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)

TITLE I

GENERAL ISSUES

CHAPTER 1

Aim, scope and application

CHAPTER 2

Definitions and general provision

TITLE II

REGISTRATION OF SUBSTANCES

CHAPTER 1

General obligation to register and information requirements

TITLE VIII

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

CHAPTER 1

General issues

CHAPTER 2

Restrictions process

TITLE IX

FEES AND CHARGES

TITLE X

AGENCY

TITLE XIV

ENFORCEMENT

TITLE XV

TRANSITIONAL AND FINAL PROVISIONS

ANNEX I

GENERAL PROVISIONS FOR ASSESSING SUBSTANCES AND PREPARING CHEMICAL SAFETY REPORTS

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

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...

0.7. 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

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...

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)

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)

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...

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...

ANNEX XI

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

ANNEX XII

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

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

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:

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...

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 — Azocolourants — List of testing methods
List of testing methods
Annex XVII Table 9

Appendix 11

Appendix 12

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

Status: *Point in time view as at 01/01/2020.*
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)*

(1) [X1OJ C 112, 30.4.2004, p. 92 and OJ C 294, 25.11.2005, p. 38.]

(2) [X1OJ C 164, 5.7.2005, p. 78.]

(3) [X1Opinion 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) [X1OJ 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) [X1OJ 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) [X1OJ 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) [X1OJ 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) [X1OJ L 158, 30.4.2004, p. 50, corrected in OJ L 229, 29.6.2004, p. 23.]

(9) [X1OJ L 131, 5.5.1998, p. 11.]

(10) [X1OJ 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) [X1OJ 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) [X1OJ L 50, 20.2.2004, p. 44.]

(13) [X1OJ L 357, 31.12.2002, p. 72.]

(14) [X1OJ 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) [X1OJ 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) [X1OJ C 218, 13.9.2003, p. 1.]

(17) [X1OJ L 41, 14.2.2003, p. 26.]

(18) [X1OJ L 145, 31.5.2001, p. 43.]

(19) [X1OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).]

(20) [X1Commission 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) [X1Commission 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) [X1Commission 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) [X1Commission 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).]

(24) **[**[X1]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) **[**[X1]OJ C 364, 18.12.2000, p. 1.**]**

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).

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Point in time view as at 01/01/2020.

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.