

STUDY OUTLINE
SKIN SENSITIZATION: LOCAL LYMPH NODE ASSAY IN MICE
(OECD 429)

<i>Purpose:</i>	Identification of skin sensitizing substances and measure the proliferation of lymphocytes isolated from the lymph nodes draining the site of exposure (ears) in mice (by determining the incorporation of ³ H-methylthymidine (³ HTdR) by liquid scintillation). The LLNA studies the induction phase of skin sensitization and provides quantitative data suitable for dose-response assessment.
<i>Test item:</i>	All available information on the test substance prior to conducting the study
<i>Test system:</i>	Mice (CBA/Ca Ola Hsd) – females - 8-12 weeks old
<i>Number of animals:</i>	4 mice /treatment groups –maximum 6 groups (including controls)
<i>Treatment:</i>	Topically (on the ears) – Once daily on three consecutive days
<i>Observation period:</i>	Daily (from Day 0 to Day 6)
<i>Observations:</i>	Mortality: at least once daily Clinical signs, irritation: individual observation at least once daily for 6 days; Body weight: on Day 1 and Day 6
<i>Sample processing:</i>	2-3 days
<i>Data treatment:</i>	In case of individual measurements, statistical evaluation of the data
<i>Report:</i>	Original and an electronic report in PDF format
<i>GLP:</i>	Compliant
<i>Archiving:</i>	Study Plan, Amendment(s), Original Final report and all raw data for 15 years; One sample of the test item for 5 years; Biological samples for 12 years;
<i>References:</i>	Study plan will specify which of the following guidelines will be followed: OECD guideline 429 Skin sensitization: Local Lymph Node Assay, Adopted 22 th July 2010 EC Directive 2004/73/EC B.42 Skin Sensitisation: Local lymph node assay EPA Guideline 712-C-03-197: OPPTS 870.2600, “Skin Sensitization” March 2003
<i>Timing:</i>	Pre-experimental period: at least five days acclimatization; Experimental period: 7-8 days Issue of draft report: 4 weeks after the termination of experimental period