

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 2A	The Agency
Article 2B	Advice from Environment Agency or other environmental regulators to Agency
Article 3	Definitions
Article 4	General provision
Article 4A	The consent requirement

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 mixtures
Article 7	Registration and notification of substances in articles
Article 8	Only representative of a non-Great British 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
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 ... 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 registrants of substances

- Article 26 Duty to inquire prior to registration

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 27 Sharing of existing data in the case of registered substances

CHAPTER 3

Rules for phase-in-substances

Article 28 Duty to pre-register for phase-in substances

Article 29 Substance Information Exchange Forums

Article 30 Sharing of data involving tests

TITLE IV

INFORMATION IN THE SUPPLY CHAIN

Article 31 Requirements for safety data sheets

Article 32 Duty to communicate information down the supply chain for substances on their own or in mixtures for which a safety data sheet is not required

Article 33 Duty to communicate information on substances in articles

Article 34 Duty to communicate information on substances and mixtures up the supply chain

Article 35 Access to information for workers

Article 36 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 Obligation for downstream users to report information

Article 39 Application of downstream user obligations

TITLE VI

EVALUATION

CHAPTER 1

Dossier evaluation

Article 40 Examination of testing proposals

Article 41 Compliance check of registrations

Article 42 Check of information submitted and follow-up to dossier evaluation

Article 43 Procedure and time periods for examination of testing proposals

CHAPTER 2

Substance evaluation

- Article 44 Criteria for substance evaluation
- Article 45 Evaluation of substances on the rolling action plan
- Article 46 Requests for further information and check of information submitted
- Article 47 Coherence with other activities
- Article 48 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 Registrants' and downstream users' rights
- Article 51 Adoption of decisions under dossier evaluation
- Article 52 Adoption of decisions under substance evaluation
- Article 53 Cost sharing for tests without an agreement between registrants and/or downstream users
- Article 54 Publication of information on evaluation

TITLE VII

AUTHORISATION

CHAPTER 1

Authorisation requirement

- Article 55 Aim of authorisation and considerations for substitution
- Article 56 General provisions
- Article 57 Substances to be included in Annex XIV
- Article 58 Inclusion of substances in Annex XIV
- Article 59 Identification of substances referred to in Article 57

CHAPTER 2

Granting of authorisations

- Article 60 Granting of authorisations
- Article 61 Review of authorisations
- Article 62 Applications for authorisations
- Article 63 Subsequent applications for authorisation
- Article 64 Procedure for authorisation decisions

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

Authorisations in the supply chain

- Article 65 Obligation of holders of authorisations
- Article 66 Downstream users

TITLE VIII

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

CHAPTER 1

General issues

- 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: risk assessment
- Article 71 Agency opinion: socio-economic analysis
- Article 72 Submission of an opinion to the appropriate authorities
- Article 73 Restriction decisions

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 Annual report by the Agency to the appropriate authorities
- Article 84 Appointment of the Executive Director
- Article 85 Establishment of the Committees
- Article 86 Establishment of the Forum

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 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 ...
Article 93	Change of decision where appeal made
Article 94	Actions before the Court of First Instance and the Court of Justice
Article 95	Conflicts of opinion with other bodies
Article 96	The budget of the Agency
Article 97	Implementation of the budget of the Agency
Article 98	Combating fraud
Article 99	Financial rules
Article 100	Legal personality of the Agency
Article 101	Liability of the Agency
Article 102	Privileges and immunities of the Agency
Article 103	Staff rules and regulations
Article 104	Languages
Article 105	Duty of confidentiality
Article 106	Participation of third countries
Article 107	Participation of international organisations
Article 108	Contacts with stakeholder organisations
Article 109	Rules on transparency
Article 110	Relations with relevant public bodies
Article 111	Formats and software for submission of information to the Agency

TITLE XI

CLASSIFICATION AND LABELLING INVENTORY

Article 112	Scope
Article 113	Obligation to notify the Agency
Article 114	Classification and labelling inventory
Article 115	Harmonisation of classification and labelling
Article 116	Transitional arrangements

TITLE XII

INFORMATION

Article 117	Reporting
Article 118	Access to information
Article 119	Electronic public access
Article 120	Cooperation with other countries and international organisations

TITLE XIII

PROVISION OF INFORMATION

Article 121	Appointment
-------------	-------------

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 122	Cooperation between competent authorities
Article 123	Communication to the public of information on risks of substances
Article 124	Other responsibilities

TITLE XIV ENFORCEMENT

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

TITLE 14A EU WITHDRAWAL: TRANSITIONAL PROVISION

Article 127A	Existing EU registrations which have effect as GB registrations
Article 127B	Application of this Regulation to transferred GB registrations
Article 127C	Decisions of ECHA relating to existing EU registrations
Article 127D	Interpretation of Articles 127A to 127C
Article 127E	Pre-IP completion downstream users and distributors that are to continue to be regarded as downstream users
Article 127EA	Appointment of only representative where Article 127E applies
Article 127EB	Import from Northern Ireland where Article 127E applies
Article 127F	Existing EU authorisations
Article 127G	Existing applications for EU authorisations
Article 127GA	Substances of very high concern: sunset dates and latest application dates
Article 127H	Existing authorised downstream users under EU law
Article 127I	Existing examinations of testing proposals
Article 127J	Existing Article 7(2) notifications
Article 127K	Existing Article 9 exemptions
Article 127L	Existing Article 17 registrations
Article 127M	Existing Article 18 registrations
Article 127N	Registrations under Article 127L and Article 127M
Article 127O	Obligation to keep information
Article 127P	Post-IP completion periods used in this Title

TITLE XV ... 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 132A	Regulations under this Regulation
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

TITLE 15A

IMPORTS FROM NORTHERN IRELAND

Article 139A	Protected NI imports
Article 139B	Notification by Northern Irish supplier where Article 139A applies
Article 139C	Authorisations and imports from Northern Ireland
Article 139D	Authorisations and qualifying Northern Ireland goods
Article 139E	Application of Article 127G to qualifying Northern Ireland goods
	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 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...
 - 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...

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)

- 1.0.2. 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
 - 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
- 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

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)

- 4.3. 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
 - 10.1.1.1Workers
 - 10.1.1.2Consumers
 - 10.1.1.3Indirect exposure to humans via the environment
 - 10.1.2. Environment
 - 10.1.2.1Aquatic compartment (including sediment)
 - 10.1.2.2Terrestrial compartment
 - 10.1.2.3Atmospheric compartment
 - 10.1.2.4Microbiological 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
- 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

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)

- 1.4. 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
 - 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 Regulation (EU) 2016/425 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
 - 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

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)

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

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)

- 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)
 - 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:

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)

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...

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

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)

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...
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

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...

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)

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 ...
 - 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

1. In this Annex “competent appropriate authority”, in relation...

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 .../category 1 ...

Appendix 2

Entry 28 — Carcinogens: category 1B .../category 2 ...

Appendix 3

Entry 29 — Mutagens: category 1A .../category 1 ...

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 4

Entry 29 — Mutagens: category 1B .../category 2 ...

Appendix 5

Entry 30 — Toxic to reproduction: category 1A .../category 1 ...

Appendix 6

Entry 30 — Toxic to reproduction: category 1B .../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
 - 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 legislation on safety and hygiene at work,...
6. The labelling of any article intended for domestic use which...
7. The labelling of articles containing asbestos shall be in English,...

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

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 10

Entry 43 List of testing methods
Annex XVII Table 9

Appendix 11

Appendix 12

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

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) [^{XI}[OJ C 112, 30.4.2004, p. 92](#) and [OJ C 294, 25.11.2005, p. 38.](#)]
- (2) [^{XI}[OJ C 164, 5.7.2005, p. 78.](#)]
- (3) [^{XI}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) [^{XI}[OJ L 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) [^{XI}[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) [^{XI}[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) [^{XI}[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) [^{XI}[OJ L 158, 30.4.2004, p. 50](#), corrected in [OJ L 229, 29.6.2004, p. 23](#).]
- (9) [^{XI}[OJ L 131, 5.5.1998, p. 11](#).]
- (10) [^{XI}[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) [^{XI}[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) [^{XI}[OJ L 50, 20.2.2004, p. 44](#).]
- (13) [^{XI}[OJ L 357, 31.12.2002, p. 72](#).]
- (14) [^{XI}[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) [^{XI}[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) [^{XI}[OJ C 218, 13.9.2003, p. 1](#).]
- (17) [^{XI}[OJ L 41, 14.2.2003, p. 26](#).]
- (18) [^{XI}[OJ L 145, 31.5.2001, p. 43](#).]
- (19) [^{XI}[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) [^{XI}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) [^{XI}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) [^{XI}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) [^{XI}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](#)).]

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) [^{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 \(Official Journal of the European Union L 396 of 30 December 2006\)](#).

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.