How to bring your registration dossier in compliance with REACH – Tips and Hints (Part 3)

Biodegradation
14th May 2013

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ECHA Guidance - Biodegradation

Endpoint specific guidance for environment (Chapter R7b, Degradation/biodegradation):

Degradation is an important endpoint to fulfil the following *regulatory* needs:

- To identify whether a chemical has <u>PBT or vPvB properties</u>

- To determine the <u>potential to cause long-term adverse effects</u> in environmental hazard classification

- To determine the <u>Predicted Environment Concentration (PEC)</u> of a chemical in environmental exposure assessment for use in risk characterisation

REACH information requirements

	Column 1	Column 2
Annex VII	9.2.1.1. Ready biodegradability	9.2.1.1. The study does not need to be conducted if the substance is inorganic.
Annex VIII	9.2. Degradation	9.2. Further degradation testing shall be considered if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance. The choice of the appropriate test(s) will depend on the results of the chemical safety assessment.
Annex IX	9.2. Degradation	9.2. Further degradation testing shall be considered if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance. The choice of the appropriate test(s) will depend on the results of the chemical safety assessment.
	9.2.1.2. Simulation testing on ultimate degradation in surface water	9.2.1.2. The study need not be conducted if: — the substances is highly insoluble in water, or — the substance is readily biodegradable.
	9.2.1.3. Soil simulation testing (for substances with a high potential for adsorption to soil)	9.2.1.3. The study need not be conducted: — if the substance is readily biodegradable, or — if direct and indirect exposure of soil is unlikely.
	9.2.1.4. Sediment simulation testing (for substances with a high potential for adsorption to sediment)	9.2.1.4. The study need not be conducted: — if the substance is readily biodegradable, or — if direct and indirect exposure of sediment is unlikely.
	9.2.3. Identification of degradation products	9.2.3. Unless the substance is readily biodegradable
Annex X	9.2. Degradation	9.2. Further degradation testing shall be considered if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance. The choice of the appropriate test(s) will depend on the results of the chemical safety assessment.

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Choose appropriate test guidelines to conclude on ready biodegradability for your substance

OECD 301* and 310 Ready Biodegradability

- 301 A: DOC Die-Away
- 301 B: CO2 Evolution (Modified Sturm Test)
- 301 C: MITI (I) (Ministry of International Trade and Industry, Japan)
- 301 D: Closed Bottle
- 301 E: Modified OECD Screening
- 301 F: Manometric Respirometry
- 310 Ready biodegradability - CO2 in sealed vessels (Headspace Test)

* and corresponding Guidelines

PASS LEVEL after 28 days (with 10–day window)

- **60% ThCO$_2$ - production**
- **60% ThOD – consumption**
- 70% DOC -removal

10 day window begins when the degree of biodegradation has reached 10 %

Substance properties e.g. stability, water solubility and volatility influence the applicability of specific test guidelines
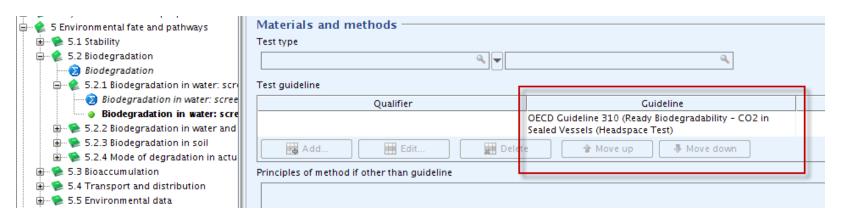
Report test guideline

Biodegradation screening tests reported in IUCLID 5.2.1

- Report test in test guideline field (Guideline dropdown menu)
- Be clear if corresponding to "accepted guideline"
- Important to report adequate information on (ECHA Guidance R7b, Appendix 7.9-2)
  - Test substance
  - Test conditions
  - Results
  - Discussion of results

Reporting in key study should include

Ready biodegradability test requirements (OECD 301 series and OECD 310)

Test substance:

✓ physical nature and, where relevant, physicochemical properties;

Test conditions:

✓ inoculum: nature and sampling site(s), concentration and any pre-conditioning treatment;

✓ proportion and nature of industrial waste water in sewage, if known;

✓ test duration and incubation temperature;

✓ in the case of poorly soluble test substances, methods of preparation of test

✓ solutions/suspensions;

✓ test method applied; scientific reasons and explanation for any change of procedure;

✓ details of controls.

Results:

✓ data in tabular form;

✓ any observed inhibition or toxicity;

✓ any observed abiotic degradation;

✓ specific chemical analytical data, if available;

✓ analytical data on intermediates, if available;

✓ the graph of percentage degradation against time for the test and reference

✓ substances to include the lag phase, degradation phase, the 10-d window and slope percentage removal at plateau, at end of test, and/or after 10-d window.

Discussion of results

Use of QSARs in ready biodegradation

- QSAR predictions are considered as adaptations of standard information requirements and therefore the conditions in REACH Annex XI 1.3 have to be fulfilled.

  - The (Q)SAR model must be scientifically valid
  - The registrant should demonstrate that the substance falls within the applicability domain of the model
  - The results must be adequate for classification and labelling and risk assessment
  - Each QSAR prediction must be **fully documented** in the IUCLID endpoint study record like any experimental study.

- Biodegradation is a complex endpoint -> QSAR predictions typically used as **supporting studies** or as part of a **weight of evidence** (WoE).

Ready biodegradation - Inoculum

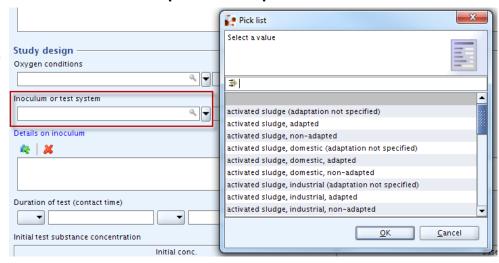Inoculum is acceptable for concluding on ready biodegradability if:

- It is not pre-adapted (or pre-exposed) to the test substance,
- It is not from industrial sources

Inoculum can/should be pre-conditioned (e.g. aerated) to test conditions according to the test guidelines.

Note: Pre-conditioning to test conditions ≠ pre-adaptation to test substance

-> Select non-adapted inocul. if it is only <u>pre-conditioned</u> but <u>not pre-adapted</u>
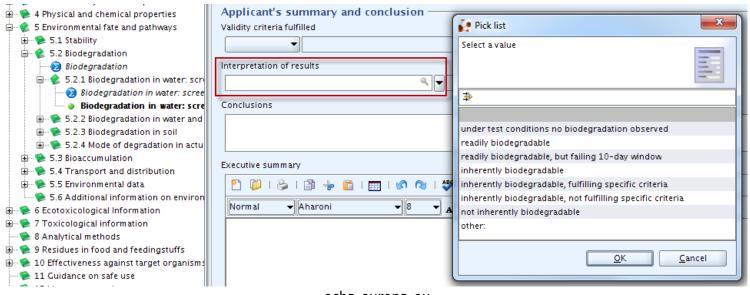
Ready biodegradation - adaptation

Adaptation/Waiving

- Annex VII Standard information requirement 9.2.1.1 Ready biodegradability

  ✓ Column 2: The study does not need to be conducted if the substance is inorganic

- Annex XI General rules for adaptation of the standard testing regime set out in Annexes VII to X

  ✓ Testing does not appear scientifically necessary (e.g. read across from other category member) OR testing is technically not possible -> Important: Acceptable justification and documentation needed in IUCLID section 5.2.1.

Conclude on ready biodegradability

In IUCLID 5.2.1.

- Endpoint study record for each biodegradation screening test
  - Applicant's summary and conclusion, interpretation of results
- Conclusion on ready biodegradability (use dropdown menu and conclusions free-text field)
  - under test conditions no biodegradation observed
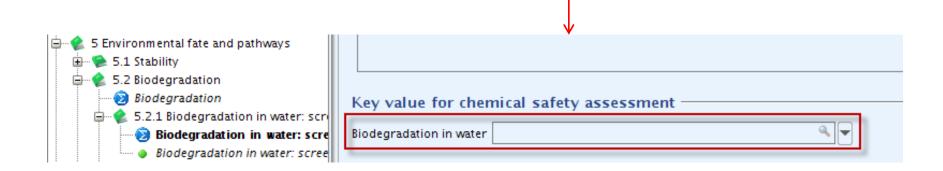 - readily biodegradable

Conclude on ready biodegradability

In IUCLID 5.2.1.

- Endpoint summary 5.2.1
  - Key value of ready biodegradability for chemical safety assessment

Possible conclusion based on ready biodegradability testing

- Readily biodegradable
- Not-readily biodegradable
- List of possible options in dropdown menu

Links to relevant Guidance documents

- Guidance on information requirements and chemical safety assessment

  - Chapter R.7b: Endpoint specific guidance / R.7.9 Degradation/biodegradation

  http://echa.europa.eu/documents/10162/13632/information_requirements_r7b_en.pdf

- Practical Guides

  - How to report weight of evidence, data waiving, (Q)SARs…

  http://echa.europa.eu/practical-guides

Thank you

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