

## COURSE OUTLINE

### 1. GENERAL

SCHOOL	SCHOOL OF HEALTH AND CARE SCIENCES		
ACADEMIC UNIT	DEPARTMENT BIOMEDICAL SCIENCES -AESTHETICS AND COSMETIC SCIENCE		
LEVEL OF STUDIES	UNDERGRADUATE		
COURSE CODE	8021	SEMESTER	8
COURSE TITLE	SAFETY EVALUATION OF COSMETIC PRODUCTS		
<b>INDEPENDENT TEACHING ACTIVITIES</b> <i>if credits are awarded for separate components of the course, e.g. lectures, laboratory exercises, etc. If the credits are awarded for the whole of the course, give the weekly teaching hours and the total credits</i>		<b>WEEKLY TEACHING HOURS</b>	<b>CREDITS</b>
LECTURES		3	
LABORATORY EXERCISES		-	
			5
<i>Add rows if necessary. The organisation of teaching and the teaching methods used are described in detail at (d).</i>			
COURSE TYPE <i>general background, special background, specialised general knowledge, skills development</i>	OCSBC		
PREREQUISITE COURSES:	NO		
LANGUAGE OF INSTRUCTION and EXAMINATIONS:	Greek		
IS THE COURSE OFFERED TO ERASMUS STUDENTS	Yes		
COURSE WEBSITE (URL)	<a href="https://bisc.uniwa.gr/course/systimata-metaforas-drastikon-oysion/">https://bisc.uniwa.gr/course/systimata-metaforas-drastikon-oysion/</a>  <a href="https://eclass.uniwa.gr/courses/AISTH163/">https://eclass.uniwa.gr/courses/AISTH163/</a>		

### 2. LEARNING OUTCOMES

#### Learning outcomes

The course learning outcomes, specific knowledge, skills and competences of an appropriate level, which the students will acquire with the successful completion of the course are described.

Consult Appendix A

- Description of the level of learning outcomes for each qualifications cycle, according to the Qualifications Framework of the European Higher Education Area
- Descriptors for Levels 6, 7 & 8 of the European Qualifications Framework for Lifelong Learning and Appendix B
- Guidelines for writing Learning Outcomes

**The aim** of the course is for students to understand the basic principles of the safety evaluation of cosmetic products, available to consumers. To be able to estimate the potential toxicological risks before the distribution in the market or to assess the risk (irritations, allergies, phototoxicity, etc.) in the distribution, in order to take any corrective action that may be needed, such as withdrawal or recall of finished products, to ensure public health.

**The goal** of the course is to teach students the basic principles of toxicity testing of raw materials, packaging materials and finished products. To be able to assess the irritability of chemicals on the skin, through irritation and sensitization testing, as well as the calculation of the Margin of Safety (MoS) for each component, as defined by the European Regulation and the National Organization for Medicines for cosmetics (EC 1223/2009).

**Learning results :**

After the end of the course the students will be able to know:

- The in vitro and in vivo toxicity tests, applied to a raw material (ingredient) in order to assess its potential risk in the final cosmetic formulation.
- The dermatological tests (Patch test, Repeated Patch test) that must be done, regarding the safety of the final cosmetic product in order to characterize a cosmetic as Non-Irritant or Hypoallergenic.
- How to calculate the Margin of Safety (MoS) for each component.
- To be able to assess the potential toxicity or hazard of impurities of raw materials, packaging materials and final formulations.
- To be able to sign as an assessor the cosmetic product safety assessment, in the technical file, which is required to be prepared by the EU and the National Organization for Medicines, before the product is placed on the market.
- To be able to cooperate with the competent authorities, if required, in order to take into account the risk that may exist and the need for corrective action by the person in charge of the product marketing.

**General Competences**

*Taking into consideration the general competences that the degree-holder must acquire (as these appear in the Diploma Supplement and appear below), at which of the following does the course aim?*

*Search for, analysis and synthesis of data and information, with the use of the necessary technology*  
*Adapting to new situations*  
*Decision-making*  
*Working independently*  
*Team work*  
*Working in an international environment*  
*Working in an interdisciplinary environment*  
*Production of new research ideas*

*Project planning and management*  
*Respect for difference and multiculturalism*  
*Respect for the natural environment*  
*Showing social, professional and ethical responsibility and sensitivity to gender issues*  
*Criticism and self-criticism*  
*Production of free, creative and inductive thinking*  
*.....*  
*Others...*  
*.....*

Working independently, team work, working in an interdisciplinary environment, working in an international environment

### 3.SYLLABUS

#### Lectures

1. Irritation tests (skin, eye irritation).
2. Phototoxicity tests – Photo-allergy
3. Carcinogenicity - Mutation tests.
4. *In vitro* & *in vivo* study of the absorption of substances from the skin.
5. Foreign impurities, traces, information on raw materials and packaging materials.
6. Exposure to the cosmetic product. The toxicological effects to be considered are also taken into account in calculating the exposure (e.g. exposure may need to be calculated per unit of skin surface area or body weight).
7. Toxicological profile of substances. All significant toxicological pathways of absorption are examined while systemic effects as well as the margin of safety (MoS) are calculated based on the level of no observed adverse effect level (NOAEL).
8. Evaluation of a cosmetic product in true conditions of use.
9. Adverse and serious adverse events.
10. Cosmeto-vigilance
11. Warnings and instructions for use in labeling.
12. Preparation of the safety report. How to submit.
13. Assessment conclusion. Explanation of the scientific reasoning that led to the assessment conclusion.

### 3. TEACHING and LEARNING METHODS - EVALUATION

<p><b>DELIVERY</b> <i>Face-to-face, Distance learning, etc.</i></p>	Face-to-face	
<p><b>USE OF INFORMATION AND COMMUNICATIONS TECHNOLOGY</b> <i>Use of ICT in teaching, laboratory education, communication with students</i></p>	Use of ICT in teaching, Support of learning process through e-class	
<p><b>TEACHING METHODS</b> <i>The manner and methods of teaching are described in detail.</i> <i>Lectures, seminars, laboratory practice, fieldwork, study and analysis of bibliography, tutorials, placements, clinical practice, art workshop, interactive teaching, educational visits, project, essay writing, artistic creativity, etc.</i></p> <p><i>The student's study hours for each learning activity are given as well as the hours of non-directed study according to the principles of the ECTS</i></p>	<b>Activity</b>	<b>Semester workload</b>
	Lectures	50
	Group independent work presentation	20
	Independent study	20
<b>Course total</b>	<b>90</b>	
<p><b>STUDENT PERFORMANCE EVALUATION</b> <i>Description of the evaluation procedure</i></p> <p><i>Language of evaluation, methods of evaluation, summative or conclusive, multiple choice questionnaires, short-answer questions, open-ended questions, problem solving, written work, essay/report, oral examination, public presentation, laboratory work, clinical examination of patient, art interpretation, other</i></p> <p><i>Specifically-defined evaluation criteria are given, and if and where they are accessible to students.</i></p>	Multiple choice questionnaires, open-ended questions, characterization of sentences as True or False, problem solving (100%)	

### 5. ATTACHED BIBLIOGRAPHY

- Suggested bibliography:

1. <http://ec.europa.eu/consumers/cosmetics/cosing/>
2. <https://www.cosmeticseurope.eu/publications-cosmetics-europe-association/recommendations.html>
3. <https://www.fda.gov/Cosmetics/GuidanceRegulation/GuidanceDocuments/default.htm>
4. [http://ec.europa.eu/consumers/sectors/medical-devices/files/meddev/2\\_7\\_1rev\\_3\\_en.pdf](http://ec.europa.eu/consumers/sectors/medical-devices/files/meddev/2_7_1rev_3_en.pdf)
5. [http://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir\\_2011\\_62/dir\\_2011\\_62\\_en.pdf](http://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2011_62/dir_2011_62_en.pdf)
6. <https://echa.europa.eu/regulations/biocidal-products-regulation>
7. <https://circabc.europa.eu/sd/a/51ca9945-167d-411f-9763-92e634af9e1c/Biocides-2002-01%20>
8. *Manual on Borderline and Classification in the community regulation framework for medical devices Version 1.17 (09-2015)*
9. *Good Manufacturing Practices for Pharmaceuticals, Sixth edition, Joseph D. Nally.*
10. *Good Laboratory Practice Regulations, Fourth Edition, Anne Sandy Weinberg.*
11. <http://toxnet.nlm.nih.gov/cqi>
12. <http://www.cir-safety.org>
13. *Lessons of Legislation for Cosmetics and Medical Devices, Papageorgiou S., Mellou F. University of West Attica (2018)*

- Related academic journals: *International Journal of Cosmetic Science, Journal of Cosmetic Science, Journal of Cosmetic Dermatology*