

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Text with EEA relevance)

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## ANNEX I GENERAL PROVISIONS FOR ASSESSING SUBSTANCES AND PREPARING CHEMICAL SAFETY REPORTS

0. INTRODUCTION
  - 0.1. The purpose of this Annex is to set out how...
  - 0.2. The chemical safety assessment shall be prepared by one or...
  - 0.3. The chemical safety assessment of a manufacturer shall address the...
  - 0.4. Substances whose physicochemical, toxicological and eco-toxicological properties are likely to...
  - 0.5. The chemical safety assessment shall be based on the information...
  - 0.6. Steps of a chemical safety assessment
    - 0.6.1. A chemical safety assessment performed by a manufacturer or an...
    - 0.6.2. In the cases referred to in point 0.6.3 the chemical...
    - 0.6.3. Where as a result of steps 1 to 4 the...
    - 0.6.4. A summary of all the relevant information used in addressing...
  - 0.7. The main element of the exposure part of the chemical...
  - 0.8. The level of detail required in describing an exposure scenario...
  - 0.9. Where information is not necessary in accordance with Annex XI,...
  - 0.10. In relation to particular effects, such as ozone depletion, photochemical...
  - 0.11. When assessing the risk of the use of one or...

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- 0.11. bis When nanoforms are covered by the chemical safety assessment, an...
- 0.12. Where the methodology described in this Annex is not appropriate,...
- 0.13. Part A of the chemical safety report shall include a...

## 1. HUMAN HEALTH HAZARD ASSESSMENT

- 1.0. Introduction
  - 1.0.1. The objectives of the human health hazard assessment shall be...
  - 1.0.2. The human health hazard assessment shall consider the toxicokinetic profile...
  - 1.0.3. The hazard assessment shall comprise the following four steps:
  - 1.0.4. The first three steps shall be undertaken for every effect...
  - 1.0.5. For any effect for which no relevant information is available,...
  - 1.0.6. Step 4 of the human health hazard assessment shall be...
- 1.1. Step 1: Evaluation of non-human information
  - 1.1.1. The evaluation of non-human information shall comprise:
  - 1.1.2. When it is not possible to establish the quantitative dose...
  - 1.1.3. All non-human information used to assess a particular effect on...
  - 1.1.4. If one study is available then a robust study summary...
- 1.2. Step 2: Evaluation of human information
- 1.3. Step 3: Classification and Labelling
  - 1.3.1. The appropriate classification developed in accordance with the criteria in...
  - 1.3.2. If the information is inadequate to decide whether a substance...
- 1.4. Step 4: Identification of DNEL(s)
  - 1.4.1. Based on the outcomes of steps 1 and 2, (a)...
  - 1.4.2. If it is not possible to identify a DNEL, then...

## 2. PHYSICOCHEMICAL HAZARD ASSESSMENT

- 2.1. The objective of the hazard assessment for physicochemical properties shall...
- 2.2. As a minimum, the potential effects to human health shall...
- 2.3. The assessment of each effect shall be presented under the...
- 2.4. For every physicochemical property, the assessment shall entail an evaluation...
- 2.5. The appropriate classification developed in accordance with the criteria in...

## 3. ENVIRONMENTAL HAZARD ASSESSMENT

- 3.0. Introduction
  - 3.0.1. The objective of the environmental hazard assessment shall be to...
  - 3.0.2. The environmental hazard assessment shall consider the potential effects on...
  - 3.0.3. For any environmental sphere, for which no effect information is...
  - 3.0.4. The hazard assessment shall comprise the following three steps, which...
- 3.1. Step 1: Evaluation of information
  - 3.1.1. The evaluation of all available information shall comprise:
  - 3.1.2. When it is not possible to establish the quantitative dose...
  - 3.1.3. All information used to assess the effects on a specific...
  - 3.1.4. All information used to assess the environmental fate of the...
  - 3.1.5. If one study is available then a robust study summary...
- 3.2. Step 2: Classification and Labelling
  - 3.2.1. The appropriate classification developed in accordance with the criteria in...
  - 3.2.2. If the information is inadequate to decide whether a substance...
- 3.3. Step 3: Identification of the PNEC



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- 3.3.1. Based on the available information, the PNEC for each environmental...
      - 3.3.2. If it is not possible to derive the PNEC, then...
  - 4. PBT AND VPVB ASSESSMENT
    - 4.0. Introduction
      - 4.0.1. The objective of the PBT and vPvB assessment shall be...
      - 4.0.2. The PBT and vPvB assessment shall comprise the following two...
- Annex I Table 1
- 4.1. Step 1: Comparison with the criteria
    - 4.2. Step 2: Emission Characterisation
5. EXPOSURE ASSESSMENT
  - 5.0. Introduction
  - 5.1. Step 1: Development of exposure scenarios
    - 5.1.1. Exposure scenarios as described in Sections 0.7 and 0.8 shall...
    - 5.1.2. Where a manufacturer, importer or downstream user applies for an...
  - 5.2. Step 2: Exposure Estimation
    - 5.2.1. The exposure shall be estimated for each exposure scenario developed...
    - 5.2.2. The emission estimation shall consider the emissions during all relevant...
    - 5.2.3. A characterisation of possible degradation, transformation, or reaction processes, and...
    - 5.2.4. An estimation of the exposure levels shall be performed for...
    - 5.2.5. Where adequately measured representative exposure data are available, special consideration...
6. RISK CHARACTERISATION
  - 6.1. The risk characterisation shall be carried out for each exposure...
  - 6.2. The risk characterisation shall consider the human populations (exposed as...
  - 6.3. The risk characterisation consists of:
  - 6.4. For any exposure scenario, the risk to humans and the...
  - 6.5. For those human effects and those environmental spheres for which...
7. CHEMICAL SAFETY REPORT FORMAT
  - CHEMICAL SAFETY REPORT FORMAT
  - PART A
  - 1. SUMMARY OF RISK MANAGEMENT MEASURES
    - 1. SUMMARY OF RISK MANAGEMENT MEASURES
    - 2. DECLARATION THAT RISK MANAGEMENT MEASURES ARE IMPLEMENTED
    - 3. DECLARATION THAT RISK MANAGEMENT MEASURES ARE COMMUNICATED
  - PART B
  - 1. IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES...
    - 1. IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES
    - 2. MANUFACTURE AND USES

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- 2.1. Manufacture
- 2.2. Identified uses
- 2.3. Uses advised against
- 3. CLASSIFICATION AND LABELLING
- 4. ENVIRONMENTAL FATE PROPERTIES
  - 4.1. Degradation
  - 4.2. Environmental distribution
  - 4.3. Bioaccumulation
  - 4.4. Secondary poisoning
- 5. HUMAN HEALTH HAZARD ASSESSMENT
  - 5.1. Toxicokinetics (absorption, metabolism, distribution and elimination)
  - 5.2. Acute toxicity
  - 5.3. Irritation
    - 5.3.1. ....
    - 5.3.2. ....
    - 5.3.3. ....
  - 5.4. Corrosivity
  - 5.5. Sensitisation
    - 5.5.1. ....
    - 5.5.2. ....
  - 5.6. Repeated dose toxicity
  - 5.7. Germ cell mutagenicity
  - 5.8. Carcinogenicity
  - 5.9. Toxicity for reproduction
    - 5.9.1. ....
    - 5.9.2. ....
  - 5.10. Other effects
  - 5.11. Derivation of DNEL(s)
- 6. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICOCHEMICAL PROPERTIES
  - 6.1. Explosivity
  - 6.2. Flammability
  - 6.3. Oxidising potential
- 7. ENVIRONMENTAL HAZARD ASSESSMENT
  - 7.1. Aquatic compartment (including sediment)
  - 7.2. Terrestrial compartment
  - 7.3. Atmospheric compartment
  - 7.4. Microbiological activity in sewage treatment systems
- 8. PBT AND VPVB ASSESSMENT
- 9. EXPOSURE ASSESSMENT
  - 9.1. (Title of exposure scenario 1)
    - 9.1.1. Exposure scenario
    - 9.1.2. Exposure estimation
  - 9.2. (Title of exposure scenario 2)
    - 9.2.1. Exposure scenario
    - 9.2.2. Exposure estimation
- 10. RISK CHARACTERISATION
  - 10.1. (Title of exposure scenario 1)
    - 10.1.1. Human health
      - 10.1.1.1 Workers
      - 10.1.1.2 Consumers

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- 10.1.1.3 Indirect exposure to humans via the environment
- 10.1.2. Environment
  - 10.1.2.1 Aquatic compartment (including sediment)
  - 10.1.2.2 Terrestrial compartment
  - 10.1.2.3 Atmospheric compartment
  - 10.1.2.4 Microbiological activity in sewage treatment systems
- 10.2. (Title of exposure scenario 2)
  - 10.2.1. Human health
    - 10.2.1.1 Workers
    - 10.2.1.2 Consumers
    - 10.2.1.3 Indirect exposure to humans via the environment
  - 10.2.2. Environment
    - 10.2.2.1 Aquatic compartment (including sediment)
    - 10.2.2.2 Terrestrial compartment
    - 10.2.2.3 Atmospheric compartment
    - 10.2.2.4 Microbiological activity in sewage treatment systems
- 10.x. Overall exposure (combined for all relevant emission/release sources)
  - 10.x.1. Human health (combined for all exposure routes)
  - 10.x.2. Environment (combined for all emission sources)

## ANNEX II

### REQUIREMENTS FOR THE COMPILATION OF SAFETY DATA SHEETS

#### PART A

0.1. Introduction 0.1.1. This Annex sets out the requirements that...

- 0.1. Introduction
  - 0.1.1. This Annex sets out the requirements that the supplier shall...
  - 0.1.2. The information provided in the safety data sheet shall be...
- 0.2. General requirements for compiling a safety data sheet
  - 0.2.1. The safety data sheet shall enable users to take the...
  - 0.2.2. The information provided by safety data sheets shall also meet...
  - 0.2.3. The information in the safety data sheet shall be written...
  - 0.2.4. The language used in the safety data sheet shall be...
  - 0.2.5. The date of compilation of the safety data sheet shall...
- 0.3. Safety data sheet format
  - 0.3.1. A safety data sheet is not a fixed length document....
  - 0.3.2. All pages of a safety data sheet, including any annexes,...
- 0.4. Safety data sheet content
- 0.5. Other information requirements
- 0.6. Units

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- 0.7. Special cases
  - 1. SECTION 1: Identification of the substance/mixture and of the company/undertaking...
    - 1.1. Product identifier
      - Other means of identification
    - 1.2. Relevant identified uses of the substance or mixture and uses...
    - 1.3. Details of the supplier of the safety data sheet
    - 1.4. Emergency telephone number
  - 2. SECTION 2: Hazards identification
    - 2.1. Classification of the substance or mixture
    - 2.2. Label elements
    - 2.3. Other hazards
  - 3. SECTION 3: Composition/information on ingredients
    - 3.1. Substances
    - 3.2. Mixtures
      - 3.2.1. For a mixture meeting the criteria for classification in accordance...
      - 3.2.2. For a mixture not meeting the criteria for classification in...
      - 3.2.3. For the substances indicated in subsection 3.2, the classification of...
      - 3.2.4. For the substances indicated in subsection 3.2 the name and,...
  - 4. SECTION 4: First aid measures
    - 4.1. Description of first aid measures
      - 4.1.1. First aid instructions shall be provided by relevant routes of...
      - 4.1.2. Advice shall be provided as to whether:
    - 4.2. Most important symptoms and effects, both acute and delayed
    - 4.3. Indication of any immediate medical attention and special treatment needed...
  - 5. SECTION 5: Firefighting measures
    - 5.1. Extinguishing media
    - 5.2. Special hazards arising from the substance or mixture
    - 5.3. Advice for firefighters
  - 6. SECTION 6: Accidental release measures
    - 6.1. Personal precautions, protective equipment and emergency procedures
      - 6.1.1. For non-emergency personnel
      - 6.1.2. For emergency responders
    - 6.2. Environmental precautions
    - 6.3. Methods and material for containment and cleaning up
      - 6.3.1. Appropriate advice shall be provided on how to contain a...
      - 6.3.2. Appropriate advice shall be provided on how to clean-up a...
      - 6.3.3. Any other information shall be provided relating to spills and...
    - 6.4. Reference to other sections
  - 7. SECTION 7: Handling and storage
    - 7.1. Precautions for safe handling
      - 7.1.1. Recommendations shall be specified to:
      - 7.1.2. Advice on general occupational hygiene shall be provided, such as:...
    - 7.2. Conditions for safe storage, including any incompatibilities
    - 7.3. Specific end use(s)
  - 8. SECTION 8: Exposure controls/personal protection

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- 8.1. Control parameters
  - 8.1.1. Where available, the following national limit values, including the legal...
  - 8.1.2. Information on currently recommended monitoring procedures shall be provided at...
  - 8.1.3. If air contaminants are formed when using the substance or...
  - 8.1.4. Where a chemical safety report is required or where a...
  - 8.1.5. Where a control banding approach is used to decide on...
- 8.2. Exposure controls
  - 8.2.1. Appropriate engineering controls
  - 8.2.2. Individual protection measures, such as personal protective equipment
    - 8.2.2.1. The information on use of personal protective equipment shall be...
    - 8.2.2.2. Taking into account Council Directive 89/686/EEC and referring to the...
  - 8.2.3. Environmental exposure controls
- 9. SECTION 9: Physical and chemical properties
  - 9.1. Information on basic physical and chemical properties
  - 9.2. Other information
- 10. SECTION 10: Stability and reactivity
  - 10.1. Reactivity
    - 10.1.1. The reactivity hazards of the substance or mixture shall be...
    - 10.1.2. If data for mixtures are not available, data on substances...
  - 10.2. Chemical stability
  - 10.3. Possibility of hazardous reactions
  - 10.4. Conditions to avoid
  - 10.5. Incompatible materials
  - 10.6. Hazardous decomposition products
- 11. SECTION 11: Toxicological information
  - 11.1. Information on toxicological effects
    - 11.1.1. Information shall be provided for each hazard class or differentiation...
    - 11.1.2. The data included in this subsection shall apply to the...
    - 11.1.3. Where there is a substantial amount of test data on...
    - 11.1.4. Where the classification criteria for a particular hazard class are...
    - 11.1.5. Information on likely routes of exposure
    - 11.1.6. Symptoms related to the physical, chemical and toxicological characteristics
    - 11.1.7. Delayed and immediate effects as well as chronic effects from...
    - 11.1.8. Interactive effects
    - 11.1.9. Absence of specific data
    - 11.1.10. Mixtures
    - 11.1.11. Mixture versus substance information
      - 11.1.11.1. The substances in a mixture may interact with each other...
      - 11.1.11.2. It is necessary to consider whether the concentration of each...
    - 11.1.12. Other information
- 12. SECTION 12: Ecological information
  - 12.1. Toxicity
  - 12.2. Persistence and degradability
  - 12.3. Bioaccumulative potential

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- 12.4. Mobility in soil
- 12.5. Results of PBT and vPvB assessment
- 12.6. Other adverse effects
- 13. SECTION 13: Disposal considerations
  - 13.1. Waste treatment methods
- 14. SECTION 14: Transport information
  - 14.1. UN number
  - 14.2. UN proper shipping name
  - 14.3. Transport hazard class(es)
  - 14.4. Packing group
  - 14.5. Environmental hazards
  - 14.6. Special precautions for user
  - 14.7. Transport in bulk according to Annex II of Marpol and...
- 15. SECTION 15: Regulatory information
  - 15.1. Safety, health and environmental regulations/legislation specific for the substance or...
  - 15.2. Chemical safety assessment
- 16. SECTION 16: Other information

#### PART B

The safety data sheet shall include the following 16 headings...

#### ANNEX III

##### CRITERIA FOR SUBSTANCES REGISTERED IN QUANTITIES BETWEEN 1 AND 10 TONNES

Criteria for substances and, when applicable, for nanoforms thereof, registered...  
substances for which it is predicted (i.e. by the application...

#### ANNEX IV

#### ANNEX V

##### EXEMPTIONS FROM THE OBLIGATION TO REGISTER IN ACCORDANCE WITH ARTICLE 2(7)(b)

- 1. Substances which result from a chemical reaction that occurs incidental...
- 2. Substances which result from a chemical reaction that occurs incidental...
- 3. Substances which result from a chemical reaction occurring upon end...
- 4. Substances which are not themselves manufactured, imported or placed on...

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5. By-products, unless they are imported or placed on the market...
6. Hydrates of a substance or hydrated ions, formed by association...
7. The following substances which occur in nature, if they are...
8. Substances which occur in nature other than those listed under...
9. The following substances obtained from natural sources, if they are...
10. The following substances if they are not chemically modified:
11. The following substances unless they meet the criteria for classification...
12. Compost, biogas and digestate.
13. Hydrogen and oxygen.

## ANNEX VI

### INFORMATION REQUIREMENTS REFERRED TO IN ARTICLE 10

#### NOTE ON FULFILLING THE REQUIREMENTS OF ANNEXES VI TO XI...

#### STEP 1 — GATHER AND SHARE EXISTING INFORMATION

#### STEP 2 — CONSIDER INFORMATION NEEDS

#### STEP 3 — IDENTIFY INFORMATION GAPS

#### STEP 4 — GENERATE NEW DATA/PROPOSE TESTING STRATEGY NOTES

#### INFORMATION REFERRED TO IN ARTICLE 10(a) (i) TO (v)

1. GENERAL REGISTRANT INFORMATION
  - 1.1. Registrant
    - 1.1.1. Name, address, telephone number, fax number and e-mail address
    - 1.1.2. Contact person
    - 1.1.3. Location of the registrant's production and own use site(s), as...
  - 1.2. Joint submission of data
  - 1.3. Third party appointed under Article 4
    - 1.3.1. Name, address, telephone number, fax number and e-mail address
    - 1.3.2. Contact person
2. IDENTIFICATION OF THE SUBSTANCE
  - 2.1. Name or other identifier of each substance
    - 2.1.1. Name(s) in the IUPAC nomenclature or other international chemical name(s)...
    - 2.1.2. Other names (usual name, trade name, abbreviation)
    - 2.1.3. EINECS or ELINCS number (if available and appropriate)
    - 2.1.4. CAS name and CAS number (if available)
    - 2.1.5. Other identity code (if available)

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**Changes to legislation:** *There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)*

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- 2.2. Information related to molecular and structural formula of each substance...
  - 2.2.1. Molecular and structural formula (including SMILES notation, if available)
  - 2.2.2. Information on optical activity and typical ratio of (stereo) isomers...
  - 2.2.3. Molecular weight or molecular weight range
- 2.3. Composition of each substance. Where a registration covers one or...
  - 2.3.1. Degree of purity (%)
  - 2.3.2. Nature of impurities, including isomers and by-products
  - 2.3.3. Percentage of (significant) main impurities
  - 2.3.4. Nature and order of magnitude (... ppm, ... %) of...
  - 2.3.5. Spectral data (e.g. ultra-violet, infra-red, nuclear magnetic resonance or mass...)
  - 2.3.6. High-pressure liquid chromatogram, gas chromatogram
  - 2.3.7. Description of the analytical methods or the appropriate bibliographical references...
- 2.4. Characterisation of nanoforms of a substance: For each of the...
  - 2.4.1. Names or other identifiers of the nanoforms or sets of...
  - 2.4.2. Number based particle size distribution with indication of the number...
  - 2.4.3. Description of surface functionalisation or treatment and identification of each...
  - 2.4.4. Shape, aspect ratio and other morphological characterisation: crystallinity, information on...
  - 2.4.5. Surface area (specific surface area by volume, specific surface area...)
  - 2.4.6. Description of the analytical methods or the appropriate bibliographical references...
3. INFORMATION ON MANUFACTURE AND USE(S) OF THE SUBSTANCE(S)
  - 3.1. Overall manufacture, quantities used for production of an article that...
  - 3.2. In the case of a manufacturer or producer of articles:...
  - 3.3. An indication of the tonnage used for his own use(s)...
  - 3.4. Form (substance, mixture or article) and/or physical state under which...
  - 3.5. Brief general description of the identified use(s)
  - 3.6. Information on waste quantities and composition of waste resulting from...
  - 3.7. Uses advised against (see Section 1 of the safety data...
4. CLASSIFICATION AND LABELLING
  - 4.1 The hazard classification of the substance(s), resulting from the application...
  - 4.2 The resulting hazard label for the substance(s), resulting from the...
  - 4.3 Specific concentration limits, where applicable, resulting from the application of...
5. GUIDANCE ON SAFE USE CONCERNING:
  - 5.1. First-aid measures (Safety Data Sheet heading 4)
  - 5.2. Fire-fighting measures (Safety Data Sheet heading 5)
  - 5.3. Accidental release measures (Safety Data Sheet heading 6)
  - 5.4. Handling and storage (Safety Data Sheet heading 7)
  - 5.5. Transport information (Safety Data Sheet heading 14)
  - 5.6. Exposure controls/personal protection (Safety Data Sheet heading 8)
  - 5.7. Stability and reactivity (Safety Data Sheet heading 10)
  - 5.8. Disposal considerations
    - 5.8.1. Disposal considerations (Safety Data Sheet heading 13)



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- 5.8.2. Information on recycling and methods of disposal for industry
- 5.8.3. Information on recycling and methods of disposal for the public...
- 6. INFORMATION ON EXPOSURE FOR SUBSTANCES REGISTERED IN QUANTITIES BETWEEN 1...
  - 6.1. Main use category:
    - 6.1.1. industrial use; and/or professional use; and/or consumer use.
    - 6.1.2. Specification for industrial and professional use:
  - 6.2. Significant route(s) of exposure:
    - 6.2.1. Human exposure:
    - 6.2.2. Environmental exposure:
  - 6.3. Pattern of exposure:

## ANNEX VII

### STANDARD INFORMATION REQUIREMENTS FOR SUBSTANCES MANUFACTURED OR IMPORTED IN QUANTITIES OF ONE TONNE OR MORE

Column 1 of this Annex establishes the standard information required...  
non-phase-in substances manufactured or imported in quantities of 1 to...  
Any other relevant physicochemical, toxicological and ecotoxicological information that is...  
Column 2 of this Annex lists specific rules according to...  
Without prejudice to the information submitted for other forms, any...  
In addition to these specific rules, a registrant may adapt...  
Before new tests are carried out to determine the properties...  
When, for certain endpoints, information is not provided for other...  
Any other relevant physicochemical, toxicological and ecotoxicological information that is...

#### 7. INFORMATION ON THE PHYSICOCHEMICAL PROPERTIES OF THE SUBSTANCE

Annex VII Table 1

#### 8. TOXICOLOGICAL INFORMATION

Annex VII Table 2

#### 9. ECOTOXICOLOGICAL INFORMATION

Annex VII Table 3

## ANNEX VIII

### STANDARD INFORMATION REQUIREMENTS FOR SUBSTANCES MANUFACTURED OR IMPORTED IN QUANTITIES OF 10 TONNES OR MORE

Column 1 of this Annex establishes the standard information required...  
Without prejudice to the information submitted for other forms, any...

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*Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)*

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In addition to these specific rules, a registrant may adapt...  
Before new tests are carried out to determine the properties...  
When, for certain endpoints, information is not provided for  
other...

7. INFORMATION ON THE PHYSICOCHEMICAL PROPERTIES OF THE  
SUBSTANCE

Annex VIII Table 1

8. TOXICOLOGICAL INFORMATION

Annex VIII Table 2

9. ECOTOXICOLOGICAL INFORMATION

Annex VIII Table 3

ANNEX IX

STANDARD INFORMATION REQUIREMENTS FOR SUBSTANCES  
MANUFACTURED OR IMPORTED IN QUANTITIES OF 100 TONNES OR MORE

At the level of this Annex, the registrant must submit...  
Column 1 of this Annex establishes the standard information  
required...  
Without prejudice to the information submitted for other forms,  
any...  
In addition to these specific rules, a registrant may propose...  
Before new tests are carried out to determine the properties...  
When, for certain endpoints, it is proposed not to provide...

7. INFORMATION ON THE PHYSICOCHEMICAL PROPERTIES OF THE  
SUBSTANCE

Annex IX Table 1

8. TOXICOLOGICAL INFORMATION

Annex IX Table 2

9. ECOTOXICOLOGICAL INFORMATION

Annex IX Table 3

10. METHODS OF DETECTION AND ANALYSIS

ANNEX X

STANDARD INFORMATION REQUIREMENTS FOR SUBSTANCES  
MANUFACTURED OR IMPORTED IN QUANTITIES OF 1 000 TONNES OR MORE

At the level of this Annex, the registrant must submit...  
Column 1 of this Annex establishes the standard information  
required...  
Without prejudice to the information submitted for other forms,  
any...  
In addition to these specific rules, a registrant may propose...

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Before new tests are carried out to determine the properties...  
When, for certain endpoints, it is proposed not to provide...

8. TOXICOLOGICAL INFORMATION  
Annex X Table 1
9. ECOTOXICOLOGICAL INFORMATION  
Annex X Table 2
10. METHODS OF DETECTION AND ANALYSIS

## ANNEX XI

### GENERAL RULES FOR ADAPTATION OF THE STANDARD TESTING REGIME SET OUT IN ANNEXES VII TO X

Annexes VII to X set out the information requirements for...  
one tonne or more in accordance with Article 12(1)(a), 10...  
In addition to the specific rules set out in column...  
The requirements specific to nanoforms in this Annex are  
without...

1. TESTING DOES NOT APPEAR SCIENTIFICALLY NECESSARY
  - 1.1. Use of existing data
    - 1.1.1. Data on physical-chemical properties from experiments not carried out according...
    - 1.1.2. Data on human health and environmental properties from experiments not...
    - 1.1.3. Historical human data
  - 1.2. Weight of evidence
  - 1.3. Qualitative or Quantitative structure-activity relationship ((Q)SAR)
  - 1.4. In vitro methods
  - 1.5. Grouping of substances and read-across approach
2. TESTING IS TECHNICALLY NOT POSSIBLE
3. SUBSTANCE-TAILORED EXPOSURE-DRIVEN TESTING
  - 3.1. Testing in accordance with Sections 8.6 and 8.7 of Annex...
  - 3.2. In all cases, adequate justification and documentation shall be provided....
  - 3.3. The specific conditions of use must be communicated through the...

## ANNEX XII

### GENERAL PROVISIONS FOR DOWNSTREAM USERS TO ASSESS SUBSTANCES AND PREPARE CHEMICAL SAFETY REPORTS

#### INTRODUCTION

- STEP 1: DEVELOPMENT OF EXPOSURE SCENARIO(S)
- STEP 2: IF NECESSARY, A REFINEMENT OF THE HAZARD ASSESSMENT...
- STEP 3: RISK CHARACTERISATION

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## ANNEX XIII

### CRITERIA FOR THE IDENTIFICATION OF PERSISTENT, BIOACCUMULATIVE AND TOXIC SUBSTANCES, AND VERY PERSISTENT AND VERY BIOACCUMULATIVE SUBSTANCES

This Annex lays down the criteria for the identification of...  
For the identification of PBT substances and vPvB substances a...  
A weight-of-evidence determination means that all available information bearing on...  
The information used for the purposes of assessment of the...  
The identification shall also take account of the PBT/vPvB-properties of...  
This Annex shall apply to all organic substances, including organo-metals....

1. CRITERIA FOR THE IDENTIFICATION OF PBT AND vPvB SUBSTANCES
  - 1.1. PBT Substances
    - 1.1.1. Persistence
    - 1.1.2. Bioaccumulation
    - 1.1.3. Toxicity
  - 1.2. vPvB Substances
    - 1.2.1. Persistence
    - 1.2.2. Bioaccumulation
2. SCREENING AND ASSESSMENT OF P, vP, B, vB and T...
  - 2.1. Registration
  - 2.2. Authorisation
3. INFORMATION RELEVANT FOR THE SCREENING AND ASSESSMENT OF P, vP,...
  - 3.1. Screening Information
    - 3.1.1. Indication of P and vP properties
    - 3.1.2. Indication of B and vB properties
    - 3.1.3. Indication of T properties
  - 3.2. Assessment Information
    - 3.2.1. Assessment of P or vP properties
    - 3.2.2. Assessment of B or vB properties
    - 3.2.3. Assessment of T properties

## ANNEX XIV

### LIST OF SUBSTANCES SUBJECT TO AUTHORISATION

## ANNEX XV

### DOSSIERS

- I. INTRODUCTION AND GENERAL PROVISIONS
- II. CONTENT OF DOSSIERS

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1. Dossier for harmonised classification and labelling for CMRs, respiratory sensitisers...
  - Proposal
  - Justification
  - Justification for other effects at Community Level
2. Dossier for the identification of a substance as a CMR,...
  - Proposal
  - Justification
  - Information on exposures, alternative substances and risks
3. Dossiers for restrictions proposal
  - Proposal
  - Information on hazard and risk
  - Information on alternatives
  - Justification for Restrictions at Community Level
  - Socio-economic assessment
  - Information on stakeholder consultation

## ANNEX XVI

### SOCIO-ECONOMIC ANALYSIS

This Annex outlines the information that may be addressed by...

The Agency shall prepare guidance for the preparation of SEAs....

However, the level of detail and scope of the SEA,...

An SEA may include the following elements:

impact of a granted or refused authorisation on the applicant(s),...

## ANNEX XVII

### RESTRICTIONS ON THE MANUFACTURE, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES, MIXTURES AND ARTICLES

#### Appendices 1 to 6

FOREWORD Explanations of column headings

Substances:

Entries for groups of substances:

Index number:

EC numbers:

CAS number:

Notes:

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#### Appendix 1

Entry 28 — Carcinogens: category 1A (Table 3.1)/category 1 (Table 3.2)

#### Appendix 2

Entry 28 — Carcinogens: category 1B (Table 3.1)/category 2 (Table 3.2)

#### Appendix 3

Entry 29 — Mutagens: category 1A (Table 3.1)/category 1 (Table 3.2)

#### Appendix 4

Entry 29 — Mutagens: category 1B (Table 3.1)/category 2 (Table 3.2)

#### Appendix 5

Entry 30 — Toxic to reproduction: category 1A (Table 3.1)/category 1 (Table 3.2)

#### Appendix 6

Entry 30 — Toxic to reproduction: category 1B (Table 3.1)/category 2 (Table 3.2)

#### Appendix 7

##### Special provisions on the labelling of articles containing asbestos

1. All articles containing asbestos or the packaging thereof must bear...
2. The label mentioned in this Appendix shall be affixed in...
3. Labelling of packaged articles containing asbestos
  - 3.1. The following particulars shall appear on clearly legible and indelible...
  - 3.2. Labelling in accordance with 3.1 shall be effected by means...
  - 3.3. Articles containing asbestos and which are packaged only in loose...
4. Labelling of unpackaged articles containing asbestos
5. Without prejudice to Community provisions on safety and hygiene at...
6. The labelling of any article intended for domestic use which...
7. The labelling of articles containing asbestos shall be in the...

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## Appendix 8

Entry 43 — Azocolourants — List of aromatic amines

List of aromatic amines  
Annex XVII Table 7

## Appendix 9

Entry 43 — Azocolourants — List of azodyes

List of azodyes  
Annex XVII Table 8

## Appendix 10

Entry 43 — List of testing methods  
Annex XVII Table 9

## Appendix 11

## Appendix 12

Entry 72 — restricted substances and maximum concentration limits by...

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- (1) [<sup>XI</sup>OJ C 112, 30.4.2004, p. 92 and OJ C 294, 25.11.2005, p. 38.]
- (2) [<sup>XI</sup>OJ C 164, 5.7.2005, p. 78.]
- (3) [<sup>XI</sup>Opinion of the European Parliament of 17 November 2005 (OJ C 280 E, 18.11.2006, p. 303), Council Common Position of 27 June 2006 (OJ C 276 E, 14.11.2006, p. 1) and Position of the European Parliament of 13 December 2006 (not yet published in the Official Journal). Council Decision of 18 December 2006.]
- (4) [<sup>XI</sup>OJ 196, 16.8.1967, p. 1. Directive as last amended by Commission Directive 2004/73/EC (OJ L 152, 30.4.2004, p. 1). Corrected in OJ L 216, 16.6.2004, p. 3.]
- (5) [<sup>XI</sup>OJ L 262, 27.9.1976, p. 201. Directive as last amended by Commission Directive 2006/139/EC (OJ L 384, 29.12.2006, p. 94).]
- (6) [<sup>XI</sup>OJ L 200, 30.7.1999, p. 1. Directive as last amended by Commission Directive 2006/8/EC (OJ L 19, 24.1.2006, p. 12).]
- (7) [<sup>XI</sup>OJ L 84, 5.4.1993, p. 1. Regulation as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).]
- (8) [<sup>XI</sup>OJ L 158, 30.4.2004, p. 50, corrected in OJ L 229, 29.6.2004, p. 23.]
- (9) [<sup>XI</sup>OJ L 131, 5.5.1998, p. 11.]
- (10) [<sup>XI</sup>OJ L 262, 27.9.1976, p. 169. Directive as last amended by Commission Directive 2007/1/EC (OJ L 25, 1.2.2007, p. 9).]
- (11) [<sup>XI</sup>OJ L 358, 18.12.1986, p. 1. Directive as amended by Directive 2003/65/EC of the European Parliament and of the Council (OJ L 230, 16.9.2003, p. 32).]
- (12) [<sup>XI</sup>OJ L 50, 20.2.2004, p. 44.]
- (13) [<sup>XI</sup>OJ L 357, 31.12.2002, p. 72.]
- (14) [<sup>XI</sup>OJ L 136, 30.4.2004, p. 1. Regulation as amended by Regulation (EC) No 1901/2006 (OJ L 378, 27.12.2006, p. 1).]
- (15) [<sup>XI</sup>OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 575/2006 (OJ L 100, 8.4.2006, p. 3).]
- (16) [<sup>XI</sup>OJ C 218, 13.9.2003, p. 1.]
- (17) [<sup>XI</sup>OJ L 41, 14.2.2003, p. 26.]
- (18) [<sup>XI</sup>OJ L 145, 31.5.2001, p. 43.]
- (19) [<sup>XI</sup>OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).]
- (20) [<sup>XI</sup>Commission Directive 91/155/EEC of 5 March 1991 defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations in implementation of Article 10 of Directive 88/379/EEC (OJ L 76, 22.3.1991, p. 35). Directive as last amended by Directive 2001/58/EC (OJ L 212, 7.8.2001, p. 24).]
- (21) [<sup>XI</sup>Commission Directive 93/67/EEC of 20 July 1993 laying down the principles for assessment of risks to man and the environment of substances notified in accordance with Council Directive 67/548/EEC (OJ L 227, 8.9.1993, p. 9).]
- (22) [<sup>XI</sup>Commission Directive 93/105/EC of 25 November 1993 laying down Annex VII D, containing information required for the technical dossier referred to in Article 12 of the seventh amendment of Council Directive 67/548/EEC (OJ L 294, 30.11.1993, p. 21).]
- (23) [<sup>XI</sup>Commission Directive 2000/21/EC of 25 April 2000 concerning the list of Community legislation referred to in the fifth indent of Article 13(1) of Council Directive 67/548/EEC (OJ L 103, 28.4.2000, p. 70).]



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- (24) [<sup>X1</sup>Commission Regulation (EC) No 1488/94 of 28 June 1994 laying down the principles for the assessment of risks to man and the environment of existing substances in accordance with Council Regulation (EEC) No 793/93 (OJ L 161, 29.6.1994, p. 3).]
- (25) [<sup>X1</sup>OJ C 364, 18.12.2000, p. 1.]

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**Editorial Information**

- X1** Substituted by Corrigendum to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Official Journal of the European Union L 396 of 30 December 2006).

**Status:**

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**Changes to legislation:**

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