

EN

ANNEX

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

"8.3. Skin sensitisation	The study does not need to be conducted if:  — the substance is classified as skin corrosion (Category 1), or — the substance is a strong acid ( $\text{pH} \leq 2,0$ ) or base ( $\text{pH} \geq 11,5$ ), or — the substance is spontaneously flammable in air or in contact with water or moisture at room temperature.
8.3.1. Skin sensitisation, <i>in vivo</i> .	The study does not need to be conducted if sufficient information is available from non-animal approaches that is adequate  - for classification, including an assessment whether the substance can be presumed to have the potential to produce significant sensitisation in humans; and  - risk assessment, where required.  The Murine Local Lymph Node Assay (LLNA) is the first-choice method for <i>in vivo</i> testing. Only in exceptional circumstances should another test be used. Justification for the use of another <i>in vivo</i> test shall be provided."