TOLERANCE OF FINISHED PRODUCTS



STUDY	TEST PROCEDURE	DELAY	STUDY CODE	
LOCAL TOLERANCE				
SKIN IRRITATION IN VIVO	Assessment of skin irritation potential on volunteers 48 hours Patch-test under dermatological control	2 weeks	ST-HICV	
SKIN IRRITATION IN VITRO	Assessment of skin irritation potential on human reconstructed epidermis ❖ Performed on in vitro Reconstructed Human Epidermis (RHE EpiSkin®) ❖ Topic application on the surface of tissues ◆ Contact period : 18 hours	5 weeks	IC-EP	
OCULAR IRRITATION 2 METHODS	Assessment of ocular irritation potential - 2 alternative methods: Het-CAM+CFIO 1. Het-Cam: performed on the chorioallantoic membrane of the hen's egg 2. CFIO: Performed on rabbit cornea fibroblasts (SIRC)	3 weeks	IOP	
OCULAR IRRITATION HET-CAM	Assessment of ocular irritation potential - Chorioallantoic membrane of hen's egg method ❖ Performed on chorioallantoic membrane of hen's egg ❖ According to OJFR dated December 28th 1996 - Decree dated November 29th 1996- Annex IV	2 weeks	MCAJO	
OCULAR IRRITATION DIFFUSION IN AGAROSE GEL	 Assessment of ocular irritation potential - Agarose gel method Performed on mouse lung fibroblasts (L929) According to OJFR dated December 30, 1999 - Decree of December 27, 1999- Annex V 	2 weeks	AGA	
OCULAR IRRITATION NEUTRAL RED UPTAKE	 Assessment of ocular irritation potential - Neutral red uptake method Performed on rabbit cornea fibroblasts (SIRC) According to OJFR dated December 30, 1999 - Decree of December 27, 1999- Annex VI 	2 weeks	RNN	
OCULAR IRRITATION ON EPITHELIUM	Assessment of ocular irritation potential on reconstructed human corneal epithelium ❖ Performed on in vitro reconstructed Human Corneal Epithelium (HCE SkinEthic™) ❖ According to OECD 492	5 weeks	IO-HCE	
OCULAR CORROSIVITY	Assessment of severe ocular irritation/corrosion potential –Fluorescein linkage method • Performed on Madin-Darby Canine Kidney cells (MDCK) • According to OECD n° 460	5 weeks	IO-COR	
OCULAR CORROSIVITY	Assessment of severe ocular irritation/corrosion potential by Short Time Exposure test • Performed on rabbit cornea fibroblasts (SIRC) • According to OECD 491	3 weeks	IO-STE	
PHOTOTOXIC POTENTIAL				
PHOTOTOXICITY	 Assessment of phototoxic potential of perfumes / hydroalcoholic formulations – NRU assay Performed on L929 (adaptation of OECD 432) or on BALB/c 3T3 : according to OECD 432 Comparison of IC50 with and without UVA irradiations 	3 weeks	PTC	



TOLERANCE OF FINISHED PRODUCTS



STUDY	TEST PROCEDURE	DELAY	STUDY CODE		
PHOTOTOXIC POTENTIAL					
PHOTOTOXICITY ON TISSUE MODEL	Assessment of phototoxic potential of perfumes / Hydroalcoholic formulations ❖ Performed on in vitro Reconstructed Human Epidermis (RHE EpiSkin®) (liposoluble products) ❖ Comparison of UVA cytotoxicity in control epidermis and treated epidermis	5 weeks	PTCE		
	Assessment of phototoxic potential of cosmetic products / Non hydroalcoholic formulations ❖ Performed on in vitro Reconstructed Human Epidermis (RHE EpiSkin®) ❖ Comparison of UVA cytotoxicity in control epidermis and treated epidermis	5 weeks	PTCE-NHA		
TOLERANCE ON SPECIFIC EPITHELIUM					
TOLERANCE OF PRODUCTS FOR LABIAL APPLICATION	Assessment of irritating potential of finished product for labial application ❖ Performed on in vitro reconstituted Human Oral Epithelium (HOE EpiSkin®) ❖ Application of product onto the epithelium • 1 contact time ❖ Determination of tissue viability	4 weeks	IML-HOE		
TOLERANCE OF PRODUCTS FOR BUCCAL HYGIENE	Assessment of irritating potential of finished product for buccal hygiene ❖ Performed on in vitro reconstituted Human Oral Epithelium (HOE EpiSkin®) ❖ Application of product onto the epithelium • 1 contact time ❖ Determination of tissue viability	4 weeks	IMO-HOE		
TOLERANCE OF PRODUCTS FOR GUM APPLICATION	Assessment of irritating potential of finished product for gum application ❖ Performed on in vitro reconstituted Human Gum Epithelium (HGE EpiSkin®) ❖ Application of product onto the epithelium • 1 contact time ❖ Determination of tissue viability	4 weeks	IMO-HGE		
TOLERANCE OF PRODUCTS FOR NASAL HYGIENE	Assessment of irritating potential of finished product for nasal hygiene ❖ Performed on in vitro human nasal epithelium (EpiAirway epithelium Model, MatTek) reconstituted from bronchial and tracheal epithelial cells ❖ Application of product onto the epithelium • 1 or 3 contact times ❖ Determination of ET50	4 weeks	MNE		
TOLERANCE OF PRODUCTS FOR INTIMATE HYGIENE	Assessment of irritating potential of finished product for intimate hygiene ❖ Performed on in vitro reconstructed Human Vaginal Epithelium (HVE EpiSkin®) ❖ Application of product onto the epithelium • 3 contact times ❖ Determination of tissue viability and the MCI (Mean cytotoxicity Index)	4 weeks	IMV-HVE		