

## 12.0 References

- Basketter D, Patlewicz G, Gerberick F, Ryan C, Kern P, Betts C, et al. 2007. Identification of skin sensitizing chemicals in a reduced LLNA. [Abstract]. *Toxicologist* 96:236.
- Basketter DA. 2007. Integrated systems and a modified local lymph node assay [Abstract]. *Toxicologist* 96:124.
- Basketter DA, Sanders D, Jowsey IR. 2007. The skin sensitization potential of resorcinol: Experience with the local lymph node assay. *Contact Dermatitis* 56:196–200.
- Basketter DA, Smith Pease CK, Patlewicz GY. 2003. Contact allergy: The local lymph node assay for the prediction of hazard and risk. *Clin Exp Dermatol* 28:218–221.
- Chaney J, Ryan C, Kern P, Patlewicz G, Basketter D, Betts C, et al. 2007. The impact of reducing animal numbers in the local lymph node assay. [Abstract]. *Toxicologist* 96:236.
- Dearman RJ, Betts CJ, Farr C, McLaughlin J, Berdasco N, Wiench K, et al. 2007. Comparative analysis of skin sensitization potency of acrylates (methyl acrylate, ethyl acrylate, butyl acrylate, and ethylhexyl acrylate) using the local lymph node assay. *Contact Dermatitis* 57:242–247.
- EPA. 2003. Health Effects Test Guideline, OPPTS 870.2600. Skin Sensitization EPA 712–C–03–197. Washington, DC: U.S. Environmental Protection Agency. Available: [http://www.epa.gov/opptsfrs/publications/OPPTS\\_Harmonized/870\\_Health\\_Effects\\_Test\\_Guidelines/Revised/870r-2600.pdf](http://www.epa.gov/opptsfrs/publications/OPPTS_Harmonized/870_Health_Effects_Test_Guidelines/Revised/870r-2600.pdf).
- EPA. 2006a. Good Laboratory Practice Standards. Toxic Substances Control Act. 40 CFR 792. Available: [http://www.access.gpo.gov/nara/cfr/waisidx\\_06/40cfr792\\_06.html](http://www.access.gpo.gov/nara/cfr/waisidx_06/40cfr792_06.html).
- EPA. 2006b. Good Laboratory Practice Standards. Federal Insecticide, Fungicide, and Rodenticide Act. 40 CFR 160. [http://www.access.gpo.gov/nara/cfr/waisidx\\_06/40cfr160\\_06.html](http://www.access.gpo.gov/nara/cfr/waisidx_06/40cfr160_06.html).
- ESAC. 2007. Statement on the Reduced Local Lymph Node Assay (rLLNA). European Commission Directorate General, Joint Research Centre, Institute for Health and Consumer Protection, European Centre for the Validation of Alternative Methods, April 2007. Available: [http://ecvam.jrc.it/ft\\_doc/ESAC26\\_statement\\_rLLNA\\_20070525-1.pdf](http://ecvam.jrc.it/ft_doc/ESAC26_statement_rLLNA_20070525-1.pdf)
- FDA. 2007a. Good laboratory practice for nonclinical laboratory studies. 21 CFR 58.
- Gerberick GF, Ryan CA, Kern PS, Schlatter H, Dearman RJ, Kimber I, et al. 2005. Compilation of historical local lymph node data for evaluation of skin sensitization alternative methods. *Dermatitis* 16:157–202.
- ICCVAM. 1997. Validation and Regulatory Acceptance of Toxicological Test Methods: A Report of the ad hoc Interagency Coordinating Committee on the Validation of Alternative Methods. NIH Publication No.: 97-3981. Research Triangle Park, NC: National Institute of Environmental Sciences. Available: [http://iccvam.niehs.nih.gov/docs/about\\_docs/validate.pdf](http://iccvam.niehs.nih.gov/docs/about_docs/validate.pdf).

- ICCVAM 1999. The Murine Local Lymph Node Assay: A Test Method for Assessing the Allergic Contact Dermatitis Potential of Chemical/Compounds. NIH Publication No. 99-4494. Research Triangle Park, NC: National Institute of Environmental Sciences. Available: [http://iccvam.niehs.nih.gov/docs/immunotox\\_docs/llna/llnarep.pdf](http://iccvam.niehs.nih.gov/docs/immunotox_docs/llna/llnarep.pdf).
- ICCVAM. 2003. ICCVAM Guidelines for the Nomination and Submission of New, Revised, and Alternative Test Methods. NIH Publication No: 03-4508. Research Triangle Park, NC: National Institute of Environmental Sciences. Available: [http://iccvam.niehs.nih.gov/SuppDocs/SubGuidelines/SD\\_subg034508.pdf](http://iccvam.niehs.nih.gov/SuppDocs/SubGuidelines/SD_subg034508.pdf).
- ICCVAM Authorization Act. 2000. Public Law 106-545, 42 U.S.C. 285l-3. Available: [http://iccvam.niehs.nih.gov/docs/about\\_docs/PL106545.pdf](http://iccvam.niehs.nih.gov/docs/about_docs/PL106545.pdf).
- ISO. 2002. Biological evaluation of medical devices -- Part 10: Tests for irritation and delayed-type hypersensitivity. Available for purchase at: <http://www.iso.org/iso/home.htm>.
- Jowsey IR, Basketter DA, Westmoreland C, Kimber I. 2006. A future approach to measuring relative skin sensitising potency: a proposal. *J Appl Toxicol* 26:341–350.
- Kimber I, Dearman RJ. 1991. Investigation of lymph node cell proliferation as a possible immunological correlate of contact sensitizing potential. *Food Chem Toxicol* 29:125–129.
- Kimber I, Dearman RJ. 1996. Contact hypersensitivity: immunological mechanisms. In: *Toxicology of Contact Hypersensitivity* (Kimber I, Maurer T, eds). London: Taylor and Francis, 4–25.
- Kimber I, Dearman RJ, Betts CJ, Gerberick GF, Ryan CA, Kern PS, et al. 2006. The local lymph node assay and skin sensitization: a cut-down screen to reduce animal requirements? *Contact Dermatitis* 54:181–185.
- Lalko J, Api AM. 2006. Investigation of the dermal sensitization potential of various essential oils in the local lymph node assay. *Food Chem Toxicol* 44:739–746.
- Meylan WM, Howard PH. 1995. Atom/fragment contribution method for estimating octanol-water partition coefficients. *J Pharm Sci* 84:83–92.
- Moriguchi I, Hirono S, Nakagome I, Hirano H. 1994. Comparison of reliability of log P values for drugs calculated by several methods. *Chem Pharm Bull* 42:976–978.
- OECD. 1998. OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring Number 1: OECD Principles on Good Laboratory Practice (as revised in 1997). ENV/MC/CHEM (98)17. Paris: OECD.
- OECD. 2002. Test No. 429. Skin Sensitisation: Local Lymph Node Assay. Adopted April 24, 2002. In: *OECD Guidelines for Testing of Chemicals*. Paris: OECD. Available: <http://oberon.sourceoecd.org/vl=2675708/cl=14/nw=1/rpsv/cgi-bin/fulltextew.pl?prpsv=/ij/oecdjournals/1607310x/v1n4/s30/p1.idx>.
- Ryan CA, Chaney JG, Kern PS, Patlewicz GY, Basketter DA, Betts CJ, et al. 2008. The reduced local lymph node assay: the impact of group size. *J Appl Toxicol* 28:518–523.
- Ryan CA, Cruse LW, Skinner RA, Dearman RJ, Kimber I, Gerberick GF. 2002. Examination of a vehicle for use with water soluble materials in the murine local lymph node assay. *Food Chem Toxicol* 40:1719–1725.

U.N. 2005. Globally Harmonised System of Classification and Labelling of Chemicals (GHS).  
Geneva: United Nations Publications.