



Vrije Universiteit Brussel

SAFETY ASSESSMENT OF COSMETICS IN THE EU TRAINING COURSE

BRUSSELS
06 - 11/02/2012



Vrije Universiteit Brussels
Faculty of Medicine and Pharmacy
Dept. Toxicology, Dermato -Cosmetology
and Pharmacognosy

TRAINING COURSE SAFETY ASSESSMENT OF COSMETICS IN THE EU

Key questions to be tackled by the Course :

- ☞ What are the current challenges in safety assessment of cosmetics in the EU?
- ☞ Which role does risk perception play in our society and how does it affect the cosmetic industry?
- ☞ What is the impact of REACH on the cosmetic industry?
- ☞ What are "validated" and "valid" alternative methods? What is their actual use and how to perform these tests?
- ☞ Which role does systemic toxicity testing play in the safety assessment of cosmetics?
- ☞ How to make a product information file for a finished cosmetic product according to the actual EU legislation?
- ☞ How to make a product information file for a cosmetic ingredient to be taken up in one of the positive lists (Annexes) of the EU Cosmetic Legislation?
- ☞ Can the process of risk assessment be improved by new methodologies?

iPAVUB
Instituut voor PostAcademische vorming VUB

OBJECTIVES

Safety is a key issue in the regulation of cosmetics in the EU.

It was firstly dealt with in Council Directive 93/35/EEC amending for the sixth time Directive 76/768/EEC. The new provisions of Article 7a §5b(4) introduced the obligation to keep available for every cosmetic product marketed in the EU a technical dossier containing a safety evaluation of the finished product. §5c(2) states that the safety evaluation must be done by a qualified professional, holding a diploma in the field of pharmacy, toxicology, medicine, dermatology, food chemistry, chemistry or a similar discipline after a minimum education period of three years.

Several reasons, however, exist that urge potential safety assessors of cosmetics to follow additional specific academic training in safety evaluation of cosmetics. Reasons include the unadapted traditional lesson packets of the diplomas mentioned in the EU legislation, the existence in some Member States of additional legal training requirements for a safety assessor, the Seventh Amendment, characterized by moving from *in vivo* to *in vitro* testing in safety assessment of cosmetic ingredients and their finished products, the special needs for small and medium sized enterprises (SMEs), the growing awareness of the consumer, and the changing task of raw material suppliers for cosmetics.

This course therefore offers an intensive training programme, designed for safety assessors of cosmetics in the EU. It is also open to raw material suppliers, responsible persons of SMEs and contract laboratories, inspectors and legislators.

The course is realized in close collaboration with the cosmetic industry and teaching is done at a high standard academic level. Particular emphasis is given to key issues in safety evaluation of cosmetics including the application of alternative 3R-methods and the interpretation of the results, how and when animal testing can be done and remains a necessity, what are the toxicological requirements by the Commission for cosmetic ingredients testing. Practical exercises, in which the realization of a technical dossier for a finished cosmetic product is central, are included.

The possibility will be given to all participants to pass a written exam at the end of the last day of the course. If necessary, a second date will be fixed in agreement with the participants.

COURSE ORGANISER: Prof. Vera ROGIERS

Doctor in Pharmaceutical Sciences. Master in Applied Toxicology, full-time professor at the Vrije Universiteit Brussel (VUB) in the faculty of Medicine and Pharmacy; head of department of Toxicology; lecturing the courses of toxicology, chemical quality and toxicity of cosmetics, and galenics (dermatological preparations) to pharmacy students; responsible for two research teams, one in experimental *in vitro* toxicology and one in dermato-cosmetology. Organizer of the course : "Safety Assessment of Cosmetics in the EU". At the European level, co-chair of the SCCS (Scientific Committee on Consumer Safety). Chairperson of *ecopa* (European Consensus Platform on 3R-Alternative Methods) from 2000-2009.

Coordinator (START-UP) and research partner (carcinoGENOMICS, Liintop, ESNATS, Sens-it-iv, HemiBio and DETECTIVE) in EU projects. Member of the mirror group of *epaa* (The European Partnership for Alternative Approaches to Animal Testing). Member of ESAC (ECVAM Scientific Advisory Committee).

COURSE SECRETARIAT: Mrs. Manon VIVIER

Vrije Universiteit Brussel, Dept. Toxicology
Laarbeeklaan 103, B - 1090 Brussels, Belgium

Tel. : +32/2.477.45.07

Fax : +32/2.477.45.82

Email : Manon.Vivier@vub.ac.be

www.safetycourse.eu

SCIENTIFIC PROGRAMME 2012

SUNDAY 5 FEBRUARY 2012

20.00 Welcome reception

MONDAY 6 FEBRUARY 2012

09.00 - 09.15 Welcome
Prof. V. Rogiers (SCCS, VUB, BE)

Session 1 : Key issues in safety assessment of cosmetics

09.15 - 10.45 Actual legislation of cosmetics in the EU and recast.
Dr. G. Renner (Colipa, BE)

10.45 - 11.00 Coffee break

11.00 - 12.00 Hazard, risk, risk assessment and risk perception :
key factors in the safety evaluation of cosmetics.
Prof. V. Rogiers (SCCS, VUB, BE)

12.00 - 13.30 LUNCH

13.30 - 14.30 Key issues in safety assessment of cosmetics
under study by the SCCS.
Dr. I. White (SCCS, St.-Thomas Hospital, UK)TBC

14.30 - 14.45 Coffee break

14.45 - 15.35 Impact of REACH on the cosmetic industry.
Dr. S. Champ (BASF, DE)

15.35 - 15.50 Coffee break

Session 2.1 : Local toxicity : dermal irritation

15.50 - 16.50 Anatomy and physiology of human skin.
Prof. D. Roseeuw (Universitair Ziekenhuis Brussel, BE)

TUESDAY 7 FEBRUARY 2012

Session 2.1 : Local toxicity : dermal irritation (continued)

09.00 - 09.50 Skin irritation : clinical aspects, mechanism, human
volunteer studies, investigated cosmetics and
ingredients.
Prof. P. Elsner (University of Jena, DE)

09.50 - 10.05 Coffee break

10.05 - 10.55 *In vitro* evaluation of skin irritation of cosmetic
ingredients and products.
Dr. A. Schepky (Beiersdorf AG, DE)

10.55 - 11.10 Coffee break

Session 2.2 : Local toxicity : eye/mucous irritation

11.10 - 12.00 *In vivo* and *in vitro* evaluation of eye irritation, including
clinical aspects, and molecules and compounds
concerned.
Dr. P. McNamee (Procter & Gamble, UK)

12.00 - 13.30 LUNCH

13.30 - 14.20 *In vitro* screening techniques of eye irritation (HET-CAM,
BCOP, cell culture, ...).
*Dr. F. Van Goethem (Johnson & Johnson
Pharmaceutical R&D, BE)*

14.20 - 14.35 Coffee break

Session 3 : Skin sensitization

14.35 - 15.25 Skin sensitization : clinical aspects, mechanism, human
volunteer studies, investigated molecules.
Prof. A. Goossens (KU Leuven, BE)

15.25 - 15.40 Coffee break

15.40 - 16.40 Actual skin sensitization testing of cosmetic ingredients
using 3R methodologies.
Prof. M. Pallardy (Université Paris-Sud, FR)

WEDNESDAY 8 FEBRUARY 2012

Session 5 : Additional studies

09.00 – 10.15 Photoirritation and photoallergy : mechanism and EU *in vitro* method for photoirritation testing.
Prof. J. Castell (Hospital La Fe, ES)

10.15 – 10.30 *Coffee break*

10.30 – 11.30 Is establishment of Safe Exposure Limits for the Induction of Contact Allergy possible ?
Dr. M. Vey (IFRA, BE)

11.30 - 11.45 *Coffee break*

Session 6 : Systemic toxicity of cosmetics

11.45 - 12.30 Dermal absorption of cosmetic ingredients : quantitative *in vitro* technique, practical and critical scientific considerations.
Dr. W. Steiling (Henkel, DE)

12.30 - 14.00 *LUNCH*

Afternoon Guided visit to Antwerp

THURSDAY 9 FEBRUARY 2012

Session 6 : Systemic toxicity of cosmetics (continued)

09.00 - 10.00 Systemic toxicity testing of cosmetics today.
Dr. G. Nohynek (L'Oréal, FR)

10.00 – 10.15 *Coffee break*

10.15 - 11.15 Genotoxicity and mutagenicity testing of cosmetics.
Dr. D. Kirkland (Kirkland Consulting, UK)

11.15 – 11.30 *Coffee break*

Session 7 : Alternatives to animal testing

11.30 – 12.30 The validation process of alternative methods in safety assessment of cosmetics. Actual status and future.
Dr. V. Zuang (ECVAM, IT)

12.30 – 14.00 *LUNCH*

14.00 – 15.00 Actual status and application of "validated" alternative methods available today for human health safety assessment of cosmetic products and their ingredients.
Prof. V. Rogiers (SCCS, VUB, BE)

15.00 – 15.15 *Coffee break*

Session 7 : Product Information File of cosmetics

15.15 - 16.15 Exposure to cosmetics : general considerations, calculations of exposure to different classes of cosmetics according to the SCCP Notes of Guidance.
Dr. E. Dufour (L'Oréal, FR)

16.15 – 16.30 *Coffee break*

16.30 – 17.45 The quest for human safety data on cosmetic ingredients and the role of the raw material suppliers.
Dr. M. Pauwels (Cefic - Euro Chlor, BE) TBC

FRIDAY 10 FEBRUARY 2012

Session 7 : Product Information File of cosmetics (continued)

9.00 - 10.00 Practical aspects of making a cosmetic dossier according to the EU legislation.
Dr. M. Pauwels (Cefic - Euro Chlor, BE) TBC

10.00 - 10.15 *Coffee break*

10.15 - 11.05 Safety Assessment of natural ingredients.
Dr. E. Gerber (Beiersdorf AG, DE)

11.05 - 11.20 *Coffee break*

11.20 - 12.20 Some practical examples of safety assessment for cosmetic products.
Dr. B. Hall (Sureconsult Ltd., UK)

12.20 - 13.50 *LUNCH*

14.00 - 18.00 Start of the group exercise on Product Information Files (about 10-15 persons/group).
The group exercise is organised under the supervision of *Dr. V. Rogiers and Dr. M. Vinken (VUB, BE)*

SATURDAY 11 FEBRUARY 2012

Session 7 : Product Information File of cosmetics (continued)

09.00 - 11.00 Group exercise on Product Information Files
The group exercise is organised under the supervision of *Dr. V. Rogiers and Dr. M. Vinken (VUB, BE)*

11.00 - 12.30 Presentation of product information files groups 1, 2, 3.

12.30 - 13.30 *LUNCH*

13.30 - 14.30 Presentation of product information files by individual groups 4, 5, 6.

14.30 Closure of the course.

15.00 - 16.00 Written exam.

16.15 Shuttle bus to the Atlas hotel.

DATE AND LOCATION

The Safety Course will be held from Monday 6 February to Saturday 11 February 2012 at the Vrije Universiteit Brussel, Medical Campus Jette, Laarbeeklaan 103, 1090 Brussels, Belgium.

More information can be obtained through our website : www.safetycourse.eu

LANGUAGE

The official language of the course is English.
No simultaneous translation will be provided.

COURSE NOTES

Complete course notes will be available for all the participants.

TRANSPORT

Brussels is easily reachable by air, train or car. A map indicating the localisation of the hotel and the university will be sent to all registered participants.

SOCIAL PROGRAMME

Sunday 5 February 2012 : welcome reception.

Wednesday 8 February 2012 : guided visit to Antwerp, get-together and course dinner.

ACCOMMODATION

Single rooms have been blocked in the Atlas Hotel at special rates: 75 euro/night during weekend and 115 euro/night from Monday till Thursday (breakfast and internet included).

Hotel reservations for the ATLAS hotel (Rue du Vieux Marché aux Grains 30, 1000 Brussels, Tel. +32-2-502.60.06, Fax +32-2-502.69.35) should be arranged through ticking the box on the [registration form](#), but payment will have to be done at the hotel and is not included in the course fee.

More information on the hotel can be obtained through the website: <http://www.atlas-hotel.be/>.

*A free shuttle bus service will operate between the **Atlas hotel** and the university.*

COURSE FEE

The inscription rate for the Safety Course is 3.780 €*.

The course fee, payable in advance, covers all lessons, examination costs, course notes, welcome reception, coffee breaks, daily shuttle bus between the ATLAS hotel and the university and the guided excursion in Antwerp on Wednesday 8 February 2012 with get-together and dinner. Lunches are served at the university and are also included in the course fee.

REGISTRATION

The [registration form](#) must be completed before January 15, 2012.

Please note that the number of participants is limited to 60. In view of the high number of participants in the Safety courses organised during the last years by the same course administrators, it is highly advisable to **send in your registration form as soon as possible**. Registration will be carried out on a **first come first served** basis.

***CANCELLATION**

Registered participants who cannot attend the course may apply for a refund of the registration fee or will have to pay a cancellation fee. A substitute delegate is, of course, welcome. Notification is made via e-mail or fax, the participant is entitled to a refund, minus a service fee, according to the following guidelines:

- 14 to 11 business days before starting date of the course - 25 % of the total amount
- 10 to 6 business days before starting date of the course - 50 % of the total amount

Regrettably, no refunds will be made if notification is made less than 5 business days prior to the course, unless a substitute delegate is able to attend.

Cancellation must be received in writing by email or fax.