



REACH *Fact Sheet*

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INFORMATION REQUIREMENTS FOR REPEATED DOSE TOXICITY AND REPRODUCTIVE TOXICITY – SUBSTANCES OVER 100 (AND 1000) TONNES

This fact sheet explains the information requirements on repeated dose toxicity and on reproductive toxicity for substances manufactured or imported at quantities greater than or equal to 100 (and 1000) tonnes per year. It highlights which options the registrant has if a short term repeated dose toxicity study and/or the screening test for reproductive and developmental toxicity test is not available at the time of the registration. The information provided here should help companies to decide which data they need to include in their dossiers for them to pass the Technical Completeness Check at ECHA.

ECHA emphasises that the information requirements indicated below constitute the minimum for a technical dossier to pass the Technical Completeness Check regarding the two endpoints.

Additional information may be necessary to comply with the REACH legislation and to ensure safe use of the substance.

Registrants who decide to postpone obtaining relevant information for repeated dose toxicity or for reproductive toxicity are reminded that this has impact on their Chemical Safety Report and Exposure Scenario/s. developed. There, they shall include the interim risk management measures that they put in place and those they recommend to downstream users to manage the risks in relation to the two endpoints being explored.

The responsibility for the safe use of the substance remains with the manufacturers, importers and downstream users.

REPEATED DOSE TOXICITY

Information requirements for substances manufactured or imported at quantities ≥ 100 t/y:

ECHA considers registration dossiers for substances ≥ 100 t/y and 1000 t/y as technically complete ***even if they do not contain the results of a 28-day repeated dose toxicity study*** if one of the following conditions is met:

- The specific rules for adaptation set out in the second bullet under Section 8.6.1 of column 2, Annex VIII of the REACH Regulation apply, i.e. the substance undergoes immediate disintegration and there are sufficient data on the cleavage products.
- Annex XI.1 or XI.2 applies.
- The dossier contains the results of a 90-day repeated dose toxicity study.
- The dossier contains the results of a chronic repeated dose toxicity study (≥ 12 months).
- The dossier contains a testing proposal for a 90-day repeated dose toxicity study in accordance with Section 8.6.2 of column 1, Annex IX.
- The conditions of Annex XI.3 are fulfilled and the dossier contains a testing proposal for a 28-day repeated dose toxicity study in accordance with Section 8.6.1 of column 1, Annex IX.
- In the case of testing proposals, Annex I, 0.5 last paragraph applies.

- The specific rules for adaptation set out in Section 8.7 of column 2, Annex IX, or Annex XI apply.
- The dossier contains either the results of, or a testing proposal for, a pre-natal developmental toxicity study.
- In the case of testing proposals, Annex I, 0.5 last paragraph applies.
- It should be noted that this does not affect the possible need to propose a 2-generation study already at this stage “if the 28-day or 90-day study indicates adverse effects on reproductive organs or tissues” (Annex IX, Section 8.7.3).

Information requirements for substances manufactured or imported at quantities ≥ 1000 t/y:

ECHA considers registration dossiers for substances ≥ 1000 t/y as technically complete ***even if they do not contain the results of a screening study for reproductive/developmental toxicity*** if one of the following conditions is met:

- The specific rules for adaptation set out in Section 8.7 of column 2, Annex IX, or Annex XI apply.
- The dossier contains either the results of, or a testing proposal for, a prenatal developmental toxicity study and either the results of, or a testing proposal for, a 2-generation reproductive toxicity study.
- In the case of testing proposals, Annex I, 0.5 last paragraph applies.

REPRODUCTIVE TOXICITY

Information requirements for substances manufactured or imported at quantities ≥ 100 t/y:

ECHA considers registration dossiers for substances ≥ 100 t/y as technically complete ***even if they do not contain the results of a screening study for reproductive/developmental toxicity*** if one of the following conditions is met:

MORE INFORMATION

Questions concerning information requirements and the technical completeness of the dossiers can be submitted to ECHA via the helpdesk web form which is available at

http://echa.europa.eu/about/contact_en.asp

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