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COVER NOTE

From:	European Commission
date of receipt:	30 November 2016
To:	General Secretariat of the Council
No. Cion doc.:	D048510_01 ANNEX
Subject:	COMMISSION REGULATION (EU) …/… of XXX amending Annex VII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards skin sensitisation and repealing Commission Regulation (EU) 2016/1688

Delegations will find attached document D048510_01 ANNEX.

Encl.: D048510_01 ANNEX

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ANNEX

Point 8.3. of Annex VII shall be replaced by the following:

"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	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 to be conducted.

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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 [date of entry into force], 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."