

REPORT ENES5 break-out sessions

BREAK-OUT SESSION	W
Presenter - SME	Sara Brennan - ATC Alison Margary + Joy Worden -Atiel
Moderator	Andreas Ahrens
Rapporteur	Eugen Anwander

Characteristics for ATIEL/ATC GES

- GES are prepared by the sector organisation for product applications
- Formulator assigns the own product to the product application and uses the relevant GES as Annex to SDS
- GES used for own product is verified against incoming raw material's ES

Minimum required information

ATIEL/ATC GES are designed to work without data from raw material ES:

- Human health - hazard classification.
- Environment:
 - PNEC_{fw}(aq)
 - Log K_{ow}
 - Vapour pressure
 - Biodegradability
- Such data is provided by ATIEL/ATC for many typical Risk Determining Substances



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Applicability domain / limitations

Formulator sectors present in group W:

plant protection, fragrance, dyes, detergents, coatings ,
lubricants

- Consumer use not covered



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Main points discussed

- Understand motivation to carry out exposure assessment and demonstration of safe use for mixtures at formulating sector level
- Understand how the hazard banding has been used for quantitative risk characterization
- Discuss whether approach promotes or undermines consistency between safe use information for mixture and the ES information in the CSRs for substances
- Understand how the single formulator generates safe use information for his products (independent from incoming ES information)
- Understand challenges of the verification step (more testing needed)
 - Compare OC and RMM; check whether substance properties fit to applicability domain of the GES
 - Carry out scaling or downstream user CSR (boundary between both)



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General Pros / Cons

- Delivers clear, concise, consistent advice to end users from all lubricant's formulators/suppliers. (+)
- Constrains the length of the e-SDS annex for the mixture to a manageable size (e.g. 2 pages) (+)
- The information on safe use of the mixture (GES) can be generated without waiting for information on all raw material becoming available. Based on use conditions and classification of mixture (+)
- Exposure assessment and risk characterisation has been carried for the RDS identified (+)
- Clear boundary to the assessment for very hazardous substances (CMR and respiratory sensitisers) (+)



General Pros / Cons

- Significant investment for setting up and maintenance of GES for the supply chain (-)
- Risk assessment expertise needed for building GES and for DU CSA for raw material outside the GES applicability domain (-)
- As is true for all schemes: synergistic effects are not addressed
- Potentially undermines the REACH concept to communicate the outcome of the registrants safety assessment down the chain (-)



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Proposed follow-up action	Who should take the lead



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