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 for substances manufactured or imported in quantities of 1 tonne or more.

Any other relevant physicochemical, toxicological and ecotoxicological information that is available shall be provided. For substances not meeting the criteria in Annex III only the physicochemical requirements as set out in section 7 of this Annex are required.

Column 2 of this Annex lists specific rules according to which the required standard information may be omitted, replaced by other information, provided at a different stage or adapted in another way. If the conditions are met under which column 2 of this Annex allows adaptations, the registrant shall clearly state this fact and the reasons for each adaptation under the appropriate headings in the registration dossier.

In addition to these specific rules, a registrant may adapt the required standard information set out in column 1 of this Annex according to the general rules contained in Annex XI with the exception of Section 3 on substance-tailored exposure waiving. In this case as well, he shall clearly state the reasons for any decision to adapt the standard information under the appropriate headings in the registration dossier referring to the appropriate specific rule(s) in column 2 or in Annex XI.

Before new tests are carried out to determine the properties listed in this Annex, all available in vitro data, in vivo data, historical human data, data from valid (Q)SARs and data from structurally related substances (read-across approach) shall be assessed first. In vivo testing with corrosive substances at concentration/dose levels causing corrosivity shall be avoided. Prior to testing, further guidance on testing strategies should be consulted in addition to this Annex.

When, for certain endpoints, information is not provided for other reasons than those mentioned in column 2 of this Annex or in Annex XI, this fact and the reasons shall also be clearly stated.

7. INFORMATION ON THE PHYSICOCHEMICAL PROPERTIES OF THE SUBSTANCE	
COLUMN 1 **STANDARD INFORMATION REQUIRED**	**COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1**
7.1. State of the substance at 20 °C and 101,3 kPa	
7.2. Melting/freezing point	7.2. The study does not need to be conducted below a lower limit of - 20 °C.
7.3. Boiling point	7.3. The study does not need to be conducted: — for gases, or

	— for solids which either melt above 300 °C or decompose before boiling. In such cases the boiling point under reduced pressure may be estimated or measured, or — for substances which decompose before boiling (e.g. auto- oxidation, rearrangement, degradation, decomposition, etc.).
7.4. Relative density	7.4. The study does not need to be conducted if: — the substance is only stable in solution in a particular solvent and the solution density is similar to that of the solvent. In such cases, an indication of whether the solution density is higher or lower than the solvent density is sufficient, or — the substance is a gas. In this case, an estimation based on calculation shall be made from its molecular weight and the Ideal Gas Laws.
7.5. Vapour pressure	7.5. The study does not need to be conducted if the melting point is above 300 °C. If the melting point is between 200 °C and 300 °C, a limit value based on measurement or a recognised calculation method is sufficient.
7.6. Surface tension	7.6. The study need only be conducted if: — based on structure, surface activity is expected or can be predicted, or — surface activity is a desired property of the material. If the water solubility is below 1 mg/l at 20 °C the test does not need to be conducted.
7.7. Water solubility	7.7. The study does not need to be conducted if: — the substance is hydrolytically unstable at pH 4, 7 and 9 (half-life less than 12 hours), or — the substance is readily oxidisable in water. If the substance appears ‘insoluble’ in water, a

	limit test up to the detection limit of the analytical method shall be performed.
7.8. Partition coefficient (n-octanol/water)	7.8. The study does not need to be conducted if the substance is inorganic. If the test cannot be performed (e.g. the substance decomposes, has a high surface activity, reacts violently during the performance of the test or does not dissolve in water or in octanol, or it is not possible to obtain a sufficiently pure substance), a calculated value for log P as well as details of the calculation method shall be provided.
7.9. Flash-point	7.9. The study does not need to be conducted if: — the substance is inorganic, or — the substance only contains volatile organic components with flash-points above 100 °C for aqueous solutions, or — the estimated flash-point is above 200 °C, or — the flash-point can be accurately predicted by interpolation from existing characterised materials.
7.10. Flammability	7.10. The study does not need to be conducted: — if the substance is a solid which possesses explosive or pyrophoric properties. These properties should always be considered before considering flammability, or — for gases, if the concentration of the flammable gas in a mixture with inert gases is so low that, when mixed with air, the concentration is all time below the lower limit, or — for substances which spontaneously ignite when in contact with air.
7.11. Explosive properties	7.11. The study does not need to be conducted if:

	— there are no chemical groups associated with explosive properties present in the molecule, or — the substance contains chemical groups associated with explosive properties which include oxygen and the calculated oxygen balance is less than -200, or — the organic substance or a homogenous mixture of organic substances contains chemical groups associated with explosive properties, but the exothermic decomposition energy is less than 500 J/g and the onset of exothermic decomposition is below 500 °C, or — for mixtures of inorganic oxidising substances (UN Division 5.1) with organic materials, the concentration of the inorganic oxidising substance is: — less than 15 %, by mass, if assigned to UN Packaging Group I (high hazard) or II (medium hazard), — less than 30 %, by mass, if assigned to UN Packaging Group III (low hazard). Note: Neither a test for propagation of detonation nor a test for sensitivity to detonative shock is required if the exothermic decomposition energy of organic materials is less than 800 J/g.
7.12. Self-ignition temperature	7.12. The study does not need to be conducted: — if the substance is explosive or ignites spontaneously with air at room temperature, or — for liquids non flammable in air, e.g. no flash point up to 200 °C, or — for gases having no flammable range, or — for solids, if the substance has a melting point ≤ 160 °C, or if preliminary results exclude self-heating of the substance up to 400 °C.

7.13. Oxidixing properties	7.13. The study does not need to be conducted if: — the substance is explosive, or — the substance is highly flammable, or — the substance is an organic peroxide, or — the substance is incapable of reacting exothermically with combustible materials, for example on the basis of the chemical structure (e.g. organic substances not containing oxygen or halogen atoms and these elements are not chemically bonded to nitrogen or oxygen, or inorganic substances not containing oxygen or halogen atoms). The full test does not need to be conducted for solids if the preliminary test clearly indicates that the test substance has oxidising properties. Note that as there is no test method to determine the oxidising properties of gaseous mixtures, the evaluation of these properties must be realised by an estimation method based on the comparison of the oxidising potential of gases in a mixture with that of the oxidising potential of oxygen in air.
7.14. Granulometry	7.14. The study does not need to be conducted if the substance is marketed or used in a non solid or granular form.
8. TOXICOLOGICAL INFORMATION	
8.1. Skin corrosion/irritation	8.1. The study/ies do(es) not need to be conducted if: — the substance is a strong acid (pH ≤ 2,0) or base (pH ≥ 11,5) and the available information indicates that it should be classified as skin corrosion (Category 1), or

	— the substance is spontaneously flammable in air or in contact with water or moisture at room temperature, or — the substance is classified as acute toxicity by the dermal route (Category 1), or — an acute toxicity study by the dermal route does not indicate skin irritation up to the limit dose level (2 000 mg/kg body weight). If results from one of the two studies under point 8.1.1 or 8.1.2 already allow a conclusive decision on the classification of a substance or on the absence of skin irritation potential, the second study need not be conducted.
8.1.1 Skin corrosion, in vitro 8.1.2 Skin irritation, in vitro	
8.2. Serious eye damage/eye irritation	8.2. The study/ies do(es) not need to be conducted if: — the substance is classified as skin corrosion, leading to classification as serious eye damage (Category 1), or — the substance is classified as skin irritation and the available information indicates that it should be classified as eye irritation (Category 2), or — the substance is a strong acid (pH ≤ 2,0) or base (pH ≥ 11,5) and the available information indicates that it should be classified as serious eye damage (Category 1), or — the substance is spontaneously flammable in air or in contact with water or moisture at room temperature.
8.2.1 Serious eye damage/eye irritation, in vitro	8.2.1. If results from a first in vitro study do not allow a conclusive decision on the classification of a substance or on the absence of eye irritation potential, (an)other in vitro study/ies) for this endpoint shall be considered.

8.3. Skin sensitisation Information allowing: — a conclusion whether the substance is a skin sensitiser and whether it can be presumed to have the potential to produce significant sensitisation in humans (Cat. 1A), and — risk assessment, where required.	The study(ies) under point 8.3.1 and 8.3.2 do not need to be conducted if: — the substance is classified as skin corrosion (Category 1), or — the substance is a strong acid (pH ≤ 2,0) or base (pH ≥ 11,5), or — the substance is spontaneously flammable in air or in contact with water or moisture at room temperature.
8.3.1. Skin sensitisation, in vitro/in chemico Information from in vitro/in chemico test method(s) recognised according to Article 14(3), addressing each of the following key events of skin sensitisation: (a) molecular interaction with skin proteins; (b) inflammatory response in keratinocytes; (c) activation of dendritic cells.	The(se) test(s) do not need to be conducted if: — an in vivo study according to point 8.3.2 is available, or — the available in vitro/in chemico test methods are not applicable for the substance or are not adequate for classification and risk assessment according to point 8.3. If information from test method(s) addressing one or two of the key events in column 1 already allows classification and risk assessment according to point 8.3, studies addressing the other key event(s) need not be conducted.
8.3.2 Skin sensitisation, in vivo	An in vivo study shall be conducted only if in vitro/in chemico test methods described under point 8.3.1 are not applicable, or the results obtained from those studies are not adequate for classification and risk assessment according to point 8.3. The murine local lymph node assay (LLNA) is the first-choice method for in vivo testing. Only in exceptional circumstances should another test be used. Justification for the use of another in vivo test shall be provided.

	In vivo skin sensitisation studies that were carried out or initiated before 11 November 2016, and that meet the requirements set out in Article 14(3) and Article 14(4) shall be considered appropriate to address this standard information requirement.
8.4. Mutagenicity 8.4.1. In vitro gene mutation study in bacteria	8.4. Further mutagenicity studies shall be considered in case of a positive result.
8.5. Acute toxicity 8.5.1. By oral route	8.5. The study/ies do(es) not generally need to be conducted if: — the substance is classified as corrosive to the skin. The study need not be conducted if a study on acute toxicity by the inhalation route (8.5.2) is available.
9. ECOTOXICOLOGICAL INFORMATION	
9.1. Aquatic toxicity 9.1.1. Short-term toxicity testing on invertebrates (preferred species *Daphnia*) The registrant may consider long-term toxicity testing instead of short-term.	9.1.1. The study does not need to be conducted if: — there are mitigating factors indicating that aquatic toxicity is unlikely to occur, for instance if the substance is highly insoluble in water or the substance is unlikely to cross biological membranes, or — a long-term aquatic toxicity study on invertebrates is available, or — adequate information for environmental classification and labelling is available.

9.1.2. Growth inhibition study aquatic plants (algae preferred)	The long-term aquatic toxicity study on *Daphnia* (Annex IX, section 9.1.5) shall be considered if the substance is poorly water soluble. 9.1.2. The study does not need to be conducted if there are mitigating factors indicating that aquatic toxicity is unlikely to occur for instance if the substance is highly insoluble in water or the substance is unlikely to cross biological membranes.
9.2. Degradation 9.2.1. Biotic 9.2.1.1. Ready biodegradability	9.2.1.1. The study does not need to be conducted if the substance is inorganic.

Any other relevant physicochemical, toxicological and ecotoxicological information that is available shall be provided.