

How to bring your registration dossier in compliance with REACH
Tips and Hints - Part 5

Adsorption/desorption

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Adsorption/desorption – Why is it important?

- Indicates the binding capacity ("stickiness") of a substance to solid surfaces
 - > Environmental partitioning behaviour
 - Environmental persistence
- Reported as the organic carbon normalized adsorption coefficient (K_{oc})



Standard information requirement REACH annexes VIII and IX

REACH Annex	COLUMN 1	COLUMN 2
	STANDARD INFORMATION REQUIRED	SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
VIII	9.3.1. Adsorption/desorption screening	 9.3.1. The study does not need to be conducted if: based on the physicochemical properties the substance can be expected to have a low potential for adsorption (e.g. the substance has a low octanol water partition coefficient), or the substance and its relevant degradation products decompose rapidly.
IX	9.3.3. Further information on adsorption/desorption depending on the results of the study required in Annex VIII	 9.3.3. The study need not be conducted if: based on the physicochemical properties the substance can be expected to have a low potential for adsorption (e.g. the substance has a low octanol water partition coefficient), or the substance and its degradation products decompose rapidly.



Adsorption/desorption information (1/2)

- Ensure that the method is appropriate for your substance.
 - Special consideration necessary for substances such as surfactants and ionisable substances.
- Complex mixtures (UVCB*, multi-constituent substances):
 - K_{oc} values can be reported separately for each (main) constituent or as a range of values.

*UVCB: Unknown, of Variable Composition, or of Biological origin



Adsorption/desorption information (2/2)

Methods presented in the ECHA Guidance:

Chapter R.7a: Endpoint specific guidance, version 2.4 (February 2014), pp. 134-143

http://echa.europa.eu/documents/10162/13632/information_requirements_r7a_en.pdf



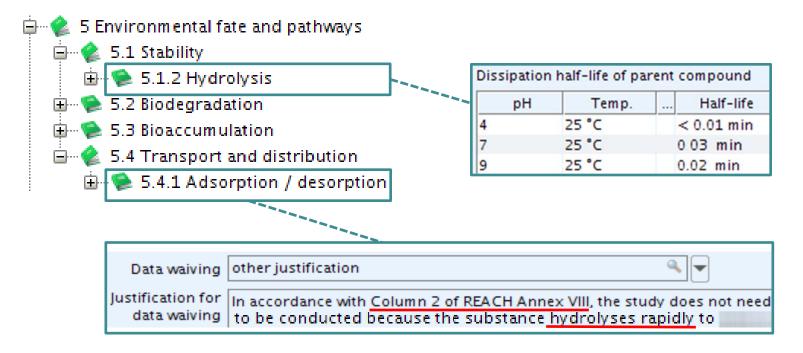
Adaptation Column 2 of Annexes VIII and IX (1/2)

- Low potential for adsorption:
 - Log K_{ow}=3 common cutoff value, but this criterion should be applied with caution
- Decompose rapidly:
 - If rapid decomposition of the substance ⇒
 possibly appropriate to determine K_{oc} of the
 decomposition products
 - Information should be provided also for readily biodegradable substances. Estimations based on read-across or QSAR (Annex XI adaptations) can be used as a starting point (if appropriate methods are available).



Adaptation Column 2 of Annexes VIII and IX (2/2)

Example





Adaptation - Annex XI (1/3)

The requirements set in the relevant section of Annex XI need to be fulfilled

1. Weight of Evidence (Annex XI, 1.2)

- At least 2 independent pieces of evidence
- One study record for each piece of evidence
- Endpoint summary: your own conclusion

ECHA Practical guide 2: How to report weight of evidence: http://echa.europa.eu/documents/10162/13655/pg_report_weight_of_evidence_en.pdf



Adaptation - Annex XI (2/3)

- 2. Grouping of substances and readacross approach (Annex XI, 1.5)
- Adequate and reliable documentation
- Scientifically sound arguments
- Assumptions supported with (experimental) data

ECHA Practical guide 6: How to report read-across and categories:

http://echa.europa.eu/documents/10162/13655/pg_report_readacross_en.pdf



Adaptation - Annex XI (3/3)

3. (Q)SAR* (Annex XI, 1.3)

- Fill in the relevant fields in the IUCLID file
- Include QMRF and QPRF
 - QMRF ((Q)SAR Model Reporting Format): describes the applied (Q)SAR model
 - QPRF ((Q)SAR Prediction Reporting Format): describes how the estimate was derived from the application of the model to a specific substance

ECHA Practical guide 5: How to report (Q)SARs: http://echa.europa.eu/documents/10162/13655/pg_report_qsars_en.pdf

^{*(}Q)SAR: Qualitative or Quantitative Structure-Activity Relationship



Adsorption/desorption Details to remember

- Make sure that the method is appropriate for your substance
- Any adaptations need to be based on Column 2 of the Annexes VIII and IX or Annex XI



Questions?

To the Q&A panel (between 11:00 and 13:30, Helsinki time), or

To the ECHA helpdesk (any time):

http://echa.europa.eu/cont
act/helpdesk-contact-form

