

metics-114101400738_1.html

その他の国際的な代替法開発の動向 (C-4) 関連

- 1) http://www.oecd.org/document/55/0,2340,en_2649_34377_2349687_1_1_1_1,00.html
- 2) http://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals_chem_guide_pkg-en
- 3) <http://www.oecd-ilibrary.org/docserver/download/9714521e.pdf?expires=1420259274&id=id&accname=guest&checksum=FE18D8C33DC9D48B35C718BD1C5B4B92>
- 4) http://www.oecd-ilibrary.org/environment/test-no-442c-in-chemico-skin-sensitisation_9789264229709-en
- 5) http://www.oecd-ilibrary.org/environment/test-no-442d-in-vitro-skin-sensitisation_9789264229822-en
- 6) <http://www.oecd-ilibrary.org/docserver/download/9714531e.pdf?expires=1420259477&id=id&accname=guest&checksum=1FC13D7F07AF9BEFCE078C336D9D8819>
- 7) <http://www.oecd-ilibrary.org/docserver/download/9714541e.pdf?expires=1420259894&id=id&accname=guest&checksum=5C379E0329ADBBF096546218FC9A6DEE>
- 8) <http://www.oecd-ilibrary.org/docserver/download/9714551e.pdf?expires=1420260007&id=id&accname=guest&checksum=4F0266688DF243EF9F8F9116393BDC5D>
- 9) <http://www.oecd-ilibrary.org/docserver/download/9714561e.pdf?expires=1420260169&id=id&accname=guest&checksum=D65206CE762CCFC74F1AAA974C3D7A7A>
- 10) <http://www.oecd-ilibrary.org/docserver/download/9714511e.pdf?expires=1420258881&id=id&accname=guest&checksum=26E3677209418556CD757ED5DE45DCD1>
- 11) <http://www.oecd.org/env/ehs/testing/section4healtheffects.htm> (2015年2月16日時点)
- 12) http://www.oecd.org/env/ehs/testing/Draft_Performance-Based-Test-Guideline-for-Human-Recombinant_Estrogen-Receptor.pdf
- 13) <http://www.oecd.org/env/ehs/testing/Draft%20Proposal%20for%20a%20Test%20Guideline%20on%20Reconstructed%20Human%20Corena%20like%20Epithelium%20Test%20Method.pdf>
- 14) <http://www.oecd.org/env/ehs/testing/The%20Short%20Time%20Exposure%20In%20Vitro%20Test%20Method.pdf>
- 15) <http://www.oecd.org/env/ehs/testing/In%20Vitro%20Mammalian%20Cell%20Gene%20Mutation%20Thymidine%20Kinase%20.pdf>
- 16) <http://www.oecd.org/chemicalsafety/testing/CYP-induction-PBTG-final-for-WNT-comments.pdf>
- 17) <http://www.oecd.org/chemicalsafety/testing/CYP-induction-PerformanceStandards-final-for-WNT-comments.pdf>
- 18) <http://www.oecd.org/chemicalsafety/testing/CYP-validation-project-report.pdf>
- 19) <http://www.oecd.org/chemicalsafety/testing/Draft-new-Test-Guideline-Skin-Sensitisation-h-CLAT-July-2014.pdf>
- 20) http://www.oecd.org/env/ehs/testing/Bhas_42_CT_A_TG_HRI_Draft_Rev_7.pdf
- 21) http://www.oecd.org/env/ehs/testing/CTA%20TG_Feb2013.pdf
- 22) [http://www.oecd.org/env/ehs/testing/DRAFT%20Cytosensor%20TG%20\(V9\)%2021%20Dec%2012_clean.pdf](http://www.oecd.org/env/ehs/testing/DRAFT%20Cytosensor%20TG%20(V9)%2021%20Dec%2012_clean.pdf)
- 23) <http://www.oecd.org/env/ehs/testing/Draft-Updated-Guideline-on-Reproduction-and-Toxicity-testing.pdf>
- 24) <http://www.oecd.org/env/ehs/testing/Draft-Updated-Guideline-on-Combined-Repeated-Dose-Toxicity-Study.pdf>
- 25) <http://www.oecd.org/env/ehs/testing/Draft%20Revised%20Test%20Guideline%20404%20Acute%20Dermal%20Irritation%20and%20Corrosion.pdf>

- 26) <http://www.oecd.org/env/ehs/testing/Draft%20Revised%20Test%20Guideline%20430%20In%20Vitro%20Skin%20Corrosion%20Transcutaneous%20Electrical%20Resistance%20Test%20Method.pdf>
- 27) <http://www.oecd.org/env/ehs/testing/Draft%20Revised%20Test%20Guideline%20431%20In%20Vitro%20Skin%20Corrosion%20Reconstructed%20Human%20Epidermis%20Test%20Method.pdf>
- 28) <http://www.oecd.org/env/ehs/testing/Draft%20Revised%20Test%20Guideline%20435%20In%20Vitro%20Membrane%20Barrier%20Test%20Method%20for%20Skin%20Corrosion.pdf>
- 29) <http://www.oecd.org/env/ehs/testing/Draft%20Revised%20Test%20Guideline%20439%20In%20Vitro%20Skin%20Irritation%20Reconstructed%20Human%20Epidermis%20Test%20Method.pdf>
- 30) <http://www.oecd.org/env/ehs/testing/Revised%20TG476.pdf>
- 31) <http://www.oecd.org/chemicalsafety/testing/TG-478-Dominant-Lethal-Assay-Revision-Sept-23-2013-CLEAN-FM-bis.pdf>
- 32) <http://www.oecd.org/chemicalsafety/testing/TG-483-Mammalian-Spermatogonial-Chromosomal-Aberrations-Revision-Sep-23-2013-CLEAN-FM-bis.pdf>
- 33) <http://www.oecd.org/chemicalsafety/testing/Draft-Updated-TG455-v3-TG-for-Stability-Transfected-Transactivation-in-vitro-Assays-to-Detect-Receptor-Angonists-and-Antagonists.pdf>
- 34) [http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono\(2014\)19&doclanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2014)19&doclanguage=en)
- 35) <http://www.oecd.org/env/ehs/testing/adverse-outcome-pathways-molecular-screening-and-toxicogenomics.htm>
- 36) [http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono\(2012\)10/part2&doclanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2012)10/part2&doclanguage=en)
- 37) [http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono\(2013\)6&doclanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2013)6&doclanguage=en)
- 38) [http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono\(2013\)6&doclanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2013)6&doclanguage=en)
- 39) <http://www.qsartoolbox.org/>
- 40) 化粧品規制協力国際会議(ICCR)第8回 結果概要
(<http://www.mhlw.go.jp/stf/houdou/0000051627.html>)
- 41) http://www.iccrnet.org/files/4114/0603/8824/press_statement_iccr8_en.pdf
- 42) Terms of Reference for ICCR
(http://www.iccrnet.org/files/6814/1820/3192/Terms_of_Reference_for_ICCR.pdf)
- 43) http://www.pmda.go.jp/ich/ich_index.html
- 44) <http://www.pmda.go.jp/ich/w/topic.pdf>
- 45) <http://www.jpma.or.jp/information/ich/sokuji/ich140710.html>
- 46) <http://www.jpma.or.jp/information/ich/sokuji/ich141211.html>
- 47) http://www.jpma.or.jp/information/ich/conference/pdf/12_ich131210.pdf
- 48) 薬食審査発 0521 第1号「医薬品の光安全性評価ガイドラインについて」
(http://www.pmda.go.jp/ich/s/s10_14_5_21.pdf)
- 49) http://www.jpma.or.jp/information/ich/conference/pdf/13_ich131210.pdf
- 50) 第30回 ICH 即時報告会より
(http://www.jpma.or.jp/information/ich/sokuji/pdf/03_ich140710.pdf)
- 51) ICH M7 (変異原性不純物) ガイドライン説明会
(<http://www.jpma.or.jp/information/ich/explanation/ich140929.html>)
- 52) http://www.jpma.or.jp/information/ich/conference/pdf/11_ich131210.pdf
- 53) http://www.pmda.go.jp/ich/s/step1_s1_13_10_25.pdf
- 54) <http://www.jpma.or.jp/information/ich/sokuji/pdf/>

06_ich140710.pdf

日本における代替法開発の動向 (C-5) の動向

- 1)小島肇ら、シンポジウム1 日本化粧品工業連合会シンポジウム 医薬部外品申請において動物実験代替法を活用するために-ガイドンス検討会活動の紹介-、第27回日本動物実験代替法学会学術大会講演要旨集, 49, 2014.
- 2)松永佳世子、皮膚界からの代替法研究者への提言、第27回日本動物実験代替法学会学術大会講演要旨集, 43, 2014.
- 3)杉山真理子、皮膚一次刺激性代替法特別委員会検討経過報告、第27回日本動物実験代替法学会学術大会講演要旨集, 94, 2014.
- 4)<http://www.pmda.go.jp/operations/shonin/info/iyakubugai/file/jimu20110204.pdf>
- 5)<http://www.pmda.go.jp/operations/shonin/info/iyakubugai/file/jimu20120426.pdf>
- 6)http://www.jacvam.jp/files/250530_LLNA.pdf
- 7)<http://www.hourei.mhlw.go.jp/hourei/doc/tsuchi/T140206I0020.pdf>
- 8)<http://www.jacvam.jp/files/news/140704.pdf>

単回投与毒性 (C-6-1) 関連

- 1)Organisation for Economic Co-operation and Development. Chemicals Testing-Guidelines. (http://www.oecd.org/document/55/0,2340,en_2649_34377_2349687_1_1_1_1,00.html)
- 2)ZEBET - Centre for Documentation and Evaluation of Alternatives to Animal Experiments (<http://www.bfr.bund.de/cd/1591>)
- 3)Report of the International Workshop on *In vitro* Methods for Assessing Acute Systemic Toxicity, NIH Publication No. 01-4499, August 2001
- 4)Clemedson, C. et al., Development of an *in vitro* test battery for the estimation of acute human systemic toxicity: An outline of the EDIT project. Evaluation-guided Development of New *In vitro* Test Batteries. ATLA, 30, 313, 2002
- 5)Ekwall, B. et al., EDIT - a New International

Multicenter Programme to Develop and Evaluate Batteries of *In vitro* Tests for Acute and Chronic Systemic Toxicity. ATLA, 27, 339, 1999

- 6)ACuteTox - Research Project For Alternative Testing. Welcome to ACuteTox. (<http://www.acutetox.eu/>)
- 7)ACuteTox Final Newsletter October 2010, ACuteTox: Prevalidation, Highlights and Main Achievements of the Project (http://www.acutetox.eu/Final_newsletter_Oct_2010.pdf)
- 8)ToxRTool - Toxicological data Reliability Assessment Tool (<http://ecvam.jrc.it/index.htm>)
- 9)http://ihcp.jrc.ec.europa.eu/our_labs/eurl-ecvam/eurl-ecvam-recommendations/files-3t3/ReqNo_JR_C79556_lbna25946enn.pdf
- 10)http://ihcp.jrc.ec.europa.eu/our_labs/eurl-ecvam/eurl-ecvam-recommendations/3t3-nru-recommendation
- 11)<https://ec.europa.eu/jrc/en/news/acute-systemic-toxicity-assessment?search>
- 12)H. J. Klimisch, et. Al., A systematic Approach for Evaluating the Quality of Experimental Toxicology and Ecotoxicological Data. Regulatory Toxicology and Pharmacology 25, 1-5, 1997
- 13)Federal Register, 69, 61504, 2004
- 14)Casati, S. et al, Preliminary (Phase I) Results of a Validation Study to Evaluate the Reliability and Relevance of Two *In vitro* Cytotoxicity Assays for Predicting Rodent and Human Acute Systemic Toxicity, 41st Congress of the European Societies of Toxicology EUROTOX 2003, 2003
- 15)Strickland, J. A. et al., Data Collection and Analysis Systems for an *In vitro* Cytotoxicity Validation Study, Society of Toxicology 43rd Annual Meeting, The Toxicologist, 50, 2004
- 16)Stokes, W. S. et al., Results of the final phase of a validation study to evaluate *in vitro* cytotoxicity assays for estimating rodent acute systemic

- toxicity, ALTEX, 22, Special Issue, Abstracts 5th World Congress 2005, 196, 2005
- 17) Background Review Document: *In vitro* Cytotoxicity Test Methods for Estimating Acute Oral Systemic Toxicity, NIH Publication No. 07-4518, November 2006
- 18) ICCVAM Test Method Evaluation Report: *In vitro* Cytotoxicity Test Methods for Estimating Starting Doses for Acute Oral Systemic Toxicity Testing, NIH Publication No. 07-4519, November 2006
- 19) JaCVAM (Japanese Center for the Validation of Alternative Methods), 急性毒性試験代替法の第三者報告書 (http://www.jacvam.jp/files/news/20100601_news_public_acute_tox.pdf)
- 20) 高橋祐次ら, 急性毒性試験代替法の第三者評価報告書 *in vitro* 細胞毒性試験による急性経口毒性試験の初回投与量設定試験, AATEX-JaCVAM, 2(1), 61-84, 2013.
- 21) https://eurl-ecvam.jrc.ec.europa.eu/eurl-ecvam-recommendations/files-3t3/ReqNo_JRC79556_lbna25946enn.pdf
- 22) Guidance Document on using Cytotoxicity Tests to Estimate Starting Doses for Acute Oral Systemic Toxicity Tests ([http://www.oecd.org/officialdocuments/displaydocumentpdf/?cote=env/jm/mono\(2010\)20&doclanguage=en](http://www.oecd.org/officialdocuments/displaydocumentpdf/?cote=env/jm/mono(2010)20&doclanguage=en))
- 23) Draft Guidance Document for the Derivation of an Acute Reference concentration (ARfC) (<http://www.oecd.org/dataoecd/13/49/45799595.pdf>)
- 24) 医薬部外品の製造販売承認申請及び化粧品基準改正要請に添付する資料に関する質疑応答集 (Q&A) について (<http://www.pmda.go.jp/operations/notice/2006/file/jimu20060719.pdf>)
- 25) The CTFA Safety Evaluation Guidelines, 2007
- 皮膚毒性 (C-6-2) 関連
- 1) Basketter, D. A. et al., Predictive testing in contact dermatitis: irritant dermatitis, *Clinics in Dermatology*, 15, 637, 1999
- 2) York, M. et al., Evaluation of a human patch test for the identification and classification of skin irritation potential, *Contact Dermatitis*, 34, 204, 1996
- 3) Van de Sandt, J. et al., The use of human keratinocytes and human skin models for predicting skin irritation, *ATLA*, 27, 723 1999
- 4) OECD, OECD test guideline 439; GUIDELINE FOR THE TESTING OF CHEMICALS: *In vitro* Skin Irritation: Reconstructed Human Epidermis Test Method, <http://iccvam.niehs.nih.gov/SuppDocs/FedDocs/OECD/OECD-TG439.pdf>
- 5) SCCP/1392/10, Memorandum (addendum) on the *in vitro* test episkin™ for skin irritation testing, adopted by the SCCS during the 9th plenary meeting on 14 December 2010
- 6) Katoh M. et al., Assessment of human epidermal model LacCyte EPI-MODEL for *in vitro* skin irritation testing according to European Centre for the Validation of Alternative Methods (ECVAM)-validation protocol, *The Journal of Toxicological Sciences*, 34, 327, 2009
- 7) 小島肇ら, 培養皮膚モデル LacCyte EPI-MODEL²⁴ を用いた皮膚刺激性試験代替法のバリデーション研究 追加試験, 第 23 回日本動物実験代替法学会学術大会講演要旨集, 105, 2010.
- 8) Peer reviews of ecotoxicity and human health test methods. (http://www.oecd.org/document/58/0,3746,en_2649_34377_44493498_1_1_1_1,00.html)
- 9) 医薬品食品衛生研究所、新規試験法提案書「ヒト皮膚モデル (3次元皮膚モデル EPISKIN) を用いた皮膚刺激性試験代替法」JACVAM 評価会議、平成 22 年 3 月 4 日

- 10)医薬品食品衛生研究所、「ヒト皮膚モデル (3次元皮膚モデル EPISKIN) を用いた皮膚刺激性試験代替法の評価会議報告書」
JaCVAM 評価会議、平成 22 年 3 月 4 日、平成 23 年 4 月 20 日 (改定)
- 11)大野泰雄ら, 24 時間閉塞による皮膚刺激性試験の代替法開発のための被験物質リストの作成, 日本動物実験代替法学会第 24 回大会講演要旨集, 116, 2011
- 12)杉山真理子ら, 皮膚一次刺激性代替法特別委員会検討経緯報告, 日本動物実験代替法学会第 26 回大会講演要旨集, 141, 2013
- 13)杉山真理子ら, 皮膚一次刺激性代替法特別委員会検討経緯報告, 日本動物実験代替法学会第 27 回大会講演要旨集, 94, 2014
- 14)OECD, DRAFT GUIDANCE DOCUMENT ON AN INTEGRATED APPROACH ON TESTING AND ASSESSMENT (IATA) FOR SKIN CORROSION AND IRRITATION
(http://www.oecd.org/env/ehs/testing/2013-10-20_IATA_GD_Skin%20th_draft_final_JB-clean+5comments.pdf#search='Integrated+Approach+on+Testing+and+Assessment+%28IATA%29+for+Skin+Corrosion+and+Irritatio')
- 15) OECD, OECD test guideline 432; OECD GUIDELINE FOR THE TESTING OF CHEMICALS: *In vitro* 3T3 NRU phototoxicity test,
(<http://iccvam.niehs.nih.gov/SuppDocs/FedDocs/OECD/OECDtg432.pdf>)
- 16)厚生労働省医薬食品局審査管理課, 皮膚感作性試験代替法及び光毒性試験代替法を化粧品・医薬部外品の安全性評価に活用するためのガイダンスについて, 事務連絡, 平成 24 年 4 月 26 日
(<http://www.pmda.go.jp/regulatory/file/guideline/generic/hifu.pdf>)
- 17)Ceridono. M. et al., The 3T3 neutral red uptake phototoxicity test: Practical experience and implications for phototoxicity testing –The report an ECVAM-EFPIA workshop, *Regul Toxicol Pharmacol.*, 63, 480, 2012
- 18)Kejlová K. et al., Phototoxicity of bergamot oil assessed by *in vitro* techniques in combination with human patch tests. *Toxicol. in vitro*, 21, 1298, 2007
- 19)Lelièvre D. et al., The Episkin Phototoxicity Assay (EPA): Development of an *in vitro* Tiered Strategy using 17 Reference Chemicals to Predict Phototoxic Potency, *Toxicol. in vitro*, 21, 977, 2007
- 20)Spielmann, H. et al., *In vitro* phototoxicity testing : The report and recommendations of ECVAM Workshop 2., *ATLA*, 22, 314, 1994
(<http://ecvam.jrc.it/publication/WorkshopReport2.pdf>)
- 21)Spielmann, H. et al., The Second ECVAM Workshop on Phototoxicity Testing: The Report and Recommendations of ECVAM Workshop 42., *ATLA*, 28, 777, 2000.
(<http://ecvam.jrc.it/publication/WorkshopReport42.pdf>)
- 22)森眞輝ら, *In vitro* 光毒性試験の動物実験代替法としての Yeast-RBC アッセイの開発の提案, 第 33 回日本環境変異原学会第 18 回日本動物実験代替法学会合同学術大会講演要旨集, 84, 2004
- 23)田中憲穂ら, 酵母光生育阻害試験及び赤血球光溶血試験を用いた光毒性: バッテリーのバリデーション及び評価委員会での検討中間報告, 第 33 回日本環境変異原学会第 18 回日本動物実験代替法学会合同学術大会講演要旨集, 85, 2004
- 24)吉村功ら, 酵母-赤血球試験の光毒性試験代替法としてのバリデーション研究, 第 33 回日本環境変異原学会第 18 回日本動物実験代替法学会合同学術大会講演要旨集, 86, 2004
- 25)医薬品食品衛生研究所、評価報告書「酵母光生育阻害試験法と赤血球光溶血性試験の組み合わせによる光毒性試験代替法」

JACVAM 評価会議、平成 22 年 1 月

26) 笛木 修ら, 光毒性試験代替法の第三者評価報告書 評価対象: 酵母光生育阻害試験と赤血球光溶血試験の組み合わせ, AATEX-JaCVAM, J1(1), 45, 2012

27) Peer Review Panel Evaluation of the Reactive Oxygen Species (ROS) Photosafety Assay, Japanese Center for the Validation of Alternative Methods National Institute of Health Sciences, Tokyo, Japan, 16 October 2013

(<http://www.jacvam.jp/news/news131017.html>)

28) 厚生労働省医薬食品局審査管理課長, 医薬品の光安全性評価ガイドラインについて, 薬食審査発 0521 第 1 号, 平成 26 年 5 月 21 日

(http://www.pmda.go.jp/ich/s/s10_14_5_21.pdf)

眼刺激性 (C-6-3) 関連

1) Kay, J. H. and Calandra, I. C., Interpretation of eye irritation tests, J. Soc. Cosmetic Chem., 13, 281, 1962

2) OECD Test No. 437: Bovine Corneal Opacity and Permeability Test Method for Identifying Ocular Corrosives and Severe Irritants, <http://www.oecdilibrary.org/oecd/content/book/9789264076303-en>

3) OECD Test No. 438: Isolated Chicken Eye Test Method for Identifying Ocular Corrosives and Severe Irritants, <http://www.oecdilibrary.org/oecd/content/book/9789264076310-en>

4) Test No. 437: Bovine Corneal Opacity and Permeability Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage

<http://www.oecd-ilibrary.org/test-no-437-bovine-corneal-opacity-and-permeability-test-method-for-identifying-i-chemicals-inducing-serious-eye-damage-and-ii-chemicals-not-requiring-classificatio>

[n-for-eye-irritation-or-serious-eye-damage_5k43bdvdfc5l.pdf?contentType=/ns/OECDBook,/ns/Book&itemId=/content/book/9789264203846-en&containerItemId=/content/serial/20745788&accessItemIds=/content/serial/20745788&mimeType=application/pdf](http://www.oecd-ilibrary.org/test-no-437-bovine-corneal-opacity-and-permeability-test-method-for-identifying-i-chemicals-inducing-serious-eye-damage-and-ii-chemicals-not-requiring-classificatio)

5) Test No. 438: Isolated Chicken Eye Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage

http://www.oecd-ilibrary.org/test-no-438-isolated-chicken-eye-test-method-for-identifying-i-chemicals-inducing-serious-eye-damage-and-ii-chemicals-not-requiring-classification-for-eye-irritation-or-serious-eye-damage_5k43bdv5nf25.pdf?contentType=/ns/OECDBook,/ns/Book&itemId=/content/book/9789264203860-en&containerItemId=/content/serial/20745788&accessItemIds=/content/serial/20745788&mimeType=application/pdf

6) 改訂 OECD TG No.437 牛摘出角膜の混濁及び透過性試験法 (BCOP 法: Bovine Corneal Opacity and Permeability Test) の評価会議報告、JaCVAM 評価会議、平成 25 年 (2013 年) 10 月 21 日

7) 眼刺激性試験代替法としての牛摘出角膜の混濁及び透過性試験法 (BCOP) を化粧品・医薬部外品の安全性評価に資するためのガイドンス、薬食審査発 0204 第 1 号、平成 26 年 (2014 年) 2 月 4 日

(<http://www.hourei.mhlw.go.jp/hourei/doc/tsuchi/T140206I0020.pdf>)

8) Overview of histopathology in ocular safety testing, November 2011., http://iccvam.niehs.nih.gov/docs/ocutox_docs/OcularHistoUpdateWEB.pdf

9) 眼刺激性試験代替法の評価会議報告書、2013 年改訂 OECD TG438 ニワトリ眼球を用いた眼刺激性試験 (ICE 法: Isolated Chicken Eye Test)、JaCVAM 評価会議、平成 26 年 (2014

- 年) 10月28日
- 10)眼刺激性試験代替法評価報告書、2013年改訂 OECD TG438 ニワトリ眼球を用いた眼刺激性試験 (ICE法: Isolated Chicken Eye Test)、JaCVAM 眼刺激性試験資料編纂委員会、平成26年9月12日
- 11)http://www.oecd-ilibrary.org/environment/test-no-460-fluorescein-leakage-test-method-for-identifying-ocular-corrosives-and-severe-irritants_9789264185401-en;jsessionid=2ai4qvw6scox1.x-oecd-live-01
- 12)<http://www.oecd.org/env/chemicalsafetyandbiosafety/testingofchemicals/section4healtheffects.htm>
- 13) Tracking System for Alternative test methods Review, Validation and Approval in the Context of EU Regulations on Chemicals <http://tsar.jrc.ec.europa.eu/>
- 14)http://ntp.niehs.nih.gov/iccvam/docs/ocutox_docs/STE-SRD-NICEATM-508.pdf
- 15)<http://www.ncbi.nlm.nih.gov/pubmed/18248950>
- 16)<http://www.oecd.org/env/ehs/testing/section4healtheffects.htm>
- 17)The two Reconstructed human Tissue (RhT)-based test methods: "SkinEthic Human Corneal Epithelium" and "EpiOcular Eye Irritation Test"
http://ihcp.jrc.ec.europa.eu/our_labs/eurl-ecvam/validation-regulatory-acceptance/topical-toxicity/eye-irritation
- 18)Prospective validation study of reconstructed human tissue models for eye irritation testing, P. McNamee, et al., 2011, World Congress on Alternatives to Animal Testing (WC8), <http://www.colipa.eu/safety-a-science-colipa-the-european-cosmetic-cosmetics-association/alternative-methods-/8thworldcongressonalternativeswc8montreal21-25august2011.html#Prospective-validation>
- 19)<http://www.sciencedirect.com/science/article/pii/S0887233312003165>
- 20)<https://eurl-ecvam.jrc.ec.europa.eu/eurl-ecvam-status-reports>
- 21)<http://www.oecd.org/env/ehs/testing/section4healtheffects.htm>
- 22)<http://www.jacvam.jp/news/news111207.html>
- 23)<http://jacvam.jp/news/news110517.html>
- 24)<http://jacvam.jp/news/news110513.html>
- 25)Hiroyuki Yamaguchi, Hajime Kojima, Toshiaki Takezawa, Vitrigel-Eye Irritancy Test Method Using HCE-T Cells. *Toxicological Sciences* DOI: 10.1093/toxsci/kft159
- 26)http://www.nias.affrc.go.jp/press/20130809/full_text.pdf
- 27)Federal Register / Vol. 76, No. 156 / Friday, August 12, 2011 / Notices / 50220-50221
- 28)Federal Register / Vol. 77, No. 196 / Wednesday, October 10, 2012 / Notices/61610-61611
<http://iccvam.niehs.nih.gov/methods/ocutox/reducedenum.htm>
- 29)<http://ntp.niehs.nih.gov/iccvam/methods/ocutox/transmit2012/ATSDR-Response-508.pdf>
- 30)<http://ntp.niehs.nih.gov/iccvam/methods/ocutox/transmit2012/NIOSH-Response-508.pdf>
- 31)<http://www.oecd.org/dataoecd/11/50/48850793.pdf>
- 32)<http://www.oecd.org/dataoecd/7/23/48108995.pdf>
- 33)<http://ntp.niehs.nih.gov/iccvam/suppdocs/feddocs/oecd/oecd-tg405-2012-508.pdf>
- 34)http://www.jacvam.jp/files/doc/06_10/06_10_all.pdf
- 皮膚感作性 (C-6-4) 関連
- 1)Gerberick, G.F. et al., (2007) Quantification of chemical peptide reactivity for screening contact allergens: a classification tree model approach. *Toxicological sciences*, 97, 417-427.
- 2) Emter, R. et al., (2010) Performance of a novel keratinocyte-based reporter cell line to screen skin sensitizers in vitro. *Toxicol Appl Pharmacol.* 245, 281-290.

- 3) Ashikaga, T. et al., (2006) Development of an *in vitro* skin sensitization test using human cell lines; human Cell Line Activation Test (h-CLAT). I. Optimization of the h-CLAT protocol. *Toxicology in vitro*, 20, 763-773.
- 4) Sakaguchi, H. et al., (2006) Development of an *in vitro* skin sensitization test using human cell lines; human Cell Line Activation Test (h-CLAT). II. An inter-laboratory study of the h-CLAT. *Toxicology in vitro*, 20, 774-784.
- 5) Ashikaga, T. et al., (2010) A comparative evaluation of *in vitro* skin sensitization tests: The human cell-line activation test (h-CLAT) versus the local lymph node assay (LLNA). *Altern Lab Anim*, 38, 275-284.
- 6) <https://eurl-ecvam.jrc.ec.europa.eu/eurl-ecvam-recommendations/public-comments>
- 7) <http://www.oecd.org/env/ehs/testing/section4healtheffects.htm>
- 8) Series on Testing and Assessment No.168 :The Adverse Outcome Pathway for Skin Sensitisation Initiated by Covalent Binding to Proteins. [http://search.oecd.org/officialdocuments/displaydocumentpdf/?cote=env/jm/mono\(2012\)10/part1&doclanguage=en](http://search.oecd.org/officialdocuments/displaydocumentpdf/?cote=env/jm/mono(2012)10/part1&doclanguage=en)
[http://search.oecd.org/officialdocuments/displaydocumentpdf/?cote=env/jm/mono\(2012\)10/part2&doclanguage=en](http://search.oecd.org/officialdocuments/displaydocumentpdf/?cote=env/jm/mono(2012)10/part2&doclanguage=en)
- 9) Jaworska, J. et al. (2013) Bayesian integrated testing strategy to assess skin sensitization potency: from theory to practice. *J. Appl. Toxicol.*, 33, 1353-1364.
- 10) Natsch, A. et al. (2013) A dataset on 145 chemicals tested in alternative assays for skin sensitization undergoing prevalidation. *J. Appl. Toxicol.*, 33, 1337-1352.
- 11) Nukada, Y. et al. (2013) Data integration of non-animal tests for the development of a test battery to predict the skin sensitizing potential and potency of chemicals. *Toxicol. In Vitro*, 27, 609-618.
- 12) Tsujita-Inoue, K. et al. (2014) Skin sensitization risk assessment model using artificial neural network analysis of data from multiple *in vitro* assays. *Toxicol. In Vitro*, 28, 626-639.
- 13) 日本動物実験代替法学会 第 27 回大会講演要旨集(S1-3), P51, 2014.
<http://www.jcia.org/n/biz/info/bizinfo5/#symposium141205>
- 14) <https://eurl-ecvam.jrc.ec.europa.eu/eurl-ecvam-recommendations>
- 15) http://www.oecd-ilibrary.org/environment/test-no-442c-in-chemico-skin-sensitisation_9789264229709-en
- 16) http://www.oecd-ilibrary.org/environment/test-no-442d-in-vitro-skin-sensitisation_9789264229822-en
- 17) <http://ntp.niehs.nih.gov/iccvam/docs/icatm/icatm-reportforiccr-jan2014-508.pdf>
- 18) 日本動物実験代替法学会 第 27 回大会講演要旨集(P-35), P111, 2014.
- 19) Suzuki, M. et al. (2009) Evaluation of changes of cell-surface thiols as a new biomarker for *in vitro* sensitization test., *Toxicol. In Vitro.*, 23, 687-96.
- 20) Saito, K. et al. (2013) Development of a new *in vitro* skin sensitization assay (Epidermal Sensitization Assay; EpiSensA) using reconstructed human epidermis., *Toxicol. In Vitro.*, 27, 2213-24.
- 21) Fujita, M. et al. (2014) Development of a prediction method for skin sensitization using novel cysteine and lysine derivatives. *J. Pharmacol. Toxicol. Methods.*, 70, 94-105.
- 22) <http://www.oecd.org/env/ehs/testing/adverse-outcome-pathways-molecular-screening-and-toxicogenomics.htm>
- 23) http://www.asas.or.jp/jsaae/pdf/info_20120808_1.pdf
- 24) 日本動物実験代替法学会 第 25 回講演要旨集, P58, P150-152, 2012.

- 25) http://www.jcia.org/n/all_pdf/anml/p2.pdf
- 26) OECD, (2002) OECD Guidelines for the Testing of Chemicals: Test No. 429: Skin Sensitization Local Lymph Node Assay
<http://iccvam.niehs.nih.gov/methods/immunotox/lnadocs/OECD429.pdf>
- 27) OECD, (2010) OECD Guidelines for the Testing of Chemicals: Test No. 429: Skin Sensitization Local Lymph Node Assay
<http://iccvam.niehs.nih.gov/SuppDocs/FedDocs/OECD/OECD-TG429-2010.pdf>
- 28) Federal Register / Vol. 76, No. 145 / Thursday, July 28, 2011 / Notices / 45254-45256
<http://www.gpo.gov/fdsys/pkg/FR-2011-07-28/pdf/FR-2011-07-28.pdf>
- 29) <http://www.pmda.go.jp/operations/shonin/info/iyakubugai/file/jimu20120426.pdf>
- 30) OECD, OECD Guidelines for the Testing of Chemicals: Test No. 442A: Skin Sensitization Local Lymph Node Assay: DA.
<http://iccvam.niehs.nih.gov/SuppDocs/FedDocs/OECD/OECD-TG442A.pdf>
- 31) OECD, OECD Guidelines for the Testing of Chemicals: Test No. 442B: Skin Sensitization Local Lymph Node Assay: BrdU-ELISA.
- 32) <http://www.pmda.go.jp/operations/shonin/info/iyakubugai/file/jimu20130530.pdf>
- 変異原性 (C-6-5) 関連
- 1) 医薬品の遺伝毒性試験及び解釈に関するガイダンス
<http://www.ich.org/>
http://www.pmda.go.jp/ich/ich_index.html
- 2) OECD GUIDELINE FOR THE TESTING OF CHEMICALS, No. 487, *In vitro* Mammalian Cell Micronucleus Test
- 3) <http://www.oecd.org/env/ehs/testing/section4healtheffects.htm>
- 4) Fairbairn DW. et al.,(1995) The comet assay: a comprehensive review., *Mutat Res.*,339(1):37-59.
- 5) 小島 肇 (2009), *Fragrance Journal*, 1 月号, 65-69.
- 6) Reisinger, K., 3rd Case study: Genotoxicity for the European Cosmetics Sector, EPAA Workshop, September 22nd, 2014 in Brussels
- 7) S. Pfueller, et al. "The Cosmetics Europe strategy for animal-free genotoxicity testing: Project status up-date, *Toxicology in vitro*, 2014, 28,18-23.
- 8) http://ihcp.jrc.ec.europa.eu/our_labs/eurl-ecvam/how-to-reduce-animal-use-in-genotoxicity-testing-eurl-ecvam-releases-its-strategy
- 反復投与毒性 (C-6-6) 関連
- 1) <http://www.seurat-1.eu/>
- 2) <http://www.epa.gov/ncct/>
- 3) http://www.safe.nite.go.jp/seika2012/pdf/slide/2012_02_s.pdf
- 4) http://ec.europa.eu/consumers/sectors/cosmetics/files/pdf/animal_testing/chapter_1_repeat_dose_toxicity_en.pdf
- 生殖発生毒性 (C-6-7) 関連
- 1) <http://ecvam.jrc.it/index.htm>
- 2) OECD Test No. 443: Extended One-Generation Reproductive Toxicity Study,
<http://www.oecd-ilibrary.org/docserver/download/fulltext/9744301e.pdf?expires=1326809913&id=id&accname=freeContent&checksum=FF837A20E00BBC6BD86A40EB4DA49A87>
- 3) http://echa.europa.eu/web/guest/view-article/-/journal_content/11d02889-6a85-4f17-a6c3-b749a2a54963
- 4) <http://www.reprotect.eu>
- 5) <http://ecvam.jrc.it/publication/ECVAM%20Technical%20Report%202006-2007%20final.pdf>
- 6) Schwarz, M., Dencker, L., Lazzari, G., Mantovani, A. And Spielmann, H.(2009) The PeProTect project, *ALTEX*, 26, Spec.Issue, 175.
- 7) Schenk, B., Weimer, M., Bremer, S., van der Burg, B., Cortvrindt, R., Freyberger, A., Lazzari,

- G., Pellizzer, C., Piersma, A., Schafer, W. R., Seiler, A., Witters, H. and Schwarz, M. (2010) The ReProTect Feasibility Study, a novel comprehensive *in vitro* approach to detect reproductive toxicants. *Reprod Toxicol* 30, 200-218.
- 8) Thematic Review: Alternative Methods for Reproductive Toxicity testing - Revision and update of the sector Reproductive Toxicity testing of the publicly available "DataBase service on ALternative Methods to animal experimentation (DB-ALM)" Final Progress Report
http://ec.europa.eu/enterprise/epaa/2_activities/2_3_comm_and_dissem/report_alternative_methods_reproductive_toxicity_testing.pdf
- 9) Akita, M. (2008). Current status and future progress of reproductive/developmental toxicity test. *Yakugaku Zasshi* 128(5), 765-772.
- 10) Schenk B, Weimer M, Bremer S, van der Burg B, Cortvrindt R, Freyberger A, Lazzari G, Pellizzer C, Piersma A, Schafer WR, Seiler A, Witters H, and Schwarz M. (2010) The ReProTect Feasibility Study, a novel comprehensive *in vitro* approach to detect reproductive toxicants. *Reproductive Toxicology* 30, 200-218.
- 11) 斎藤幸一, 鈴木紀之, 安藤寛, 堀江宣行 (2009) 発生毒性試験の代替法開発: 1) ES 細胞を用いたレポータージーンアッセイの開発, 日本動物実験代替法学会第 22 回大会要旨集, 大阪, 50,51.
- 12) 秋田正治, 石塚典子, 横山篤 (2009) 胎児培養法の改良, 日本動物実験代替法学会第 22 回大会, 大阪, 52,53.
- 13) 鈴木紀之, 斎藤幸一, 秋田正治 (2010) 発生毒性試験の代替法開発 - ES 細胞を用いたレポータージーンアッセイの開発とラット胎児培養法の改良 -, 日本動物実験代替法学会第 23 回大会要旨集, 東京, 71.
- 14) NEDO 「高機能簡易型有害性評価手法の開発」事後評価分科会 資料
- 15) 山影康次, 鈴木紀之, 斎藤幸一, 渡辺美香, 池田直弘, 柳和則, 大森崇, 小島肇, 田中憲穂 (2014) 産業利用促進を目指した新規 *in vitro* 発生毒性試験の応用研究 - Hand1-Luc Embryonic Stem Cell Test (Hand1-Luc EST) の開発と検証試験の進捗状況 -, 日本動物実験代替法学会第 27 回大会要旨集, 横浜, 55.
- 16) 横山篤, 秋田正治 (2012) 培養ラット胎児へのフオルスコリンの影響, 日本動物実験代替法学会第 25 回大会要旨集, 東京, 178.
- 17) 横山篤, 秋田正治 (2012) 培養ラット胎児への α -リポ酸の影響, 日本動物実験代替法学会第 25 回大会要旨集, 東京, 179.
- 18) 秋田正治, 横山篤 (2012) 培養ラット胎児へのルテインの影響, 日本動物実験代替法学会第 25 回大会要旨集, 東京, 180.
- 19) <http://jacvam.jp/effort/index.html>
- 20) <http://www.oecd-ilibrary.org/docserver/download/9712221e.pdf?expires=1358130553&id=id&accname=guest&checksum=B4B083B1AD1030D643DA48B3E342956A>
- 21) http://www.oecd-ilibrary.org/environment/test-no-456-h295r-steroidogenesis-assay_9789264122642-en
- 22) <http://www.oecd-ilibrary.org/docserver/download/9712231e.pdf?expires=1358130787&id=id&accname=guest&checksum=F2F5F4772DE30986BB1D2ACDD02B2792>
- 経皮吸収性 (C-6-8) 関連
- 1) OECD guidelines for testing chemicals, 427, Paris, OECD (2004)
- 2) OECD guidelines for testing chemicals, 428, Paris, OECD (2004)
- 3) http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_02j.pdf
- 4) Fujii M. et al., Review of an alternative to animal testing for safety evaluation of cosmetic ingredients using Quasi-drug -Skin permeation

- and absorption test task force-.AATEX, Suppl.13,235, 2008
- 5)杉林堅次ら, *In vitro* 経皮吸収試験 (*In vitro* 皮膚透過試験) 評価報告書, AATEX, 3, 55, 2014.
 - 6)<http://www.oecd.org/dataoecd/63/12/48532204.pdf>
 - 7)http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_s_002.pdf
 - 8)Worth, A. et al. (2014) JRC SCIENCE AND POLICY REPORTS Alternative methods for regulatory toxicology – a state-of-the-art review, 336-337
http://publications.jrc.ec.europa.eu/repository/bitstream/111111111/32662/1/echa_jrc_sla_report_public_05-09-14_withcover%20ipo.pdf
 - 9) EUAL ECVAM DB-ALM: method summary Reconstructed skin models for percutaneous absorption testing - Summary
<http://ecvam-dbalm.jrc.ec.europa.eu/>
 - 10) EUAL ECVAM DB-ALM: method summary Artificial membranes for percutaneous absorption testing – Summary
<http://ecvam-dbalm.jrc.ec.europa.eu/>
 - 11)Kansy M, et al., Physicochemical high throughput screening : parallel artificial membrane permeation assay in the description of passive absorption processes. *J Med Chem*, 1007, 1998.
 - 12)Sinkó B, et al., Skin-PAMPA: a new method for fast prediction of skin penetration. *Eur J Pharm Sci*, 45, 698, 2012.
 - 13)EURL ECVAM progress report on the development, validation and regulatory acceptance of alternative methods (2010-2013)(http://ec.europa.eu/environment/chemicals/lab_animals/pdf/EURL_ECVAM_progress_report_cosmetics_2013.pdf)
 - 14)上月裕一, *In silico* 経皮吸収予測手法を用いた化粧品安全性リスク評価, 日本動物実験代替法学会第 25 回大会プログラム/講演要旨集,80,2012.
 - 15)東條角治ら,薬物皮膚吸収の *In silico* 予測, 日本動物実験代替法学会第 25 回大会プログラム/講演要旨集,81,2012.
 - 16)森大輔ら, 経皮吸収型製剤の *in vitro-in silico* 血中濃度予測法, 日本薬剤学会第 25 年会, 第 30 回日本 DDS 学会学術集会, 2014 年 7 月 31 日.
 - 17)Garrigues-Mazert A. et al., Alternative approach to maximum flux for TTC applied to safety evaluation of cosmetic ingredients, *ALTEX*, 28 Spec Issue, 285, 2011.
 - 18)http://www.cosmostox.eu/docs/posters/EUROT_OX_2013_poster_cosmos.pdf
 - 19) 藤堂浩明ら, 3Rs の Reduction を考慮した High-throughput 皮膚透過性試験に向けて, 第 24 回日本動物実験代替法学会要旨集, 125, 2011.
 - 20) Zaldívar JM, et al., Modelling *in vitro* cell-based assays experiments: cell population dynamics. In models of the ecological hierarchy: from molecules to the ecosphere, F Jørgensen & SE Jordán (Eds), pp 51-71. *Developments in Environmental Modelling Vol 25*. Elsevier. 2012.
 - 21)Diaz Ochoa JG, et al., A multi-scale modeling framework for individualized, spatiotemporal prediction of drug effects and toxicological risk. *Frontiers in Pharmacology*,3,204,2013.
 - 22)Diembeck W. et al., Skin absorption and penetration. *ATLA*, 33, Suppl.1, 105, 2005.

G. 研究発表

G-1. 論文発表

- 1)S. Onoue, G. Suzuki, M. Kato, M. Hirota, H. Nishida, M. Kitagaki, H. Kouzuki, S, Yamada, Non-animal photosafety assessment approaches for cosmetics based on the photochemical and photobiochemical properties, *Toxicol. In Vitro*,

27(8) 2316-24, 2013

- 2)杉山真理子, 低刺激性製剤の開発, 化粧品
安全・安心の科学 (シーエムシー出版) 26-35,
2014

G-2. 学会発表 (講演及び学会発表)

- 1)杉山真理子, 化粧品 (医薬部外品) の安全性
評価に関するガイドンス作成活動について,
第3回株式会社化合物安全性研究所 学術講
演会 生物学的安全性評価の新たな動向につ
いて, 2014/3/7.
- 2)中田美奈子, 稲田理恵, 杉山真理子, 武岡永
里子, 鈴木 裕美子, 鷺崎久美子, 敏感肌の皮
膚刺激感受性の検討, 第39回日本化粧品学
会, 2014/6/5.
- 3)杉山真理子, 化粧品、医薬部外品の安全性評
価における皮膚刺激性試験代替法の課題と今
後の展望, 皮膚基礎研究クラスターフォーラ
ム, 2014/9/6.
- 4)杉山真理子, 今井教安, 大森崇, 藤堂浩明, 豊
田明美, 杉林堅次, 萩野滋延, 皮膚刺激性代替
法特別委員会検討経緯報告, 日本動物実験代
替法学会第27回大会, 2014/12/5.
- 5)杉山真理子, 皮膚刺激性試験代替法の課題と
今後の展開, 日本動物実験代替法学会第27回
大会, 2014/12/5.
- 6)今井教安, 岡本裕子, 杉山真理子, *in vitro*3T3
NRU 光毒性試験ガイドンス作成のポイント,
日本動物実験代替法学会第27回大会,
2014/12/5.

H. 知的財産権の出願・登録状況

なし

研究成果の刊行に関する一覧表

書籍

著者氏名	論文タイトル名	書籍全体の編集者名	書籍名	出版社名	出版地	出版年	ページ
小島肇夫	技術移転で整備すべき文章・報告書類	佐藤章弘	実験者／試験検査員の誤ったデータの取扱い・試験誤操作防止策	技術情報協会	東京	2014	57-58
小島肇夫	動物実験代替法を取り入れた安全性保証の考え方	前田憲寿	美肌化学の最前線	シーエムシー出版	東京	2014	157-163
小島肇夫	代替法における工学的新技術の可能性	酒井康行, 民谷栄一	動物実験代替のためのバイオマテリアル・デバイス	シーエムシー出版	東京	2014	1-5
小島肇夫	化粧品・医薬部外品 安全性評価試験法	小島肇夫	化粧品・医薬部外品 安全性評価試験法	じほう	東京	2014	1-138
小島肇夫	化粧品の安全性評価	田崎裕人	エマルションの特性評価と新製品開発, 品質管理への活用	技術情報協会	東京	2014	326-331
杉山 真理子	低刺激性製剤の開発	島田邦男	化粧品の安全・安心の科学	シーエムシー出版	東京・大阪	2014	26-35

雑誌

発表者氏名	論文タイトル名	発表誌名	巻号	ページ	出版年
小島肇夫, 西川秋佳	日本動物実験代替法評価センター (JaCVAM) 平成24年度報告書.	AATEX-JaCVAM	3(1)	46-53	2014
小島肇夫	動物実験代替法を用いた「これからの化粧品・医薬部外品の安全性評価とその根拠の示し方」	COSMETIC STAGE	8 (3)	1-8	2014
小島肇夫	代替試験法の重要性とJaCVAMの貢献, および代替法の推進のための問題	消費者法ニュース	No.98	186-187	2014
小島肇夫	技術講座 安全性評価試験 (29) 再び化粧品の安全性を考える	COSME TECH JAPAN	4 (3)	62-65	2014
小島肇夫	動物実験を用いないで医薬部外品の承認申請を取ることは可能か?	日皮協ジャーナル	36 (2)	1-7	2014
小島肇夫	化粧品・医薬部外品の安全性評価のための動物実験代替法開発の現状と課題	フレグランスジャーナル	42(9)	12-19	2014
小島肇夫, 西川秋佳	日本動物実験代替法評価センター (JaCVAM) 平成25年度報告書.	AATEX-JaCVAM	3(2)	115-123	2014

中澤憲一, 篠田和俊, <u>小島肇</u> , 吉村 功, 西岡吾朗, 石井健	<i>in vitro</i> 発熱性物質試験の評価報告書	AATEX-JaCVAM	3(2)	71-96	2014
Sugino M, Todo H, Suzuki T, Nakada K, Tsuji K, Tokunaga H, Jinno H, <u>Sugibayashi K.</u>	Safety prediction of topically exposed biocides using permeability coefficients and the desquamation rate at the stratum corneum	<i>J. Toxicol. Sci.</i> ,	39	474-485	2014
Uchida T, Kadhum WR, Kanai S, Todo H, Oshizaka T, <u>Sugibayashi K.</u>	Prediction of skin permeation by chemical compounds using the artificial membrane, Strat-M™	<i>Eur J Pharm Sci</i> ,	67	113-118	2015
<u>Kawamura T</u> , Ogawa Y, Aoki R, Shimada S.	Innate and intrinsic antiviral immunity in skin.	J Dermatol Sci.	75(3)	159-166.	2014
Matsuzawa T, <u>Kawamura T</u> , Ogawa Y, Maeda K, Nakata H, Moriishi K, Koyanagi Y, Gatanaga H, Shimada S, Mitsuya H.	EFdA, a reverse transcriptase inhibitor, potently blocks HIV-1 ex vivo infection of Langerhans cells within epithelium.	J Invest Dermatol.	134(4)	1158-1161	2014
Ahmed Z, <u>Kawamura T</u> , Shimada S, Piguet V.	The role of human dendritic cells in HIV-1 infection.	J Invest Dermatol.	In press	In press	2015
<u>松永佳世子</u>	ロドデノール誘発性脱色素斑	皮膚病診療	37(1)	6-13	2015
Nishigori C, Aoyama Y, Ito A, Suzuki K, Suzuki T, Tanemura A, Ito M, Katayama I, Oiso N, Kagohashi Y, Sugiura S, Fukai K, Funasaka Y, Yamashita T, <u>Matsunaga K.</u>	Guide for medical professionals (i.e. derma-tologists) for the man-agement of Rhodo-denol-induced leukoderma.	J Dermatol.	42	113-128	2015

Sasaki M, Kondo M, Sato K, Umeda M, Kawa-bata K, Takahashi Y, Suzuki T, <u>Matsunaga K</u> and Inoue D.	Rhododendrol, a depigmentation-inducing phenolic compound, exerts melanocyte cytotoxicity via a tyrosinase-dependent mechanism.	Pigment Cell Melanoma Res.	27(5)	754-63	2014
<u>松永佳世子</u>	化粧品による皮膚障害	現代医学	62(1)	101-105	2014
Tatebayashi M, Oiso N, Wada T, Suzuki K, <u>Matsunaga K</u> , Kawada A.	Possible allergic contact dermatitis with reticulate postinflammatory pigmentation caused by hydroquinone.	J Dermatol.	41(7)	669-670	2014
Nakamura M, Yagami A, Hara K, Sano A, Kobayashi T, Aihara M, Hide M, Chinuki Y, Morita E, Teshima R, <u>Matsunaga K</u> .	A new reliable method for detecting specific IgE antibodies in the patients with immediate type wheat allergy due to hydrolyzed wheat protein: correlation of its titer and clinical severity.	Allergol Int	63(2)	243-9	2014
Horita K, Tanoue C, Yasoshima M, Ohtani T, <u>Matsunaga K</u> .	Study of the usefulness of patch testing and use test to predict the safety of commercial topical drugs.	J Dermatol.	41(6)	505-13	2014
青山裕美, 伊藤明子, 鈴木加余子, 鈴木民夫, 種村篤, 錦織千佳子, 伊藤雅章, 片山一朗, 杉浦伸一, <u>松永佳世子</u> .	ロドデノール誘発性脱色素斑症例における一次全国疫学調査結果	日皮会誌	124(11)	2095-2109	2014
Kasamatsu S, Hachiya A, Nakamura S, Yasuda Y, Fujimori T, Takano K, Moriwaki S, Hase T, Suzuki T, <u>Matsunaga K</u> .	Depigmentation caused by application of the active brightening material, rhododendrol, is related to tyrosinase activity at a certain threshold.	J Dermatol Sci.	76(1)	16-24	2014

Kuroda Y, Takahashi Y, Sakaguchi H, Matsunaga K, Suzuki T.	Depigmentation of the skin induced by 4-(4-hydroxyphenyl)-2-butanol is spontaneously re-pigmented in brown and black guinea pigs.	J Toxicol Sci.	39(4)	615-23	2014
Yagami A, Suzuki K, Morita Y, Iwata Y, Sano A, Matsunaga K.	Allergic contact derma-titis caused by 3-o-ethyl-L-ascorbic acid (vitamin C ethyl)	Contact Dermatitis.	70(6)	376-7	2014
矢上 晶子, 松永佳世子.	皮膚のアレルギーのトピックス	皮膚と美容	46(2)		2014
Morihiko Hirota, Shiho Fukui, Kenji Okamoto, Satoru Kurotani, Noriyasu Imai, Miyuki Fujishiro, Daiki Kyoutani, Yoshinao Kato, Toshihiko Kasahara, Masaharu Fujita, Akemi Toyoda, Daisuke Sekiya, Shinichi Watanabe, Hirokazu Seto, Osamu Takenouchi, Takao Ashikaga, Masaaki Miyazawa	Evakuation of cosmetic s of in vitro sensitization test descriptors for the artificial neural network-based risk assessment model of skin sensitization	Journal of Applied Toxicology	In press		2015

Osamu Takenouchi, Shiho Fukui, Kenji Okamoto, Satoru Kurotani, Noriyasu Imai, Miyuki Fujishiro, Daiki Kyotani, Yoshinao Kato, Toshihiko Kasahara, Masaharu Fujita, Akemi Toyoda, Daisuke Sekiya, Shinichi Watanabe, Hirokazu Seto, Morihiro Hirota, Takao Ashikaga, Masaaki Miyazawa	Test battery with h-CLAT, DPRA, and DEREK based on a 139 chemical dataset for predicting skin sensitizing potential and potency of chemicals	Journal of Applied Toxicology	In press	2015
--	---	----------------------------------	----------	------

