REACH CHEMICAL SAFETY ASSESSMENT

Hazard Assessment
Determination of hazard classification; establishment of Derived No Effect Levels (DNELs) for human exposure and environmental Predicted No Effect Concentrations (PNECs); PBT and vPvB assessment for persistence, bioaccumulation & toxic properties.

Exposure Assessment
Exposure evaluation for substances classified as dangerous or having PBT/vPvB concerns; generation of exposure scenarios (ESs); estimation of exposure for each ES; analysis to demonstrate that risks are adequately controlled.

Risk Characterization
Compare human and environmental exposure with DNEL and PNEC values; refine hazard assessment or exposure assessment – generate more data as necessary; consider risk management measures (RMMs) and operational conditions (OCs) to refine exposure scenarios.

Final Exposure Scenario
Specify conditions of use (RMMs and OCs) where risks are adequately controlled; summarize final exposure scenario – attach to extended Safety Data Sheet (eSDS) for supply chain communication.

Chemical Safety Report
Documentation of registrant’s chemical safety assessment (CSA) summarizing environmental and human health hazard properties of the substance; assessment of exposure and risk; required for all substances manufactured or imported into EU at quantities of 10 tonnes or more per year.

Technical Dossier Preparation & Submission
Compilation of necessary information regarding manufacturer/importer; substance identity, use, classification, and labeling; robust study summaries; proposals for further testing; IUCLID 5 dossier format; submission of documentation to the European Chemicals Agency (ECHA).

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