

**Data & Cost sharing [5/6]****XIII Additional requirements (ownership, disputes, etc.)****XIII.1 Nature of the data**

- A. Full study report ;
- B. The study summary or robust study summary;
- C. The results of the study;

XIII.2 Right to the data (Full Study Report)

- A. Ownership of the full study report;
- B. Legitimate possession of the full study report;
- C. Right to refer to the full study report;
- D. Possibly other rights.

XIII.3 Definition of data ownership

The state of being an owner of the data, have the right, the possession, legal title, and proprietorship on these data.

XIII.4 How to secure legitimate possession or right to refer to data?

- 1. Granted by owners of the full study report:

Granting legitimate possession or a right to refer to the full study report normally requires some form of agreement between parties.

- 2. In some cases, the right to use or refer to data is granted by law or regulatory authorities. This is the case of the so-called "12 years rule".

XIII.5 Dispute resolution in data sharing

The REACH Regulation sets out a specific procedure in case the owner of a study refuses to provide proof of costs of the study or the study itself within a month from the request. The procedure differs for data on vertebrate or non-vertebrate animals.

This process is described in Article 30 (3 to 6) of REACH

XIII.6 Data on vertebrate animals

The owner of the study will not be able to proceed with his registration until he provides the requested information and he shall be sanctioned (penalties to be laid down by Member States). In cases where the data holder refuses to provide proof of the cost of the study or the study itself, the potential registrant requesting the information will be able to register without fulfilling the relevant information requirements, which he has to explain in the dossier.

XIII.7 Data on non-vertebrate animals

The other SIEF Participants must proceed with registration as if no relevant study is available in the SIEF. They will therefore have to carry out the test in order to obtain the information needed to meet the requirements of the registration dossier.

However, the owner of the study who refused to provide proof of cost or the study will be penalized (penalties to be laid down by Member States).

XIII.8 Information requirement based on tonnage band and intrinsic properties of the substances

Information requirement	1-10T/y	10-100T/y	100-1000T/y	≥1000T/y
Physico-chemical Properties				
State of the substance at 20°C and 101,3 kPa	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Melting/freezing point	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Boiling point	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Relative density	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Vapour pressure	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Surface tension	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Water solubility	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Partition coefficient n-octanol/water	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Flash-point	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Flammability	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Explosive properties	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Self-ignition temperature	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Oxidising properties	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Granulometry	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Stability in organic solvents and identity of relevant degradation products			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Dissociation constant			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Viscosity			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Toxicological Informations				
Skin irritation or skin corrosion (in vitro)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
In vivo skin irritation		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Eye irritation (in vitro)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
In vivo eye irritation		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Skin sensitisation	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
In vitro gene mutation study in bacteria	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
In vitro cytogenicity study in mammalian cells or in vitro micronucleus study		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
In vitro gene mutation study in mammalian cells		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>



Acute toxicity: by oral route	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Acute toxicity: by inhalation		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Acute toxicity: by dermal route		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Short-term repeated dose toxicity study (28 days)		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Sub-chronic toxicity study (90-day), one species			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Long-term repeated toxicity study (= 12 months)				<input checked="" type="checkbox"/>
Further study on repeated dose toxicity				<input checked="" type="checkbox"/>
Screening for reproductive/developmental toxicity		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Pre-natal developmental toxicity study			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Two-generation reproductive toxicity study			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Toxicokinetics (Assessment derived from the relevant available information)		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Carcinogenicity study				<input checked="" type="checkbox"/>
Ecotoxicological Informations				
Short-term toxicity testing on invertebrates (preferred species Daphnia)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Growth inhibition study aquatic plants (algae preferred)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Short-term toxicity testing on fish		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Activated sludge respiration inhibition testing		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Long-term toxicity testing on invertebrates (preferred species Daphnia)			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Long-term toxicity testing on fish			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Ready biodegradability	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Simulation testing on ultimate degradation in surface water			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Soil simulation testing (for substances with a high potential for adsorption to soil)			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Sediment simulation testing (for substances with a high potential for adsorption to sediment)			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Hydrolysis as a function of pH		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Identification of degradation products			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Adsorption/desorption screening		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Bioaccumulation in aquatic species, preferably fish			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Further information on adsorption/desorption			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Further information on the environmental fate and behaviour of the substance and/or degradation products				<input checked="" type="checkbox"/>
Short-term toxicity to invertebrates			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Effects on soil micro-organisms			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Short-term toxicity to plants			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Long-term toxicity testing on invertebrates				<input checked="" type="checkbox"/>
Long-term toxicity testing on plants				<input checked="" type="checkbox"/>
Long-term toxicity to sediment organisms				<input checked="" type="checkbox"/>
Long-term or reproductive toxicity to birds				<input checked="" type="checkbox"/>