

6 Literaturverzeichnis

Literaturverzeichnis

- Aeby, P., Wyss, C., Beck, H., Griem, P., Scheffler, H. and Goebel, C. (2004) Characterization of the sensitizing potential of chemicals by in vitro analysis of dendritic cell activation and skin penetration. *J Invest Dermatol*, **122**, 1154-1164.
- Anezo, C. (2003) Molecular models for drug permeation across phospholipid membranes. Dissertation, Heinrich-Heine-Universität Düsseldorf.
- Asselineau, D., Bernhard, B., Bailly, C. and Darmon, M. (1985) Epidermal morphogenesis and induction of the 67 kD keratin polypeptide by culture of human keratinocytes at the liquid-air interface. *Exp Cell Res*, **159**, 536-539.
- Bartek, M.J., LaBudde, J.A. and Maibach, H.I. (1972) Skin permeability in vivo: comparison in rat, rabbit, pig and man. *J Invest Dermatol*, **58**, 114-123.
- Barry, B.W. (2002) Drug delivery routes in skin: a novel approach. *Advanced drug delivery review*, **54 Suppl 1**, 31-40.
- Baskettter, D., Pease, C., Kasting, G., Kimber, I., Casati, S., Cronin, M., Diembeck, W., Gerberick, F., Hadgraft, J., Hartung, T., Marty, J.P., Nikolaidis, E., Patlewicz, G., Roberts, D., Roggen, E., Rovida, C. and van de Sandt, J.J. (2007) Skin sensitisation and epidermal disposition: the relevance of epidermal disposition for sensitisation hazard identification and risk assessment. The report and recommendations of ECVAM workshop 59. *Altern Lab Anim*, **35**, 137-154.
- Baynes, R.E. (2004) In vitro dermal disposition of abamectin (avermectin B(1)) in livestock. *Res Vet Sci*, **76**, 235-242.
- Baynes, R.E., Halling, K.B. and Riviere, J.E. (1997) The influence of diethyl-m-toluamide (DEET) on the percutaneous absorption of permethrin and carbaryl. *Toxicol Appl Pharmacol*, **144**, 332-339.
- Benfeldt, E. (1999) In vivo microdialysis for the investigation of drug levels in the dermis and the effect of barrier perturbation on cutaneous drug penetration. Studies in hairless rats and human subjects. *Acta Derm Venereol Suppl (Stockh)*, **206**, 1-59.
- Bodde, H.E., Holman, B., Spies, F., Weerheim, A., Kempenaar, J., Mommaas, M. and Ponec, M. (1990) Freeze-fracture electron microscopy of in vitro reconstructed human epidermis. *J Invest Dermatol*, **95**, 108-116.
- Boelsma, E., Gibbs, S., Faller, C. and Ponec, M. (2000) Characterization and comparison of reconstructed skin models: morphological and immunohistochemical evaluation. *Acta Derm Venereol*, **80**, 82-88.
- Bos, J.D. and Meinardi, M.M. (2000) The 500 Dalton rule for the skin penetration of chemical compounds and drugs. *Exp Dermatol*, **9**, 165-169.
- Boyce, S., Michel, S., Reichert, U., Shroot, B. and Schmidt, R. (1990) Reconstructed skin from cultured human keratinocytes and fibroblasts on a collagen-glycosaminoglycan biopolymer substrate. *Skin Pharmacol*, **3**, 136-143.
- Bridges, J.W., French, M.R., Smith, R.L. and Williams, R.T. (1970) The fate of benzoic acid in various species. *Biochem J*, **118**, 47-51.

- Bronaugh, R.L., Collier, S.W., Macpherson, S.E. and Kraeling, M.E. (1994) Influence of metabolism in skin on dosimetry after topical exposure. *Environ Health Perspect, 102 Suppl 11*, 71-74.
- Bronaugh, R.L., Stewart, R.F. and Simon, M. (1986) Methods for in vitro percutaneous absorption studies. VII: Use of excised human skin. *J Pharm Sci, 75 (11)*, 1094-1097.
- Chambin, O., Bevenan, B. and Teillaud, E. (1993) Pig skin as an animal model for in-vitro percutaneous absorptions studies. *Prediction Percutan Penetrant, 38*, 111-116.
- Chilcott, R.P., Barai, N., Beezer, A.E., Brain, S.I., Brown, M.B., Bunge, A.L., Burgess, S.E., Cross, S., Dalton, C.H., Dias, M., Farinha, A., Finnin, B.C., Gallagher, S.J., Green, D.M., Gunt, H., Gwyther, R.L., Heard, C.M., Jarvis, C.A., Kamiyama, F., Kasting, G.B., Ley, E.E., Lim, S.T., McNaughton, G.S., Morris, A., Nazemi, M.H., Pellett, M.A., Du Plessis, J., Quan, Y.S., Raghavan, S.L., Roberts, M., Romonchuk, W., Roper, C.S., Schenk, D., Simonsen, L., Simpson, A., Traversa, B.D., Trottet, L., Watkinson, A., Wilkinson, S.C., Williams, F.M., Yamamoto, A. and Hadgraft, J. (2005) Inter- and intralaboratory variation of in vitro diffusion cell measurements: an international multicenter study using quasi-standardized methods and materials. *J Pharm Sci, 94*, 632-638.
- COLIPA (1995) Cosmetic Ingredients: Guidelines for Percutaneous Absorption/Penetration. 6pp. Brussels, Belgium: COLIPA.
- Cooper, E.R. and Berner, B. (1985) *Methods in Skin Research*, John Wiley and Sons.
- Cotovio, J., Grandidier, M.H., Portes, P., Roguet, R. and Rubinstenn, G. (2005) The in vitro skin irritation of chemicals: optimisation of the EPISKIN prediction model within the framework of the ECVAM validation process. *Altern Lab Anim, 33*, 329-349.
- de Heer, C., Bosman-Hoefakker, S. and Hakkert, B.C. (1999) Principles for study protocols addressing the dermal absorption of pesticides. TNO report, **V98.356**.
- Diembeck, W., Beck, H., Benech-Kieffer, F., Courtellemont, P., Dupuis, J., Lovell, W., Paye, M., Spengler, J. and Steiling, W. (1999) Test guidelines for in vitro assessment of dermal absorption and percutaneous penetration of cosmetic ingredients. European Cosmetic, Toiletry and Perfumery Association. *Food Chem Toxicol, 37*, 191-205.
- DIN. (2002) DIN ISO 5725-2: Genauigkeit (Richtigkeit und Präzision) von Messverfahren und Messergebnissen – Teil 2: Grundlegende Methode für Ermittlung der Wiederhol- und Vergleichspräzision eines vereinheitlichten Messverfahrens. Beuth Verlag GmbH, Berlin.
- DIN. (1994) DIN 32645: Chemische Analytik; Nachweis-, Erfassungs- und Bestimmungsgrenze; Ermittlung unter Wiederholbedingungen; Begriffe, Verfahren, Auswertung. Beuth Verlag GmbH, Berlin.
- Doucet, O., Garcia, N., Rosdy, M., Fartasch, M. and Zastrow, L. (1997) Critical events in the barrier development of reconstituted epidermis. *Perspectives in Percutaneous Penetration, 5B*, 141-144.
- Doucet O., Garcia, N. and Zastrow L. (1998) o/w emulsion and w/o/w multiple emulsion: physical characterization and skin pharmacokinetic

- comparison in the delivery process of caffeine. *Int J Cosm Sci*, **20**, 283-295.
- Dreher, F., Fouchard, F., Patouillet, C., Andrian, M., Simonnet, J.T. and Benech-Kieffer, F. (2002a) Comparison of cutaneous bioavailability of cosmetic preparations containing caffeine or alpha-tocopherol applied on human skin models or human skin ex vivo at finite doses. *Skin Pharmacol Appl Skin Physiol*, **15 Suppl 1**, 40-58.
- Dreher, F., Patouillet, C., Fouchard, F., Zanini, M., Messager, A., Roguet, R., Cottin, M., Leclaire, J. and Benech-Kieffer, F. (2002b) Improvement of the experimental setup to assess cutaneous bioavailability on human skin models: dynamic protocol. *Skin Pharmacol Appl Skin Physiol*, **15 Suppl 1**, 31-39.
- EC. (1998) EC Directive concerning the placing of biocidal products on the market (L123/1-63).
- EC. (2003a) 7th Amendment to the EC Cosmetic Directive (L66/26-35).
- EC. (2003b) Amendment to the EC Directive relating to medicinal products for human use (L159/46-94).
- Eckert, R.L., Yaffe, M.B., Crish, J.F., Murthy, S., Rorke, E.A. and Welter, J.F. (1993) Involucrin-structure and role in envelope assembly. *J Invest Dermatol*, **100**, 613-617.
- Elias P.M. (1983) Epidermal lipids, barrier function and desquamation. *J Invest Dermatol*, **80**, 44-49.
- Faller, C., Bracher, M., Dami, N. and Roguet, R. (2002) Predictive ability of reconstructed human epidermis equivalents for the assessment of skin irritation of cosmetics. *Toxicol In Vitro*, **16**, 557-572.
- Feldmann, R.J. and Maibach, H.I. (1969) Percutaneous penetration of steroids in man. *J Invest Dermatol*, **52**, 89-94.
- Fentem, J.H. (1999) Validation of in vitro tests for skin corrosivity. *Altex*, **16**, 150-153.
- Fentem, J.H. and Botham, P.A. (2002) ECVAM's activities in validating alternative tests for skin corrosion and irritation. *Altern Lab Anim*, **30 Suppl 2**, 61-67.
- Förster, T., Pittermann, W., Schmitt, M. and Kietzmann, M. (1999) Skin penetration properties of cosmetic formulations using a perfused bovine udder model. *J Cosmet Sci*, **50**, 147-157.
- Frantz, S.W., Ballantyne, B., Beskitt, J.L., Tallant, M.J. and Greco, R.J. (1995) Pharmacokinetics of 2-ethyl-1,3-hexanediol. III. In vitro skin penetration comparisons using the excised skin of humans, rats, and rabbits. *Fundam Appl Toxicol*, **28**, 1-8.
- Franz, T.J. (1975) Percutaneous absorption on the relevance of in vitro data. *J Invest Dermatol*, **64**, 190-195.
- Gibbs, S., Boelsma, E., Kempenaar, J. and Ponec, M. (1998) Temperature-sensitive regulation of epidermal morphogenesis and the expression of cornified envelope precursors by EGF and TGF alpha. *Cell Tissue Res*, **292**, 107-114.
- Gibbs, S., Vicanova, J., Bouwstra, J., Valstar, D., Kempenaar, J. and Ponec, M. (1997) Culture of reconstructed epidermis in a defined medium at 33

- degrees C shows a delayed epidermal maturation, prolonged lifespan and improved stratum corneum. *Arch Dermatol Res*, **289**, 585-595.
- Grubauer, G., Feingold, K.R., Harris, R.M. and Elias, P.M. (1989) Lipid content and lipid type as determinants of the epidermal permeability barrier. *J Lipid Res*, **30**, 89-96.
- Grubbs, F. (1969) Procedures for detecting outlying observations in samples. *Technometrics*, **11**, 1-21.
- Gysler, A., Kleuser, B., Sippl, W., Lange, K., Kortting, H.C., Holtje, H.D. and Schäfer-Kortting, M. (1999) Skin penetration and metabolism of topical glucocorticoids in reconstructed epidermis and in excised human skin. *Pharm Res*, **16**, 1386-1391.
- Gysler, A., Lange, K., Kortting, H.C. and Schäfer-Kortting, M. (1997) Prednicarbate biotransformation in human foreskin keratinocytes and fibroblasts. *Pharm Res*, **14**, 793-797.
- Haberland, A., Santos Maia, C., Jores, K., Durrfeld, M., Mehnert, W., Schimke, I., Christ, B. and Schäfer-Kortting, M. (2003) Albumin effects on drug absorption and metabolism in reconstructed epidermis and excised pig skin. *Altex*, **20**, 3-9.
- Haberland, A., Schreiber, S., Maia, C.S., Rübbelke, M.K., Schaller, M., Kortting, H.C., Kleuser, B., Schimke, I. and Schäfer-Kortting, M. (2006) The impact of skin viability on drug metabolism and permeation-BSA toxicity on primary keratinocytes. *Toxicol In Vitro*, **20**, 347-354.
- Hadgraft, J. (2001a) Modulation of the barrier function of the skin. *Skin Pharmacol Appl Skin Physiol*, **14 Suppl 1**, 72-81.
- Hadgraft, J. (2005) Skin deep. *Eur J Pharm Biopharm*, **58**, 291-299.
- Hadgraft, J. (2001b) Skin, the final frontier. *Int J Pharm*, **224**, 1-18.
- Hadgraft, J., Walters, K.A. and Guy, R.H. (1992) Epidermal lipids and topical drug delivery. *Semin Dermatol*, **11**, 139-144.
- Harrison, S.M., Barry, B.W. and Dugard, P.H. (1984) Effects of freezing on human skin permeability. *J Pharm Pharmacol*, **36**, 261-262.
- Hartung, T., Bremer, S., Casati, S., Coecke, S., Corvi, R., Fortaner, S., Gribaldo, L., Halder, M., Hoffmann, S., Roi, A.J., Prieto, P., Sabbioni, E., Scott, L., Worth, A. and Zuang, V. (2004) A modular approach to the ECVAM principles on test validity. *Altern Lab Anim*, **32**, 467-472.
- Hewitt, P.G., Perkins, J. and Hotchkiss, S.A. (2000) Metabolism of fluroxypyrr, fluroxypyrr methyl ester, and the herbicide fluroxypyrr methylheptyl ester. I: during percutaneous absorption through fresh rat and human skin in vitro. *Drug Metab Dispos*, **28**, 748-754.
- Heylings, J.R., van de Sandt, J.J., Gilde, A.J. and Ward, R.J. (1998) Evaluation of SkinEthic human reconstituted epidermis for in vitro percutaneous absorption testing. *Poster presentation: ICT*.
- Hirvonen, J., Rytting, J.H., Paronen, P. and Urtti, A. (1991) Dodecyl N,N-dimethylamino acetate and azone enhance drug penetration across human, snake, and rabbit skin. *Pharm Res*, **8**, 933-937.
- Hoeck, U., Orup Jacobsen, L. and Kreilgard, B. (1994) Comparison of pig skin and human skin for in vitro percutaneous study of morphine prodrug. *Proc Int Symp Control Release Bioact Mater*, **21**, 425-426.

- Höfer, T., Gerner, I., Gundert-Remy, U., Liebsch, M., Schulte, A., Spielmann, H., Vogel, R. and Wettig, K. (2004) Animal testing and alternative approaches for the human health risk assessment under the proposed new european chemicals regulation. *Arch Toxicol*, **78**, 549-564.
- Howes, D., Guy, R., Hadgraft, J., Heylings, J., Hoeck, U., Kemper, F., Maibach, H., Marty, J.P., Merk, H., Parra, J., Rekkas, D., Rondelli, I., Schaefer, H., Täuber, U. and Verbiese, N. (1996) Methods for assessing percutaneous absorption. The report and recommendations of ECVAM workshop 13. *Altern Lab Anim*, **24**, 81-106.
- Hueber, F., Besnard, M., Schaefer, H. and Wepierre, J. (1994) Percutaneous absorption of estradiol and progesterone in normal and appendage-free skin of the hairless rat: lack of importance of nutritional blood flow. *Skin Pharmacol*, **7**, 245-256.
- Jacobs, J.J., Lehe, C.L., Cammans, K.D., Das, P.K. and Elliott, G.R. (2004) Assessment of contact allergens by dissociation of irritant and sensitizing properties. *Toxicol In Vitro*, **18**, 681-90.
- Jäckle, E., Schäfer, U.F. and Loth, H. (2003) Comparison of effects of different ointment bases on the penetration of ketoprofen through heat-separated human epidermis and artificial lipid barriers. *J Pharm Sci*, **92**, 1396-1406.
- Jowsey, I.R., Basketter, D.A., Westmoreland, C. and Kimber, I. (2006) A future approach to measuring relative skin sensitising potency: a proposal. *J Appl Toxicol*, **26**, 341-350.
- Kaca, M., Bock, U., Jalal, M.T., Harms, M., Hoffmann, C., Müller-Goymann, C., Netzlaff, F., Schäfer, U.F., Lehr, C.M. and Haltner-Ukomadu, E. (in press) Physicochemical parameters of marker compounds and vehicle properties for in vitro percutaneous absorption studies. *Altern Lab Anim*.
- Kandárová, H., Liebsch, M., Genschow, E., Gerner, I., Traue, D., Slawik, B. and Spielmann, H. (2004) Optimisation of the EpiDerm test protocol for the upcoming ECVAM validation study on in vitro skin irritation tests. *Altex*, **21**, 107-114.
- Kandárová, H., Liebsch, M., Gerner, I., Schmidt, E., Genschow, E., Traue, D. and Spielmann, H. (2005) The EpiDerm test protocol for the upcoming ECVAM validation study on in vitro skin irritation tests - an assessment of the performance of the optimised test. *Altern Lab Anim*, **33**, 351-367.
- Kandárová, H., Liebsch, M., Schmidt, E., Genschow, E., Traue, D., Spielmann, H., Meyer, K., Steinhoff, C., Tornier, C., De Wever, B. and Rosdy, M. (2006a) Assessment of the skin irritation potential of chemicals by using the SkinEthic reconstructed human epidermal model and the common skin irritation protocol evaluated in the ECVAM skin irritation validation study. *Altern Lab Anim*, **34**, 393-406.
- Kandárová, H., Liebsch, M., Spielmann, H., Genschow, E., Schmidt, E., Traue, D., Guest, R., Whittingham, A., Warren, N., Gamer, A.O., Remmele, M., Kaufmann, T., Wittmer, E., De Wever, B. and Rosdy, M. (2006b) Assessment of the human epidermis model SkinEthic RHE for in vitro skin corrosion testing of chemicals according to new OECD TG 431. *Toxicol In Vitro*, **20**, 547-559.

- Kellner, H.M., Eckert, H.G., Fehlhaber, H.W., Hornke, I. and Oekonomopoulos, R. (1986) [Pharmacokinetics and biotransformation following topical use of the local corticoid prednicarbate]. *Z Hautkr*, **61 Suppl 1**, 18-40.
- Kietzmann, M., Loscher, W., Arens, D., Maass, P. and Lubach, D. (1993) The isolated perfused bovine udder as an in vitro model of percutaneous drug absorption. Skin viability and percutaneous absorption of dexamethasone, benzoyl peroxide, and etofenamate. *J Pharmacol Toxicol Methods*, **30**, 75-84.
- Kitagawa, S. and Li, H. (1999) Effects of removal of stratum corneum, delipidization and addition of enhancers, ethanol and l-menthol, on skin permeation of benzoic acid and its 4-n-alkyl substituents in excised guinea pig dorsal skin. *Chem Pharm Bull (Tokyo)*, **47**, 44-47.
- Kligman, A.M. and Christophers, E. (1963) Preparation of Isolated sheets of human stratum corneum. *Arch Dermatol Res*, **88**, 702-705.
- Lademann, J., Otberg, N., Richter H., Weigmann, H.J., Lindemann, U., Schaefer, H. and Sterry, W. (2001) Investigation of follicular penetration of topically applied substances. *Skin Pharmacol Appl Skin Physiol*, **14 Suppl 1**, 17-22.
- Lee, S.C., Lee, J.B., Kook, J.P., Seo, J.J., Nam, K.I., Park, S.S. and Kim, Y.P. (1999) Expression of differentiation markers during fetal skin development in humans: immunohistochemical studies on the precursor proteins forming the cornified cell envelope. *J Invest Dermatol*, **112**, 882-886.
- Lenoir, M.C. and Bernard, B.A. (1990) Architecture of reconstructed epidermis on collagen lattices varies according to the method used: a comparative study. *Skin Pharmacol*, **3**, 97-106.
- Liebsch, M., Traue, D., Barrabas, C., Spielmann, H., Uphill, P., Wilkins, S., McPherson, J.P., Wiemann, C., Kaufmann, T., Remmele, M. and Holzhütter, H.G. (2000) The ECVAM prevalidation study on the use of EpiDerm for skin corrosivity testing. *Altern Lab Anim*, **28**, 371-401.
- Liebsch, M. and Spielmann, H. (2002) Currently available in vitro methods used in the regulatory toxicology. *Toxicol Lett*, **127**, 127-134.
- Liebsch, M., Spielmann, H., Pape, W., Krul, C., Deguercy, A. and Eskes, C. (2005) UV-induced effects. *Altern Lab Anim*, **33 Suppl 1**, 131-146.
- Lindner, W. and Wainer, I.W. (1998) Requirements for initial assay validation and publication. *Chromatography B*, **707**, 1-2.
- Lombardi Borgia, S., Schlupp, P., Mehnert, W. and Schäfer-Korting, M. (2008) In vitro skin absorption and drug release – a comparison of six commercial prednicarbate preparations for topical use. *Eur J Pharm Biopharm*, **68**, 380-389.
- Lotte, C., Patouillet, C., Zanini, M., Messager, A. and Roguet, R. (2002) Permeation and skin absorption: reproducibility of various industrial reconstructed human skin models. *Skin Pharmacol Appl Skin Physiol*, **15 Suppl 1**, 18-30.
- Lundehn, J.R. (1992) Uniform principles for safeguarding the health of applicators of plant protection products (uniform principles for operator protection). *Mitteilungen aus der Biologischen Bundesanstalt*, **Heft 277**.

- Macpherson, S.E., Barton, C.N. and Bronaugh, R.L. (1996) Use of in vitro skin penetration data and a physiologically based model to predict in vivo blood levels of benzoic acid. *Toxicol Appl Pharmacol*, **140**, 436-443.
- Magnusson, B.M., Anissimov, Y.G., Cross, S.E. and Roberts, M.S. (2004a) Molecular size as the main determinant of solute maximum flux across the skin. *J Invest Dermatol*, **122**, 993-999.
- Magnusson, B.M., Pugh, W.J. and Roberts, M.S. (2004b) Simple rules defining the potential of compounds for transdermal delivery or toxicity. *Pharm Res*, **21**, 1047-1054.
- Mahmoud, A., Haberland, A., Durrfeld, M., Heydeck, D., Wagner, S. and Schäfer-Korting, M. (2005) Cutaneous estradiol permeation, penetration and metabolism in pig and man. *Skin Pharmacol Physiol*, **18**, 27-35.
- Menon, G.K. and Elias, P.M. (1997) Morphologic basis for a pore-pathway in mammalian stratum corneum. *Skin Pharmacol*, **10**, 235-246.
- Michel, M., Germain, L., Belanger, P.M. and Auger, F.A. (1995) Functional evaluation of anchored skin equivalent cultured in vitro: percutaneous absorption studies and lipid analysis. *Pharm Res*, **12**, 455-458.
- Moser, K., Kriwet, K., Naik, A., Kalia, Y.N. and Guy, R.H. (2001) Passive skin penetration enhancement and its quantification in vitro. *Eur J Pharm Biopharm*, **52**, 103-112.
- Moss, G.P. and Cronin, M.T. (2002) Quantitative structure-permeability relationships for percutaneous absorption: re-analysis of steroid data. *Int J Pharm*, **238**, 105-109.
- Münster, U., Nakamura, C., Haberland, A., Jores, K., Mehnert, W., Rummel, S., Schaller, M., Korting, H.C., Zouboulis Ch, C., Blume-Peytavi, U. and Schäfer-Korting, M. (2005) RU 58841-myristate-prodrug development for topical treatment of acne and androgenetic alopecia. *Pharmazie*, **60**, 8-12.
- Nathan, D., Sakr, A., Lichtin, J.L. and Bronaugh, R.L. (1990) In vitro skin absorption and metabolism of benzoic acid, p-aminobenzoic acid, and benzocaine in the hairless guinea pig. *Pharm Res*, **7**, 1147-1151.
- Navidi, W.C. and Bunge, A.L. (2002) Uncertainty in measurements of dermal absorption of pesticides. *Risk Anal*, **22**, 1175-1182.
- Netzlaff, F. (2007) Haut und Hautmodelle. Dissertation, Universität des Saarlandes, Saarbrücken.
- Netzlaff, F., Kaca, M., Bock, U., Haltner-Ukomadu, E., Meiers, P., Lehr, C.M. and Schäfer, U.F. (2007) Permeability of the reconstructed human epidermis model Episkin((R)) in comparison to various human skin preparations. *Eur J Pharm Biopharm*, **66**, 127-134.
- Netzlaff, F., Kostka, K.H., Lehr, C.M. and Schäfer, U.F. (2006a) TEWL measurements as a routine method for evaluating the integrity of epidermis sheets in static Franz type diffusion cells in vitro. Limitations shown by transport data testing. *Eur J Pharm Biopharm*, **63**, 44-50.
- Netzlaff, F., Lehr, C.M., Wertz, P.W. and Schäfer, U.F. (2005) The human epidermis models EpiSkin, SkinEthic and EpiDerm: an evaluation of morphology and their suitability for testing phototoxicity, irritancy, corrosivity, and substance transport. *Eur J Pharm Biopharm*, **60**, 167-178.

6 Literaturverzeichnis

- Netzlaff, F., Schäfer, U.F., Lehr, C.M., Meiers, P., Stahl, J., Kietzmann, M. and Niedorf, F. (2006b) Comparison of bovine udder skin with human and porcine skin in percutaneous permeation experiments. *Altern Lab Anim*, **34**, 499-513.
- Niedorf, F., Schmidt, E. and Kietzmann, M. (in press) Automated, accurate and reproducible determination of steady-state permeation parameters from percutaneous permeation data. *Altern Lab Anim*.
- Nokhodchi, A., Shokri, J., Dashbolaghi, A., Hassan-Zadeh, D., Ghafourian, T. and Barzegar-Jalali, M. (2003) The enhancement effect of surfactants on the penetration of lorazepam through rat skin. *Int J Pharm*, **250**, 359-369.
- OECD. (2003) Guidance Document No 28 for the conduct of skin absorption studies. *Adopted at 35th Joint Meeting August 2003*.
- OECD. (2007) OECD Environment Health and Safety Publications. Series on Testing and Assessment No. 69. Guidance Document on the Validation of (Quantitative)Structure-Activity Relationships [(Q)SAR] Models. *ENV/JM/MONO(2007)2*, 15-Feb-2007, 154p.
- OECD. (2005) OECD series on testing and assessment No. 34: Guidance Document on the Validation and International acceptance of new or updated test methods for Hazrd assessment. *ENV/JM/MONO(2005)14*, 18-Aug-2005, 96p.
- OECD. (1992) Test Guideline 406: Skin Sensitisation. *Adopted on 17th July 1992*.
- OECD. (2004a) Test Guideline 427: Skin absorption: in vivo Method. *Adopted on 13th April 2004*.
- OECD. (2004b) Test Guideline 428: Skin absorption: in vitro Method. *Adopted on 13th April 2004*.
- OECD. (2004c) Test Guideline 431: In vitro skin corrosion: Human Skin Model Test. *Adopted on 13th April 2004*.
- OECD. (2004d) Test Guideline 432: In vitro 3T3 NRU phototoxicity test. *Adopted on 13th April 2004*.
- Onuki, M., Yokoyama, K., Kimura, K., Sato, H., Nordin, R.B., Naing, L., Morita, Y., Sakai, T., Kobayashi, Y. and Araki, S. (2003) Assessment of urinary cotinine as a marker of nicotine absorption from tobacco leaves: a study on tobacco farmers in Malaysia. *J Occup Health*, **45**, 140-145.
- Parry, G.E., Bunge, A.L., Silcox, G.D., Pershing, L.K. and Pershing, D.W. (1990) Percutaneous absorption of benzoic acid across human skin. I. In vitro experiments and mathematical modeling. *Pharm Res*, **7**, 230-236.
- Pittermann, W. and Kietzmann, M. (2006) [Bovine udder skin (BUS): testing of skin compatibility and skin protection]. *Altex*, **23**, 65-71.
- Pittermann, W., Kietzmann, M. and Jackwerth, B. (1995) [The isolated perfused Bovine Udder Skin]. *Altex*, **12**, 196-200.
- Ponec, M. (1991) Reconstruction of human epidermis on de-epidermized dermis: Expression of differentiation-specific protein markers and lipid composition. *Toxicol In Vitro*, **5**, 597-606.
- Ponec, M., Boelsma, E., Gibbs, S. and Mommaas, M. (2002) Characterization of reconstructed skin models. *Skin Pharmacol Appl Skin Physiol*, **15 Suppl 1**, 4-17.

- Ponec, M., Boelsma, E., Weerheim, A., Mulder, A., Bouwstra, J. and Mommaas, M. (2000) Lipid and ultrastructural characterization of reconstructed skin models. *Int J Pharm*, **203**, 211-225.
- Ponec, M., Gibbs, S., Pilgram, G., Boelsma, E., Koerten, H., Bouwstra, J. and Mommaas, M. (2001) Barrier function in reconstructed epidermis and its resemblance to native human skin. *Skin Pharmacol Appl Skin Physiol*, **14 Suppl 1**, 63-71.
- Ponec, M., Weerheim, A., Kempenaar, J., Mommaas, A.M. and Nugteren, D.H. (1988) Lipid composition of cultured human keratinocytes in relation to their differentiation. *J Lipid Res*, **29**, 949-961.
- Ponec, M., Weerheim, A., Kempenaar, J., Mulder, A., Gooris, G.S., Bouwstra, J. and Mommaas, A.M. (1997) The formation of competent barrier lipids in reconstructed human epidermis requires the presence of vitamin C. *J Invest Dermatol*, **109**, 348-355.
- Pont, A.R., Charron, A.R. and Brand, R.M. (2004) Active ingredients in sunscreens act as topical penetration enhancers for the herbicide 2,4-dichlorophenoxyacetic acid. *Toxicol Appl Pharmacol*, **195**, 348-354.
- Potts, R.O., Bommannan, D.B. and Guy, R.H. (1992) Percutaneous Absorption. In Muktha, H. (ed.), *Pharmacology of the skin*, CRC Press, Boca Raton, Ann Arbor, 13-27.
- Potts, R.O. and Francoeur, M.L. (1991) The influence of stratum corneum morphology on water permeability. *J Invest Dermatol*, **96**, 495-499.
- Potts, R.O. and Guy, R.H. (1991) A pore pathway is not necessary to explain skin permeability. In Kellaway, I.W. (ed.), *Proc Int Symp Controlled Release Bioact Mater*, 18th Controlled Release Soc, Deerfield.
- Potts, R.O. and Guy, R.H. (1992) Predicting skin permeability. *Pharm Res*, **9**, 663-669.
- Qiao, G.L. and Riviere, J.E. (2002) Systemic uptake and cutaneous disposition of pentachlorophenol in a sequential exposure scenario: effects of skin preexposure to benzo[a]pyrene. *J Toxicol Environ Health A*, **65**, 1307-1331.
- Ramsey, J.D., Woollen, B.H., Auton, T.R. and Scott, R.C. (1994) The predictive accuracy of in vitro measurements for the dermal absorption of a lipophilic penetrant (fluazifop-butyl) through rat and human skin. *Fundam Appl Toxicol*, **23**, 230-236.
- Regnier, M., Schweizer, J., Michel, S., Bailly, C. and Prunieras, M. (1986) Expression of high molecular weight (67K) keratin in human keratinocytes cultured on dead de-epidermized dermis. *Exp Cell Res*, **165**, 63-72.
- Reifenrath, W.G., Hawkins, G.S. and Kurtz, M.S. (1989) Evaporation and skin penetration characteristics of mosquito repellent formulations. *J Am Mosq Control Assoc*, **5**, 45-51.
- Riviere, J.E., Baynes, R.E., Brooks, J.D., Yeatts, J.L. and Monteiro-Riviere, N.A. (2003) Percutaneous absorption of topical N,N-diethyl-m-toluamide (DEET): effects of exposure variables and coadministered toxicants. *J Toxicol Environ Health A*, **66**, 133-151.
- Robert, M., Dusser, I., Muriel, M.P., Noel-Hudson, M.S., Aubery, M. and Wepierre, J. (1997) Barrier function of reconstructed epidermis at the air-

- liquid interface: influence of dermal cells and extracellular components. *Skin Pharmacol*, **10**, 247-260.
- Roguet, R., Cohen, C., Dosso, K.G., and Rougier, A. (1993) Episkin, a reconstituted human epidermis for assessing in vitro the irritancy of topically applied compounds. *Toxicol In Vitro*, **8**, 283-291.
- Rosdy, M. and Clauss, L.C. (1990) Terminal epidermal differentiation of human keratinocytes grown in chemically defined medium on inert filter substrates at the air-liquid interface. *J Invest Dermatol*, **95**, 409-414.
- Santos Maia, C., Mehnert, W., Schaller, M., Kortting, H.C., Gysler, A., Haberland, A. and Schäfer-Kortting, M. (2002) Drug targeting by solid lipid nanoparticles for dermal use. *J Drug Target*, **10**, 489-495.
- SCCP. (2003) The SCCNFP's Notes of Guidance for the testing of cosmetic ingredients and their safety evaluation. *Adopted at 25th plenary meeting October 2003*.
- SCCP/0546/02. (2002) The actual status of alternative methods to the use of animals in the safety testing of cosmetic ingredients. *Adopted by the SCCP during the 20th plenary meeting of 4 June 2002*.
- SCCP/0599/02. (2002) Opinion Concerning a Consultation on the Progress in Developing Satisfactory Methods to Replace Animal Testing. *Adopted by the SCCP on 29 July 2002*.
- SCCP. (2006) Basic criteria for the in vitro assessment of dermal absorption of cosmetic ingredients - updated March 2006. *Adopted by the SCCP during the 7th plenary of 28 March 2006*.
- Schaefer, H. and Lademann, J. (2001) The role of follicular penetration. A differential view. *Skin Pharmacol Appl Skin Physiol*, **14 Suppl 1**, 23-27.
- Schäfer, U.F. and Loth, H. (1996) An ex-vivo model for the study of drug penetration into human skin. *Pharm Res*, **13 Suppl**, 366.
- Schäfer-Kortting, M. and Schreiber, S. (2007) Use of skin equivalences for dermal absorption and toxicity. In Roberts, M.S. and Walters, K.A. (eds.), *Dermal absorption and toxicitiy assessment. 2nd edition*. Informa Healthcare.
- Scheuplein, R.J. (1976) Permeability of the skin: a review of major concepts and some new developments. *J Invest Dermatol*, **67**, 672-676.
- Scheuplein R.J. and Blank, I.H. (1971) Permeability of the skin. *Physiol Rev*, **51**, 702-747.
- Schmook, F.P., Meingassner, J.G. and Billich, A. (2001) Comparison of human skin or epidermis models with human and animal skin in in-vitro percutaneous absorption. *Int J Pharm*, **215**, 51-56.
- Schreiber, S. (2006) Charakterisierung humaner Hautmodelle – Stabilität und metabolische Kapazität sowie vergleichende Untersuchungen zur perkutanen Absorption. Dissertation, Freie Universität Berlin.
- Schreiber, S., Mahmoud, A., Vuia, A., Rübelke, M.K., Schmidt, E., Schaller, M., Kandárová, H., Haberland, A., Schäfer, U.F., Bock, U., Kortting, H.C., Liebsch, M. and Schäfer-Kortting, M. (2005) Reconstructed epidermis versus human and animal skin in skin absorption studies. *Toxicol In Vitro*, **19**, 813-822.
- Scott, R.C., Batten, P.L., Clowes, H.M., Jones, B.K. and Ramsey, J.D. (1992) Further validation of an in vitro method to reduce the need for in vivo

- studies for measuring the absorption of chemicals through rat skin. *Fundam Appl Toxicol*, **19**, 484-492.
- Sivaramakrishnan, R., Nakamura, C., Mehnert, W., Korting, H.C., Kramer, K.D. and Schäfer-Korting, M. (2004) Glucocorticoid entrapment into lipid carriers-characterisation by parelectric spectroscopy and influence on dermal uptake. *J Control Release*, **97**, 493-502.
- Spielmann, H. (2003) Validation and regulatory acceptance of new carcinogenicity tests. *Toxicol Pathol*, **31**, 54-59.
- Spielmann, H., Liebsch, M., Doring, B. and Moldenhauer, F. (1994) First results of an EC/COLIPA validation project of in vitro phototoxicity testing methods. *Altex*, **11**, 22-31.
- Spielmann, H., Muller, L., Averbeck, D., Balls, M., Brendler-Schwaab, S., Castell, J.V., Curren, R., de Silva, O., Gibbs, N.K., Liebsch, M., Lovell, W.W., Merk, H.F., Nash, J.F., Neumann, N.J., Pape, W.J., Ulrich, P. and Vohr, H.W. (2000) The second ECVAM workshop on phototoxicity testing. The report and recommendations of ECVAM workshop 42. *Altern Lab Anim*, **28**, 777-814.
- Steiling, W., Kreutz, J. and Höfer, H. (2001) Percutaneous penetration/dermal absorption of hair dyes in vitro. *Toxicol In Vitro*, **15**, 565-570.
- Suhonen, M.T., Pasonen-Seppanen, S., Kirjavainen, M., Tammi, M., Tammi, R. and Urtti, A. (2003) Epidermal cell culture model derived from rat keratinocytes with permeability characteristics comparable to human cadaver skin. *Eur J Pharm Sci*, **20**, 107-113.
- Swart, H., Breytenbach, J.C., Hadgraft, J. and du Plessis, J. (2005) Synthesis and transdermal penetration of NSAID glycoside esters. *Int J Pharm*, **301**, 71-79.
- Tang, H., Blankschtein, D. and Langer, R. (2002) Prediction of steady-state skin permeabilities of polar and nonpolar permeants across excised pig skin based on measurements of transient diffusion: characterization of hydration effects on the skin porous pathway. *J Pharm Sci*, **91**, 1891-1907.
- Theobald, F. (1998) In-vitro Methoden zur biopharmazeutischen Qualitätsprüfung von Dermatika unter Berücksichtigung der Lipidzusammensetzung des Stratum Corneum, in: *Institut für Biopharmazie und pharm. Technologie*. Universität des Saarlandes Saarbrücken.
- Tinois, E., Tiollier, J., Gaucherand, M., Dumas, H., Tardy, M. and Thivolet, J. (1991) In vitro and post-transplantation differentiation of human keratinocytes grown on the human type IV collagen film of a bilayered dermal substitute. *Exp Cell Res*, **193**, 310-319.
- U.S. (1999) U.S. department of health and human services Guidance for industry 64 – Validation of analytical procedures: methodology. <http://www.fda.gov/cvm/guidance/guida64.pdf>.
- U.S. (2001) U.S. department of health and human services, food and drug administration, center of drug administration and research, center for veterinary medicine Guidance for industry – bioanalytical method validation. <http://www.fda.gov/cder/guidance/4252fnl.pdf>.

6 Literaturverzeichnis

- van de Sandt, J.J., van Burgsteden, J.A., Cage, S., Carmichael, P.L., Dick, I., Kenyon, S., Korinth, G., Larese, F., Limasset, J.C., Maas, W.J., Montomoli, L., Nielsen, J.B., Payan, J.P., Robinson, E., Sartorelli, P., Schaller, K.H., Wilkinson, S.C., and Williams, F.M. (2004) In vitro predictions of skin absorption of caffeine, testosterone, and benzoic acid: a multi-centre comparison study. *Regul Toxicol Pharmacol*, **39**, 271-281.
- van Ravenzwaay, B. and Leibold, E. (2004) The significance of in vitro rat skin absorption studies to human risk assessment. *Toxicol In Vitro*, **18**, 219-225.
- Wagner, H., Kostka, K.H., Lehr, C.M. and Schäfer, U.F. (2000) Drug distribution in human skin using two different in vitro test systems: comparison with in vivo data. *Pharm Res*, **17**, 1475-1481.
- Wagner, H., Kostka, K.H., Lehr, C.M. and Schäfer, U.F. (2002) Human skin penetration of flufenamic acid: in vivo/in vitro correlation (deeper skin layers) for skin samples from the same subject. *J Invest Dermatol*, **118**, 540-544.
- Wagner, H., Kostka, K.H., Lehr, C.M. and Schäfer, U.F. (2001) Interrelation of permeation and penetration parameters obtained from in vitro experiments with human skin and skin equivalents. *J Control Release*, **75**, 283-295.
- Wagner, S.M., Nogueira, A.C., Paul, M., Heydeck, D., Klug, S. and Christ, B. (2003) The isolated normothermic hemoperfused porcine forelimb as a test system for transdermal absorption studies. *J Artif Organs*, **6**, 183-191.
- Weigmann, H.J., Lademann, J., Schanzer, S., Lindemann, U., von Pelchrzim, R., Schaefer, H., Sterry, W. and Shah, V. (2001) Correlation of the local distribution of topically applied substances inside the stratum corneum determined by tape-stripping to differences in bioavailability. *Skin Pharmacol Appl Physiol*, **14 Suppl 1**, 98-102.
- Welss, T., Basketter, D.A. and Schröder, K.R. (2004) In vitro skin irritation: facts and future. State of the art review of mechanisms and models. *Toxicol In Vitro*, **18**, 231-243.
- Wertz, P.W. and Downing, D.T. (1989) Stratum corneum: biological and biochemical considerations. Marcel Dekker, New York.
- Wertz, P.W., Miethke, M.C., Long, S.A., Strauss, J.S. and Downing, D.T. (1985) The composition of the ceramides from human stratum corneum and from comedones. *J Invest Dermatol*, **84**, 410-412.
- Wester, R.C. and Maibach, H.I. (1985) Animal models for percutaneous absorption. Karger Verlag, Basel, **Vol. 2**, 159-169.
- Wester, R.C. and Maibach, H.I. (1976) Relationship of topical dose and percutaneous absorption in rhesus monkey and man. *J Invest Dermatol*, **67**, 518-520.
- Williams, B.L., and Wilson, K. (1978) Praktische Biochemie: Grundlagen und Techniken. Georg Thieme Verlag, Stuttgart.
- Wilschut, A., ten Berge, W.F., Robinson, P.J. and McKone, T.E. (1995) Estimating skin permeation. The validation of five mathematical skin permeation models. *Chemosphere*, **30**, 1275-1296.

6 Literaturverzeichnis

- Yagi, S., Nakayama, K., Kurosaki, Y., Higaki, K. and Kimura, T. (1998) Factors determining drug residence in skin during transdermal absorption: studies on beta-blocking agents. *Biol Pharm Bull*, **21**, 1195-1201.
- Yoshida, N., Egami, H., Yamashita, J., Takai, E., Tamori, Y., Fujino, N., Kitaoka, M., Schalkwijk, J. and Ogawa, M. (2002) Immunohistochemical expression of SKALP/elafin in squamous cell carcinoma of human lung. *Oncol Rep*, **9**, 495-501.
- Zghoul, N., Fuchs, R., Lehr, C.M. and Schäfer, U.F. (2001) Reconstructed skin equivalents for assessing percutaneous drug absorption from pharmaceutical formulations. *Altex*, **18**, 103-106.
- Zuang, V., Alonso, M.A., Botham, P.A., Eskes, C., Fentem, J., Liebsch, M. and van de Sandt, J.J. (2005) Skin irritation and corrosion. *Altern Lab Anim*, **33 Suppl 1**, 35-46.