Study Request Form (human patch test) (Example)

Date:

Company		Study Monitor	
Address	TEL FAX		
Test substance	(Lot No.)		
Control substance	(Lot No.)		
Purpose: Application / In-house use	Quasi-drug/cosmetics/SEK/Product Liability Act		
Test conditions	Application period (24 h/48 h) Number of subjects (20/30/40)		
Test substance after study completion	Return / Storage ("Storage" during the study materials storage period (fee-based); thereafter return or storage (fee-based))		
Deadline of final report	Desired:		

1. Name of the chemical (by IUPAC nomenclature system, etc.):

   Abbreviation:

2. Structural, rational or molecular formula, molecular weight:

   Please enter detailed test substance information (composition, etc.)

3. Purity or content (composition of active and other ingredients):

   Active ingredient xx wt%, other ingredients oo wt%

4. Description:

   Yellow liquid (powder)

5. Solubility (Solubility/insolubility in water, organic solvents, etc.):

   Freely soluble in XX, insoluble in OO (practically insoluble)

6. Stability (stability in solvents, to heat, to light, etc.; stability period):

   Stable in the vehicle and to heat and light

7. Storage conditions (required if any):

   Storage temperature (room temperature, under refrigeration, frozen)/light-resistant, hermetically closed

8. Precaution on handling (required if any):

9. Safety information:

   Single dose (acute) toxicity study: Approximate lethal dose (LD_{50}): 2000 mg/kg

   Primary skin irritation study: (irritant effects: no/weak/moderate/severe)

   Mutagenicity (Ames test) (negative/positive)

   Skin sensitization study: (negative/positive)

   Other studies:

Notes

(1) Please let us know if you apply the test substance for approval.

(2) Regarding GLP studies, please let us know the results of pre- and post-study analyses and stability test of the test substance and stability in the solvents on procedural grounds.

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