

Appendix 1

Standard Registration- Information Requirement of Chemical Safety Assessment Report

- 1. Basic identification of the registrant and substances**
Information of the registrant; Substance Identification
- 2. Substances manufacture, use and exposure information**
Manufacture and importation; Use information; Exposure information
- 3. Hazards Classification and Labelling**
Physical hazards; Health hazards; Environmental hazards; Labelling
- 4. Safe use information**
First aid measures; Firefighting measures; Accidental release measures; Handling and storage; Transport information; Exposure controls / personal protection
- 5. Physical and chemical properties**
Physical state; Melting / freezing point; Boiling point; Density; Octanol/water partition coefficient; Water solubility; Vapor pressure; Flash point; Flammability; Explosive properties; Oxidation properties; pH value; Auto-ignition temperature; Viscosity; Corrosive to metals
- 6. Toxicological Information**
Acute toxicity: oral, dermal, inhalation; Skin corrosion/irritation; Eye irritation; Skin sensitization; Genetic toxicity; Basic toxicokinetics; Repeat Dose Toxicity: oral, inhalation, dermal; Reproductive/Developmental toxicity; Carcinogenicity
- 7. Hazard assessment**
Physicochemical-property-to-human-health hazard assessment; Health hazard assessment
- 8. Exposure Assessment**
Exposure scenarios description; Exposure estimation; Risk characterization

Note:

1. For detailed information requirements, please refer to the content of the registration tool announced by the central competent authority.
2. Substances in volume of 1 ton or more, and less than 10 tons, or substances which do not fall within definition of CMR substance are exempted from submission of hazard assessment and exposure Assessment.
3. Chemical substances which do not possess health hazards or environmental hazard, in annual manufactured or imported volume of 10 tons or more, and which physical and chemical properties are not hazardous to human health shall be exempted from submission of exposure assessment.
4. Chemical substance fall within definition of On-site Isolated Intermediates, Polymers, Scientific Research and Development, or PPORD, shall be exempted from submission of hazard assessment and exposure assessment.
5. Submission of the aforesaid information, physical and chemical properties and toxicological information shall refer to respective registration information requirements of four levels, which is tabulated as supplementary appendix below. In each level of registration information requirements, items marked with “V” should be submitted.

Supplementary Appendix

Physical and chemical properties	I	II	III	IV
Physical state	V	V	V	V
Melting / freezing point	V	V	V	V
Boiling point	V	V	V	V
Density	V	V	V	V
Octanol/water partition coefficient	V	V	V	V
Water solubility	V	V	V	V
Vapor pressure	V	V	V	V
Flash point	V	V	V	V
Flammability	V	V	V	V
Explosive properties	V	V	V	V
Oxidation properties	V	V	V	V
pH value	V	V	V	V
Auto-ignition temperature	V	V	V	V
Viscosity			V	V
Corrosive to metals			V	V
Toxicological Information	I	II	III	IV
Acute toxicity: oral, dermal, inhalation	V	V	V	V
Skin corrosion/irritation	V	V	V	V
Eye irritation	V	V	V	V
Skin sensitization	V	V	V	V
Genetic toxicity	V	V	V	V
Basic toxicokinetics		V	V	V
Repeat Dose Toxicity: oral, inhalation, dermal		V	V	V
Reproductive/Developmental toxicity		V	V	V
Carcinogenicity				V

Note

1. For new chemical substances in annual manufactured or imported volume reaching 1 ton or more, but less than 10 tons; 10 tons or more, but less than 100 tons; 100 tons or more, but less than 1,000 tons; 1,000 tons or more, the registrant shall respectively provide minimum information on physical/chemical properties and toxicological test data with reference to level I, II, III, IV data set.
2. For new chemical substances which fit the definition of On-site isolated intermediates, Polymers, substances used for Scientific Research, or for Product and Process Orientated Research and Development, PPORD, in annual manufactured or imported volume of 10 tons or more, the minimum information on physical/chemical properties and toxicological information referred to level I testing data shall be submitted.
3. For new chemical substances that fall within definition of carcinogenic, mutagenic

or toxic to reproduction (CMRs) substances, category 1, in annual manufactured or imported volume of less than 1 ton; 1 ton or more, but less than 10 tons; 10 tons or more, but less than 100 tons; 100 tons or more, the minimum information submitted on physical/chemical properties and toxicological information shall respectively refer level I, II, III, IV testing data.

4. Testing items in level I, II, III, IV testing data set of physical/chemical properties and toxicological information shall be conducted according to relevant guidance issued by the central competent authority.