

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

- Purpose:* 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 ³H-methylthymidine (³HTdR) by liquid scintillation). The LLNA studies the induction phase of skin sensitization and provides quantitative data suitable for dose-response assessment.
- Test item:* All available information on the test substance prior to conducting the study
- Test system:* Mice (CBA/Ca Ola Hsd) – females - 8-12 weeks old
- Number of animals:* 4 mice /treatment groups –maximum 6 groups (including controls)
- Treatment:* Topically (on the ears) – Once daily on three consecutive days
- Observation period:* Daily (from Day 0 to Day 6)
- Observations:* 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
- Sample processing:* 2-3 days
- Data treatment:* In case of individual measurements, statistical evaluation of the data
- Report:* Original and an electronic report in PDF format
- GLP:* Compliant
- Archiving:* 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;
- References:* Study plan will specify which of the following guidelines will be followed:
OECD guideline 429 Skin sensitization: Local Lymph Node Assay, Adopted 22th 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
- Timing:* 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