Review of the safety of tattoo equipment

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Introduction

- MT.DERM GmbH produces medical and cosmetic devices
  - Devices for Permanent Make up and Tattoo
  - Ink for both applications
- Transport of pigments or cosmetic actives into the skin
- Company´s aims: Innovation, Safety & Quality
- Member of the VCP (Verband Cosmetic Professionals)

Opinion about the current safety

- Tattoo pigments are mostly non-toxic, inert and chemically stable (no UV-stability)
- Usually other ingredients of tattoo inks have minor toxic potential
- Microbiological problems
- Regulatories are too weak
- Strict controlling of products necessary

Suggested efforts by VCP

- New regulatories for the registration of products
- Certified manufacturers (e.g. ISO 9001)
- Validated sterile products
- Defined standards for the analysis of pigments
- Required education standards for tattooists and cosmetician

Suggested efforts by MT.DERM GmbH

Short-term:

- New Prohibitions and Requirements:
  - EU Permission required (not only registration without any proper control)
  - List of non permitted auxiliary ingredients for tattoo inks
  - Prohibition of Azo-Pigments
  - Compulsion of single-use equipment

Suggested efforts by MT.DERM GmbH

Short-term:

- Compulsory analysis/certificates for end products and for ingredients **before** registration
  - Heavy metals, PAH, aromatic amines
  - Proof of sterile products & conservation stability
  - GMP Production
  - Limitation on residual of hazardous monomers

Suggested efforts by MT.DERM GmbH

Long-term:

- Studies on the safety & stability of pigments due to long-term stay in the skin & under different conditions:
  - UV- and VIS-Light
  - pH and electrolytes
  - Enzymes and immune cells
- Cytotoxicity, Genotoxicity studies
- Tattoo product specific regulations similar to medical product regulations (ISO 9001, ISO 13485, 93/42/EEC)

Efforts in achieving higher tattoo safety

- Production of ink which is conform to the regulations
- Continious study of the latest research on tattoo safety
- Continious study about the general toxicology of ingredients
- Research in biocompatible pigments
- Testing new formulations and documenting side effects
- Initiating new project ideas for the study of pigment safety

Thank you for your attention!