Subject Index

A-Cute Tox project 133 Acute toxicity, animal testing alternatives 131-134 Aerosol dispenser's label directive, relevance for cosmetics 25 AGRICOLA, databases 105 Animal testing alternative analysis in SCCP dossiers acute toxicity background 131-133 oral toxicity 133, 134 eye irritation background 136, 137 data in opinions 137, 138 mutagenicity/genotoxicity background 146 data in opinions 146, 147 photo-induced toxicity background 147-149 data in opinions 149 repeated dose toxicity testing background 142, 143 data in opinions 143 reproductive toxicity background 144, 145 data in opinions 145, 146 skin irritation background 134, 135 data in opinions 135, 136 skin sensitization background 138-140 data in opinions 140-142 study design 131 summary 173-177 toxicokinetics 144 ban challenges 44, 45

Cosmetic Products Directive 6, 7 numbers and time frame historical perspective 149–153 projection under REACH 153, 154 prospects 154–157 technical information file 123

Beilstein, chemical data and software 103 Benchmark dose (BMD), hazard identification 35 **Biocidal Products Directive** general provisions 17 relevance for cosmetics 17 Biosis, databases 105 Bovine corneal opacity and permeability test (BCOP) 137, 138 Buehler test 139 Chembank, databases 105 Chemical Abstracts, databases 104 Chemical Safety NewsBase (CSNB), databases 105 CMR substances, provisions 10 Cosmetic Ingredient Review (CIR) commercial data 102 Internet resources 99 **Cosmetic Products Directive** animal testing ban 6,7 Annexes 5 cosmetic product definition 1 milestones 1, 2 public information prerequisite 4 recasting proposals 9-11 safety assessment pathways 7-9

safety assessment pathways 7–9 safety prerequisite and responsibilities 3, 4 summary 167

transposition into Belgian law 183-187 Cosmetic, Toiletry, and Fragrance Association (CTFA), commercial data 102, 103 **Dangerous Preparations Directive** general provisions 15 relevance for cosmetics 15-17 Dangerous Substances Directive general provisions 11-13 relevance for cosmetics 13-15 Data availability, combined impact of vertical legislations 19-21 Database search, safety information on cosmetic ingredients data quality evaluation 109, 110 data sources bibliographical databases 103-105 CD-ROMs 105 commercial data 102, 103 Internet resources 98-102 manufacturer data 105, 106 types 97 general considerations 96, 97 risk assessment of cosmetic ingredients in finished products 110-112 steps commercial database search 109 free Internet search 107 identification 107 legal restriction check 108 toxicological data search 108 summary 171, 172 Dermal absorption studies alternatives 81, 82 controversies 79-81 margin of safety calculations 78, 79 principles 74-76 Scientific Committee on Consumer Products requirements 74 shortcomings in reports 76, 77 Detergents, legislation 18, 19 Directorate General Enterprise, Internet resources 98 Dose-response, assessment 35, 36 Draize test eye irritation 136 skin irritation 134

EMBASE, databases 104 Embryotoxic stem cell test 145

Episkin test 134, 135 EUR-Lex, Internet resources 98 European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC), Internet resources 101 European Chemicals Bureau (ECB), Internet resources 98, 99 European Food Safety Authority (EFSA) general provisions 16 relevance for cosmetics 16, 17 European Inventory of Existing Commercial Chemical Substances (EINCS), components 13, 14 European List of Notified Chemical Substances (ELINCS), components 13, 14 Exposure assessment data needs 45 exposure levels per cosmetic product type 36-38 principles 36 systemic dose calculation 38, 39 Eye irritation, animal testing alternatives 136-138 Food additives, legislation 16, 17 Fragrances, risk assessment challenges 46

General Product Safety Directive (GPSD), relevance for cosmetics 23, 24 Gmelin, commercial data 103

Hair dye industry-Scientific Committee on Consumer Products interactions 70, 71 risk assessment challenges 46 Hazard identification benchmark dose 35 no adverse effects are observed 31, 34, 35 physiochemical and toxicological property determination 31-33 protocols 31-34 HEALSAFE, databases 104 Hen's egg test-chorio allantoic membrane assay (HET-CAM) 137, 138 Human and Environmental Risk Assessment (HERA), Internet resources 101 Human testing, ethical constraints 48

Industry, Scientific Committee on Consumer Products interaction analysis 69–71 International Agency for Research on Cancer (IARC), Internet resources 101 International Fragrance Association (IFRA), Internet resources 101 International Nomenclature for Cosmetic Ingredients (INCI) recasting 11 technical information file 118 International Pharmaceutical Abstracts (IPA), databases 104 International Programme on Chemical Safety (IPCS), Internet resources 100, 101 Isolated chicken eye assay (ICE) 137 Isolated rabbit eye assay (IRE) 137 IUCLID, databases 105

Kosmet, database 103, 104

LED₁₀, dose descriptor 35 Lethal dosage LD₅₀ tests 131, 132 LIFESCI, databases 105 LINTOP project 144 Local lymph node assay (LLNA) 139–142, 148 Low volume eye test (LVET) 136

Magnusson-Kligman test 138, 139 Margin of safety (MoS) calculation 39, 40 dermal absorption studies 78, 79 Material Safety Data Sheet (MSDS), commercial data 103, 105, 106 Medical devices general provisions 19 relevance for cosmetics 19 Medicinal Products Directive general provisions 17, 18 relevance for cosmetics 18 Medline, databases 104 MicroMass test 145 Mutagenicity/genotoxicity studies animal testing alternatives 146, 147 Scientific Committee on Consumer Products reports presence of studies 84, 85 shortcomings 85 requirements 82, 83

Nanoparticles, risk assessment challenges 47 National Library of Medicine (NLM), Internet resources 99, 100 National Toxicology Program (NTP), Internet resources 100
No adverse effects are observed (NOAEL) hazard identification 31, 34, 35 repeated dose toxicity testing 142, 143
Nominal Capacities Directive, relevance for cosmetics 24, 25

Occupational Safety and Health Administration (OSHA), Internet resources 102

Organisation for Economic Co-operation and Development (OECD), risk assessment protocols 31–34

Perfumes, *see* Fragrances
Photo-induced toxicity, animal testing alternatives 147–149
Plant Protection Products Directive general provisions 19 relevance for cosmetics 19
Prepackaged products, legislation 24
Protection of Experimental Animals Directive, relevance for cosmetics 22, 23
Public information, Cosmetic Products Directive prerequisite 4

Raw material suppliers, responsibilities and challenges 46, 47 Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) animal testing numbers and time frame 153, 154 general provisions 11-13 relevance for cosmetics 13-15, 112 Regulation, versus directive 9, 10 Repeated dose toxicity, animal testing alternatives 142, 143 Reproductive toxicity, animal testing alternatives 144-146 ReProTect project 145 Risk assessment challenges 44-49 cosmetic ingredients in finished products 110 - 112dose-response assessment 35, 36 exposure assessment exposure levels per cosmetic product type 36-38 principles 36 systemic dose calculation 38, 39

hazard identification benchmark dose 35 no adverse effects are observed 31, 34, 35 physiochemical and toxicological property determination 31-33 protocols 31-34 overview 29, 30 risk characterization lifetime cancer risk 40 margin of safety calculation 39, 40 threshold of toxicological concern 40, 41 risk communication 42, 43 risk management 41, 42 Scientific Committee on Consumer Products (SCCP) animal testing alternatives, see Animal testing data requirements 94 dermal absorption study alternatives 81, 82 controversies 79-81 margin of safety calculations 78, 79 principles 74-76 requirements 74 shortcomings in reports 76, 77 functions 5-7, 9, 29 identity and physiochemistry requirements 72, 73 shortcomings in reports 73, 74 mutagenicity/genotoxicity studies reports presence of studies 84, 85 shortcomings 85 requirements 82, 83 opinions classification 58, 59 critical analysis content comparison of submissions discussed in 2003 and 2006 64-69 industry interplay analysis 69-71 ingredient types 62, 63 methodology 60, 61 number of opinions in new millennium 61, 62 success rate 63, 64 summary 167, 168

tables 188-190 SciSearch, databases 104 Skin irritation, animal testing alternatives 134-136 Skin sensitization, animal testing alternatives 138-142 Small businesses, risk assessment challenges 48,49 Standards, harmonization 10 Systemic exposure dosage (SED), calculation 38, 39 T_{25} , dose descriptor 35 TD_{50} , dose descriptor 35 Technical information file (TIF) components 115, 116 Cosmetic Products Directive prerequisite 5 database search, see Database search, safety information on cosmetic ingredients practical aspects 123-125 proposal for legal requirements administration part 125, 193, 194 animal testing data 123 existing data of undesirable effects 121, 122 finished product part 125, 126, 201-209 ingredients part 125, 195-200 manufacturing method 120 microbiological checks 119 physiochemical data 118, 119 proof of effects claimed 122 prospects for change 126, 127 purity 119, 120 qualitative and quantitative composition 117, 118 safety assessment of finished product 120, 121 safety assessor name and address 121 stability 119 summary 172, 173 3T3 Neutral Red Uptake Phototoxicity Test 148, 149 Threshold of toxicological concern (TTC), risk characterization 40, 41 TOXCENTER, databases 104 Toxicokinetics, animal testing alternatives 144 Training, risk assessment challenges 47, 48

Whole embryo culture test 145

Downloaded from http://content.karger.com/books/book/chapter-pdf/2097266/000154461.pdf by guest on 23 April 2024