Analytical challenges and issues of biological active substances in Environmental fate and Ecotoxicological testing regimes

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Analytical challenges are important!

- Regulatory studies are required
- Financial implications
- The science must be sound
- Pioneering products

Dialogue needed in order for the science to advance
Environmental Fate Study
OECD 307 - Degradation in soils
Data is used to predict the likelihood of environmental persistence

Key Challenges:
• Rapid degradation of test item
• Exact adherence to guideline impossible

Solutions:
• Careful planning
• Study design modifications
Study design modification: very instable test item

- Small soil aliquots
- Modified extraction method
- Omit sample concentration
- Exaggerated application rate
- Immediate freezing

Similar modifications for parallel adsorption/desorption (OECD 106) study
Algal polysaccharide test item – 2

Aquatic Ecotox Study
OECD 221- *Lemna* growth inhibition test
Data is used to assess toxicity to *Lemna* (duckweed)

Key Challenges:
• Utilisation of test item as a carbon source by the plants
• Rapid degradation of test item
• Suitable analytical method

Solutions:
• Semi-static test design
• Tailor made HPLC/MS method (detecting multiple charged ions)
Botanical extract test item – Organic acids

Another OECD 221- *Lemna* growth inhibition test

Key Challenges:

• Extensive bacterial growth was induced by the test item

• Test item itself was significantly bacteriologically degraded

• Concentrations of the test item in the test media could not be maintained

• Not possible to handle the test item under standard static, semi-static or flow-through conditions
Botanical extract test item – Organic acids

Aquatic Ecotox Study
OECD 211- *Daphnia magna* reproduction test
Survival, growth, and reproduction of *Daphnia magna* investigated over 21 days

Key Challenges:
• Oxidation of the unsaturated fatty acids
• Adsorption to feed/separation from water

Solutions:
• Extensive stability assessment, exhaustive recovery from test vessels
• Flow through conditions
Microbial test item – Fungal spores

Pollinator Study
GD 239 - Chronic toxicity to honey bee larvae

Key Challenges:
• Artefacts
• Enumeration method
• Statistical analysis

Solutions:
• Interdisciplinary approach
• Dialogue
Conclusions

- Rapid test item degradation is common across diverse compounds and study types
- Stability issues require expert handling, rapid communication and action
- Experience is everything
- Need for dialogue – share the challenges
Thank you for listening!

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