to do:

To fulfil the environmental information requirements for your substance, you need to gather information for the following properties:

- algal growth inhibition;
- short-term toxicity to aquatic invertebrates;
- toxicity to (sewage treatment plant) microorganisms;
- short-term toxicity to fish.

The ready biodegradability test can be waived because it does not apply to inorganic substances.

As your substance dissociates readily, it will be present in the environment as its dissociated ions (cation (+) and anion (-)). Therefore, if you do not already have the above information on your substance, either from the literature or your own existing studies from within the SIEF, you have the option to consider whether you can predict the effects of the registered substance, the metal salt, from information on the environmental properties of other salts containing the same cation or the same anion. This is called the 'read-across' approach and is covered in more detail below. If a read-across approach is not feasible, you will have to conduct studies on your metal salt.

To investigate if you can apply a read-across approach[1] and use the existing information from two salts of the same metal as in your substance (that you discovered have been registered) in order to complete your registration dossier of your own metal salt:

- you need to create an overview of all available physicochemical and environmental information available for all three metal salts;

- from this overview, you may decide (if necessary, together with a scientific expert) if you can conclude that the three metal salts can be regarded as similar;

- based on all available information, you will need to scientifically justify why you can apply read-across in your registration dossier, and you will need to submit all supporting evidence;

- if you can conclude that the three metal salts can be regarded as similar and you want to use read-across, you may contact the relevant SIEFs to see whether they are ready to provide you with a Letter of Access (LoA) for the relevant studies.
  To contact the relevant SIEFs:
  - as most probably you have not pre-registered the other three metal salts, you can conduct a search on the ECHA website, which contains names of the companies who already registered the substances. Another route is via the pre-registration REACH-IT profile of your substance (by adding in the "similar substance" tab the substances you are interested in). You will not become part of those SIEFs for the salts (regarded as similar) but will be able to see who are the members and their contact details.
  - if you did pre-register any of the other three metal salts, you are already aware of the pre-SIEFs or possibly also the SIEFs: https://echa.europa.eu/regulations/reach/registration/data-sharing/pre-registration

[1] See https://echa-term.echa.europa.eu/home and https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

Remarks:

- Advanced scientific expertise is required to build the read-across justification. If read-across cannot be applied, you have to perform/subcontract the required environmental tests (see sections I.2 and II.1 of the Practical guide for SME managers and REACH coordinators). ECHA's Read-across Assessment Framework is a good starting point for structuring the read-across justification documentation.

- If no information for environmental properties is available, i.e. you only have information for physicochemical properties and have concluded on structural similarity, then you may not have sufficient information to build a read-across justification. Structural similarity and comparable physicochemical properties are not sufficient to conclude that the toxicities of the substances are also comparable. You must provide supporting evidence to show that the toxicities of the substances are comparable.

- The key point is:
  - to establish similar bioavailability (based e.g. on water solubility); and
  - to establish that the aquatic organism toxicity is determined by the metal ion that is common to all three salts and not by the associated anions.

- If, based on the available information for your substance, you conclude that your substance needs to be classified for any of the endpoints mentioned in Article 14(4) of REACH, characterisation of risk will need to be performed. This involves combining the evidence from the environmental studies to derive the predicted no-effect concentrations (PNECs) and estimating the environmental exposure to derive predicted environmental concentrations (PECs) for the different environmental compartments for each exposure scenario. Risk characterisation consists of comparing the PECs with the PNECs.

4.2. Indicative steps to gather (some of) the human health information

What you know:

Your substance is a solid (powder) metal salt that is soluble in water. You have reliable information for all relevant physicochemical properties and you have reliable information available for some human health properties:

- skin irritation and corrosion (*in vivo* study);
- eye irritation (*in vivo* study);
- acute oral toxicity;
- acute inhalation toxicity;
- skin sensitisation;
- *in vitro* gene mutation study in bacteria;
- *in vitro* gene mutation in mammalian cells;
- *in vitro* cytogenicity study.

From a search on ECHA's web page 'Information on Chemicals' you know that a full REACH registration (Annex X, more than 1000 tonnes per year) is available for a metal salt that, according to your technical people, is very similar to your metal salt.

What you need to do:

To fulfil the human health information requirements for your substance, you need to gather information for the following properties:

- short-term repeated dose toxicity;
- screening for reproductive/developmental toxicity.

Option 1

In REACH, animal testing should be the last choice. Therefore, you need to investigate whether you can apply a read-across approach[2] and use the information from the similar metal salt for the registration dossier of your own metal salt:

- you need to create an overview of all available physicochemical and human health information available for both metal salts;
- from this overview, you may decide, with a scientific expert, whether you can conclude that both metal salts can be regarded as similar;
- you need to scientifically justify why you can apply read-across in your registration dossier, and you need to submit all supporting evidence;
- if you can conclude that the three metal salts can be regarded as similar you may contact the relevant SIEFs to see if they are ready to provide you with a Letter of Access (LoA) for the relevant studies.

  To contact the relevant SIEFs:
  - as most probably you have not pre-registered the other three metal salts you can conduct a search on the ECHA website, which contains names of the companies who already registered the substances. Another route is via the pre-registration REACH-IT profile of your substance (by adding in the "similar substance" tab the substances you are interested in). You will not become part of those SIEFs for the salts (regarded as similar) but will be able to see who are the members and their contact details.
  - if you did pre-register any of the other three metal salts you are already aware of the pre-SIEFs or possibly also SIEFs: https://echa.europa.eu/regulations/reach/registration/data-sharing/pre-registration

Option 2

To avoid unnecessary duplication of animal tests, you investigate the most appropriate test guideline to perform the screening study for reproductive/developmental toxicity, so that the need to perform a short-term repeated dose toxicity (28-day treatment) would be fulfilled simultaneously. You decide to perform the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test.

Remarks:

- ⓘ The REACH annexes have changed in 2016, and *in vitro* testing has become the standard requirement for three properties: (i) skin irritation and corrosion; (ii) eye

[2] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

irritation; (iii) skin sensitisation.

- Because your information for skin irritation and corrosion and eye irritation are from *in vivo* studies, you need to prepare a scientific justification as to why you are not submitting an *in vitro* test (to comply with the current Annex VII requirements). Otherwise, your dossier will not pass the technical completeness check.

- For skin sensitisation, you may have to complete your current information using the *in vitro* methods in line with the current Annex VII requirement.

- *In vivo* mutagenicity testing is not necessary because all *in vitro* tests showed negative results.

- ECHA's Read-across Assessment Framework is a good starting point for structuring the read-across justification documentation.

- If no information for human health endpoints is available, but you only have information for physicochemical properties and have concluded on structural similarity, then you do not have sufficient information to build a read-across justification. Structural similarity and comparable physicochemical properties are not sufficient to conclude that the toxicities of the substances are also comparable.

- It is possible that while a read-across justification may be built for one property, it cannot be used for another property.

- Advanced scientific expertise is required to build the read-across justification[4)]. If read-across cannot be applied, you have to perform/ subcontract the required human health tests yourself (see chapters I.3 and II.2 of the Practical guide for SME managers and REACH coordinators).

- If, based on the available information for your substance, you conclude that your substance needs to be classified for any of the endpoints mentioned in Article 14(4) of REACH, characterisation of risk will need to be performed. This involves combining the evidence from the toxicology studies to derive the derived no-effect levels (DNELs) and estimating the human exposure for different populations for each exposure scenario. Note that the impact of some adverse health effects, such as eye irritation, is assessed qualitatively.

5. Gathering of information on use(s)

A critical element of your dossier is the information you have to provide on the manufacture and use(s) of your substance. We assume that you, as the manufacturer, know the ins and outs of your manufacturing process.

In addition, whether you are a manufacturer or an importer, you also need to submit data on the use(s) of your substance during its whole life cycle in the EU. Considering you may not have all knowledge on these uses at hand, you will find below (Table 3) examples and suggestions for gathering information on use(s) and for reporting information on the manufacture (if relevant) and uses. In the scenario below, there are various uses of your substance.

!	You should start gathering information on use(s) right at the beginning of preparing your dossier. Information on use(s) may be difficult to obtain. Furthermore, information on use(s) may influence the need to gather other necessary information on the properties of your substance.

Table 3: Steps to gather information on general use(s)

Table 3 What you know	What you need to do	Remarks
You have to register the substance.	Gather information: • on the conditions of manufacturing at your plant(s); and • on what the substance is sold and used for.	Internal information (at the sales department and technical department) is always a good starting point.
Your plant manager informs you of the details on manufacturing that are relevant. Your technical people tell you that the substance can be used as an additive or colourant in many products, such as coatings, plastics, rubber.	Ask the sales people to what clients and to what market the substance is actually sold.	Theoretical use in a market is not necessarily also the actual use. Be careful not to include potential uses that do not really occur.
Your sales people tell you that the substance is sold to polymer manufacturer and the rubber industry and also via a distributor.	Check if the relevant sectors have prepared use maps. If not, contact representative clients in the polymer and rubber industry and ask in what final products the substance ends up and its condition and use. Also ask for the processes used (consider asking directly for 'use descriptors' from ECHA Guidance R.12). Ask the distributor to what sectors they sell your substance.	You have to report all uses throughout the relevant life cycles of your substance. A polymer is later converted into a plastic object – the producer and the user of the object (made with your substance) are part of the life cycle. The distributor may inform you that also another industry sector uses your substance.
The rubber industry reports that your substance is used in technical rubber products only.	You can conclude that there is no consumer exposure or widespread environmental emission from rubber.	

Table 3 What you know	What you need to do	Remarks
You have now knowledge on the following parts of the life cycle: • manufacture (by you) • use in polymer masterbatches • use in rubber industry • use in technical rubber • use in coatings.	Check if the relevant sectors have prepared use maps or websites of polymer industry, rubber industry and coating industry. Or contact relevant sector associations and ask for more information. Or ask a consultant to gather more information and create your life cycle and use description.	Many downstream user associations have created overviews of relevant uses and conditions of use of many types of substances that can be used in the registration. There are various consultants that already have made several use descriptions and who can help you to efficiently describe the uses of your substance.
The distributor indicates that the substance has been sold to polymer industry and coatings industry, but that he cannot provide more details.	Check if the relevant sectors have prepared use maps. Decide, based on knowledge on the substance properties, what kind of coatings may contain your substance. Consider whether consumer use is relevant.	Type of coating into which the substance is formulated will influence what further uses are relevant.
You have several pieces of information on the uses.	Describe the manufacture and uses briefly in text. Describe the manufacture and uses using the 'use descriptor system' of the REACH Regulation. Or ask a consultant to describe the uses.	A brief textual description is required. For harmonised description of uses, you should use the use descriptor system that is described in Guidance Document R.12 of ECHA. The interpretation of the use descriptor system requires experience; since the use descriptors directly influence exposure estimates in some models, correct interpretation can be critical.

The manufacturing of the substance as such or its formulation into a mixture or its incorporation into an article needs to be described. A possible use description of your substance is presented in Table 3 and is detailed as an example in Table 4.

Table 4: Use description for manufacture and use(s) of the substance

Table 4 Identifiers*)	Use descriptors	Other information
M-1: Manufacture of substance	**Environmental release category (ERC):** ERC 1: Manufacture of substances **Process category (PROC):** PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions PROC 8a: Transfer of substance or mixture (charging/discharging) at non-dedicated facilities PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing)	Tonnage of substance: 95.0 tonnes/year
F-2: Formulation of liquid mixtures	**Environmental release category (ERC):** ERC 2: Formulation of preparations **Process category (PROC):** PROC 8b: Transfer of substance or mixture (charging/discharging) at dedicated facilities PROC 3: Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition PROC 5: Mixing or blending in batch processes PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing) PROC 8a: Transfer of substance or mixture (charging/discharging) at non-dedicated facilities **Technical function of the substance during formulation:** No technical function	Tonnage of substance: 4.0 tonnes/year Substance supplied to that use: **As such**
F-3: Formulation of polymer	**Environmental release category (ERC):** ERC 3: Formulation into solid matrix **Process category (PROC):** PROC 8b: Transfer of substance or mixture (charging/discharging) at dedicated facilities PROC 3: Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition PROC 5: Mixing or blending in batch processes PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing) PROC 8a: Transfer of substance or mixture (charging/discharging) at non-dedicated facilities **Technical function of the substance during formulation:** No technical function	Tonnage of substance: 40.0 tonnes/year Substance supplied to that use: **As such**

Table 4 Identifiers*)	Use descriptors	Other information
IW-4: Industrial use in the production of technical rubbers	**Environmental release category (ERC):** ERC 5: Industrial use resulting in inclusion into or onto a matrix **Process category (PROC):** PROC 8b: Transfer of substance or mixture (charging/discharging) at dedicated facilities PROC 5: Mixing or blending in batch processes PROC 14: Tabletting, compression, extrusion, pelletisation, granulation **Article category used:** AC 10g: Other rubber articles **Technical function of the substance during formulation:** Pigment	Tonnage of substance: 51.0 tonnes/year Substance supplied to that use: **As such** Subsequent service life[a] relevant for that use: Yes[b]
IW-5: Industrial use in the production of plastic articles	**Environmental release category (ERC):** ERC 5: Industrial use resulting in inclusion into or onto a matrix **Process category (PROC):** PROC 8b: Transfer of substance or mixture (charging/discharging) at dedicated facilities PROC 5: Mixing or blending in batch processes PROC 14: Tabletting, compression, extrusion, pelletisation, granulation **Article category used:** AC 13: Plastic articles **Technical function of the substance during formulation:** Pigment	Tonnage of substance: 40.0 tonnes/year Substance supplied to that use: **In a mixture** Subsequent service life[a] relevant for that use: Yes[b]
IW-6: Industrial use of coatings	**Environmental release category (ERC):** ERC 5: Industrial use resulting in inclusion into or onto a matrix **Process category (PROC):** PROC 8b: Transfer of substance or mixture (charging/discharging) at dedicated facilities PROC 5: Mixing or blending in batch processes PROC 8a: Transfer of substance or mixture (charging/discharging) at non-dedicated facilities PROC 7: Industrial spraying PROC 10: Roller application or brushing PROC 13: Treatment of articles by dipping and pouring **Product category used**: PC 9a: Coatings and paints, thinners, paint removers **Technical function of the substance during formulation:** Pigment	Tonnage of substance: 4.0 tonnes/year Substance supplied to that use: **In a mixture** Subsequent service life[a] relevant for that use: Yes[b)]

a) If a substance is incorporated into an article, service life refers to the period of time that the article is in use.

b) The subsequent service life is not described here, but it should be included in the registration dossier.

6. Exposure assessment and risk characterisation

You have gathered information on the use(s) of your substance and know that the substance is used in the rubber industry, the plastic industry and as an ingredient in coatings (Table 3). You also know that your substance needs to be classified for a human health property and an environmental property. This implies that you will have to do an exposure assessment, develop exposure scenarios (ESs), estimate exposure levels, and characterise the risks. The aim of a chemical safety assessment (CSA) is to ensure that the risks related to the substance are controlled. In general, when carrying out a CSA, you need to decide whether exposure assessment and risk characterisation are needed[3].

If yes, then you need to decide on what is the required scope of the exposure assessment. Thus, the result of the hazard assessment may trigger one of the following scenarios:

a) The substance meets the criteria for **at least one** of the hazard classes or categories (physical, health or environmental), or is assessed as having any of the properties set out in Article 14(4) of REACH – in this case, exposure assessment is **mandatory** and should be considered for **all** standard estimated exposure levels.

b) The substance does **not meet** the criteria for **any** of Article 14(4) hazard classes, categories or properties – in this case, an exposure assessment is **not mandatory**.

If exposure assessment is triggered, it has to cover **all** hazards that have been identified for your substance. Such identified hazards are in general of three types:

1) hazards for which there are classification criteria and there is information to establish that the substance meets the criteria and is therefore classified;

2) hazards for which there are classification criteria and there is information on these properties of the substance showing that it does have these properties, but the severity of the effects is lower than the criteria for classification and so the substance is not classified;

3) hazards for which currently no classification criteria exist, but there is information to show that the substance has such hazardous properties.

[3] Guidance on Information Requirements and Chemical Safety Assessment – Part D: Framework for exposure assessment: https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

!	Article 14(4) of REACH states the following hazard classes, categories or properties: (a) hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F; These are: explosives, flammable gases, flammable aerosols, oxidizing gases, flammable liquids, flammable solids, self-reactive mixtures and solids, pyrophoric liquids, pyrophoric solids, substances and mixtures which in contact with water emit flammable gases, oxidizing liquids, oxidizing solids, organic peroxides), excluding gases under pressure, self-heating substances and mixtures and corrosive to metals. (b) hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10; These are: acute toxicity, skin corrosion-irritation, serious eye damage-eye irritation, respiratory or skin sensitization, germ cell mutagenicity, carcinogenicity, reproductive toxicity, specific target organ toxicity - single exposure, specific target organ toxicity - repeated exposure, aspiration hazard. (c) hazard class 4.1 - Hazardous to the aquatic environment; (d) hazard class 5.1 - Hazardous to the ozone layer; (e) or the substance is assessed to be a persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB).

Risk characterisation for human health involves combining the evidence from the toxicology studies to derive the derived no-effect levels (DNELs) and estimating the human exposure for different populations (e.g. workers at manufacturing site, consumers of a finished product containing the substance) for each exposure scenario.

Risk characterisation for environment involves combining the evidence from the environmental studies to derive the predicted no-effect concentrations (PNECs) and estimating the environmental exposure to derive predicted environmental concentrations (PECs) for the different environmental compartments (water, soil, sediment) for each exposure scenario.

Risk characterisation consists of:

- comparing the PECs with the PNECs and human exposure levels with the DNELs, and establishing the so-called risk characterisation ratio (RCR);
- an assessment of the likelihood and severity of an event occurring due to physicochemical properties of the substance.

The aim is to ensure that, for each relevant use and separate assessment, the level of exposure remains lower than the level leading to no effects. It means the RCR is below 1.

If an RCR is close to or above 1, you need to amend the recommended operational conditions and/or risk management measures or to improve the details of the information you know on the substance's properties. Subsequently, you need to repeat the assessment and check the level of the RCR(s).

All this needs to be recorded in a chemical safety report (CSR) and submitted as part of a registration dossier.

!	The Chesar tool (chemical safety assessment and reporting tool) was developed to help you to create your exposure assessment, undertake your risk characterisation in a structured manner and to create a chemical safety report and exposure scenarios.

Exposure scenarios (ESs)

!	Good quality exposure scenarios (ESs) are of high importance! They are the main outcome of the CSA and they deliver clear advice on safe use into the supply chain! This is one of the main goals of REACH.

In practice, the ES usually consist of a number of so-called 'contributing scenarios'. You need to develop the conditions of safe use of your substances and report them for each contributing scenario.

Table 5: Steps to assess levels of exposure and to create an exposure scenario (ES)

Table 5		
What you know	**What you need to do**	**Remarks**
Your use description is based on a use map.	Put the life cycle of your substance in Chesar.	It is not obligatory to use Chesar, but it is recommended as it is a free tool in which you can create your exposure assessment and risk characterisation. As the information used by Chesar is synchronised with IUCLID, updating of your chemical safety assessment will be relatively easy. You may also use other tools.

Table 5

What you know	What you need to do	Remarks
You have relevant information on use conditions for workers and for environment from the plastics and rubber industry, but not from the coatings industry.	Use the Chesar tool to create: • exposure assessments for all process categories (PROCs) in each ES; • environmental emission assessments and exposure assessments for all environmental release categories (ERCs) in each ES. Fill in the conditions as indicated by the source of information from the sector association. Obtain the relevant threshold levels (DNELs[4] and PNECs) and classifications of your substance from the IUCLID file. Check whether the exposure levels are all below the DNELs.	Using the input from the downstream user industries ensures that the conditions of safe use resulting from your chemical safety assessment are based on realistic assumptions. Chesar can import various kinds of information: • relevant information on properties of your substance, DNELs, PNECs, classification - directly from IUCLID; • some of the documents from industry associations (such as specific environmental release categories (ERCs)). Chesar will indicate what kind of assessments you need to do.
You have relevant information on use conditions for workers from the plastics and rubber industry, but not from the coatings industry.	Use the Chesar tool to create exposure assessments for all Process Categories in each Exposure Scenario. Fill in the conditions as indicated by the source of information from the sector association. Obtain the relevant threshold levels (DNELs) and classifications of your substance from the IUCLID file. Check whether the exposure levels are all below the DNELs.	Using the input from the downstream user industries ensures that the conditions of safe use resulting from your chemical safety assessment are based on realistic assumptions. Chesar can import various kinds of information: • relevant information on properties of your substance, DNELs, classification - directly from IUCLID; • some of the documents from industry associations (such as specific environmental release categories (ERCs)). Chesar will indicate what kind of assessments you need to do.
All exposure levels for workers for the rubber industry are below the relevant DNELs.	You do not have to iterate the assessment for the rubber industry.	Please be aware that for some adverse health effects (e.g. carcinogenicity) you may also need to do a qualitative assessment! It requires scientific expertise to create an appropriate qualitative assessment.
All environmental exposures for the rubber and plastics industry lead to conclusions of safe use.	You do not have to iterate these assessments.	

[4] See https://echa-term.echa.europa.eu/home.

Table 5

What you know	What you need to do	Remarks
Not all exposure levels for workers are below the DNELs for the plastics industry.	You have to iterate the risk assessment in order to make sure there is no uncontrolled risk from this use. This means you should re-examine the conditions of use (restrict operational conditions or add risk management measures) until the exposure levels are below the DNELs. You probably need to involve an expert.	Proper iteration takes into account of the so-called 'occupational hygiene strategy', with risk management measures "close to the source" as the first option and "use of personal protection equipment" as the last option. You can also refine the hazard assessment, e.g. by obtaining better information on adsorption to modify the DNEL. However, for substances registered in low volumes, the iteration of the exposure assessment is more common and more practical. **NB:** If neither iteration of exposure assessment nor refinement of hazard assessment are possible or lead to acceptable results, you may need to declare a certain use as a "use advised against" and stop supply of your substance for that use. It requires advanced scientific expertise to make a good quantitative assessment if the defaults from industry associations do not lead to a conclusion of safe use.
You do not have inputs on the conditions of use and on environmental emissions and conditions from the coatings industry.	You can try to use defaults in Chesar, i.e. no restrictions in the operational conditions and no risk management measures, based on the environmental release categories (ERCs).	Chesar can do a full automatic assessment with default assumptions for all ESs at once.
Default assumptions for the uses in the coatings industry do not lead to conclusions of safe use.	You have to iterate the conditions of use, based on realistic assumptions. You probably need to involve an expert.	It requires advanced scientific expertise to make a good quantitative assessment if the defaults do not lead to a conclusion of safe use. If conclusions on the safe use for coatings industry cannot be reached, then this use cannot be included within the registration of your substance.

Table 5 What you know	What you need to do	Remarks
Your substance is incorporated in articles.	You have to consider whether there will be exposure to workers or consumers through the use of the articles. You need to assess the environmental exposures due to the service life of the articles.	If there is potential exposure to workers or consumers through the use of the articles, you need to assess that exposure as well. It usually requires advanced scientific expertise to assess environmental exposure for service life scenarios.
You have to make an exposure assessment for exposure due to the use of an article.	Create a 'service life' scenario in which exposure for workers or consumers due to the use of the articles is assessed. You probably need to involve an expert.	Very often, advanced scientific expertise is needed to do a proper assessment for service life of articles.
After iterations and full assessments, all ESs are shown to be safe for human health and the environment.	You can create the Chapters 9 and 10 (Exposure assessment and Risk characterisation) of the CSR from Chesar. You can create the ES for communication to be annexed to the safety data sheet from Chesar or in another way.	If you do not use Chesar, you can use another tool that also creates these chapters or you must create the chapters by other means. However, Chesar provides ESs for communication in a harmonised format, which is beneficial for your customers.

!	Exposure models are tools for predicting exposure. All exposure models, including the ones in Chesar, have specific application domains. The use of a model outside its application domain can lead to very uncertain results and is not considered good practice. See the relevant Guidance documents R.14, R.15 and R.16 on the ECHA website for more information on relevant tools. You can also use measured exposure levels to estimate exposure for contributing scenarios. The use of such data is also discussed in the Guidance documents.

Figure 2 summarises the entire process starting at gathering information on use(s) and resulting in Chapters 9 and 10 of the CSR.

Figure 2: Flow diagram of the process from gathering information on use(s) to reporting in Chapters 9 and 10 of the CSR