



Comité Científico de Seguridad de los Consumidores (CCSC): Directrices sobre la evaluación de seguridad

Prof. Dra María Pilar Vinardell Martínez-Hidalgo
Directora Departamento de Fisiología
Universitat de Barcelona



Universitat de Barcelona

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Dirección General de Salud y Consumidores

http://ec.europa.eu/dgs/health_consumer/index_en.htm



HEALTH AND CONSUMERS

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Health and consumers related agencies

- » European Food Safety Authority
- » European Medicines Agency
- » European Centre for Disease Prevention and Control
- » Community Plant Variety Office
- » Executive Agency for Health & Consumer

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OUR JOB IS TO HELP MAKE EUROPE'S CITIZENS HEALTHIER, SAFER AND MORE CONFIDENT.



Consumers Health Food Animals Plants

What's new? Consumers | Health | Food | Animals | Plants

A new EFSA opinion on genetically modified maize for food and feed uses, import, processing and cultivation was published on 26 March 2013. In accordance with Regulation (EC) No 1829/2003 on genetically modified food and feed, the public may make comments on this opinion during 1 month.

» Read more

One new EFSA opinion on genetically modified oilseed rape for food uses with the exception of refined oil and food additives has been published on the 12 February 2013. In

In our magazines



EUROPE IN ACTION
FOR HEALTHIER,
SAFER, MORE
CONFIDENT CITIZENS

February 2013

HEALTH AND CONSUMER VOICE



Cosmetics

Cosmetic products are important consumer products with an essential role in everyone's life: apart from "traditional" cosmetic products, such as make-up and perfumes, it also includes products for personal hygiene, for example tooth-care products, shampoos and soaps.

Today's cosmetic market is driven by innovation including new colour pallets, treatments targeted to specific skin types and unique formulas concentrating on different needs. Most cosmetics products have a lifespan of less than five years and manufacturers reformulate 25% of their products every year. They need to improve products constantly in order to stay ahead in a highly competitive market where more choice and ever greater efficacy are expected by the consumer.

The European cosmetics industry is a world leader and dominant cosmetics exporter, a highly innovative sector and a significant employer in Europe. The EU's involvement concerns mainly the regulatory framework for market access, international trade relations and regulatory convergence, all aiming to ensure the highest level of consumer safety while promoting the innovation and the competitiveness of this sector.



Regulatory framework



Scientific and technical
assessment



Cosmetic ingredients
database - CosIng



Cosmetic Products
Notification Portal (CPNP)



Cosmetic products



Ban on animal testing



Market Surveillance



Cooperation

En relación con los cosméticos

News

11 March 2013 Full Ban on Animal Testing for Cosmetics – Commission Communication adopted 11 march 2013

The Cosmetics Products Notification Portal (CPNP) module on Nanomaterials

Events

International Cooperation on Cosmetic Regulation - ICCR-5 Public Session (open to all stakeholders) 30 June 2011, Paris

Contracts & Grants

Expert evaluators for Intelligent Energy Europe 30-09-2013



Publications

The financing of biopharmaceutical product development in Europe
Published by DG Enterprise and Industry and the Danish Technological Institute, 1 December 2009

Public consultations

Public consultation on 2-Chloroacetamide in the framework of Regulation (EC) 1223/2009 on Cosmetic products
Deadline: 15 April 2013





Comité Científico de Seguridad de los Consumidores (CCSC)



HEALTH AND CONSUMERS

Scientific Committees

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Scientific Committees

- on consumer safety
- on health and environmental risks
- on emerging and newly identified health risks

☐ Opinions only

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Scientific Committee on Consumer Safety (SCCS)

The Committee provides opinions on **health and safety risks** (chemical, biological, mechanical and other physical risks) of **non-food consumer products** (e.g. cosmetic products and their ingredients, toys, textiles, clothing, personal care and household products) and **services** (e.g. tattooing, artificial sun tanning).

MEMBERSHIP

- [List of members](#) (with CVs and declarations).
- Members can be contacted via the Secretariat.
- The [declarations of working group-members and other supporting experts](#) are published after an opinion has been adopted.

MANDATES

The committee usually produces its reports in response to a specific [request](#).

OPINIONS AND STATEMENTS

At the end of the risk assessment process, the Committee adopts [opinions](#). The Committee can also, at its own initiative, publish [statements](#) on specific topics.

OPINIONS IN PLAIN LANGUAGE

For some opinions - of direct relevance to the public - a [plain-language version](#) is produced for non-specialists.

MEETINGS

THE COMMITTEES

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Comité Científico de Seguridad de los Consumidores (CCSC)



Da opiniones en temas relacionados con:

Salud y seguridad de productos de consumo no-alimentarios (cosméticos y sus ingredientes, juguetes, textiles, ropa, productos de cuidado personal y del hogar como detergentes, etc.) y servicios (tatuajes, cabinas de bronceado, etc.).



Previos Comités

**Scientific Committee on Cosmetology SCC
1977**



**Scientific Committee on Cosmetic
Products and Non-food products intended
for Consumers SCCPNFP 1997-2004**



**Scientific Committee on Consumer
Products SCCP 2004-2009**

Otros comités:

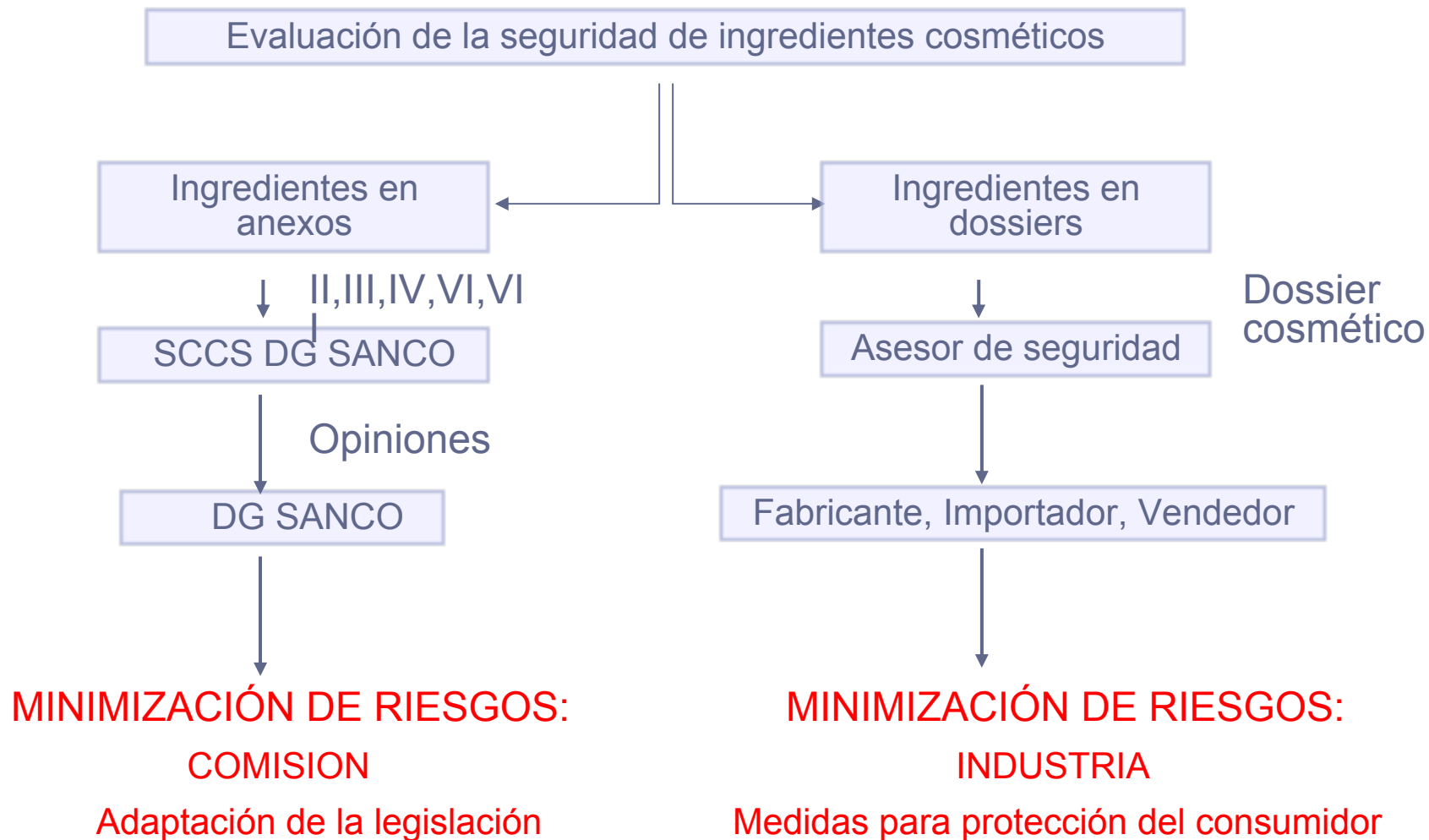
- ✓ Scientific Committee on Health and Environmental Risks (SCHER)
- ✓ Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)

La coordinación entre los tres comités se realiza a través de un grupo de coordinación (**ICCG**)



Funcionamiento del SCCS

- ✓ Consta de científicos con más de 10 años de experiencia profesional y de diferentes disciplinas
- ✓ Su labor se basa en la independencia, transparencia, confidencialidad (Documento de reglamento)
- ✓ Información pública del CV, compromiso de confidencialidad y de obligaciones, conflicto de intereses
- ✓ Información pública de las agendas de cada reunión
- ✓ Diferentes grupos de trabajo: Ingredientes cosméticos, Tintes de cabello, Metodologías, Nanomateriales, Sensibilización y fragancias, Triclosan y resistencia antimicrobiana, Nitrosaminas , Threshold of Toxicological Concern (TTC), Food Imitating Products





ANEXOS 1223/2009

Ingredientes con
potencial riesgo
para la salud

II prohibidos

III con restricciones

IV colorantes

V conservantes

VI filtros UV

Notes of guidance

- ✓ Notes of Guidance for the toxicity testing of cosmetic ingredients:
28 June 1982, EU Report 8794.
- ✓ Notes of Guidance for testing of cosmetic ingredients for their safety evaluation:
1st Revision: SPC/803/5/90,
2nd Revision: DGXXIV/1878/97,
3rd Revision: SCCNFP/0119/99,
4th Revision: SCCNFP/0321/00.
- ✓ Notes of Guidance for the testing of cosmetic ingredients and their safety evaluation:
5th Revision: SCCNFP/0690/03,
6th Revision: SCCP/1005/06.
- ✓ Notes of Guidance for the testing of cosmetic ingredients and their safety evaluation:
7th Revision: SCCS/1416/11
8th Revision: SCCS/1501/12



Opiniones del SCCS



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SCCS - Opinions

OPINIONS

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Opinions open for comments

The opinions in this section have been developed by the SCCS on the basis of a specific set of data (dossier) submitted by an applicant (e.g. Industry, Member State authorities, etc) in order to satisfy specific regulatory requirements (e.g. Directive 76/768/EEC, Directive 2009/48/EC, etc). The opinions have been approved for adoption by the SCCS in its most recent plenary meeting and are now open for comments by applicants, national authorities and other interested parties for a period of four weeks after publication (the exact deadline is given for each opinion). The intent of this commenting period is for applicants and other interested parties to provide limited additional perspective and/or clarification on the evaluation, interpretation,

Opinión del SCCS (ejemplo)

2. TERMS OF REFERENCE

1. Does the Scientific Committee on Consumer Safety (SCCS) consider HC Red n° 16 safe for use as non-oxidative hair dye formulations with a concentration of maximum 1.5% on the head taken into account the scientific data provided?
2. Does the SCCS consider HC Red n° 16 safe for use in oxidative hair dye formulations with a concentration of 1.5% in the finished cosmetic products resulting in a concentration of 0.75% on the head after mixing with an oxidising agent taken into account the scientific data provided?
3. Does the SCCS recommend any restrictions with regard to the use of HC Red n° 16 in oxidative or non-oxidative hair dye formulations (e.g. max conc. in the finish cosmetic product, dilution ratio with hydrogen peroxide, warning etc?)

¿Qué se pide a un Dossier?

Características físicas y químicas:

- 1) identidad química
- 2) forma física
- 3) peso molecular
- 4) identificación y pureza
- 5) identificación de impurezas o contaminantes
- 6) solubilidad
- 7) coeficiente de partición (Log Pow)
- 8) otras características físicas o químicas relevantes
- 9) homogeneidad y estabilidad
- 10) funciones y usos



Opinion SCCS (ejemplo)

3.1. Chemical and Physical Specifications

3.1.1. Chemical identity

3.1.1.1. Primary name and/or INCI name

HC Red n° 16 (INCI name)

3.1.1.2. Chemical names

1,4-Benzenediamine, 2-nitro-N1-2-propenyl- (9CI)
N-(2-Nitro-4-aminophenyl)-allylamine

3.1.1.3 Trade names and abbreviations

Ro 1318
COLIPA B 114

3.1.1.4 CAS /EC number

CAS: 160219-76-1
EC: / (substance not in use in EU)

Opinion SCCS (ejemplo)

3.1.6 Solubility

Water: < 1 g/l room temperature

Ethanol: 5 – 50 g/l room temperature

DMSO: > 100 g/l room temperature

Comment

Method for water solubility determination is not reported.

3.1.7 Partition coefficient (Log Pow)

Log Po/w: 1.4 (calculated)

Comment

Log Po/w has not been determined by EEC method A.8.

3.1.8 Additional physicochemical specifications

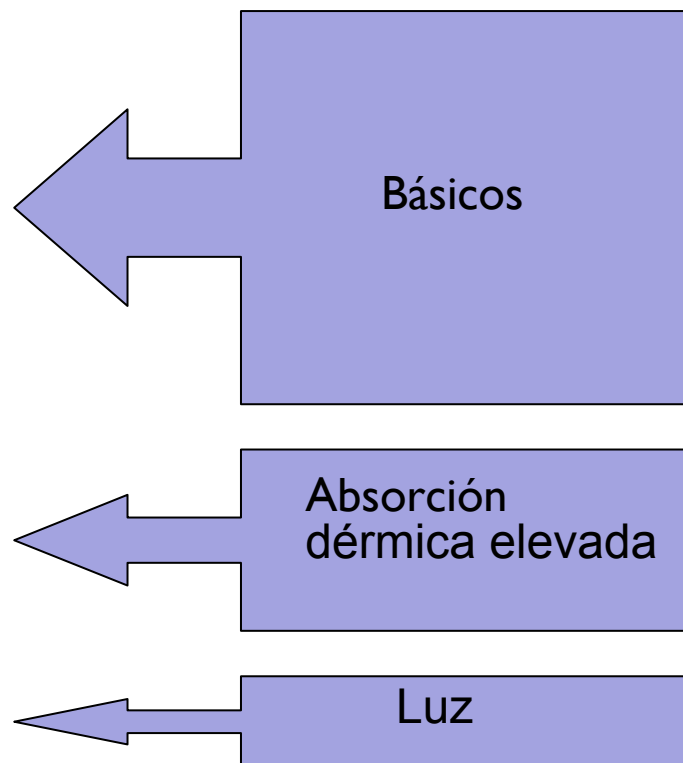
Melting point: 77 – 84 °C

UV/Visible spectrum: $\lambda_{\max}$ at 247nm and 505 nm

Dossier en estudio por SCCS

Toxicidad:

- ✓ Toxicidad aguda
 - ✓ Irritación y corrosión
 - ✓ Sensibilización dérmica
 - ✓ Absorción dérmica
 - ✓ Toxicidad repetida
 - ✓ Mutagenicidad / genotoxicidad
-
- ✓ Carcinogenicidad
 - ✓ Toxicidad de la reproducción
 - ✓ Toxicocinética
-
- ✓ Fototoxicidad
 - ✓ Datos Humanos



Estudios de toxicidad

- ✓ Resumen
- ✓ Descripción breve metodología
- ✓ Resultados
- ✓ Conclusiones

- ✓ Comentario del SCCS

Opinion SCCS (ejemplo)

3.3.4. Dermal / percutaneous absorption

Comment

The skin of only two pigs was used.

4.52 $\mu\text{g}/\text{cm}^2$ (the mean + 2SD) will be used to calculate the MOS under oxidative conditions and 19.52 $\mu\text{g}/\text{cm}^2$ (the mean + 2SD) under nonoxidative conditions



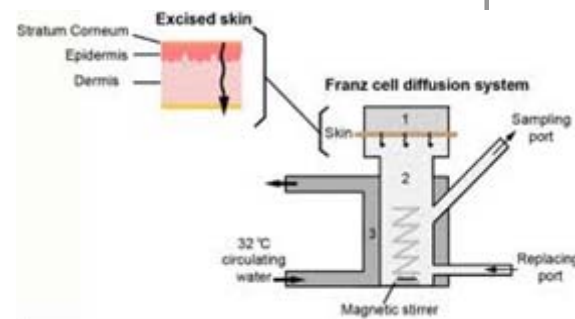
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agencia española de
medicamentos y
productos sanitarios

JORNADA INFORMATIVA SOBRE EVALUACIÓN DE LA SEGURIDAD DE PRODUCTOS COSMÉTICOS

SCCS/1358/10



Scientific Committee on Consumer Safety

SCCS

**Basic criteria for the *in vitro* assessment of dermal
absorption of cosmetic ingredients**



Documentos básicos SCCS

- Notes of Guidance. 8th Revision: SCCS/I501/I2
- Basic criteria for the *in vitro* assessment of dermal absorption of cosmetic ingredients, 22 Junio 2010. SCCS/I358/I0
- MEMORANDUM on Alternative Test Methods in Human Health Safety Assessment of Cosmetic Ingredients in the European Union, 8 Diciembre 2009. SCCS/I294/I0.
- Memorandum (addendum) on the *in vitro* test EPISKIN™ for skin irritation testing, 14 Diciembre 2010. SCCS/I392/I0
- Guidance on the safety assessment of nanomaterials in cosmetics, Junio 2012. SCCS/I484/I2
- Memorandum on hair dye Chemical Sensitisation, Febrero 2013, SCCS/I509/I3



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MUCHAS GRACIAS

Prof. Dra María Pilar Vinardell Martínez-Hidalgo
Facultad de Farmacia
Email: mpvinardellmh@ub.edu



Universitat de Barcelona