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

Article 1	Aim and scope
Article 2	Application

CHAPTER 2

Definitions and general provision

Article 3	Definitions	
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TITLE II REGISTRATION OF SUBSTANCES

CHAPTER 1

General obligation to register and information requirements

Article 5	No data, no market
Article 6	General obligation to register substances on their own or in
	preparations
Article 7	Registration and notification of substances in articles
Article 8	Only representative of a non-Community manufacturer
Article 9	Exemption from the general obligation to register for product and
	process orientated research and development (PPORD)
Article 10	Information to be submitted for general registration purposes
Article 11	Joint submission of data by multiple registrants
Article 12	Information to be submitted depending on tonnage
Article 13	General requirements for generation of information on intrinsic
	properties of substances

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)

Article 14 Chemical safety report and duty to apply and recommend risk reduction measures

CHAPTER 2

Substances regarded as being registered

Article 15	Substances in plant protection and biocidal products
Article 16	Duties of the Commission, the Agency and registrants of
	substances regarded as being registered

CHAPTER 3

Obligation to register and information requirements for certain types of isolated intermediates

Article 17	Registration of on-site isolated intermediates
Article 18	Registration of transported isolated intermediates
Article 19	Joint submission of data on isolated intermediates by multiple
	registrants

CHAPTER 4

Common provisions for all registrations

Article 20	Duties of the Agency
Article 21	Manufacturing and import of substances
Article 22	Further duties of registrants

CHAPTER 5

Transitional provisions applicable to phase-in substances and notified substances

Article 23	Specific provisions for phase-in substances
Article 24	Notified substances

TITLE III

DATA SHARING AND AVOIDANCE OF UNNECESSARY TESTING

CHAPTER 1

Objectives and general rules

Article 25 Objectives and general rules

CHAPTER 2

Rules for non-phase-in substances and registrants of phase-in substances who have not pre-registered

Article 26	Duty to inquire prior to registration
Article 27	Sharing of existing data in the case of registered substances

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)

CHAPTER 3

	Rules for phase-in-substances
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	TITLE IV
	INFORMATION IN THE SUPPLY CHAIN
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Article 33 Article 34	Duty to communicate information on substances in articles Duty to communicate information on substances and preparations up the supply chain
Article 35 Article 36	Access to information for workers Obligation to keep information
	TITLE V
	DOWNSTREAM USERS
Article 37	Downstream user chemical safety assessments and duty to identify, apply and recommend risk reduction measures
Article 38 Article 39	Obligation for downstream users to report information Application of downstream user obligations
	TITLE VI
	EVALUATION
	CHAPTER 1
	Dossier evaluation
Article 40 Article 41	Examination of testing proposals Compliance check of registrations

CHAPTER 2

Check of information submitted and follow-up to dossier

Procedure and time periods for examination of testing proposals

Substance evaluation

Article 44	Criteria for substance evaluation
Article 45	Competent authority

evaluation

Article 42

Article 43

Status: Point in time view as at 12/10/2008.

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)

Article 46	Requests for further information and check of information submitted
Article 47 Article 48	Coherence with other activities Follow-up to substance evaluation
	CHAPTER 3
	Evaluation of intermediates
Article 49	Further information on on-site isolated intermediates
	CHAPTER 4
	Common provisions
Article 50 Article 51 Article 52 Article 53 Article 54	Registrants' and downstream users' rights Adoption of decisions under dossier evaluation Adoption of decisions under substance evaluation Cost sharing for tests without an agreement between registrants and/or downstream users Publication of information on evaluation
	TITLE VII
	AUTHORISATION
	CHAPTER 1
	Authorisation requirement
Article 55 Article 56 Article 57 Article 58 Article 59	Aim of authorisation and considerations for substitution General provisions Substances to be included in Annex XIV Inclusion of substances in Annex XIV Identification of substances referred to in Article 57
	CHAPTER 2
	Granting of authorisations
Article 60 Article 61 Article 62 Article 63 Article 64	Granting of authorisations Review of authorisations Applications for authorisations Subsequent applications for authorisation Procedure for authorisation decisions
	CHAPTER 3
	Authorisations in the supply chain
Article 65 Article 66	Obligation of holders of authorisations Downstream users

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)

TITLE VIII

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

CHAPTER 1

General issues

1 1 6	O 1	
Article 67	General	provisions

CHAPTER 2

Restrictions process

Article 68	Introducing new and amending current restrictions
Article 69	Preparation of a proposal
Article 70	Agency opinion: Committee for Risk Assessment
Article 71	Agency opinion: Committee for Socio-economic Analysis
Article 72	Submission of an opinion to the Commission
Article 73	Commission decision

TITLE IX

FEES AND CHARGES

Article 74 Fees and charges

TITLE X

AGENCY

Article 75	Establishment and review
Article 76	Composition
Article 77	Tasks
Article 78	Powers of the Management Board
Article 79	Composition of the Management Board
Article 80	Chairmanship of the Management Board
Article 81	Meetings of the Management Board
Article 82	Voting of the Management Board
Article 83	Duties and powers of the Executive Director
Article 84	Appointment of the Executive Director
Article 85	Establishment of the Committees
Article 86	Establishment of the Forum
Article 87	Rapporteurs of Committees and use of experts
Article 88	Qualification and interests
Article 89	Establishment of the Board of Appeal
Article 90	Members of the Board of Appeal
Article 91	Decisions subject to appeal
Article 92	Persons entitled to appeal, time-limits, fees and form
Article 93	Examination and decisions on appeal
Article 94	Actions before the Court of First Instance and the Court of Justice

Status: Point in time view as at 12/10/2008.

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)

Article 95 Article 96 Article 97 Article 98 Article 99 Article 100 Article 101 Article 102 Article 103 Article 104 Article 105 Article 106 Article 107 Article 108 Article 109 Article 110 Article 111	Conflicts of opinion with other bodies The budget of the Agency Implementation of the budget of the Agency Combating fraud Financial rules Legal personality of the Agency Liability of the Agency Privileges and immunities of the Agency Staff rules and regulations Languages Duty of confidentiality Participation of third countries Participation of international organisations Contacts with stakeholder organisations Rules on transparency Relations with relevant Community bodies Formats and software for submission of information to the Agency
	TITLE XI
	CLASSIFICATION AND LABELLING INVENTORY
Article 112 Article 113 Article 114 Article 115 Article 116	Scope Obligation to notify the Agency Classification and labelling inventory Harmonisation of classification and labelling Transitional arrangements
	TITLE XII
	INFORMATION
Article 117 Article 118 Article 119 Article 120	Reporting Access to information Electronic public access Cooperation with third countries and international organisations
	TITLE XIII
	COMPETENT AUTHORITIES
Article 121 Article 122 Article 123 Article 124	Appointment Cooperation between competent authorities Communication to the public of information on risks of substances Other responsibilities

Status: Point in time view as at 12/10/2008.

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)

TITLE XIV

ENFORCEMENT

Article 125	Tasks of the Member States
Article 126	Penalties for non-compliance
Article 127	Report

TITLE XV

TRANSITIONAL AND FINAL PROVISIONS

Article 128	Free movement
Article 129	Safeguard clause
Article 130	Statement of reasons for decisions
Article 131	Amendments to the Annexes
Article 132	Implementing legislation
Article 133	Committee procedure
Article 134	Preparation of establishment of the Agency
Article 135	Transitional measures regarding notified substances
Article 136	Transitional measures regarding existing substances
Article 137	Transitional measures regarding restrictions
Article 138	Review
Article 139	Repeals
Article 140	Amendment of Directive 1999/45/EC
Article 141	Entry into force and application
	Signature

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 ecotoxicological properties are likely to...
- 0.5. The chemical safety assessment shall be based on the information...
- 0.6. A chemical safety assessment performed by a manufacturer or an...
- 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...
- 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

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)

1.0. Introduction

- 1.0.1. The objective 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 and labelling developed in accordance with the...
 - 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 and labelling developed in accordance with the...

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 and labelling developed in accordance with the...
 - 3.2.2. If the information are inadequate to decide whether a substance...
- 3.3. Step 3: Identification of the PNEC
 - 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

Document Generated: 2024-06-20

Status: Point in time view as at 12/10/2008.

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)

- 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...
- 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
 - 2.1. Manufacture
 - 2.2. Identified uses
 - 2.3. Uses advised against
- 3. CLASSIFICATION AND LABELLING
- 4. ENVIRONMENTAL FATE PROPERTIES
 - 4.1. Degradation

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)

- 4.2. Environmental distribution
- 4.3. Bioaccumulation
- 4.4. Secondary poisoning
- HUMAN HEALTH HAZARD ASSESSMENT 5.
 - Toxicokinetics (absorption, metabolism, distribution and 5.1. elimination)
 - 5.2. Acute toxicity
 - 5.3. Irritation
 - 5.3.1. Skin
 - 5.3.2. Eye
 - 5.3.3. Respiratory tract
 - 5.4. Corrosivity
 - 5.5. Sensitisation
 - 5.5.1. Skin
 - 5.5.2. Respiratory system
 - 5.6. Repeated dose toxicity
 - 5.7. Mutagenicity
 - 5.8. Carcinogenicity
 - 5.9. Toxicity for reproduction
 - 5.9.1. Effects on fertility
 - 5.9.2. Developmental toxicity
 - 5.10. Other effects
 - Derivation of DNEL(s) 5.11.
- HEALTH **ASSESSMENT** OF 6. **HUMAN HAZARD** PHYSICOCHEMICAL PROPERTIES
 - 6.1. **Explosivity**
 - Flammability 6.2.
 - Oxidising potential 6.3.
- 7. ENVIRONMENTAL HAZARD ASSESSMENT
 - 7.1. Aquatic compartment (including sediment)
 - 7.2. Terrestrial compartment
 - 7.3. Atmospheric compartment
 - Microbiological activity in sewage treatment systems
- PBT AND VPVB ASSESSMENT 8.
- 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
 - (Title of exposure scenario 1) 10.1.
 - 10.1.1. Human health
 - 10.1.1.1.Workers
 - 10.1.1.2Consumers
 - 10.1.1.3Indirect exposure to humans via environment
 - 10.1.2. Environment
 - 10.1.2.1 Aquatic compartment (including sediment)
 - 10.1.2.2Terrestrial compartment
 - 10.1.2.3 Atmospheric compartment

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10.1.2.4Microbiological activity in sewage treatment systems

- (Title of exposure scenario 2) 10.2.
 - 10.2.1. Human health
 - 10 2 1 1 Workers
 - 10.2.1.2Consumers
 - 10.2.1.3Indirect 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
 - 10.2.2.4Microbiological 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

GUIDE TO THE COMPILATION OF SAFETY DATA SHEETS

This Annex sets out the requirements for a Safety Data...

The purpose of this Annex is to ensure consistency and...

The information provided by Safety Data Sheets shall also meet...

The information in the Safety Data Sheet shall be written...

For preparations not classified as dangerous, but for which a...

Additional information may be necessary in some cases in view...

Give the date of issue of the Safety Data Sheet...

Note

IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE 1. COMPANY/UNDERTAKING

- Identification of the substance or preparation 1.1.
- 1.2. Use of the substance/preparation
- 1.3. Company/undertaking identification
- 1.4. Emergency telephone

HAZARDS IDENTIFICATION 2

3. COMPOSITION/INFORMATION ON INGREDIENTS

- 3.1. It is not necessary to give the full composition (nature...
- For a preparation classified as dangerous according to Directive 1999/45/EC,... 3.2.
- For a preparation not classified as dangerous according to Directive... 3.3.
- 3.4. The classification (derived either from Articles 4 and 6 of...
- 3.5. The name and the Registration number, assigned under Article 20(1)...
- 3.6. If, in accordance with the provisions of Article 15 of...

4. FIRST AID MEASURES

Status: Point in time view as at 12/10/2008. 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)

ACCIDENTAL RELEASE MEASURES 6.

Note

HANDLING AND STORAGE 7.

Note

- 7.1. Handling
- 7.2. Storage
- Specific use(s) 7.3.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

- 8.1. Exposure limit values
- 8.2. Exposure controls
 - 8.2.1. Occupational exposure controls
 - 8.2.2. Environmental exposure controls

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. General information

Appearance:

Odour:

- Important health, safety and environmental information 9.2.
- 9.3. Other information

Note 1

Note 2

10. STABILITY AND REACTIVITY

- Conditions to avoid 10.1.
- 10.2. Materials to avoid
- Hazardous decomposition products 10.3.

Note

11. TOXICOLOGICAL INFORMATION

ECOLOGICAL INFORMATION 12.

- 12.1. **Ecotoxicity**
- 12.2. Mobility
- 12.3. Persistence and degradability
- Bioaccumulative potential 12.4.
- Results of PBT assessment 12.5.
- 12.6. Other adverse effects

Remarks

13. **DISPOSAL CONSIDERATIONS** Note

- 14. TRANSPORT INFORMATION
- 15. REGULATORY INFORMATION
- 16. OTHER INFORMATION

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)

ANNEX III

CRITERIA FOR SUBSTANCES REGISTERED IN QUANTITIES BETWEEN 1 AND 10 TONNES

Criteria for substances registered between 1 and 10 tonnes, with... substances for which it is predicted (ie 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 and biogas.
- 13. Hydrogen and oxygen.

ANNEX VI

INFORMATION REQUIREMENTS REFERRED TO IN ARTICLE 10

GUIDANCE NOTE ON FULFILLING THE REQUIREMENTS OF ANNEXES VI TO...

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)

- 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
 - 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 (ultra-violet, infra-red, nuclear magnetic resonance or mass spectrum)...
 - 2.3.6. High-pressure liquid chromatogram, gas chromatogram
 - 2.3.7. 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, preparation 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 Safety Data Sheet heading 16)
- 4. CLASSIFICATION AND LABELLING
 - 4.1. The hazard classification of the substance(s), resulting from the application...

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)

- 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)
 - 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...

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

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)

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...

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...

- 8. TOXICOLOGICAL INFORMATION Annex VIII Table 1
- 9. ECOTOXICOLOGICAL INFORMATION Annex VIII Table 2

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...

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...

Status: Point in time view as at 12/10/2008.

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)

Column 1 of this Annex establishes the standard information required...

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...

- 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...

- 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 Commission shall adopt the measures designed to amend non-essential...

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

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)

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:... persistent, bioaccumulative and toxic substances (PBT-substances), and very persistent and...

A substance is identified as a PBT substance if it...

- 1. PBT-SUBSTANCES
 - 1.1 Persistence
 - 1.2. Bioaccumulation
 - 1.3. Toxicity
- 2. vPvB-SUBSTANCES
 - 2.1. Persistence
 - 2.2. Bioaccumulation

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

Status: Point in time view as at 12/10/2008.

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)

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, PREPARATIONS AND ARTICLES

Appendices 1 to 6

FOREWORD

Explanations of column headings

Substances:

Index number:

EINECS number:

ELINCS number

CAS number:

Notes:

Note A:

Note C:

Note D.

Note E:

Note H:

Note J:

Note K:

Note L:

Note M:

Note N:

Note P:

Note R:

Note S:

Status: Point in time view as at 12/10/2008. 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)

Appendix 1

Point 28 — Carcinogens: category 1

Appendix 2

Point 28 — Carcinogens: category 2

Appendix 3

Point 29 — Mutagens: category 1

Appendix 4

Point 29 — Mutagens: category 2

Appendix 5

Point 30 — Toxic to reproduction: category 1

Appendix 6

Point 30 — Toxic to reproduction: category 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
 - The following particulars shall appear on clearly legible and indelible... 3.1.
 - 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...

Status: Point in time view as at 12/10/2008.

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)

Appendix 8

Point 43 — Azocolourants

List of aromatic amines Annex XVII Table 7

Appendix 9

Point 43 — Azocolourants

List of azodyes Annex XVII Table 8

Appendix 10

Point 43 — Azocolourants

List of testing methods Annex XVII Table 9

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) [XIOpinion 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) [XIOJ 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) [XIOJ 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) [XIOJ 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) [XIOJ 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) [XIOJ 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) $[^{X1}OJ L 50, 20.2.2004, p. 44.]$
- (13) [X1OJ L 357, 31.12.2002, p. 72.]
- (14) $[^{XI}OJL\ 136, 30.4.2004, p.\ 1.$ Regulation as amended by Regulation (EC) No 1901/2006 (OJ L 378, 27.12.2006, p. 1).]
- (15) [XIOJ 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) [XIOJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).]
- (20) [XICommission 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) [XICommission 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) [XICommission 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).]

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)

- [24] [XICommission 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) [X1OJ 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 12/10/2008.

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.