[X1ANNEX VII

STANDARD INFORMATION REQUIREMENTS FOR SUBSTANCES MANUFACTURED OR IMPORTED IN QUANTITIES OF ONE TONNE OR MORE (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).

8. TOXICOLOGICAL INFORMATION

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
[F1 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:

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, Division 8. . (See end of Document for details)*

	— 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.**]**
[X2 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 13(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 10 May 2017 , and that meet the requirements set out in Article 13(3), first subparagraph, and Article 13(4) shall be considered appropriate to address this standard information requirement.**]**
8.4. Mutagenicity	8.4. Further mutagenicity studies shall be considered in case of a positive result.
[F2 8.4.1. *In vitro* gene mutation study in bacteria	8.4.1. The study does not need to be conducted for nanoforms where it is not appropriate. In this case other studies involving one or more *in vitro* mutagenicity study(ies) in mammalian cells (Annex VIII, sections 8.4.2. and 8.4.3 or other internationally recognised *in vitro* methods) shall be provided.**]**
8.5. Acute toxicity	8.5. The study/ies do(es) not generally need to be conducted if: — the substance is classified as corrosive to the skin.
[F2 8.5.1. By oral route	8.5.1. The study need not be conducted if a study on acute toxicity by the inhalation route (8.5.2) is available. For nanoforms, a study by the oral route shall be replaced by a study by the inhalation route (8.5.2), unless exposure of humans via inhalation is unlikely, taking into account the possibility of exposure to aerosols, particles or droplets of an inhalable size.**]]**

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, Division 8. . (See end of Document for details)*

(1) **[**[X1]This Annex shall apply to producers of articles that are required to register in accordance with Article 7 and to other downstream users that are required to carry out tests under this Regulation adapted as necessary.**]**

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