

Introduction to REACH Requirements for Safety Data Sheet and Exposure Scenario

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Registration

- Any manufacturer or importer of articles shall submit a registration dossier for any substance contained in articles, if both of the following conditions are met:
 - Technical Dossier
 - for substances in quantities of 1 tonne or more per year
 - Chemical Safety Report
 - for substances in quantities of 10 tonnes or more

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Evaluation

- Evaluation
 - Evaluation for substances in quantities above 10 tonnes per year
 - Requires detailed Chemical Safety Assessment and Report
 - Chemical Safety Report
 - Hazard Assessment
 - Exposure Assessment
 - Risk Management Measures
 - Risk Characterisation
 - Exposure Scenarios

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Authorization

- Substances of major concern must be authorized under REACH and their use may be subject to restrictions. This applies to:
 - CMR substances
 - PBT substances
 - vPvB substances
 - Substances with particular properties

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Authorization

- CMR substances
 - Substances which are considered Carcinogenic
 - Substances which are considered Mutagenic
 - Substances which are considered toxic to Reproduction

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Authorization

- PBT substances
 - Substances which are persistent, bioaccumulative and toxic according to Annex XIII
- vPvB substances
 - Substances which are very persistent and very bioaccumulative according to Annex XIII

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Authorization

- Substances with particular properties
 - which according to scientific knowledge have a likely latent effect upon humans and the environment, giving rise to the same concerns as the above-mentioned substance groups, e.g. endocrine disruptors

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REACH

- Technical Dossier
- Chemical Safety Assessment and Chemical Safety Report
 - Exposure Scenarios
- Safety Data Sheet
 - Annex to Exposure Scenarios

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Technical Dossier

- Identify of the manufacturer/importer
- Identity of substance
- Information about the manufacturing and all uses of the substance
- Classification and Labelling of substance
 - Globally Harmonised System for classification and labelling (GHS)
- Guidance on safe use of the substance
- Study summaries – substance properties
- Exposure information

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Chemical Safety Assessment

- A chemical safety assessment shall be performed and a Chemical Safety Report completed for all substances subject to registration if the registrant manufactures or imports such a substance in quantities of 10 tonnes or more per year

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Chemical Safety Assessment

- Human health hazard assessment
- Environmental hazard assessment
- PBT and vPvB assessment
- If classified as Dangerous, PBT or vPvB, the chemical safety assessment must have
 - Exposure assessment including exposure scenarios
 - Risk characterization
- Manufacturer/importer must identify risk management measures and recommend them in safety data sheets

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Chemical Safety Assessment

- Substances of major concern are:
 - (Carcinogen, Mutagen or Toxic for Reproduction Cat.1 or 2)
 - PBT (Persistent & Bioaccumulative & Toxic) or
 - vPvB (Very Persistent & Very Bioaccumulative & Toxic)
 - substances of equivalent level of concern

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Chemical Safety Assessment

- Health and Environmental Hazard Assessment
 - 1) Evaluation of non-human information
 - 2) Evaluation of human information
 - 3) Classification and labelling
 - 4) Derivation of Derived No-effect levels (DNELs)
 - 5) Derivation of Predicated no-effect concentrations (PNECs)

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Chemical Safety Report (CSR)

- Chemical Safety Assessment must be recorded in writing in a Chemicals Safety Report
- Needed for all substances manufactured or imported in quantities starting at 10 tonnes
- Must be documented the hazards and classification of substance and the assessment as to whether the substance is PBT or vPvB.

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Chemical Safety Report (CSR) – Part A

- 1) Summary of risk management measures
- 2) Declaration that risk management measures are implemented
- 3) Declaration that risk management measures are communicated

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Chemical Safety Report (CSR) – Part B

- 1) Identity of the substance and physical and chemical properties
- 2) Manufacture and uses
- 3) Classification and labelling
- 4) Environmental fate properties
- 5) Human health hazard assessment

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Chemical Safety Report (CSR) – Part B

- 6) Human health hazard assessment of physicochemical properties
- 7) Environmental hazard assessment
- 8) PBT and vPvB assessment
- 9) Exposure assessment
- 10) Risk characterization

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Chemical Safety Report (CSR)

- Human Health Hazard Assessment
 - Evaluate animal and epidemiological data
 - Toxicokinetic, metabolism and distribution
 - Acute effects (acute toxicity, irritation and corrosivity)
 - Sensitization
 - Repeated dose toxicity
 - CMR effects
 - Decide on classification and labelling
 - Determine the Derived No-Effect Level (DNEL)
 - Derived level of exposure to the substance above which humans should not be exposed

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Chemical Safety Report (CSR)

- Physicochemical Hazard Assessment
 - Explosivity
 - Flammability
 - Oxidising potential

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Chemical Safety Report (CSR)

- Environmental Hazard Assessment
 - Evaluate data, including PBT and vPvB assessment
 - Identify potential environmental effects
 - Aquatic
 - Terrestrial compartment
 - Atmospheric compartment
 - Via food-chain accumulation
 - Microbial activity of sewage treatment systems

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Chemical Safety Report (CSR)

- Decide on classification and labelling
- Establish Predicted No-Effect Concentration (PNEC)
 - Identify the concentration of the substance below which adverse effects in the environmental spore of concern are not expected to occur

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Exposure Scenarios

- An Exposure Scenarios is the set of conditions that describe how the substance is manufactured or used during its life-cycle and how the Manufacturers/Importers controls, or recommends Downstream Users to control, exposures of humans and the environment.
- These sets of conditions contain a description of both the Risk Management Measures and operational conditions which the manufacturer or importer has implemented or recommends to be implemented by downstream users.

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Exposure Scenarios

- Name of process or activity
- Scenario description
- Maximum amount of substance used per time
- Concentration of substance in product
- Duration of activity
- Frequency of activity
- Other relevant conditions of use
- Recommended process controls
- Recommended risk management measures

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Exposure scenarios

- Exposure scenarios and exposure estimation need to cover
 - Manufacture
 - Manufacturers / importer own use(s)
 - All identified uses
 - All life cycle stages resulting from the uses manufacture, own uses and identified uses

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Exposure scenarios

- Exposure scenarios and exposure estimation need to address, where relevant,
 - Human Health
 - Workers
 - Consumers
 - Humans exposure via the environment
 - Environmental spheres for which exposure is known or reasonably foreseeable

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Exposure Scenarios

- Cover manufacture and intended uses throughout substance life cycle
 - Cradle to Grave
- For each human population exposed as workers, consumers, indirectly via the environment, or a combination
- Included as an appendix to Extended Safety Data Sheet

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Exposure scenario

- Exposure scenario process as part of the Chemical Safety Assessment
 - Identification and uses and use processes
 - Description of manufacturing or use process
 - Development of a tentative ES
 - Assessment of exposure and risks
 - Defining the final ES
 - Developing the Annex to the SDS

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Steps in Developing an Exposure Scenario

- 1) Identify the use(s) for which an exposure scenario shall be developed
- 2) Describe manufacture or use in standard structure
 - Life cycle stage
 - Type of technical process or article type
 - Broad function of substance
 - Relevant routes of exposure

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Steps in Developing an Exposure Scenario

- 3) List the operational conditions as usually occurring in the market
- 4) List risk management measures typically applied in the market

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Steps in Developing an Exposure Scenario

- 5) Develop a tentative Exposure Scenario (referring to current practise)
 - Select a suitable name for the use/process addressed in the exposure scenario
 - Prepare a short process description
 - List the relevant operational conditions for which the Exposure Scenario is applicable
 - List which Risk Management Measures should be in place and which efficacy is assumed
 - Select the determinants for exposure estimates

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Steps in Developing an Exposure Scenario

- 6) Assess exposure and risk:
 - Carry out exposure estimate bases on tentative exposure scenario and compare with the PNEC and DNEL
 - Risk characterization
 - A comparison of exposure of human population with DNELs (Exposure < DNEL)
 - A comparison of predicted environmental concentrations in each environmental compartment with PNEC (Exposure < PNEC)

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Steps in Developing an Exposure Scenario

- 7) Iterate assessment if needed
 - the assumptions and derive the final Exposure Scenario following one of the options under 6.
- 8) Integrate the Exposure Scenario and translate the final Exposure Scenario into the Safety Data Sheet

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Safety Data Sheet (SDS)

- Provide information relating to health, safety and environmental properties, risks and risk management measures to
 - Manufacturer, importer, customers (downstream user or distributor)
- If classified as dangerous, PBT or vPvB substances and preparations containing them, and on the candidate list for inclusion in Annex XIV (substances subject to authorization, eg endocrine disruptors), recipient customers (downstream user or distributor) must be supplied with SDS

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Safety Data Sheet (SDS)

- Information must be supplied up and down the chain Information
- Annex contains relevant exposure scenarios

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Safety Data Sheet (SDS)

- Safety Data Sheet and information in Chemical Safety Report must be consistent
- 16 Section of GHS Safety Data Sheet

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Major Changes of SDS

- **Section 1.**
 - E-mail of competent person responsible for the SDS should be added.
 - Registration number added.
 - It is recommended that the use heading in Section 1 should be generic use conditions (closed systems, open systems operated by trained staff, etc) and application conditions (use in textiles, printing inks, etc.)

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Major Changes of SDS

- **Sections 2 and 3** are reversed, compared to current practice.
- **Section 3** (information on ingredients)
 - PBTs and vPvBs should be mentioned if present at $\geq 0.1\%$.
 - Registration numbers should also be given, when available.

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Major Changes of SDS

- **Section 8.**
 - Where a chemical safety report is required, the relevant DNELs (health) and PNECs (environment) for the substance shall be given for the exposure scenarios set out in the annex to the SDS.
 - Summary of the RMMs for both health and the environment are required here too, for the ESs given in the annex to the SDS.

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Major Changes of SDS

- **Section 11.**
 - Information provided shall be consistent with the chemical safety report
 - Information on toxicokinetics, metabolism and distribution; acute effects; sensitization; repeated dose toxicity and
 - Statement on the CMR category 1 or 2 status of the substance or preparation.

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Major Changes of SDS

- **Section 12.**
 - Results of the PBT/vPvB assessment, and the emission characterisation (only required if the PBT and vPvB conditions are met) shall be summarized in Section 12 of the SDS.
 - Effects such as ozone depletion, photochemical ozone creation potential, and strong odour and tainting should be summarised in the SDS for substances with chemicals with a CSR. Information, if available, on endocrine disrupting potential should be included.

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Major Changes of SDS

● Section 15.

- Indicate if a Chemical Safety Assessment (CSA) has been carried out for the substance, or a substance in the preparation.

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Safety Data Sheet (SDS)

- 1) Identification of the substance/ preparation and of the company/ undertaking
 - Identification of the substance or preparation
 - Use of the substance/preparation
 - Company/undertaking identification
 - Emergency telephone

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Safety Data Sheet (SDS)

2) Hazards Identification

- Extract from step 1 to 4 of the Chemical Safety Assessment (CSR Part C). It includes
 - Health hazards
 - Human health hazards from physiochemical properties
 - Environmental hazards
 - Specially the hazard of bioaccumulation via the food chain (PBT, vPvB)

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Safety Data Sheet (SDS)

- 3) Composition/Information on ingredients
 - Chemical Name
 - Identification number (EINEC/ELINCS or CAS)
 - Classification
 - Concentration range of the preparation
 - Registration number (if community workplace exposure limits are available)
- 4) First Aid Measures

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Safety Data Sheet (SDS)

5) Fire-Fighting Measures

- Suitable extinguishing media
- Extinguishing media which shall not be used for safety reasons
- Special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases
- Special protective equipment and personal protective equipment

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Safety Data Sheet (SDS)

6) Accidental Release and Measures

7) Handling and Storage

- Specifies precautions for safe handling and Storage and Specific use(s)
 - The information shall be relevant with the Exposure Scenarios and Risk Management Measures in the Annex

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Safety Data Sheet (SDS)

8) Exposure Controls and Personal Protection

- Exposure limit values
- DNELs and PNECs values
- Exposure controls
- Occupational exposure controls
- Respiratory protection
- Hand protection
- Eye protection
- Skin protection
- Environmental exposure controls

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Safety Data Sheet (SDS)

9) Physical and Chemical

- General information
 - Physical states, color, etc
- Important health, safety and environmental information
 - pH, concentration, etc
- Other information
 - Miscibility, conductivity, melting/boiling point, etc.

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Safety Data Sheet (SDS)

10) Stability and Reactivity

- Conditions to avoid
- Materials to avoid
- Hazardous decomposition products

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Safety Data Sheet (SDS)

11) Toxicology Information

- Description of the various toxicological effects, which can arise if the user comes into contacts with the substance or preparation.
- Information includes
 - Toxicokinetic, metabolism and distribution
 - Acute effect (acute toxicity, irritation and corrosivity)
 - Sensitization
 - Repeated dose toxicity and
 - CMR effects

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Safety Data Sheet (SDS)

12) Ecological Information

- Ecotoxicity
- Mobility
- Persistence and degradability
- Bioaccumulative potential
- Results of PBT assessment (if CSR is required)
- Other adverse effects

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Safety Data Sheet (SDS)

13) Disposal Considerations

14) Transport Information

- UN number
- IMDG Class
- Proper shipping name
- Packing group
- Marine pollutant
- Other applicable information

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Safety Data Sheet (SDS)

15) Regulatory Information

16) Other Information

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Annex to SDS – Exposure Scenarios

- Name of process or activities
- Scenarios description
- Operational conditions
 - Maximum amount used per time
 - Duration and frequency of activities
 - Other relevant information of operational conditions of use
 - Characteristics and physical dimensions of surroundings

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Annex to SDS – Exposure Scenarios

- Product specifications
- Recommendations conditions and process or activity preventing substance losses
- Recommended risk management measures
 - RMMs integrated in process or products
 - RMMs under direct control of the user
 - RMMs outside the direct control of the user
- Reference
- Date

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Annex to SDS – Exposure Scenarios

BASIC INFORMATION:

The preparation is a physical mixture of polymers, colorants and additives.

Physical form: powder.

Application: Roto-moulding. Typical let down ratio: 1 to 5%.

Contains:

- Octabenzene:
 - Physical form: powder
 - Typical use: UV stabiliser for plastic material
 - Classified by the industry as Skin Irritant (Xi – R43) and Potential hazard (long-term effects) in the aquatic environment (R53)
- 6,6'-di-tert-Butyl-4,4'-thiodi-m-cresol :
 - Physical form: powder
 - Typical use: Antioxidant for plastic material
 - Classified by the industry as Eyes Irritant (Xi – R36) and Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment (R50/53)

Annex to SDS – Exposure Scenarios

EXPOSURE SCENARIO:

Main route of Human Exposure:

- Inhalation of dust when handling product and waste and when charging.
- Ingestion when handling product and waste and when charging.
- Dermal contact when handling product and waste, when charging and when processing (contact with hot material).

May cause sensitization by skin contact.

Main route of Environmental Exposure:

- Contamination of Air possible when handling product and waste, when charging and when processing (release of fumes when hot material in contact with air).
- Contamination of Soil possible when handling product and waste and when charging.
- Contamination of Water when handling product and waste and when charging.

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Annex to SDS – Exposure Scenarios

RISK MANAGEMENT MEASURES:

Use: Roto-moulding

General Recommendation:

Handle in accordance with good industrial hygiene and safety practice. Due to the colouring properties of the product, closed work clothes should be used, to avoid stains during manipulation.

No eating, drinking, smoking or tobacco use at the place of work. Hands and/or face should be washed before breaks and at the end of the shift.

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Annex to SDS – Exposure Scenarios

Handling & Charging and Waste handling:

- Inhalation of dust, Ingestion and Dermal contact: Avoid spillage from bags, dispose of residues in bags carefully to avoid dust and prevent inhalation. In case of manual charging, work in an area equipped with dust extraction system, to minimise dust dispersion.
PPE:
 - Respiratory protection: Particle filter EN 143 Type P1 (low efficiency – inert particles).
 - Hand protection: Chemical resistant protective gloves (EN 374) e.g. nitrile rubber (0.4 mm), chloroprene rubber (0.5 mm), polyvinylchloride (0.7 mm) and other.
 - Eye protection: Safety glasses with side-shields (frame goggles) (EN 166).
 - Overall protection: Working clothes, closed shoes.
- Contamination of Air: Avoid dust formation. Pneumatic charging is preferred to manual one. In case of manual charging, work in an area equipped with dust extraction system, to minimise dust dispersion.
- Contamination of Soil and Water: Do not allow released material to enter drains or waterways. Wastewater contaminated by the substance has to be collected and treated before releasing into public drains or waterways, according to Directives 91/271/EC, 91/676/EC and local regulations.

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Annex to SDS – Exposure Scenarios

- Miscellaneous:
 - Take precautions against accumulation of electrostatic charge by grounded equipment.
 - Vacuum spilled material, or sweep spilled substance into containers. If appropriate, moisten first to prevent dusting. Carefully collect remainder, then remove to safe place. Waste must be taken to special waste disposal site in accordance to EC regulations (91/156/EEC; 91/689/EEC; 94/62/EC) and following amendments considering the possible dangerous ingredients listed in chapter 2, 10 or 15. Clean packaging material should be subjected to waste management schemes (recovery recycling, reuse) according to local legislation.

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Annex to SDS – Exposure Scenarios

Processing:

- Dermal contact: Avoid contact with hot material. After contact with molten product, cool quickly with cold water. Do not pull solidified product from the skin. Seek medical attention.
- Contamination of Air: Formation of production gases is to be expected in those production steps where temperature is higher and the melted product comes directly in contact with air. Collective protective equipment (like air exhauster) should be preferred, or, as a minimum, personal protective equipment (like face mask and breathing apparatus) should be worn, according to Directive 89/686/EC.