Solubility and Dissolution Rate: Overarching Issues

5th November 2020

NanoHarmony

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 885931

Overarching picture

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	Solubility	**Dissolution rate**	~~**Transformation**~~	
Assessment area	**Environmental fate and toxicity**	**Human toxicity**	**PC Analysis**	
Test method	**Batch reactor**	**Flow through cell**		**Sequential batch system**

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Test methods

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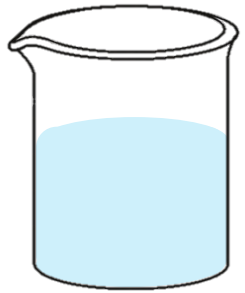
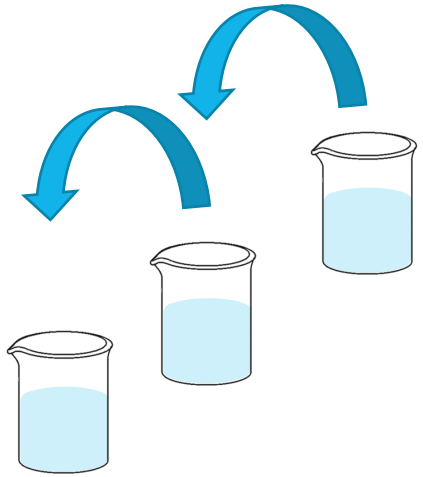
Static methods

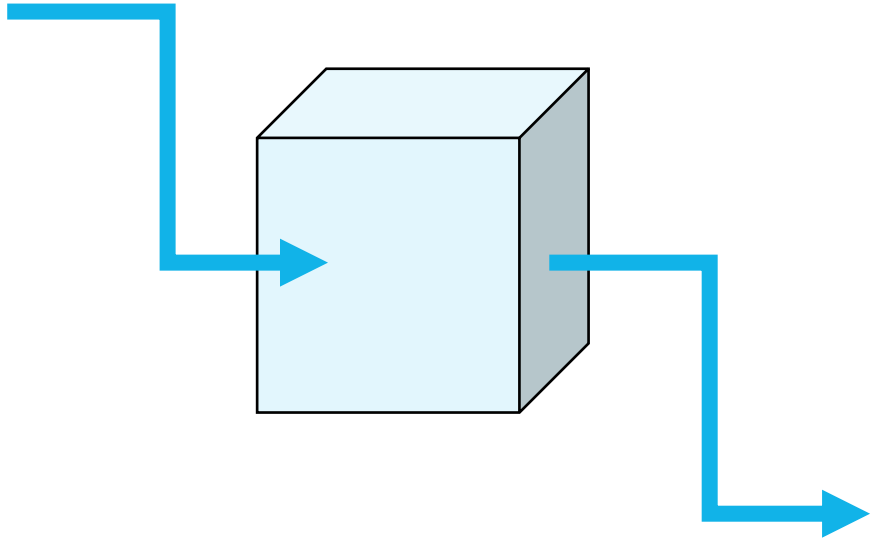


Batch

Sequential batch



Dynamic methods



Flow through

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Overarching picture

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	Solubility	**Dissolution rate**	**~~Transformation~~**
Assessment area	**Environmental fate and toxicity**	**Human toxicity**	**PC Analysis**
Test method	**Batch reactor**	**Flow through cell**	**Sequential batch system**
Test medium	**Solubility in…..**	**Dissolution rate in….**	

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Overarching picture

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Solubility

Dissolution rate

Transformation

OECD Project AUT/ v. Kammer

OECD Project DK / K. Jensen

OECD Project ITA / De Angelis

OECD Project ???

OECD Project UK/ R. Smith

OECD Project NLD/ S. Dekker

OECD Project ESP/ M. Cruz

OECD Project UK/ R. Handy

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Aim of this session

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- To make all aware of each other activity
- Raise awareness on problems/peculiarities
- Introduce the approaches
- Seek for comments and facilitate international involvement
- Introduce timelines for ILCs/Round Robins for international participation

➔ Facilitate the development of internationally agreed Test Guidelines

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Results

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- Awareness of the different test guideline and guidance document developments and their peculiarities was raised

→ Results of tests depend on test conditions (suspension medium, test system chosen,…) not only on nanomaterial

→ The set-ups and results for different assessment areas do not have to be comparable! They have to be different to be fit for their purpose!

→ Scientific advice on possible use of data for a given purpose is needed.

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Results

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- Recommendation to assess methods from other harmonisation organisations (e.g. from pharmaceutical (USP) and fibre industry)
- International participation in the TG development and ILCs
- Comments and Recommendations to the specific development activities were given in the corresponding sessions

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