Integrated testing strategy for skin sensitisation under REACH

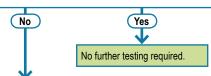
The substance¹ is manufactured or imported in quantities ≥ 1 tonne per year

The available information indicates that the substance should be classified for skin sensitisation or corrosivity;

the substance is a strong acid (pH < 2,0) or base (pH > 11,5);

OR

the substance is spontaneously flammable in air at room temperature.



Perform² in vivo study for skin sensitisation.

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 test shall be provided.

No further testing required.

^{2.} A registrant may adapt the standard testing regime in accordance with the general rules set out in annexe XI section 1 (Testing does not appear scientifically necessary) and 2 (Testing is technically not possible). Under dossier evaluation the Agency may assess these adaptations to the standard testing regime.





^{1.} The substances concerned are:

a. non-phase-in substances manufactured or imported in quantities of 1 to 10 tonnes;

b. phase-in substances manufactured or imported in quantities of 1 to 10 tonnes and meeting the criteria in annexe III;

c. phase-in substances not meeting the criteria in annexe III and manufactured or imported in quantities of 10 tonnes or more.