

# How to bring your registration dossier in compliance with REACH

## Tips and Hints - Part 5

### Adsorption/desorption

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11:00 - 14:00 Helsinki Time (EEST, GMT +2)

# 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 STANDARD INFORMATION REQUIRED	COLUMN 2 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: <ul style="list-style-type: none"> <li>➤ 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</li> <li>➤ the substance and its relevant degradation products decompose rapidly.</li> </ul>
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: <ul style="list-style-type: none"> <li>➤ 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</li> <li>➤ the substance and its degradation products decompose rapidly.</li> </ul>

# 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](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:
  - $\text{Log } K_{ow}=3$  common cutoff value, but this criterion should be applied with caution
- Decompose rapidly:
  - If rapid decomposition of the substance  $\Rightarrow$  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

- 5 Environmental fate and pathways
  - 5.1 Stability
    - 5.1.2 Hydrolysis
  - 5.2 Biodegradation
  - 5.3 Bioaccumulation
  - 5.4 Transport and distribution
    - 5.4.1 Adsorption / desorption

Dissipation half-life of parent compound			
pH	Temp.	...	Half-life
4	25 °C		< 0.01 min
7	25 °C		0.03 min
9	25 °C		0.02 min

Data waiving	other justification
Justification for data waiving	In accordance with <u>Column 2 of REACH Annex VIII</u> , the study does not need to be conducted because the substance <u>hydrolyses rapidly</u> to

# 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](http://echa.europa.eu/documents/10162/13655/pg_report_weight_of_evidence_en.pdf)



# Adaptation - Annex XI (2/3)

## 2. Grouping of substances and read-across 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](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](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/contact/helpdesk-contact-form>