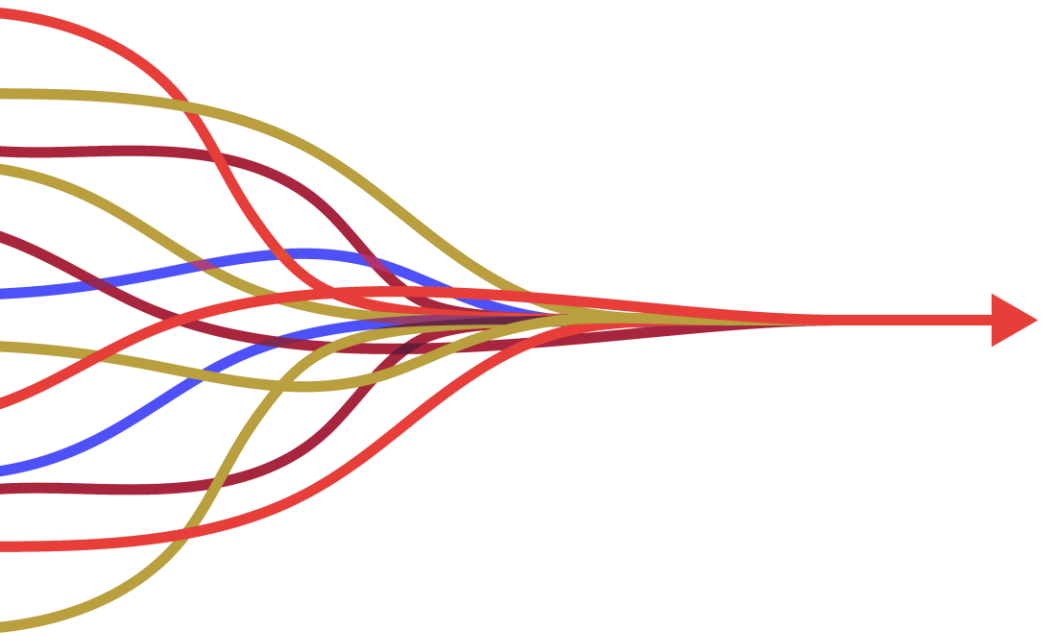


The choice of the right ingredient: UV filter

Giovanna Ecclesia – ACEF

Milano, 22-23 Novembre

Relatrice

Giovanna Ecclesia

Product Specialist and Technical Support

giovanna.ecclesia@acef.it

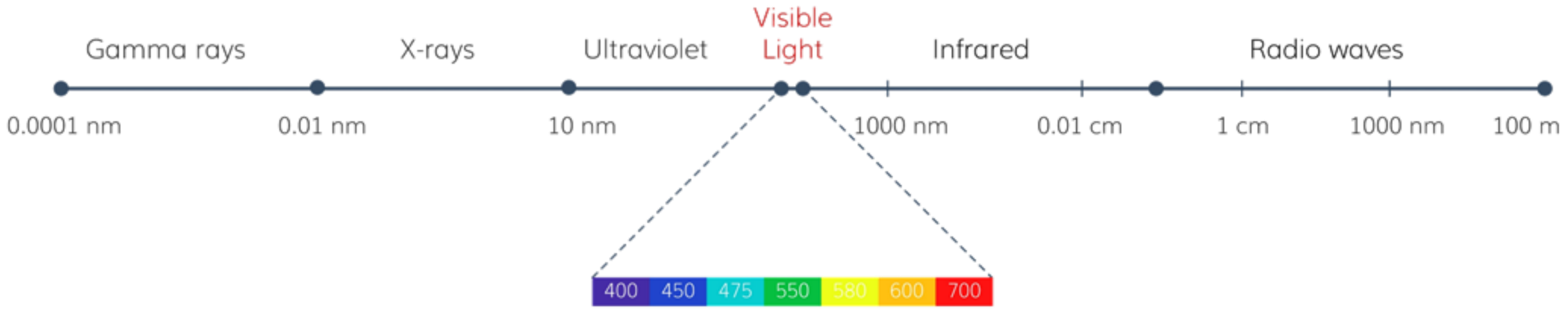
ACEF COSMETICA

Meccanismo d'azione

Il sole emette **radiazioni elettromagnetiche (REM)** caratterizzate da un parametro fondamentale, la **lunghezza d'onda.**

Grazie all'assorbimento atmosferico, lo spettro solare che raggiunge la superficie terrestre è composto da radiazioni comprese tra 290 e 2500-3000 nm.

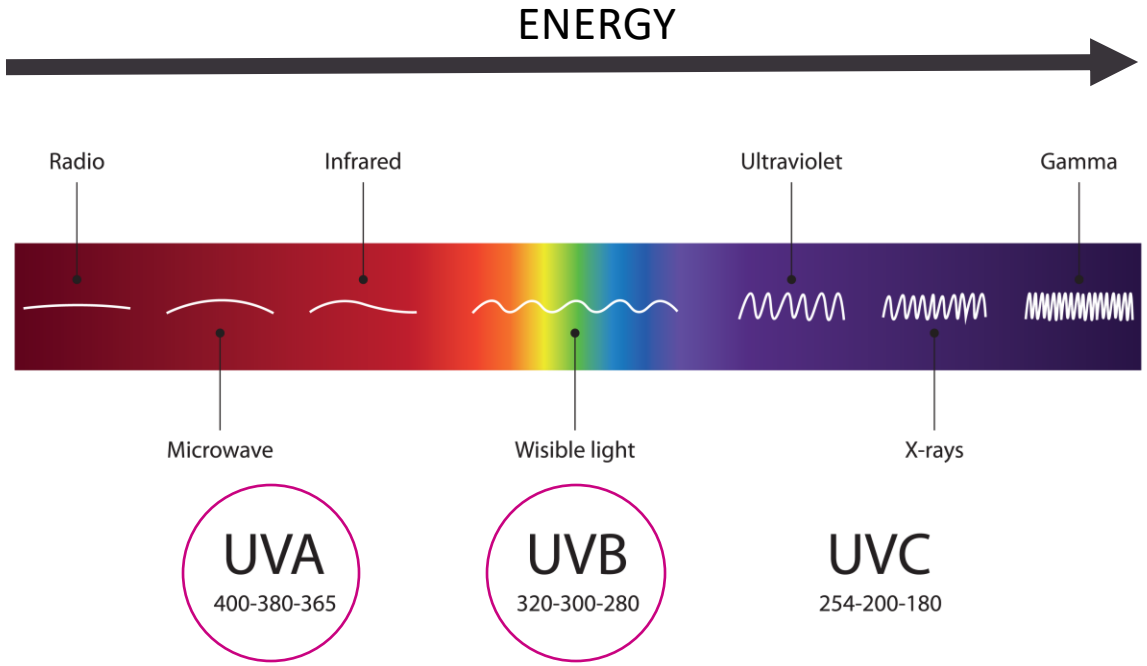
UVC	UVB	UVA	VISIBILE	INFRAROSSO
100	280	315	400	760



Meccanismo d’azione

UVA → energia minore, lunghezza d’onda maggiore

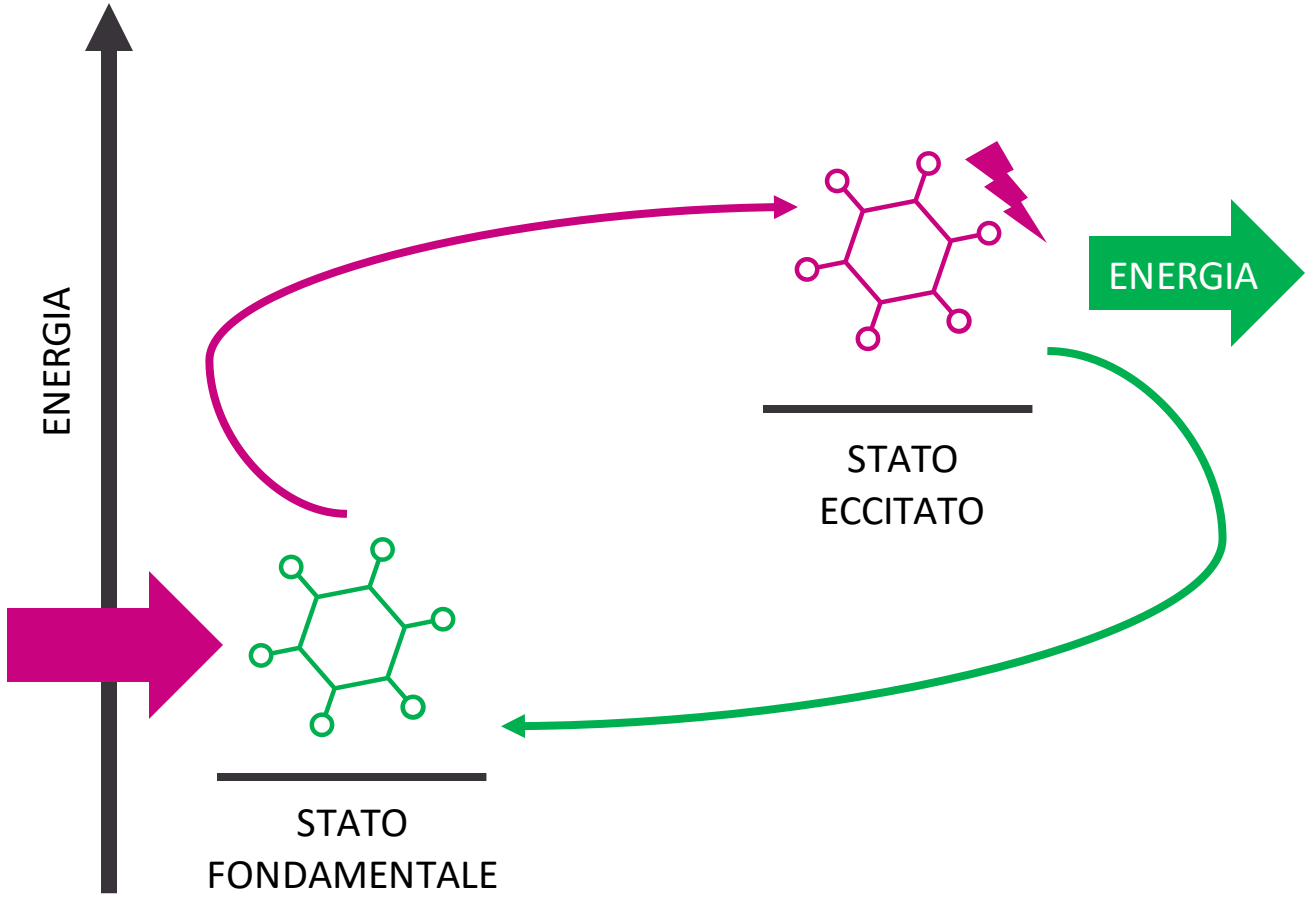
UVB → energia maggiore, lunghezza d’onda minore



Meccanismo d'azione

«Nulla si crea, nulla si distrugge, tutto si **trasforma**.»

A. Lavoisier



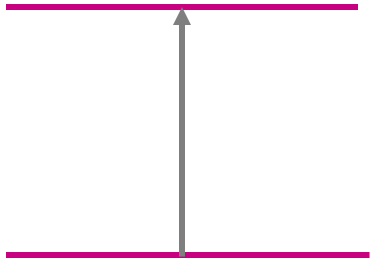
Meccanismo d’azione

All’interno dei filtri solari distinguiamo due categorie:

Organici → impropriamente definiti «chimici», rappresentano la categoria più numerosa;

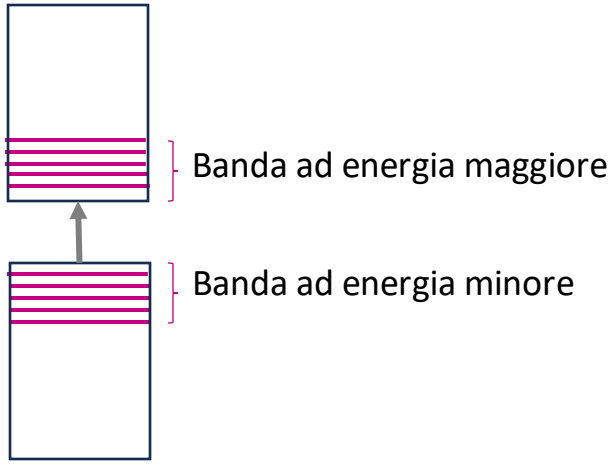
Inorganici → impropriamente definiti «fisici»: ossido di zinco e ossido di titanio.

FILTRI ORGANICI

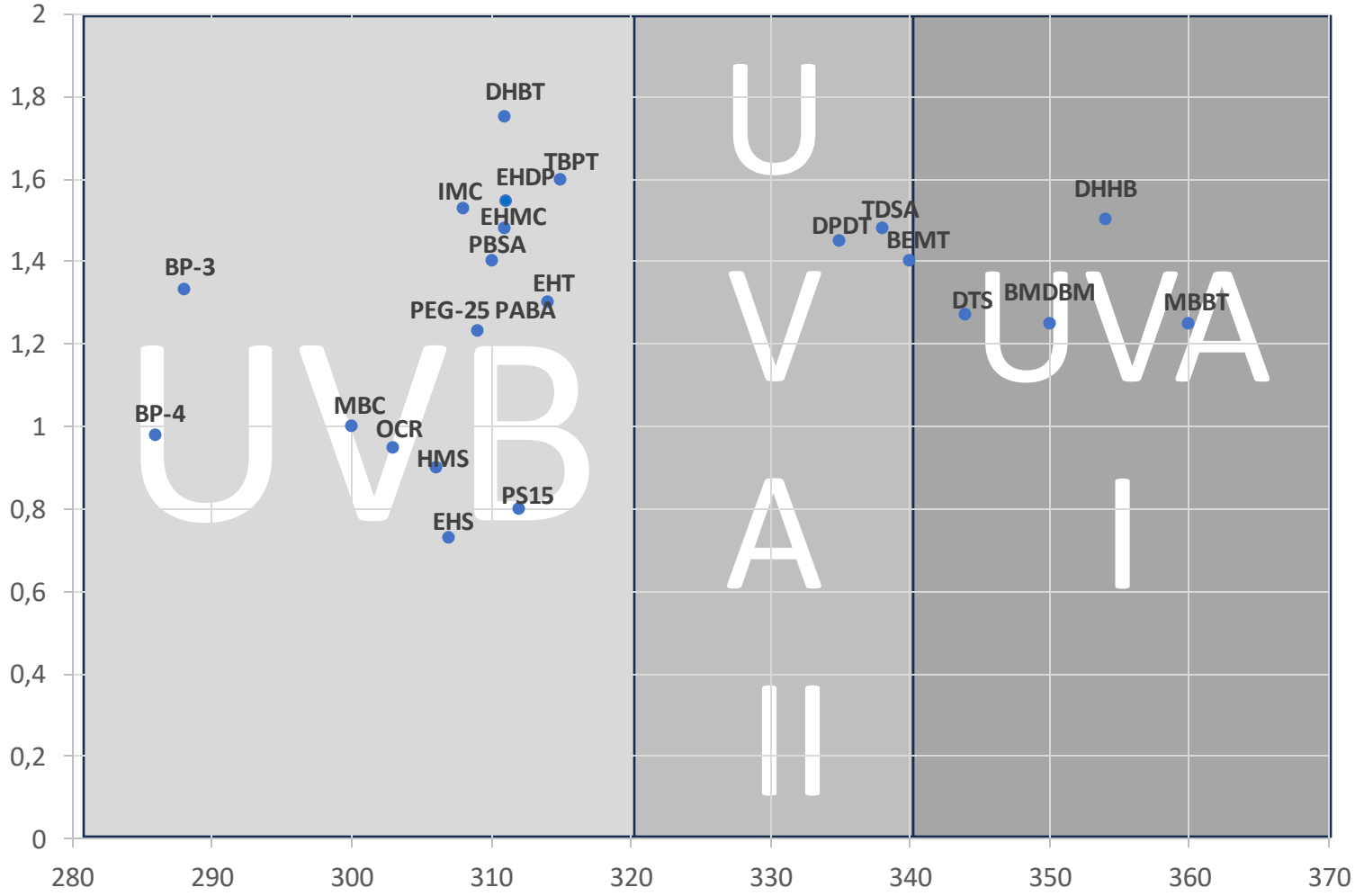


$\uparrow = E \longrightarrow \lambda \longrightarrow$ assorbimento

FILTRI INORGANICI



Meccanismo d’azione

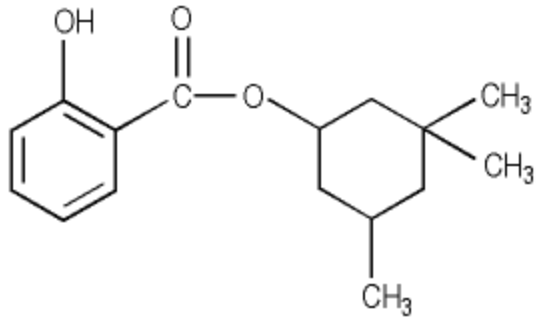


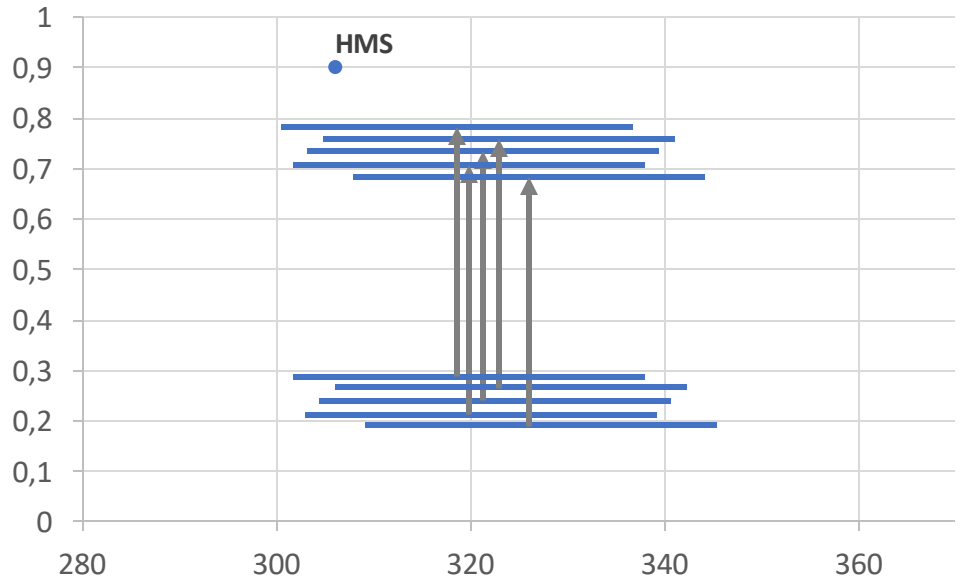
Meccanismo d'azione

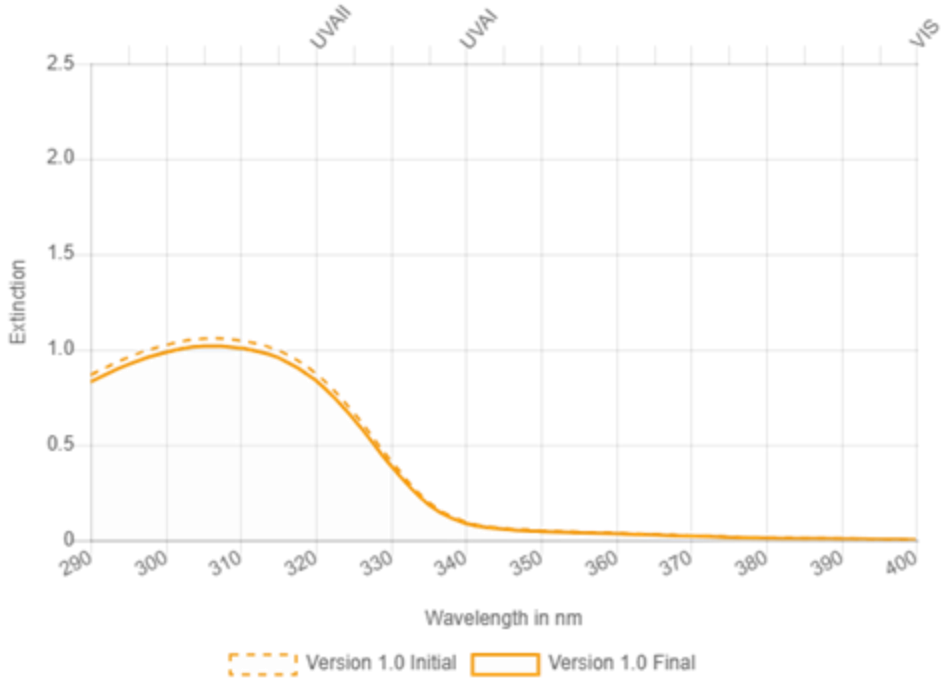
HOMOSALATE

$= E \longrightarrow \lambda$

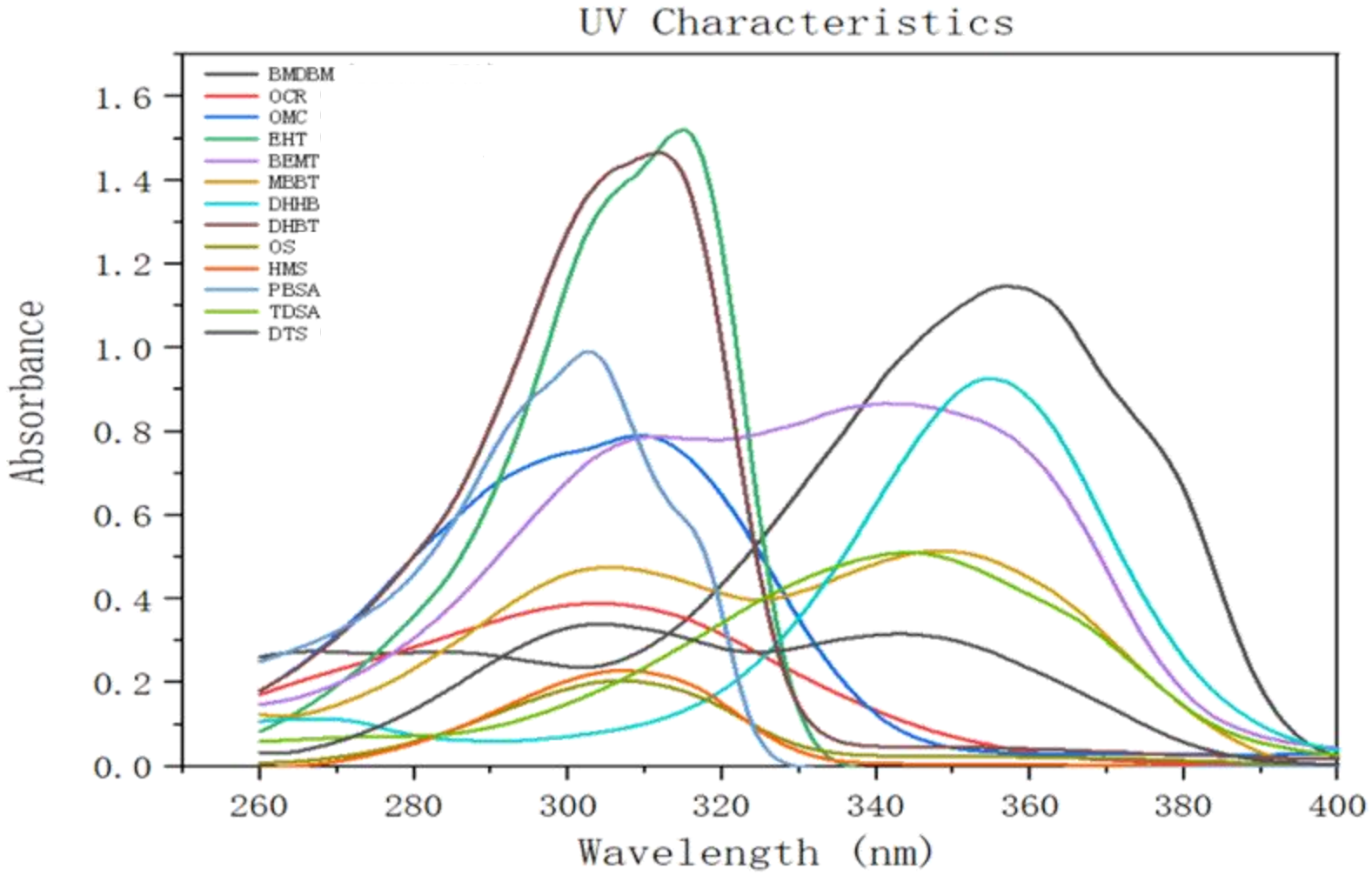
λmax = 306 nm







Meccanismo d’azione



Panoramica filtri Allegato VI

COSING COSMETICS INGREDIENTS

https://ec.europa.eu/growth/tools-databases/cosing/reference/annexes

ANNEX VI,Last update: 17/10/2023

LIST OF UV FILTERS ALLOWED IN COSMETIC PRODUCTS

Reference Number	Substance identification				Conditions			Wording of conditions of use and warnings	Update date
	Chemical name / INN / XAN	Name of Common Ingredients Glossary	CAS Number	EC Number	Product Type, body parts	Maximum concentration in ready for use preparation	Other		
2	N,N,N-Trimethyl-4-(2-oxoborn-3-ylidenemethyl) anilinium methyl sulphate	Camphor benzalkonium methosulfate	52793-97-2	258-190-8	6%				15/10/2010
3	Benzoic acid, 2-hydroxy-, 3,3,5-trimethylcyclohexyl ester / Homosalate	HOMOSALATE	118-56-9	204-260-8	7,34 %	From 1 January 2025 cosmetic products containing that substance and not complying with the conditions shall not be placed on the Union market. From 1 July 2025 cosmetic products containing that substance and not complying with the conditions shall not be made available on the Union market.			11/11/2022
4	2-Hydroxy-4-methoxybenzophenone / Oxybenzone	BENZOPHENONE-3	131-57-7	205-031-5	a) 6% b) 2,2% c) 0,5% Footnote 1: However, cosmetic products containing '2-Hydroxy-4-methoxy-benzophenone/Oxybenzone' and complying with the restrictions set out in Regulation (EC) No 1223/2009 as applicable on 27 July 2022 may be placed on the Union market until 28 January 2023 and be made available on the Union market until 28 July 2023.	a) If used at 0,5 % to protect product formulation, the levels used as UV filter must not exceed 5,5 %. b) If used at 0,5 % to protect product formulation, the levels used as UV filter must not exceed 1,7 %.	For a) and b): Contains Benzophenone-3 (*) Footnote (*): Not required if concentration is 0,5 % or less and when it is used only for product protection purposes.		29/08/2022
5	Moved or deleted								03/10/2016
6	2-Phenylbenzimidazole-5-sulphonic acid and its potassium, sodium and triethanolamine salts / Ensulizole	PHENYLBENZIMIDAZOLE SULFONIC ACID	27503-81-7	248-502-0	8%(as acid)				08/03/2011
7	3,3'-(1,4-Phenylenedimethylene) bis (7,7-dimethyl-2-oxobicyclo-[2.2.1] hept-1-ylmethanesulfonic acid) and its salts / Ecamsule	TEREPHTHALYLIDENE DICAMPHOR SULFONIC ACID	92761-26-7 / 90457-82-2	410-960-6 / -	10%(as acid)				26/10/2010
8	1-(4-tert-Butylphenyl)-3-(4-methoxyphenyl) propane-1,3-dione / Avobenzone	Butyl Methoxydibenzoylmethane	70356-09-1	274-581-6	5%				15/10/2010
9	alpha-(2-Oxoborn-3-ylidene)toluene-4-sulphonic acid and its salts	BENZYLIDENE CAMPHOR SULFONIC ACID	56039-58-8	-	6%(as acid)				26/10/2010

Panoramica filtri Allegato VI

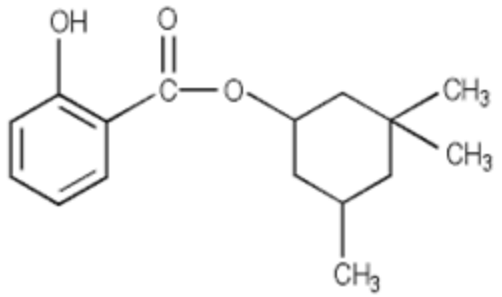
ANNEX VI, Last update: 17/10/2023

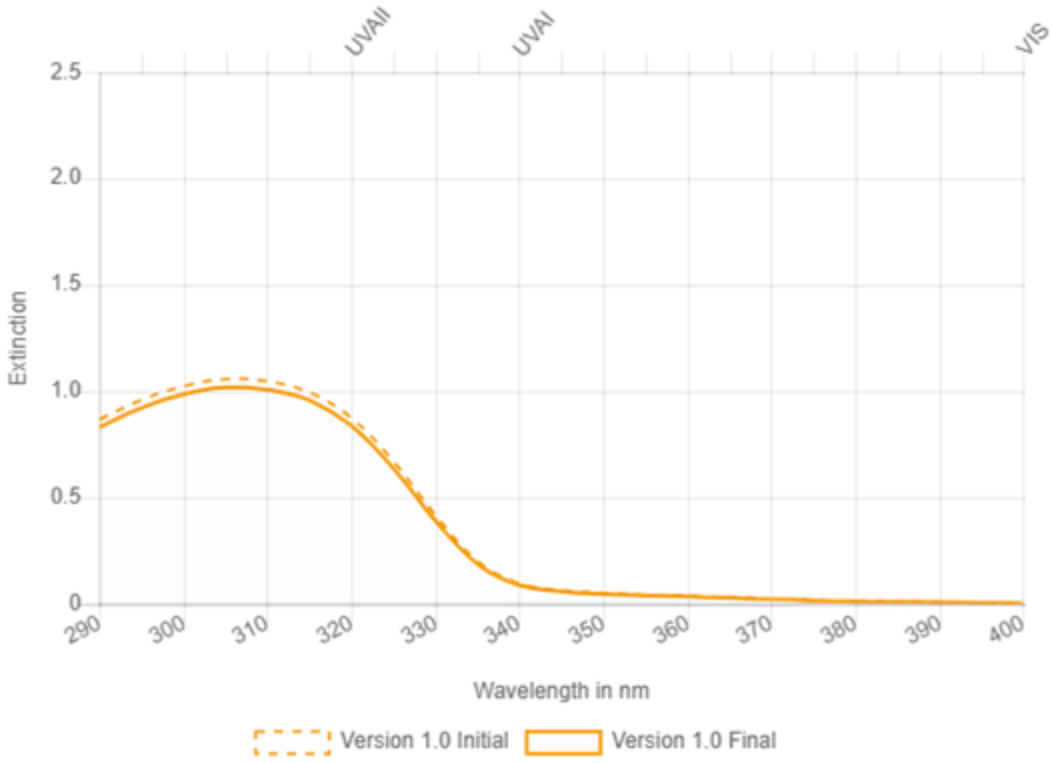
Reference Number	Substance identification				Conditions			Other	Update date
	Chemical name / INN / XAN	Name of Common Ingredients Glossary	CAS Number	EC Number	Product Type, body parts	Maximum concentration in ready for use preparation			
3	Benzoic acid, 2-hydroxy-, 3,3,5-trimethylcyclohexyl ester / Homosalate	HOMOSALATE	118-56-9	204-260-8	7,34 %	From 1 January 2025 cosmetic products containing that substance and not complying with the conditions shall not be placed on the Union market. From 1 July 2025 cosmetic products containing that substance and not complying with the conditions shall not be made available on the Union market.			11/11/2022

Panoramica filtri Allegato VI

HOMOSALATE

Aspetto	LIQUIDO LIPOSOLUBILE
Concentrazione massima ammessa	Globale 10%
λmax	306 nm





SCCS OPINION

Panoramica filtri Allegato VI

HOMOSALATE

4. CONCLUSION 2007

Based on the information provided, the SCCP is of the opinion that the use of homosalate at a maximum concentration of 10% w/w in cosmetic sun screen product does not pose a risk to the health of the consumer.

Uses of homosalate in other types of cosmetic products at concentrations up to 10.0% also does not pose a risk to the health of the consumer.

Only the dermal application of homosalate was considered, not its use in 'spray'-applications.

4. CONCLUSION 2021

1. In light of the information provided and taking under consideration the concerns related to potential endocrine disrupting properties of Homosalate, does the SCCS consider Homosalate safe when used as a UV-filter in face products (face cream and pump spray) up to a maximum concentration of 7.34 %?

On the basis of safety assessment, and considering the concerns related to potential endocrine disrupting properties of Homosalate, the SCCS is of the opinion that Homosalate is safe as a UV-filter at concentrations up to 7.34% in face cream and pump spray.

4. CONCLUSION 2021

1. In light of the data provided and taking under consideration the concerns related to potential endocrine disrupting properties of homosalate, does the SCCS consider homosalate safe when used as a UV-filter in cosmetic products up to a maximum concentration of 10%?

On the basis of safety assessment of homosalate, and considering the concerns related to potential endocrine disrupting properties, the SCCS has concluded that homosalate is not safe when used as a UV-filter in cosmetic products at concentrations of up to 10%.

2. Alternatively, what is according to the SCCS, the maximum concentration considered safe for use of homosalate as a UV-filter in cosmetic products?

In the SCCS's opinion, the use of homosalate as a UV filter in cosmetic products is safe for the consumer up to a maximum concentration of 0.5% homosalate in the final product.

3. Does the SCCS have any further scientific concerns with regard to the use of homosalate in cosmetic products?

It needs to be noted that the SCCS has regarded the currently available evidence for endocrine disrupting properties of homosalate as inconclusive and at best equivocal. This applies to all of the available data derived from *in silico* modelling, *in vitro* tests and *in vivo* studies, when considered individually or taken together. The SCCS considers that, whilst there are indications from some studies to suggest that homosalate may have endocrine effects, the evidence is not conclusive enough at present to enable deriving a specific endocrine-related toxicological point of departure for use in safety assessment.

Exposure to homosalate from other products than those in this Opinion has not been considered.

Combined exposure to salicylic acid either formed by metabolic transformation from homosalate, other salicylates (e.g. methylsalicylate) or directly from salicylic acid itself has not been considered in this opinion.

The use of Homosalate at the lower concentrations may have a bearing on efficacy as UV-filter, however this is outside the SCCS remit to assess the efficacy of cosmetic ingredients.

Panoramica filtri Allegato VI

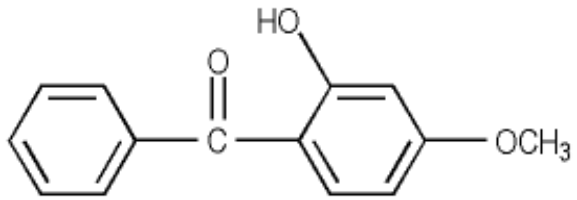
ANNEX VI, Last update: 17/10/2023

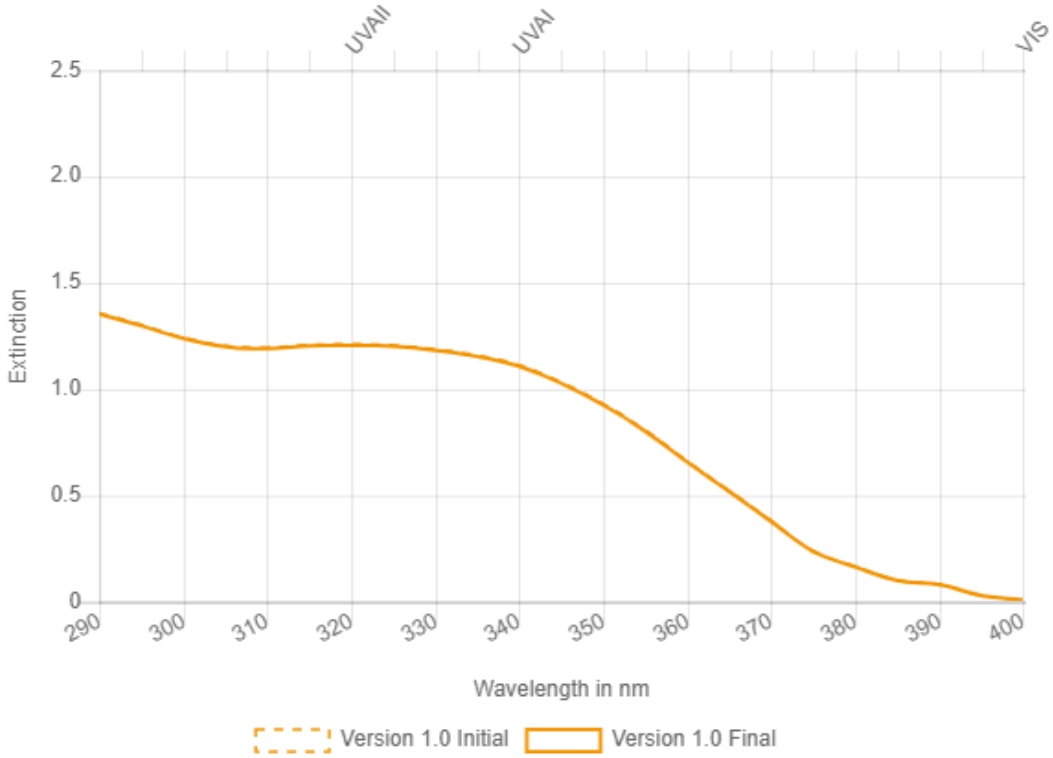
Reference Number	Substance identification				Conditions			Update date
	Chemical name / INN / XAN	Name of Common Ingredients Glossary	CAS Number	EC Number	Product Type, body parts	Maximum concentration in ready for use preparation	Other	
4	2-Hydroxy-4-methoxybenzophenone / Oxybenzone	**BENZOPHENONE-3**	131-57-7	205-031-5	a) 6% b) 2,2% c) 0,5% Footnote 1: However, cosmetic products containing '2-Hydroxy-4-Methoxy-benzophenone/Oxybenzone' and complying with the restrictions set out in Regulation (EC) No 1223/2009 as applicable on 27 July 2022 may be placed on the Union market until 28 January 2023 and be made available on the Union market until 28 July 2023.	a) If used at 0,5 % to protect product formulation, the levels used as UV filter must not exceed 5,5 %. b) If used at 0,5 % to protect product formulation, the levels used as UV filter must not exceed 1,7 %	For a) and b): Contains Benzophenone-3 (*) Footnote (*): Not required if concentration is 0,5 % or less and when it is used only for product protection purposes	29/08/2022

Panoramica filtri Allegato VI

BENZOPHENONE-3

Aspetto	POLVERE LIPOSOLUBILE
Concentrazione massima ammessa	Globale 5%
λmax_{UVA}	327 nm
λmax_{UVB}	288 nm





SCCS OPINION

Panoramica filtri Allegato VI

BENZOPHENONE-3

4. Conclusion 2006

It is the opinion of the SCCP that insufficient data are presented to calculate the Margin of Safety of Benzophenone-3 under the proposed conditions of use.

The following additional information is required:

- A dermal absorption study with Benzophenone-3 under its in-use concentrations (up to 10%) according to OECD Guideline 428 combined with SCCP/0970/06.

These data are requested before end of March 2007.

4. Conclusion 2008

The SCCP is of the opinion that the use of benzophenone-3 as a UV-filter up to 6% in cosmetic sunscreen products and up to 0.5% in all types of cosmetic products to protect the formulation does not pose a risk to the health of the consumer, apart from its contact allergenic and photoallergenic potential.

4. Conclusion 2020

1. In light of the data provided and taking under consideration the concerns related to potential endocrine disrupting properties of Benzophenone-3, does the SCCS consider Benzophenone-3 safe when used as a UV-filter in cosmetic products up to a maximum concentration of 6% and up to 0.5% in cosmetic products to protect product formulation?

On the basis of safety assessment, and considering the concerns related to potential endocrine disrupting properties of benzophenone-3 (BP-3), the SCCS has concluded that:

f. The use of BP-3 as a UV-filter up to a maximum concentration of 6% in sunscreen products, either in the form of body cream, sunscreen propellant spray or pump spray, is not safe for the consumer.
g. The use of BP-3 as a UV-filter up to a maximum concentration of 6% in face cream, hand cream, and lipsticks is safe for the consumer.
h. The use of BP-3 up to 0.5% in cosmetic products to protect the cosmetic formulation is safe for the consumer.

2. *Alternatively, what is according to the SCCS the maximum concentration considered safe for use of Benzophenone-3 as a UV-filter in cosmetic products?*

In the SCCS's opinion, the use of BP-3 as a UV filter in the following sunscreen products is safe for the consumer up to a maximum concentration of:

a. 2.2% in body creams, in propellant sprays and in pump sprays, provided that there is no additional use of BP-3 at 0.5% in the same formulation for protecting the cosmetic formulation.
b. Where BP-3 is also used at 0.5% in the same formulation, the levels of BP-3 used as UV filter should not exceed 1.7% in body creams, in propellant sprays and in pump sprays.

3. *Does the SCCS have any further scientific concerns with regard to the use of Benzophenone-3 in cosmetic products?*

It needs to be noted that the SCCS has regarded the currently available evidence for endocrine disrupting properties of BP-3 as inconclusive, and at best equivocal. This applies to all of the available data derived from *in silico* modelling, *in vitro* tests and *in vivo* studies, either considered individually or taken together. The SCCS considers that, whilst there are indications from some studies to suggest that BP-3 may have endocrine effects, the overall evidence is not conclusive enough at present for the SCCS to ascertain whether or not BP-3 is an ED substance, and this warrants further investigations.

The SCCS mandates do not address environmental aspects. Therefore, this assessment did not cover the safety of BP-3 for the environment.

Panoramica filtri Allegato VI

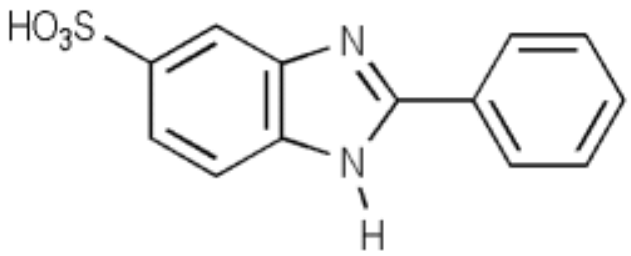
ANNEX VI, Last update: 17/10/2023

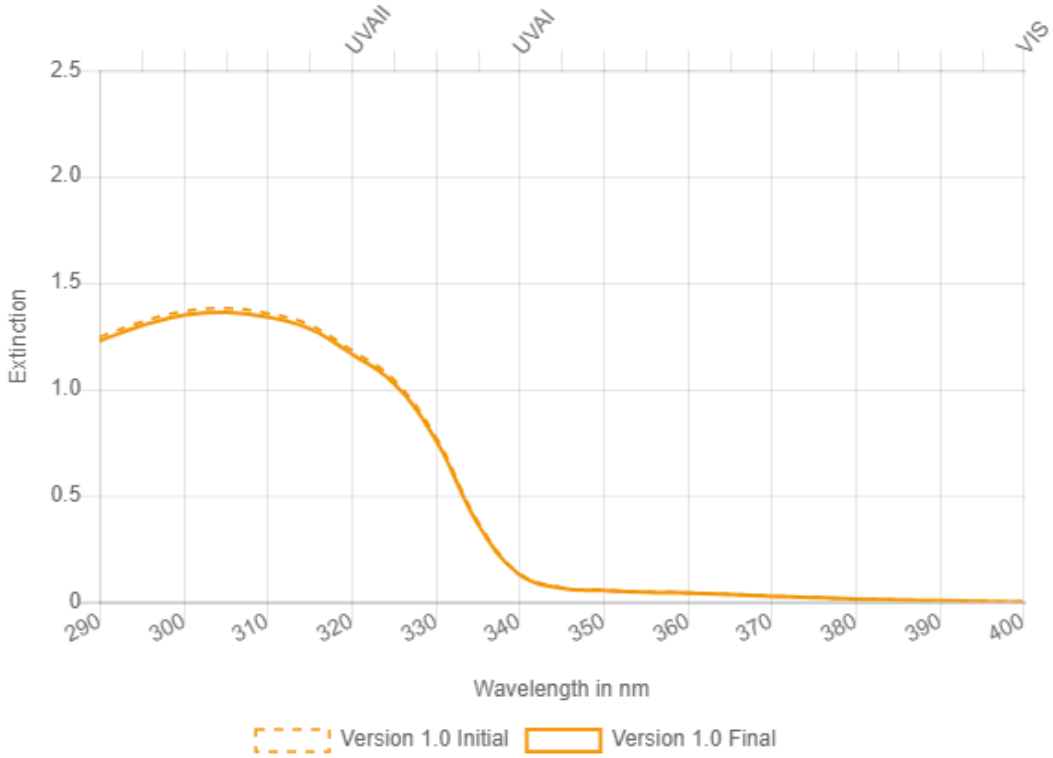
Reference Number	Substance identification				Conditions	Update date
	Chemical name / INN / XAN	Name of Common Ingredients Glossary	CAS Number	EC Number	Product Type, body parts	
6	2-Phenylbenzimidazole-5-sulphonic acid and its potassium, sodium and triethanolamine salts/ Ensulizole	PHENYLBENZIMIDAZOLE SULFONIC ACID	27503-81-7	248-502-0	8% (as acid)	08/03/2011

Panoramica filtri Allegato VI

PHENYLBENZIMIDAZOLE SULFONIC ACID

Aspetto	SOLUBILE IN ACQUA
Concentrazione massima ammessa	Globale 3%
λmax	310 nm





Panoramica filtri Allegato VI

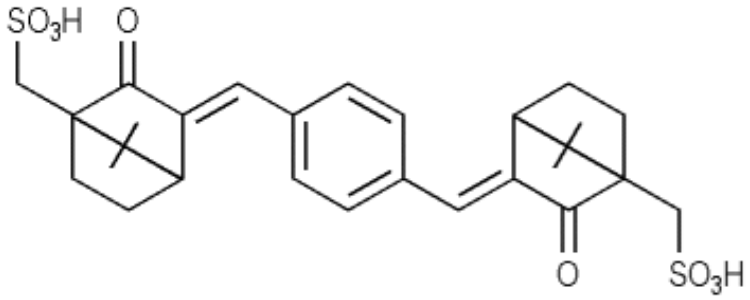
ANNEX VI, Last update: 17/10/2023

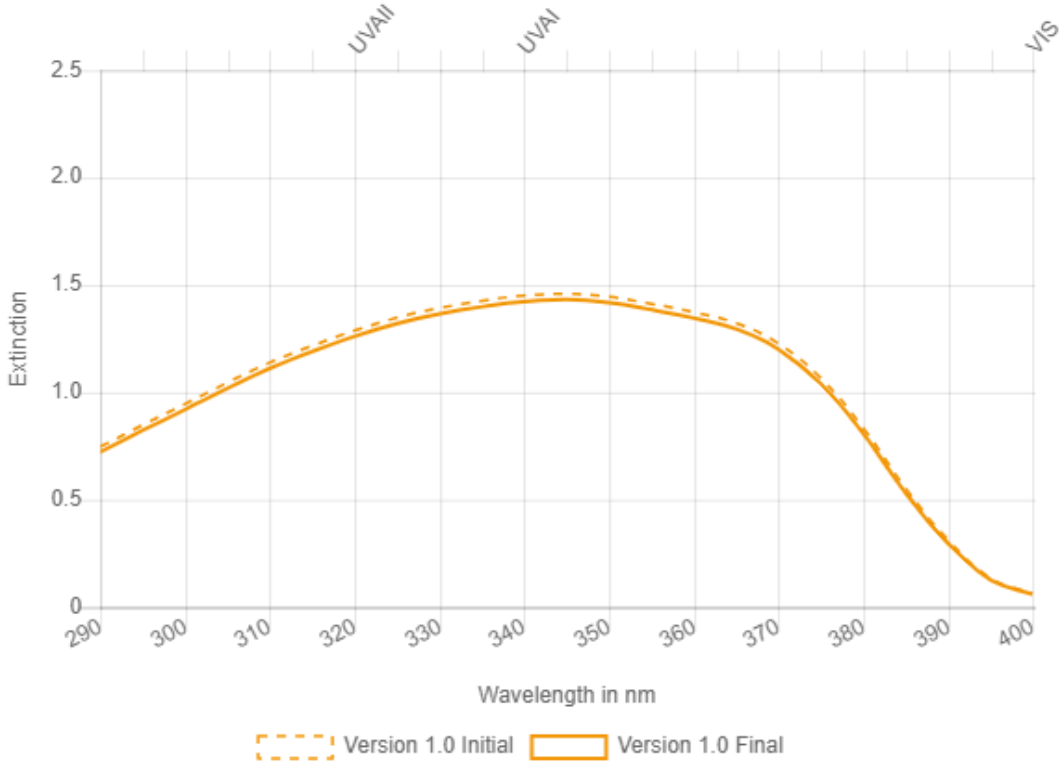
Reference Number	Substance identification				Conditions	Update date
	Chemical name / INN / XAN	Name of Common Ingredients Glossary	CAS Number	EC Number	Product Type, body parts	
7	3,3'-(1,4-Phenylenedimethylene) bis (7,7-dimethyl-2 -oxobicyclo-[2.2.1] hept-1-ylmethanesulfonic acid) and its salts / Ecamsule	TEREPHTHALYLIDENE DICAMPHOR SULFONIC ACID	92761-26-7 / 90457-82-2	410-960-6 / -	10%(as acid)	26/10/2010

Panoramica filtri Allegato VI

TEREPHTHALYLIDENE DICAMPHOR SULFONIC ACID

Aspetto	SOLUBILE IN ACQUA
Concentrazione massima ammessa	3%
λmax	338 nm





Panoramica filtri Allegato VI

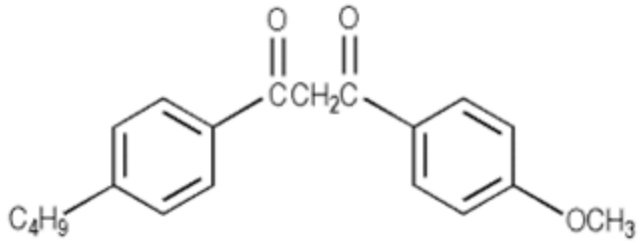
ANNEX VI, Last update: 17/10/2023

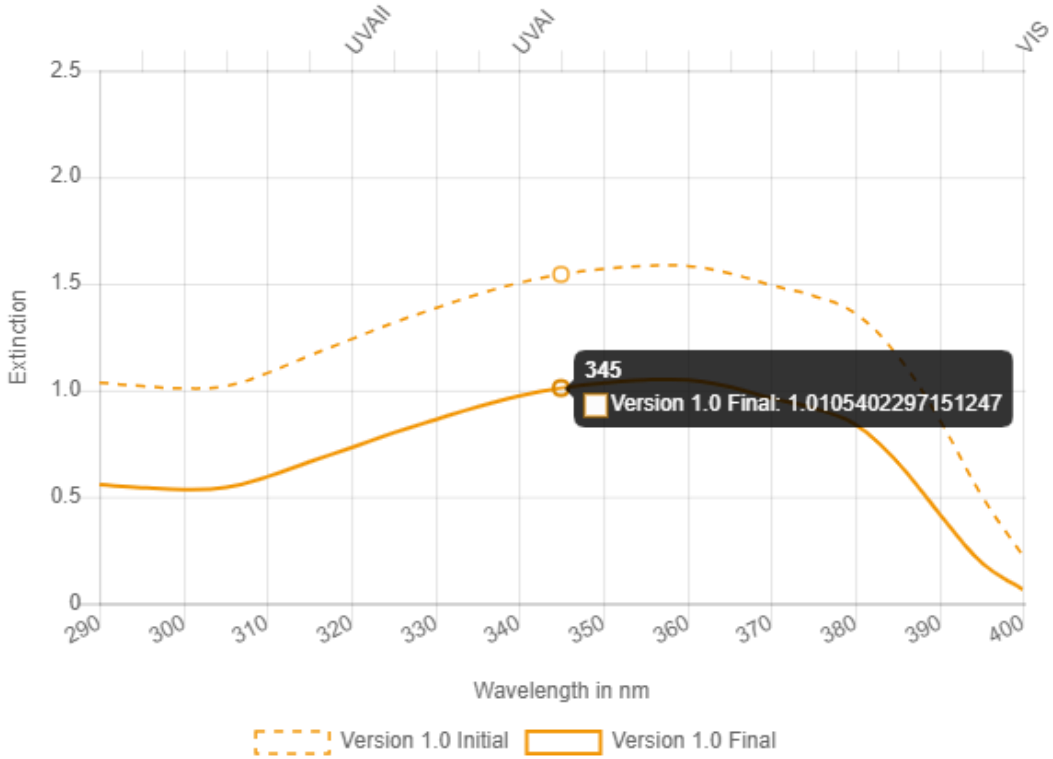
Reference Number	Substance identification				Conditions	Update date
	Chemical name / INN / XAN	Name of Common Ingredients Glossary	CAS Number	EC Number	Product Type, body parts	
8	1-(4-tert-Butylphenyl)-3-(4-methoxyphenyl) propane-1,3-dione / Avobenzone	BUTYL METHOXYDIBENZOYLMETHANE	70356-09-1	274-581-6	5%	15/10/2010

Panoramica filtri Allegato VI

BUTYL METHOXYDIBENZOYLMETHANE

Aspetto	POLVERE LIPOSOLUBILE
Concentrazione massima ammessa	Globale 3%
λmax_{ENOL}	350 nm
λmax_{CHETO}	260 nm





Panoramica filtri Allegato VI

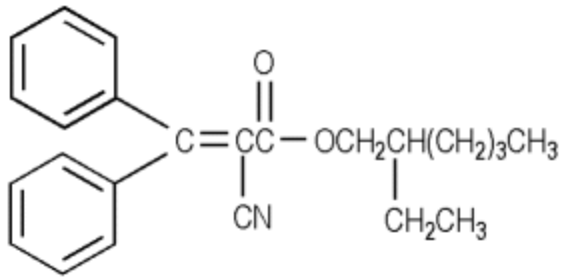
ANNEX VI, Last update: 17/10/2023

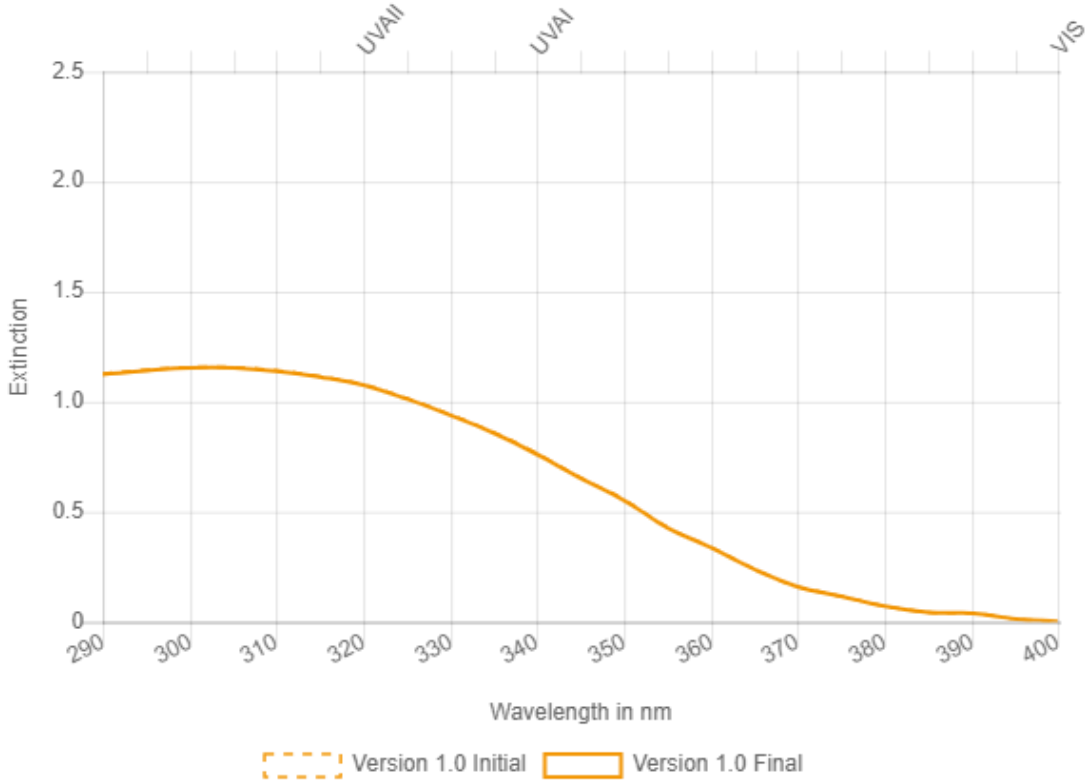
Reference Number	Substance identification				Conditions	Update date
	Chemical name / INN / XAN	Name of Common Ingredients Glossary	CAS Number	EC Number	Product Type, body parts	
10	2-Cyano-3,3-diphenyl acrylic acid 2-ethylhexyl ester / Octocrilene	OCTOCRYLENE	6197-30-4	228-250-8	a) 9% b) 10% Footnote (*3): Benzophenone as an impurity and/or degradation product of Octocrylene shall be kept at trace level.	31/01/2023

Panoramica filtri Allegato VI

OCTOCRYLENE

Aspetto	LIQUIDO MISCIBILE IN OLIO
Concentrazione massima ammessa	Globale 10%
λmax	303 nm





SCCS OPINION

Panoramica filtri Allegato VI

OCTOCRYLENE

4. CONCLUSION 2021

1. In light of the data provided and taking under consideration the concerns related to potential endocrine disrupting properties of Octocrylene, does the SCCS consider Octocrylene safe when used as a UV-filter in cosmetic products up to a maximum concentration of 10% (as acid)?

On the basis of safety assessment, and considering the concerns related to potential endocrine disrupting properties of Octocrylene, the SCCS is of the opinion that Octocrylene is safe as a UV-filter at concentrations up to 10% in cosmetic products when used individually.

Octocrylene is also considered safe for a combined use of sunscreen cream/lotion, sunscreen *pump* spray, face cream, hand cream and lipstick at a concentration up to 10%. However, the use of Octocrylene at 10% or above in sunscreen *propellant* spray is not considered safe for the combined use.

2. Alternatively, what is according to the SCCS the maximum concentration considered safe for use of Octocrylene as a UV-filter in cosmetic products?

The use of Octocrylene in sunscreen *propellant* spray is considered safe when its concentration does not exceed 9% when used together with face cream, hand cream, and lipstick containing 10% Octocrylene.

3. Does the SCCS have any further scientific concerns with regard to the use of Octocrylene in cosmetic products?

The SCCS considers that, whilst there are indications from some *in vivo* studies to suggest that Octocrylene may have endocrine effects, the evidence is not conclusive enough at present to enable deriving a specific endocrine-related toxicological point of departure for use in safety assessment.

Contact sensitisation to Octocrylene has been reported, however, taking into consideration the widespread use of Octocrylene in cosmetic products, the number of reported cases of allergic contact dermatitis appears to be negligible.

It should be noted that occurrence of photoallergy to Octocrylene is strongly related to a previous photoallergy to topical ketoprofen.

Exposure to Octocrylene from other products than those in this Opinion has not been considered.

The SCCS mandates do not address environmental aspects. Therefore, this assessment did not cover the safety of Octocrylene for the environment.

Panoramica filtri Allegato VI

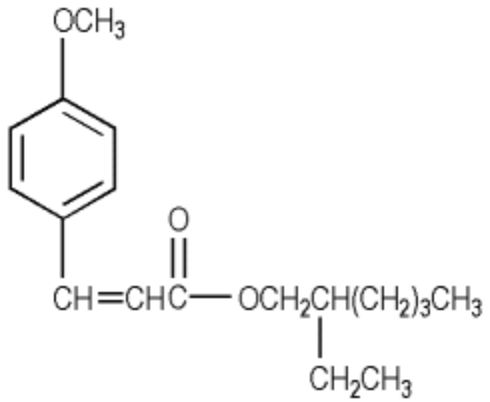
ANNEX VI, Last update: 17/10/2023

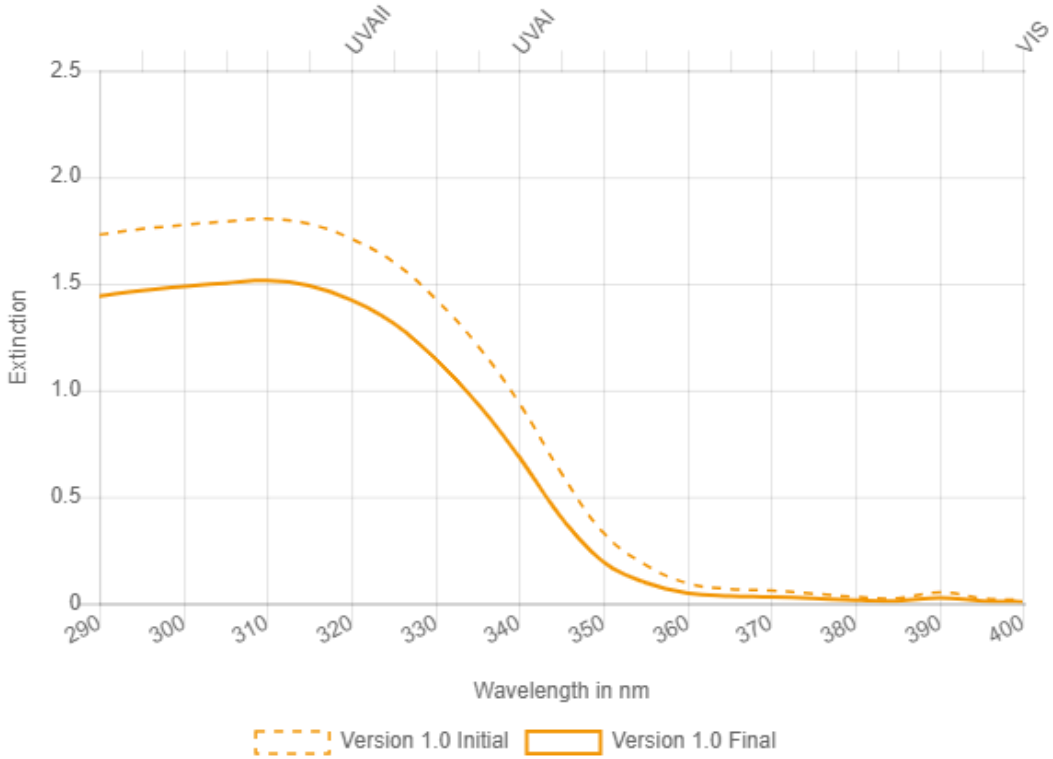
Reference Number	Substance identification				Conditions		Update date
	Chemical name / INN / XAN	Name of Common Ingredients Glossary	CAS Number	EC Number	Product Type, body parts	Maximum concentration in ready for use preparation	
12	2-Ethylhexyl 4-methoxycinnamate / Octinoxate	ETHYLHEXYL METHOXYCINNAMATE	5466-77-3	226-775-7	10%		18/07/2019

Panoramica filtri Allegato VI

ETHYLHEXYL METHOXYCINNAMATE

Aspetto	LIQUIDO MISCIBILE IN OLIO
Concentrazione massima ammessa	Globale 7,5%
λmax	311 nm





Panoramica filtri Allegato VI

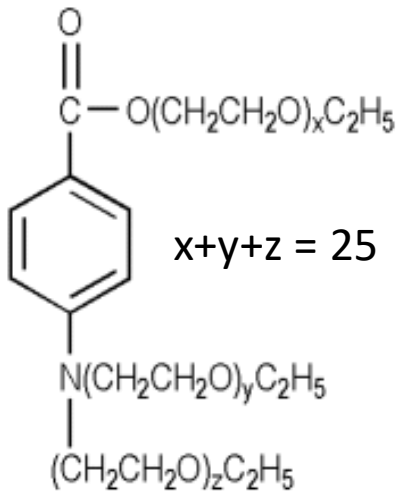
ANNEX VI, Last update: 17/10/2023

Reference Number	Substance identification				Conditions		Update date
	Chemical name / INN / XAN	Name of Common Ingredients Glossary	CAS Number	EC Number	Product Type, body parts	Maximum concentration in ready for use preparation	
13	Ethoxylated Ethyl-4-Aminobenzoate	PEG-25 PABA	116242-27-4	-	10%		15/10/2010

Panoramica filtri Allegato VI

PEG-25 PABA

Aspetto	LIQUIDO MISCIBILE IN ACQUA
Concentrazione massima ammessa	NON AMMESSO FDA
λmax	309 nm



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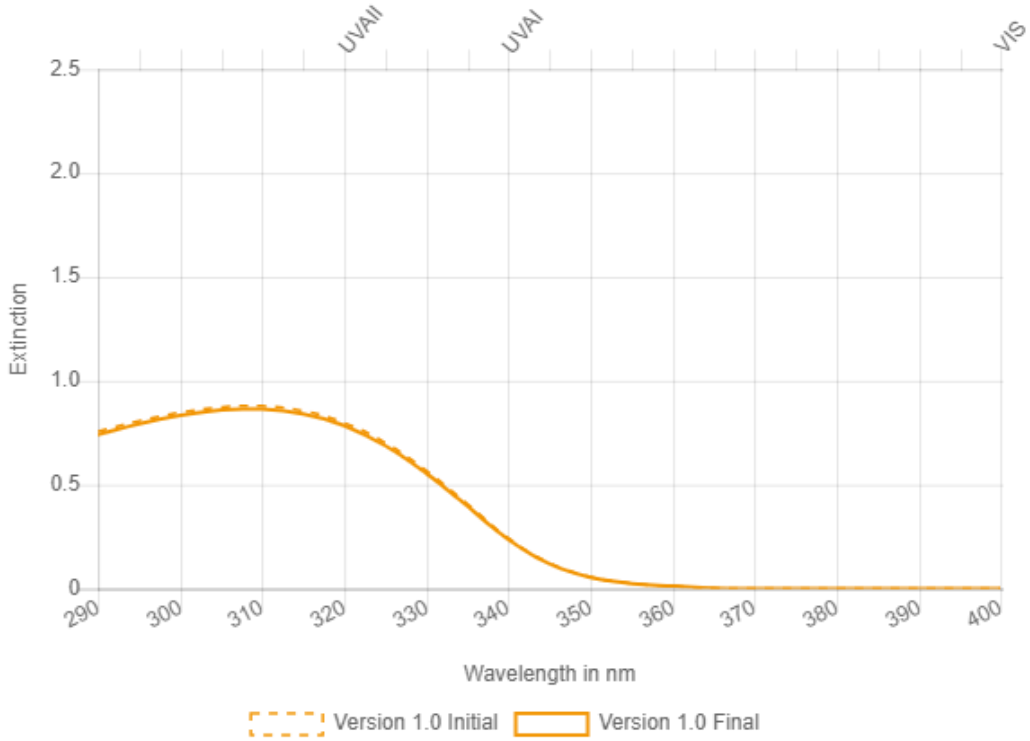


Panoramica filtri Allegato VI

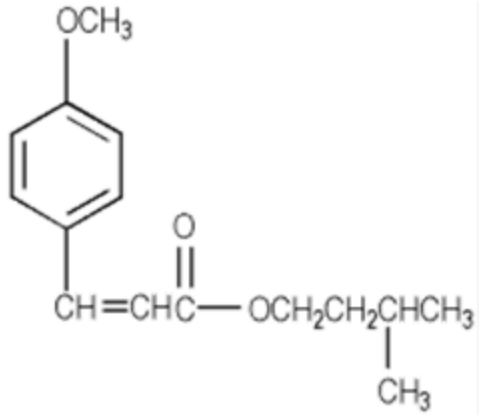
ANNEX VI, Last update: 17/10/2023

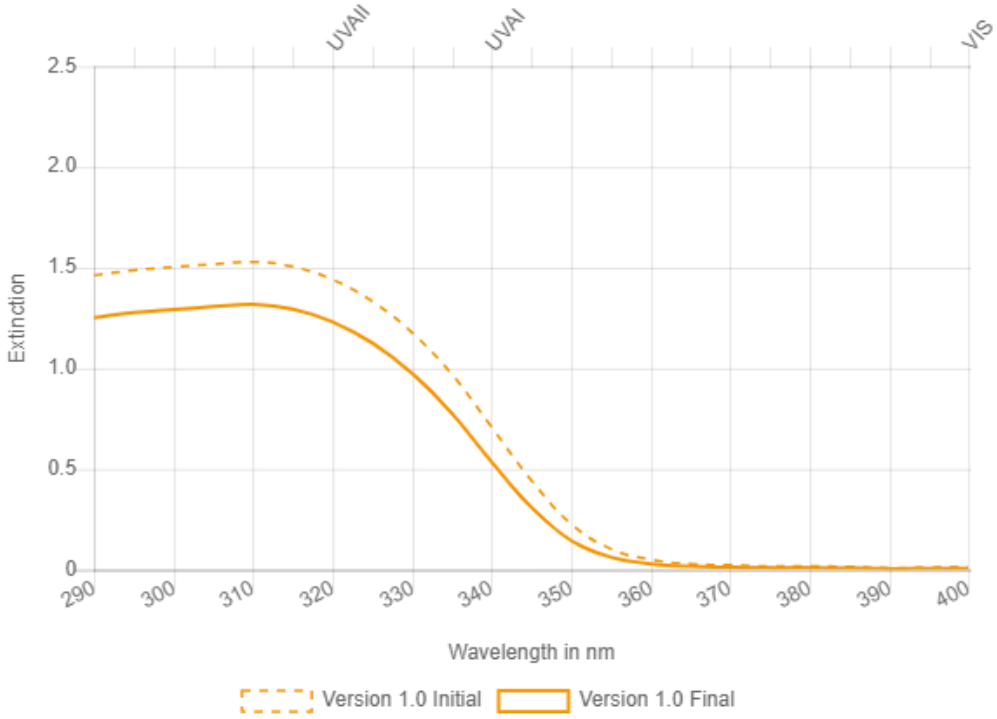
Reference Number	Substance identification				Conditions		Update date
	Chemical name / INN / XAN	Name of Common Ingredients Glossary	CAS Number	EC Number	Product Type, body parts	Maximum concentration in ready for use preparation	
14	Isopentyl-4-methoxycinnamate / Amiloxate	ISOAMYL P-METHOXYCINNAMATE	71617-10-2	275-702-5	10%		15/10/2010

Panoramica filtri Allegato VI

ISOAMYL P-METHOXYCINNAMATE

Aspetto	LIQUIDO MISCIBILE IN OLIO
Concentrazione massima ammessa	NON APPROVATO FDA
λmax	308 nm





Panoramica filtri Allegato VI

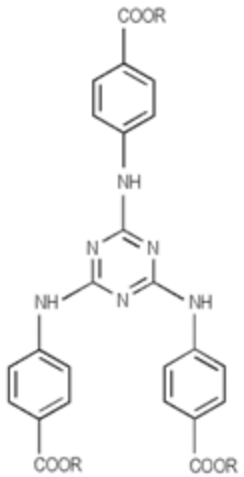
ANNEX VI, Last update: 17/10/2023

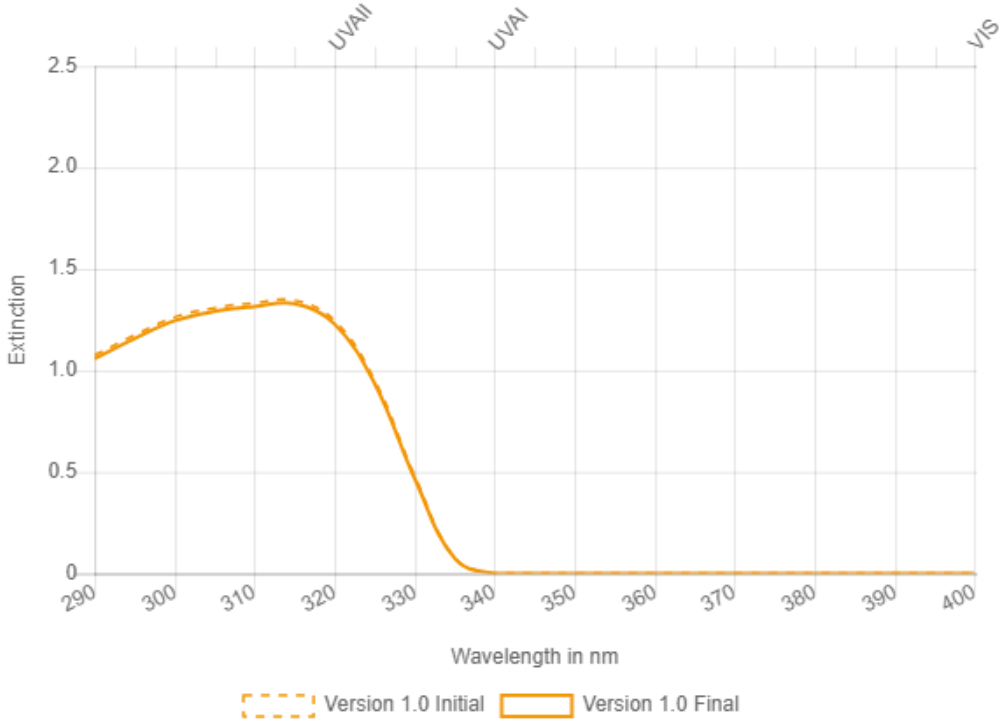
Reference Number	Substance identification				Conditions		Update date
	Chemical name / INN / XAN	Name of Common Ingredients Glossary	CAS Number	EC Number	Product Type, body parts	Maximum concentration in ready for use preparation	
15	2,4,6-Trianilino-(p-carbo-2'-ethylhexyl-1'-oxy)-1,3,5-triazine	ETHYLHEXYL TRIAZONE	88122-99-0	402-070-1	5%		15/10/2010

Panoramica filtri Allegato VI

ETHYLHEXYL TRIAZONE

Aspetto	POLVERE LIPOSOLUBILE
Concentrazione massima ammessa	NON APPROVATO FDA
λmax	314 nm





Panoramica filtri Allegato VI

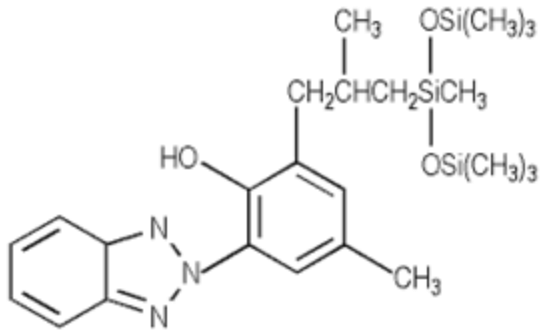
ANNEX VI, Last update: 17/10/2023

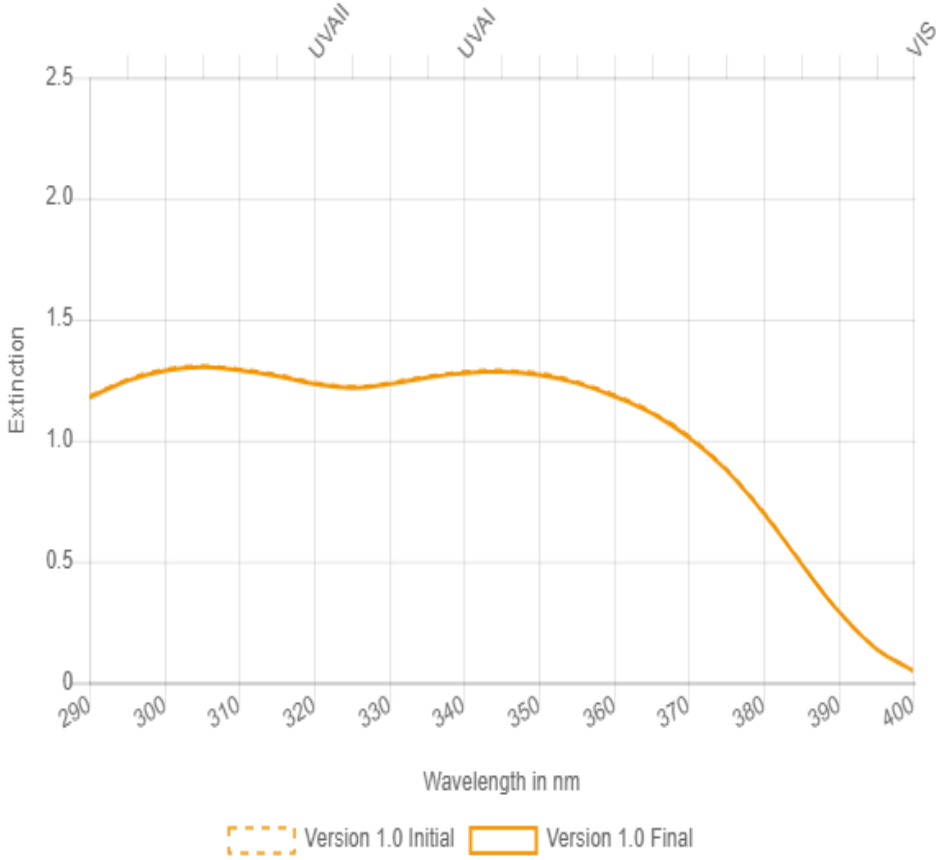
Reference Number	Substance identification				Conditions		Update date
	Chemical name / INN / XAN	Name of Common Ingredients Glossary	CAS Number	EC Number	Product Type, body parts	Maximum concentration in ready for use preparation	
16	Phenol, 2-(2H-Benzotriazol-2-yl)-4-Methyl-6-(2-Methyl-3-(1,3,3,3-Tetramethyl-1-(Trimethylsilyl)Oxy)-Disiloxanyl)Propyl	DROMETRIZOLE TRISILOXANE	155633-54-8	-	15%		08/03/2011

Panoramica filtri Allegato VI

DROMETRIZOLE TRISILOXANE

Aspetto	LIPOSOLUBILE
Concentrazione massima ammessa	NON AMMESSO FDA
λmax_{UVA}	344 nm
λmax_{UVB}	303 nm





Panoramica filtri Allegato VI

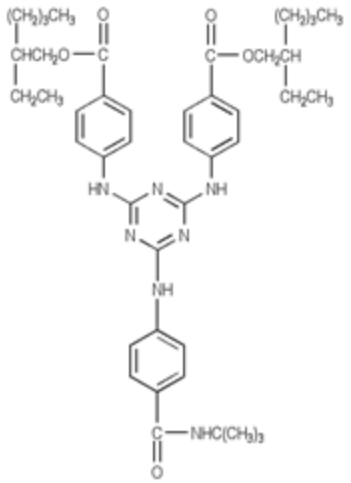
ANNEX VI, Last update: 17/10/2023

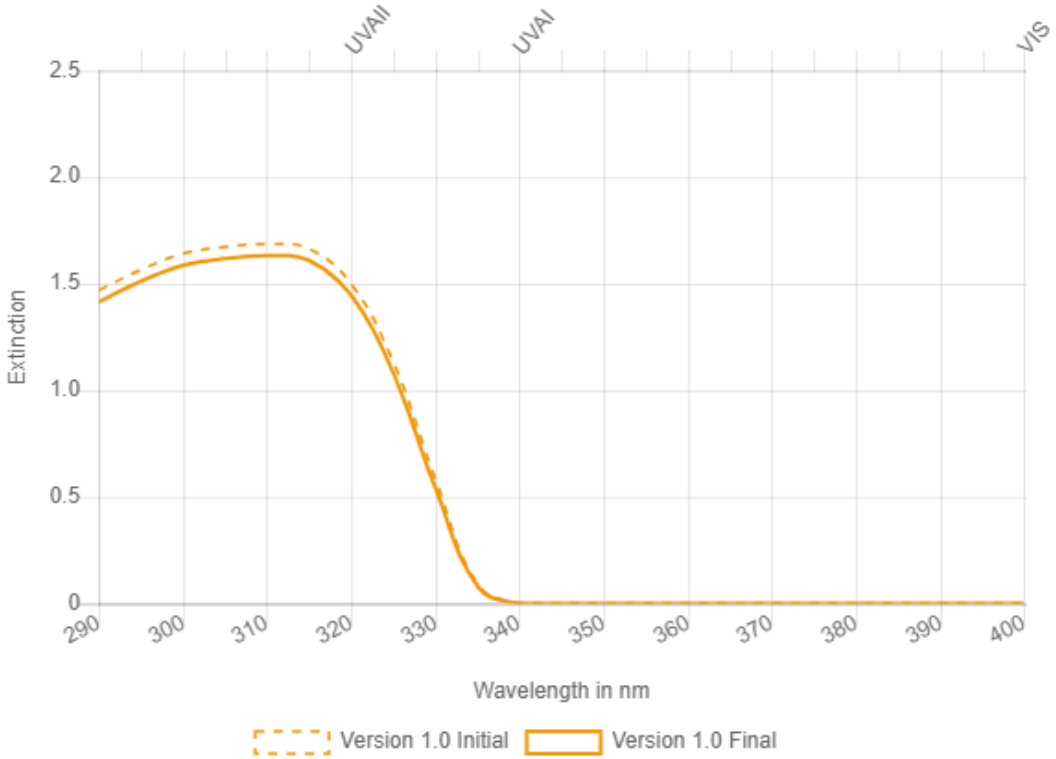
Reference Number	Substance identification				Conditions		Update date
	Chemical name / INN / XAN	Name of Common Ingredients Glossary	CAS Number	EC Number	Product Type, body parts	Maximum concentration in ready for use preparation	
17	Benzoic acid, 4,4-{[6-[[[(1,1-dimethylethyl)amino]carbonyl]phenyl]amino]-1,3-5-triazine-2,4-diyl]diimino}bis-, bis(2-ethylhexyl)ester / Iscotrizinol	DIETHYLHEXYL BUTAMIDO TRIAZONE	154702-15-5	-	10%		26/10/2010

Panoramica filtri Allegato VI

DIETHYLHEXYL BUTAMIDO TRIAZONE

Aspetto	POLVERE LIPOSOLUBILE
Concentrazione massima ammessa	NON APPROVATO FDA
λmax	311 nm





Panoramica filtri Allegato VI

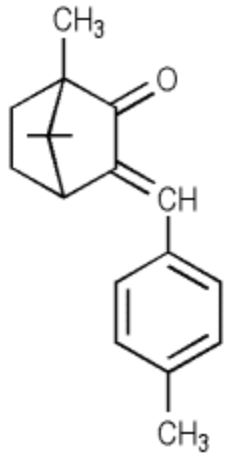
ANNEX VI, Last update: 17/10/2023

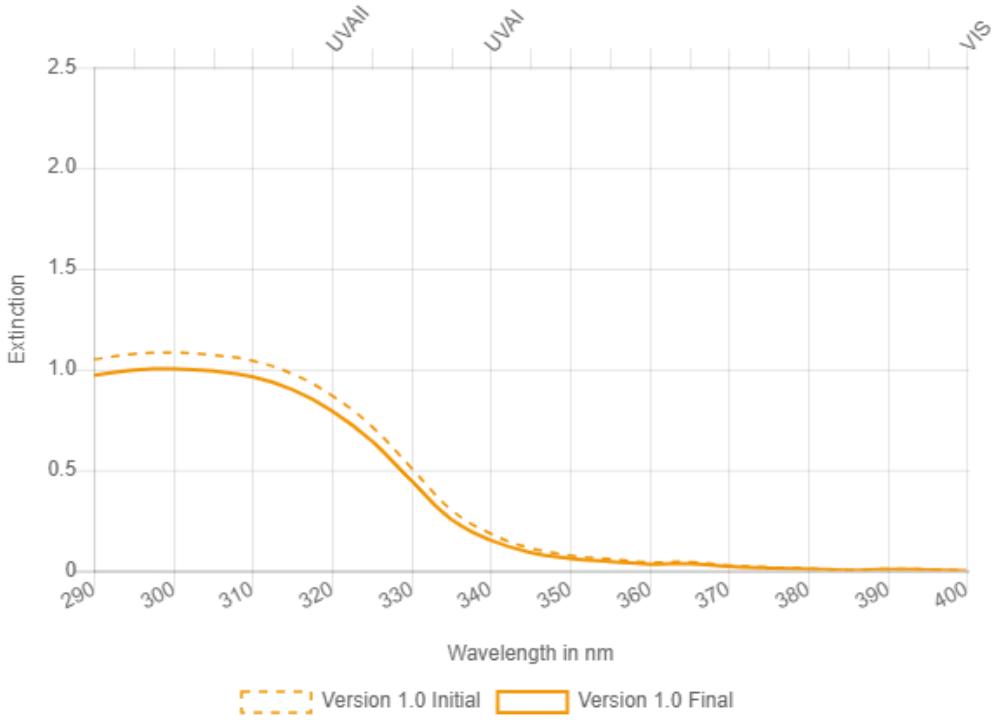
Reference Number	Substance identification				Conditions		Update date
	Chemical name / INN / XAN	Name of Common Ingredients Glossary	CAS Number	EC Number	Product Type, body parts	Maximum concentration in ready for use preparation	
18	3-(4'-Methylbenzylidene)-dlcamphor / Enzacamene	4-METHYLBENZYLIDENE CAMPHOR	36861-47-9 / 38102-62-4	253-242-6 /	4%		08/03/2011

Panoramica filtri Allegato VI

4-METHYLBENZYLIDENE CAMPHOR

Aspetto	POLVERE LIPOSOLUBILE
Concentrazione massima ammessa	NON AMMESSO FDA
λmax	300 nm





Panoramica filtri Allegato VI

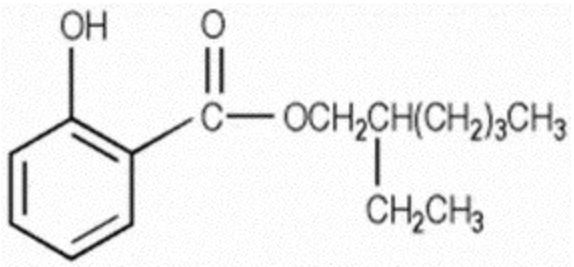
ANNEX VI, Last update: 17/10/2023

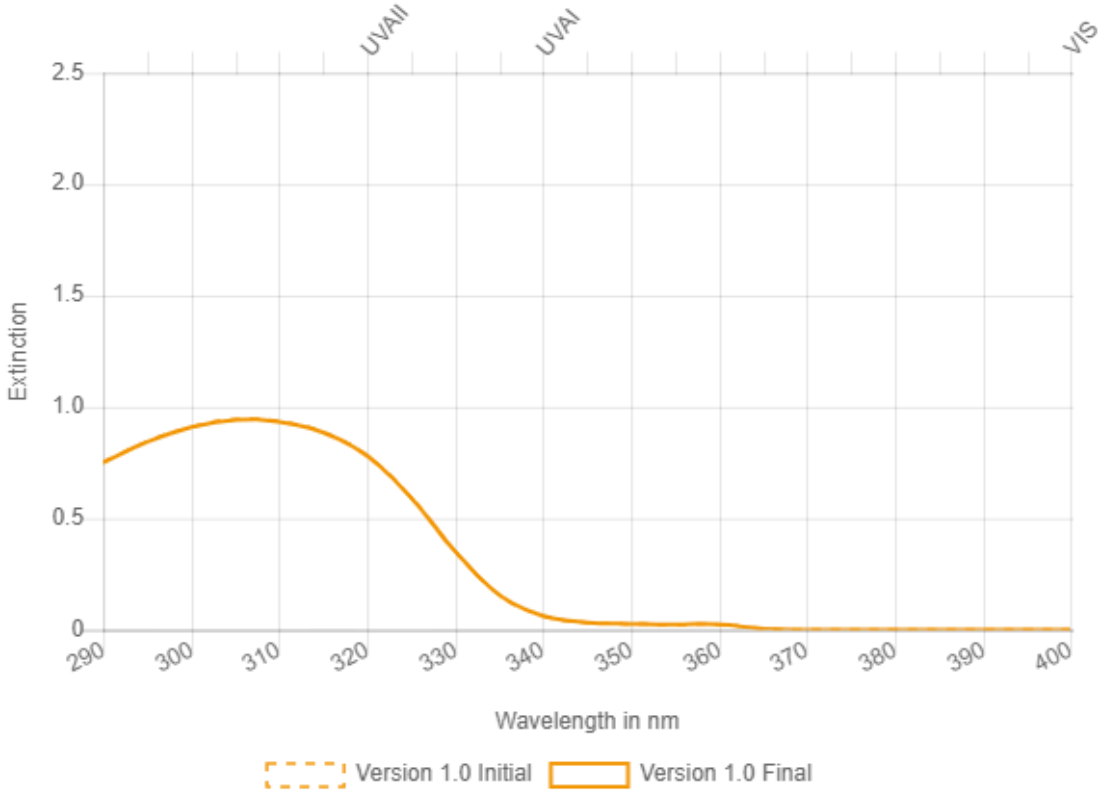
Reference Number	Substance identification				Conditions		Update date
	Chemical name / INN / XAN	Name of Common Ingredients Glossary	CAS Number	EC Number	Product Type, body parts	Maximum concentration in ready for use preparation	
20	2-Ethylhexyl salicylate / Octisalate)	ETHYLHEXYL SALICYLATE	118-60-5	204-263-4	5%		08/03/2011

Panoramica filtri Allegato VI

ETHYLHEXYL SALICYLATE

Aspetto	LIQUIDO MISCIBILE IN OLIO
Concentrazione massima ammessa	Globale 5%
λmax	307 nm





Panoramica filtri Allegato VI

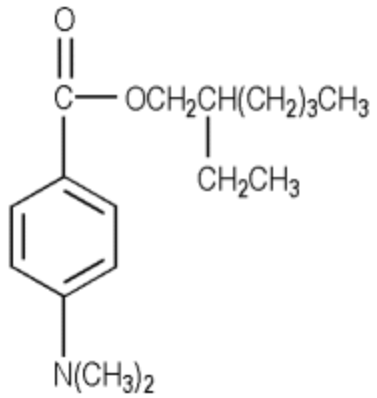
ANNEX VI, Last update: 17/10/2023

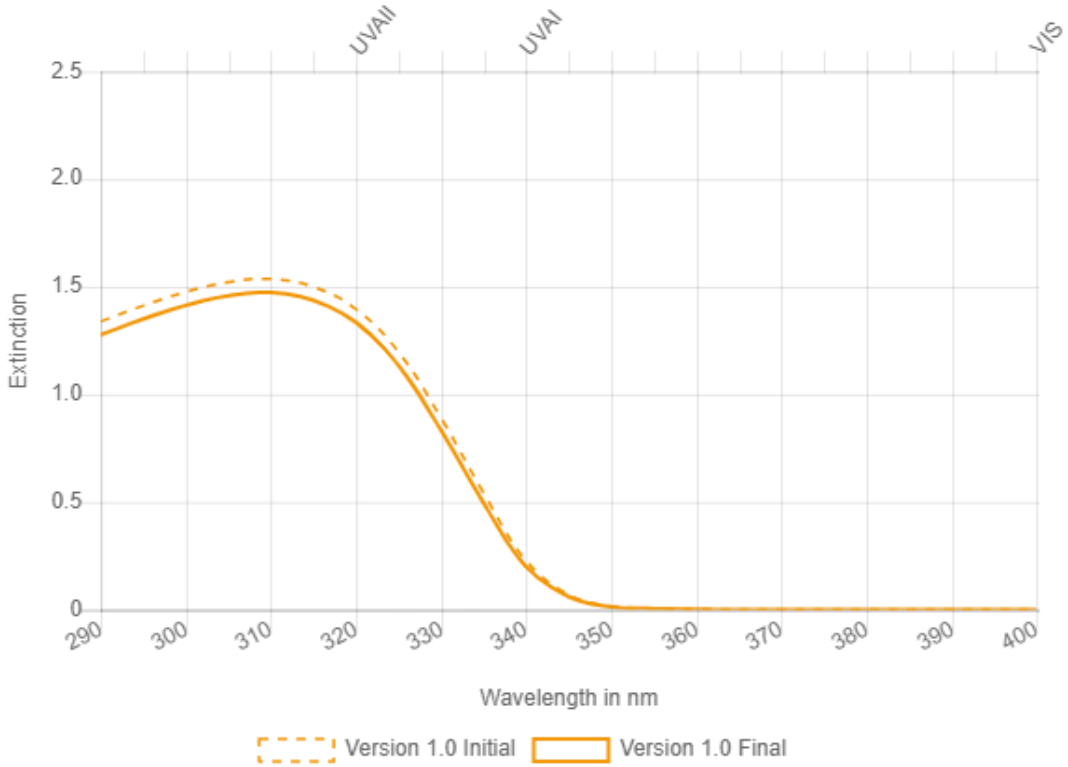
Reference Number	Substance identification				Conditions		Update date
	Chemical name / INN / XAN	Name of Common Ingredients Glossary	CAS Number	EC Number	Product Type, body parts	Maximum concentration in ready for use preparation	
21	2-Ethylhexyl 4-(dimethylamino)benzoate / Padimate O (USAN:BAN)	ETHYLHEXYL DIMETHYL PABA	21245-02-3	244-289-3		8%	26/10/2010

Panoramica filtri Allegato VI

ETHYLHEXYL DIMETHYL PABA

Aspetto	LIQUIDO MISCIBILE IN OLIO
Concentrazione massima ammessa	Globale 8%
λmax	311 nm





Panoramica filtri Allegato VI

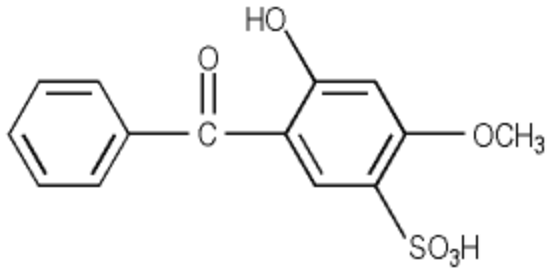
ANNEX VI, Last update: 17/10/2023

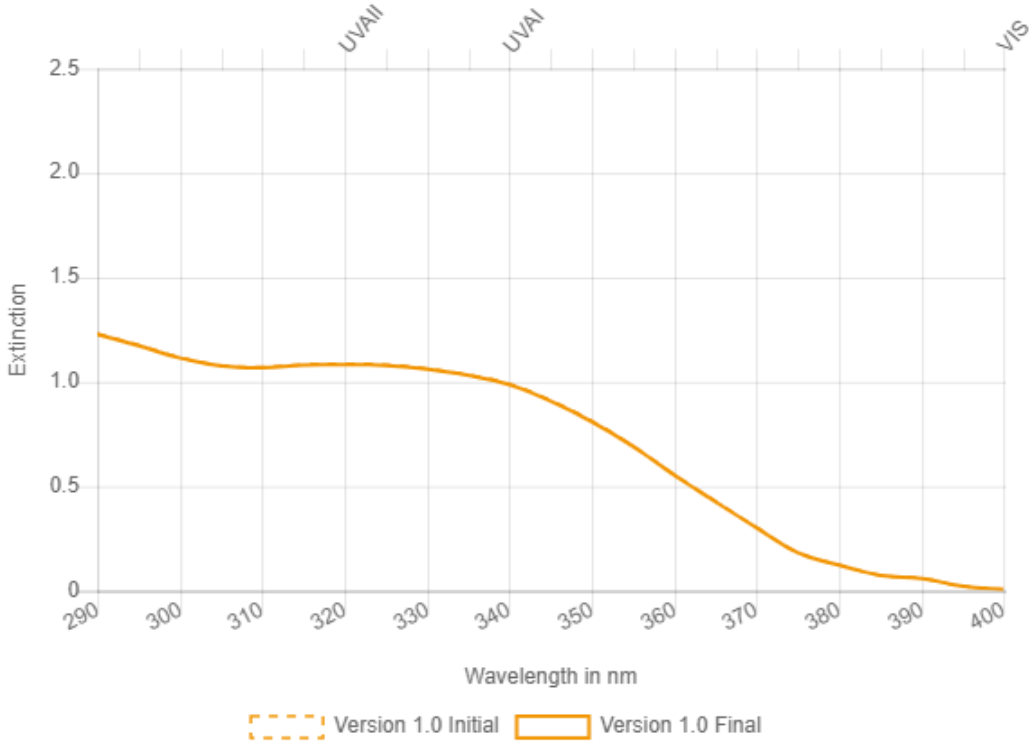
Reference Number	Substance identification				Conditions		Update date
	Chemical name / INN / XAN	Name of Common Ingredients Glossary	CAS Number	EC Number	Product Type, body parts	Maximum concentration in ready for use preparation	
22	2-Hydroxy-4-methoxybenzophenone-5-sulfonic acid (Benzophenone-5) and its sodium salt / Sulisobenzone	BENZOPHENONE-4; BENZOPHENONE-5	4065-45-6 / 6628-37-1	223-772-2 / -	5% (as acid)		15/10/2010

Panoramica filtri Allegato VI

BENZOPHENONE-4; BENZOPHENONE-5

Aspetto	POLVERE IDROSOLUBILE
Concentrazione massima ammessa	Globale 5%
λmax_{UVA}	324 nm
λmax_{UVB}	286 nm





Panoramica filtri Allegato VI

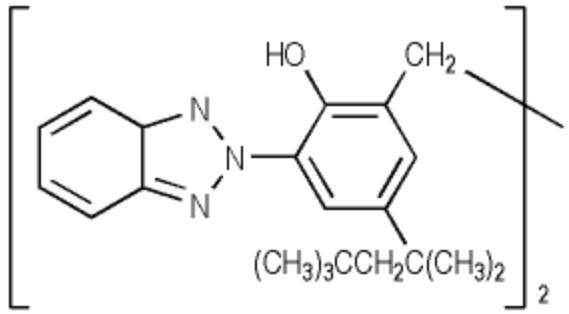
ANNEX VI, Last update: 17/10/2023

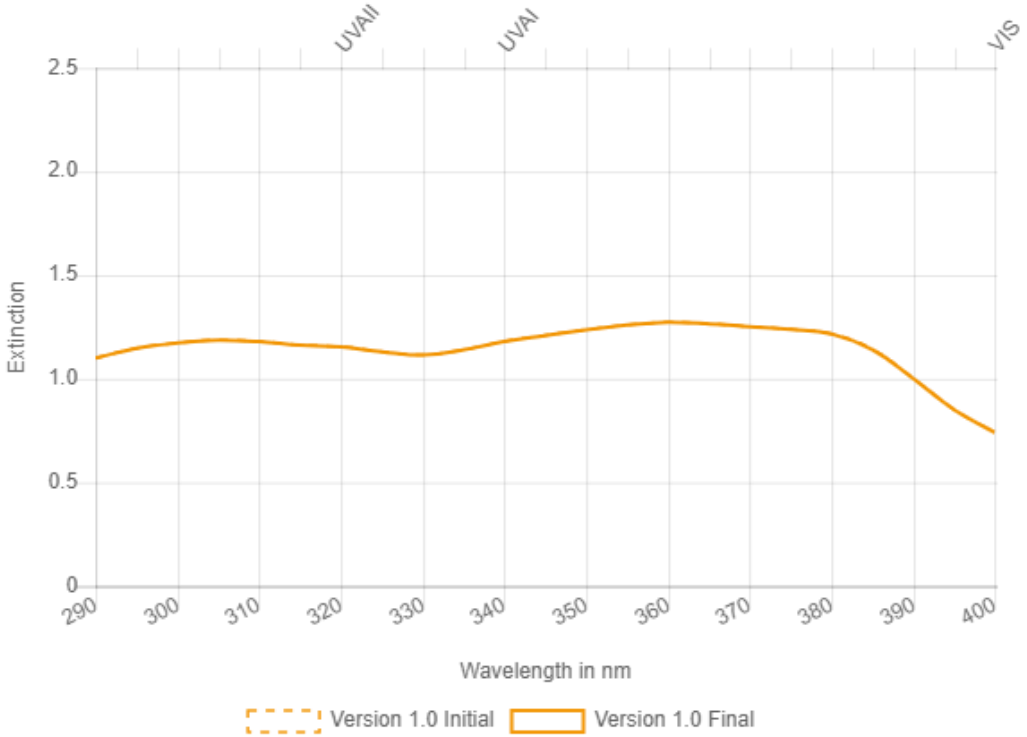
Reference Number	Substance identification				Conditions		Update date
	Chemical name / INN / XAN	Name of Common Ingredients Glossary	CAS Number	EC Number	Product Type, body parts	Maximum concentration in ready for use preparation	
23/23 a)	Methylene bis(6-(2Hbenzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl) phenol) / Bisoctrizole / Methylene Bis-Benzotriazolyl Tetramethylbutylphenol (nano)	METHYLENE BIS-BENZOTRIAZOLYL TETRAMETHYLBUTYLPHENOL (NANO)	103597-45-1	403-800-1	10 %(*) (*) In case of combined use of Methylene Bis-Benzotriazolyl Tetramethylbutylphenol and Methylene Bis-Benzotriazolyl Tetramethylbutylphenol (nano), the sum shall not exceed the limit given in column g.'	Not to be used in applications that may lead to exposure of the end user's lungs by inhalation. Only nanomaterials having the following characteristics are allowed: — Purity ≥ 98,5 %, with 2,2'-methylene-bis- (6(2Hbenzotriazol-2-yl)-4-(isooctyl)phenol) isomer fraction not exceeding 1,5 %; — Solubility < 5 ng/L in water at 25 °C; — Partition coefficient (Log Pow): 12,7 at 25 °C; — Uncoated; — Median particle size D50 (50 % of the number below this diameter): ≥ 120 nm of mass distribution and/or ≥ 60 nm of number size distribution.	06/08/2020

Panoramica filtri Allegato VI

METHYLENE BIS-BENZOTRIAZOLYL TETRAMETHYLBUTYLPHENOL (NANO)

Aspetto	DISPERDIBILE IN ACQUA
Concentrazione massima ammessa	NON APPROVATO FDA
λmax	360 nm





SCCS OPINION

Panoramica filtri Allegato VI

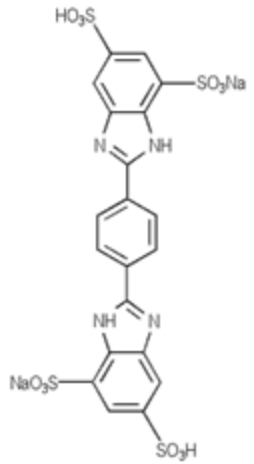
ANNEX VI, Last update: 17/10/2023

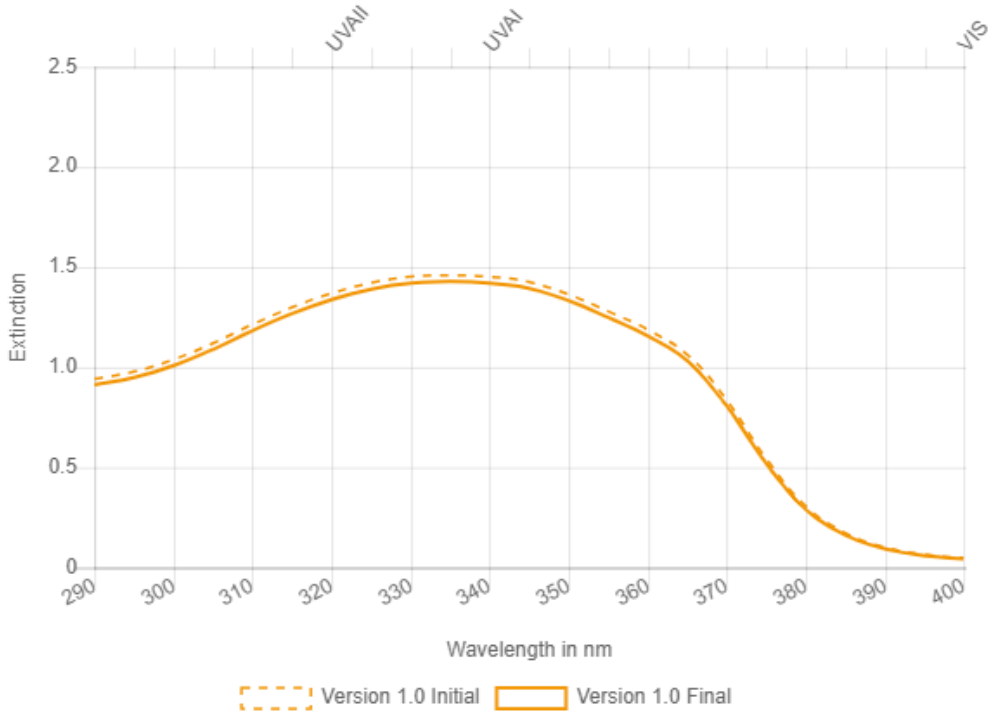
Reference Number	Substance identification				Conditions		Update date
	Chemical name / INN / XAN	Name of Common Ingredients Glossary	CAS Number	EC Number	Product Type, body parts	Maximum concentration in ready for use preparation	
24	Sodium salt of 2,2'-bis(1,4-phenylene)-1H-benzimidazole-4,6-disulfonic acid / Bisdisulizole disodium (USAN)	DISODIUM PHENYL DIBENZIMIDAZOLE TETRASULFONATE	180898-37-7	429-750-0	10% (as acid)		27/07/2020

Panoramica filtri Allegato VI

DISODIUM PHENYL DIBENZIMIDAZOLE TETRASULFONATE

Aspetto	POLVERE IDROSOLUBILE
Concentrazione massima ammessa	NON APPROVATO FDA
λmax	335 nm





Panoramica filtri Allegato VI

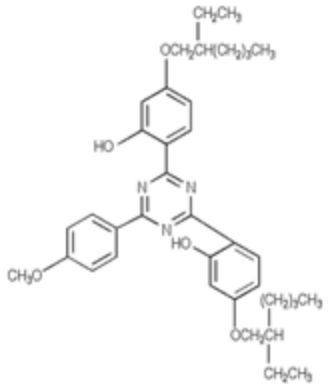
ANNEX VI, Last update: 17/10/2023

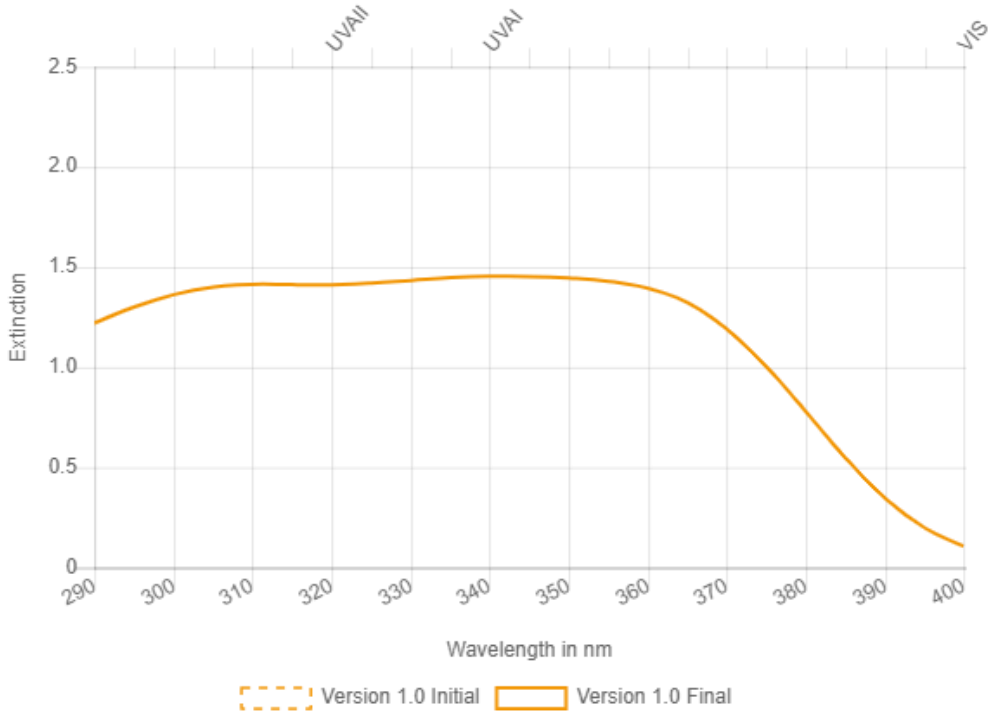
Reference Number	Substance identification				Conditions		Update date
	Chemical name / INN / XAN	Name of Common Ingredients Glossary	CAS Number	EC Number	Product Type, body parts	Maximum concentration in ready for use preparation	
25	2,2'-(6-(4-Methoxyphenyl)-1,3,5-triazine-2,4-diyl)bis(5-((2-ethylhexyl)oxy)phenol) / Bemotrizinol	BIS-ETHYLHEXYLOXYPHENOL METHOXYPHENYL TRIAZINE	187393-00-6	-	10%		08/03/2011

Panoramica filtri Allegato VI

BIS-ETHYLHEXYLOXYPHENOL METHOXYPHENYL TRIAZINE

Aspetto	POLVERE LIPOSOLUBILE
Concentrazione massima ammessa	NON AMMESSO FDA
λmax_{UVA}	340 nm
λmax_{UVB}	310 nm





Panoramica filtri Allegato VI

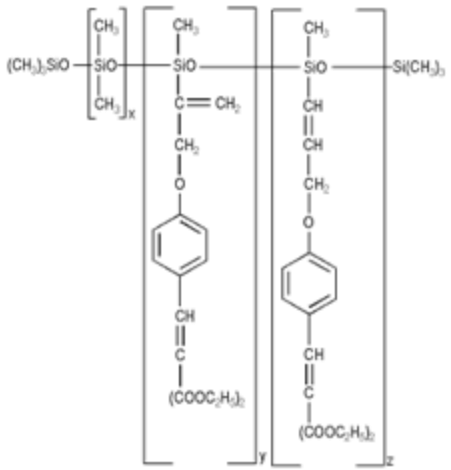
ANNEX VI, Last update: 17/10/2023

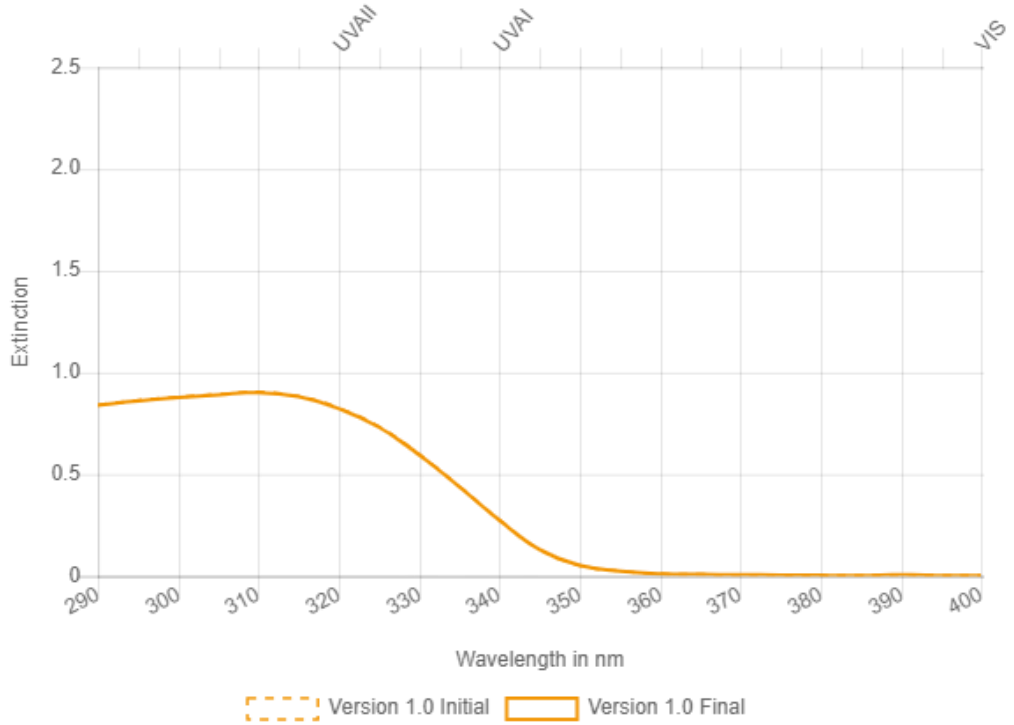
Reference Number	Substance identification				Conditions		Update date
	Chemical name / INN / XAN	Name of Common Ingredients Glossary	CAS Number	EC Number	Product Type, body parts	Maximum concentration in ready for use preparation	
26	Dimethicodiethylbenzalmalonate	POLYSILICONE-15	207574-74-1	426-000-4	10%		15/10/2010

Panoramica filtri Allegato VI

POLYSILICONE-15

Aspetto	LIQUIDO – PRIMO FILTRO UV POLIMERICO
Concentrazione massima ammessa	NON APPROVATO FDA
λmax	312 nm





Panoramica filtri Allegato VI

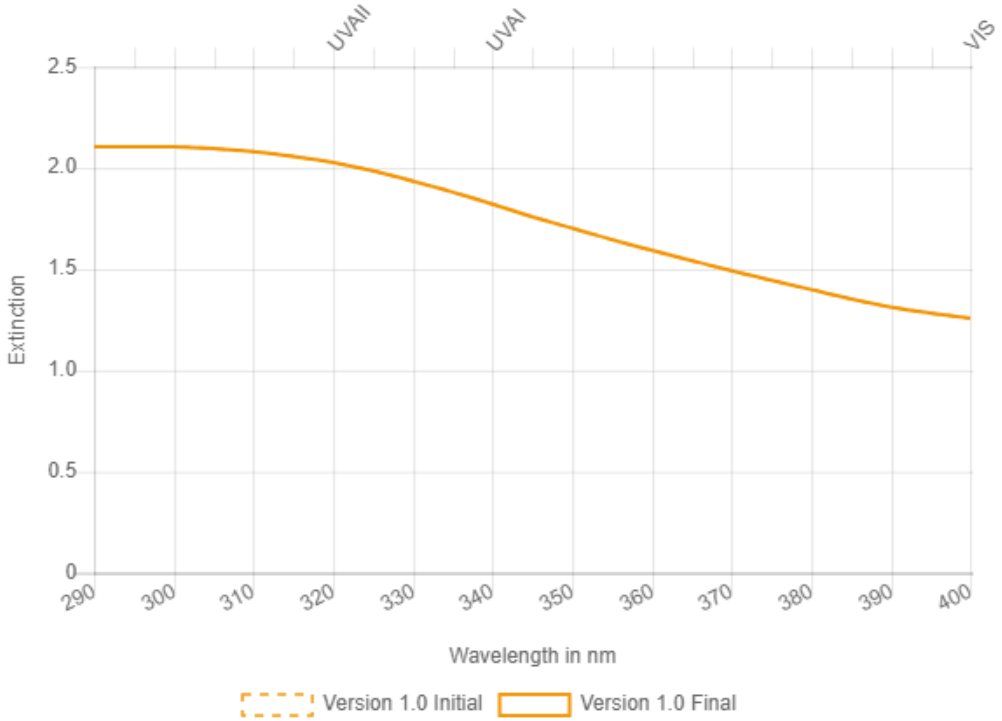
ANNEX VI, Last update: 17/10/2023

Reference Number	Substance identification				Conditions			Update date
	Chemical name / INN / XAN	Name of Common Ingredients Glossary	CAS Number	EC Number	Product Type, body parts	Maximum concentration in ready for use preparation	Other	
27/27 a)	Titanium Dioxide / Titanium Dioxide (nano)	TITANIUM DIOXIDE / TITANIUM DIOXIDE (NANO)	13463-67-7[1]/ 1317-70-0[2]/ 1317-80-2[3]	236-675-5[1] /215-280-1[2]/ 215-282-2[3]	25% - In case of combined use of Titanium Dioxide and Titanium Dioxide (nano), the sum shall not exceed the limit of 25%.	Titanium dioxide in powder form containing 1 % or more of particles with aerodynamic diameter ≤ 10 µm, to be used in compliance with Annex III, No 321. For the product types under letter (c) of column (f) in Annex III, No 321, the maximum concentration in ready for use preparation provided in column (g) of this entry applies. (For use as a colourant, see Annex IV, No 143)	Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation Only nanomaterials having the following characteristics are allowed: — purity ≥ 99 %, — rutile form, or rutile with up to 5 % anatase, with crystalline structure and physical appearance as clusters of spherical, needle, or lanceolate shapes, — median particle size based on number size distribution ≥ 30 nm, — aspect ratio from 1 to 4,5, and volume specific surface area ≤ 460 m2/cm3, — coated with Silica, Hydrated Silica, Alumina, Aluminium Hydroxide, Aluminium Stearate, Stearic Acid, Trimethoxycaprylylsilane, Glycerin, Dimethicone, Hydrogen Dimethicone, Simethicone; or coated with one of the Following combinations: —Silica at a maximum	21/06/2021

Panoramica filtri Allegato VI

TITANIUM DIOXIDE / TITANIUM DIOXIDE (NANO)

Aspetto	POLVERE
Concentrazione massima ammessa	25%
λmax_{UVA}	/
λmax_{UVB}	/



SCCS OPINION

Panoramica filtri Allegato VI

TITANIUM DIOXIDE / TITANIUM DIOXIDE (NANO)

3. Opinion of the SCCNFP 1998

The SCCNFP is of the opinion that titanium dioxide is safe for use in cosmetic products at a maximum concentration of 25% in order to protect the skin from certain harmful effects of UV radiation.

This opinion concerns crystalline (anatase and/or rutile) titanium dioxide, whether or not subjected to various treatments (coating, doping, etc.), irrespective of particle size, provided only that such treatments do not compromise the safety of the product.

The SCCNFP proposes no further restrictions or conditions for its use in cosmetic products.

New text: **2015**

"On the basis of the available evidence, the SCCS has concluded that the use of TiO_2 nanomaterials with the characteristics as indicated below, at a concentration up to 25% as a UV-filter in sunscreens, can be considered not to pose a risk of adverse effects in humans after application on healthy, intact or sunburnt skin. This, however, does not apply to spray applications that might lead to exposure of the consumer's lungs to TiO_2 nanoparticles by inhalation."

4. CONCLUSION 19/01/2018

1. *In light of the data provided, does the SCCS consider Titanium Dioxide (nano) safe when used as UV-Filter in sunscreens and personal care spray products at a concentration up to 5.5%?*

From analysis of the submitted dossier, the SCCS has concluded that the information provided is insufficient to allow assessment of the safety of the use of nano-TiO_2 in spray applications that could lead to exposure of the consumer's lungs.

The dossier provides exposure studies that have been conducted with water-based sprayable products with low alcohol content, which according to the market overview currently represent around 80% of the sprayable sunscreen products on the EU market. For the non-water-based formulations or formulations that contain alcohol >10% per weight, which currently may represent around 20% of the sprayable sunscreen products on the EU market, no exposure data were submitted, so that these could not be evaluated at all. The submission also does not provide adequate toxicological evaluation of nano-TiO_2 relevant to the inhalation route, which would allow deriving a point of departure for the safety evaluation using worst-case assumptions. During the commenting period on the preliminary Opinion, the Applicant provided a new submission, the analysis of which (Section 3.3.13) showed that it has also not addressed the SCCS concerns over the safety of titanium dioxide (nano) when used as UV-filter in sunscreen and personal care sprayable products.

2. *Does the SCCS have any further scientific concerns regarding the use of Titanium Dioxide (nano) when used as UV-Filter in sunscreens and personal care spray products?*

The SCCS has been made aware by the new submission of the Applicant that there are already sprayable products on the market containing nano forms of TiO_2. Such uses need to be carefully evaluated so that the chance of harmful effects through consumer's lung exposure by inhalation is avoided.

4. CONCLUSION 22/06/2018

(1) *In light of the data provided, does the SCCS consider safe the use of Cetyl Phosphate, Manganese Dioxide and Triethoxycaprylylsilane as coatings for Titanium Dioxide (nano) used as UV-filter in dermally-applied cosmetic products?*

In view of the above discussion, which indicates a general lack of dermal absorption and low general toxicity of nano-forms of titanium dioxide, the SCCS considers that the use of the three TiO2 nanomaterials (A, B, C), coated with either silica and cetyl phosphate (up to 16% and 6% respectively); alumina and manganese dioxide (up to 7% and 0.7% respectively); or alumina and triethoxycaprylylsilane (up to 3% and 9% respectively), can be considered safe for use in cosmetic products intended for application on healthy, intact or sunburnt skin. This, however, does not apply to applications that might lead to exposure of the consumer's lungs to the TiO2 nanoparticles through the inhalation route (such as powders or sprayable products).

Panoramica filtri Allegato VI

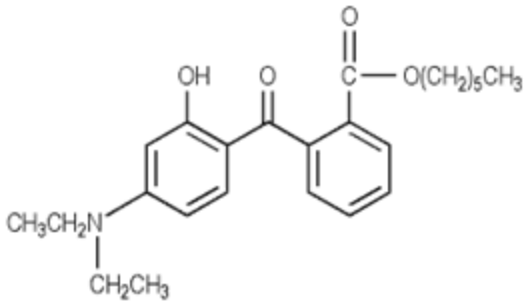
ANNEX VI, Last update: 17/10/2023

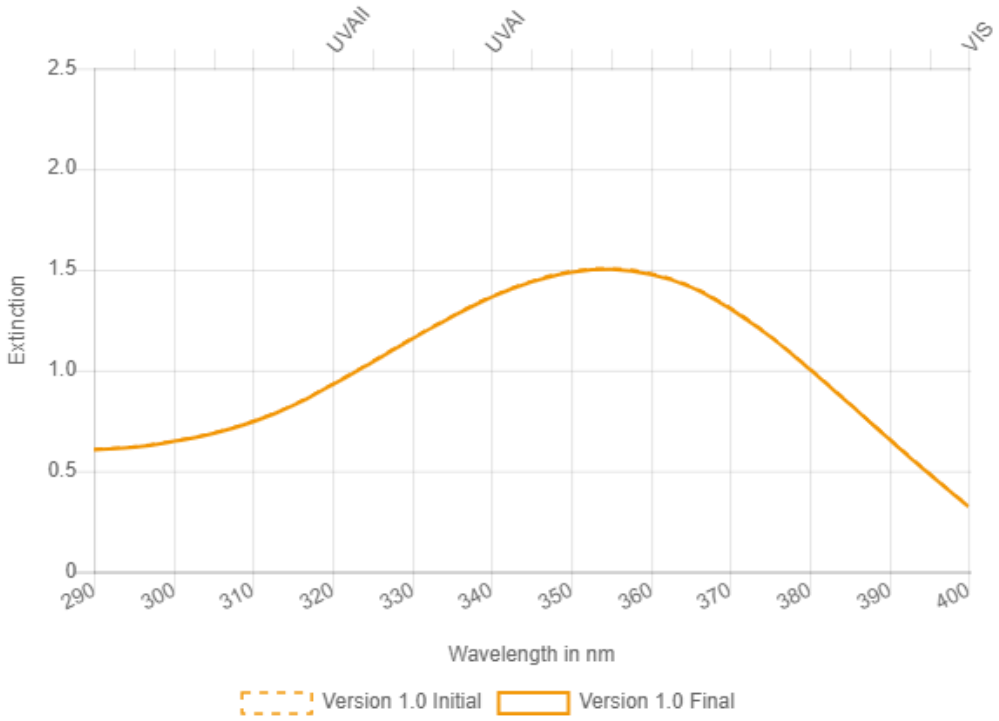
Reference Number	Substance identification				Conditions		Update date
	Chemical name / INN / XAN	Name of Common Ingredients Glossary	CAS Number	EC Number	Product Type, body parts	Maximum concentration in ready for use preparation	
28	Benzoic acid, 2-[4-(diethylamino)-2-hydroxybenzoyl]-, hexylester	DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE	302776-68-7	443-860-6	10 %		29/07/2013

Panoramica filtri Allegato VI

DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE

Aspetto	GRANULI LIPOSOLUBILI
Concentrazione massima ammessa	NON AMMESSO FDA
λmax	354 nm





Panoramica filtri Allegato VI

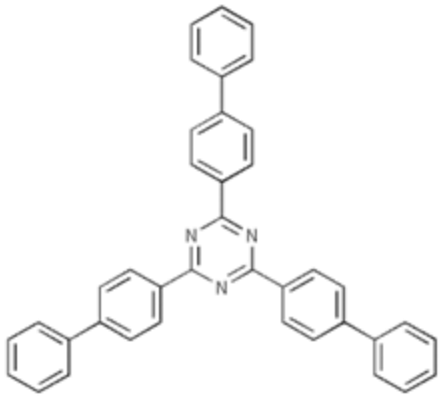
ANNEX VI, Last update: 17/10/2023

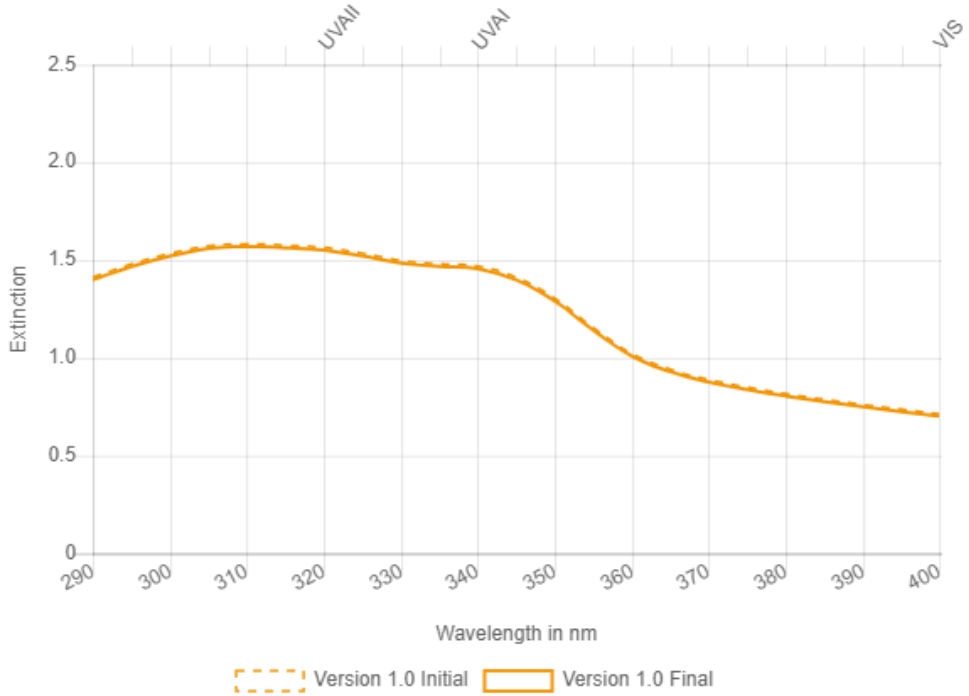
Reference Number	Substance identification				Conditions		Update date
	Chemical name / INN / XAN	Name of Common Ingredients Glossary	CAS Number	EC Number	Product Type, body parts	Maximum concentration in ready for use preparation	
29	1,3,5-Triazine, 2,4,6-tris(1,1'-biphenyl)-4-yl-, including as Nanomaterial	TRIS-BIPHENYL TRIAZINE / TRISBIPHENYL TRIAZINE (NANO)	31274-51-8	-	10%	Not to be used in sprays. Only nanomaterials having the folloing characteristics are allowed: - Median primary particle size >80 nm; - Purity ≥ 98%; - Uncoated	10/10/2016

Panoramica filtri Allegato VI

TRIS-BIPHENYL TRIAZINE / TRISBIPHENYL TRIAZINE (NANO)

Aspetto	DISPERDIBILE IN ACQUA
Concentrazione massima ammessa	NON APPROVATO FDA
λmax	315 nm





Panoramica filtri Allegato VI

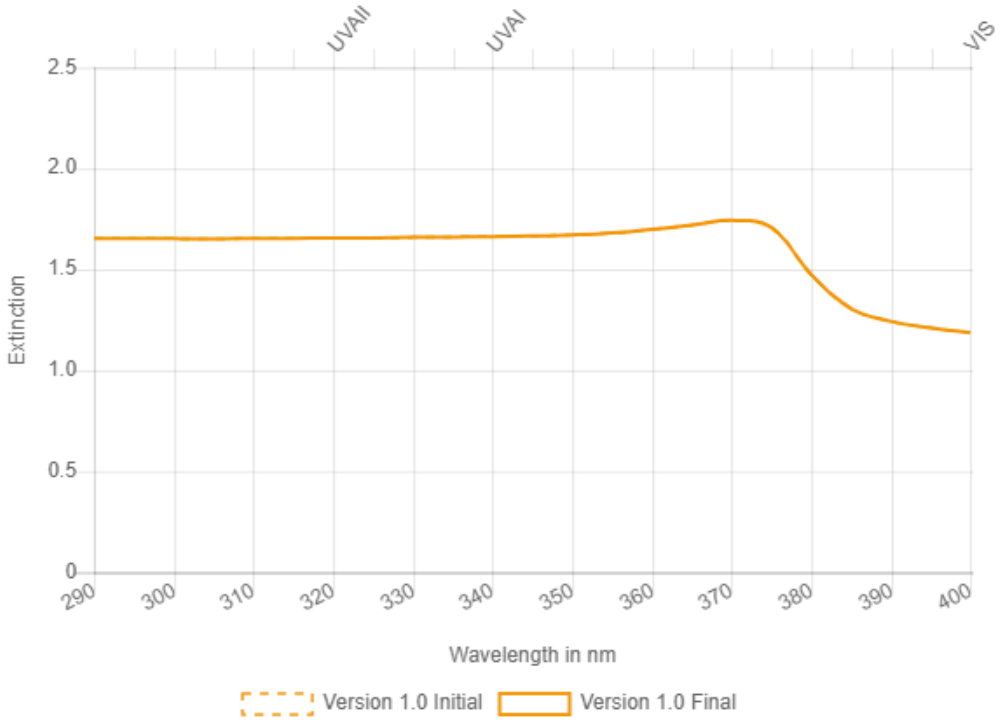
ANNEX VI, Last update: 17/10/2023

Reference Number	Substance identification				Conditions		Update date
	Chemical name / INN / XAN	Name of Common Ingredients Glossary	CAS Number	EC Number	Product Type, body parts	Other	
30/30 a)	Zinc oxide / Zinc oxide (nano)	ZINC OXIDE / ZINC OXIDE (NANO)	1314-13-2	215-222-5	25% - In case of combined use of zinc oxide and zinc oxide (nano), the sum shall not exceed the limit of 25%	Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation. Only nanomaterials having the following characteristics are allowed: — purity ≥ 96 %, with wurtzite crystalline structure and physical appearance as clusters that are rod-like, star-like and/or isometric shapes, with impurities consisting only of carbon dioxide and water, whilst any other impurities are less than 1 % in total, — median diameter of the particle number size distribution D50 (50 % of the number below this diameter) > 30 nm and D1 (1 % below this size) > 20 nm, — water solubility < 50 mg/L —uncoated, or coated with triethoxycaprylylsilane, dimethicone, dimethoxydiphenylsilanetriethox ycaprylylsilane cross- polymer, or octyl triethoxy silane.	13/09/2016 – 01/03/2019

Panoramica filtri Allegato VI

ZINC OXIDE / ZINC OXIDE (NANO)

Aspetto	POLVERE
Concentrazione massima ammessa	25%
λmax	/



SCCS OPINION

Panoramica filtri Allegato VI

ZINC OXIDE / ZINC OXIDE (NANO)

2.13. Opinion 2003

Based on the conclusions (point 2.12), the SCCNFP is of the opinion that there more information is needed to enable a proper safety evaluation of micronised Zinc oxide for use as a UV filter in cosmetic products. Consequently, an appropriate safety dossier on micronised ZnO itself, including possible pathways of cutaneous penetration and systemic exposure, is required.

2005

Hitherto, the requested safety dossier has not been provided. It is understood that microfine and ultrafine zinc oxide is widely used in sunscreen products on the European market. The safety to the consumer of this use remains to be assessed. The attention of the Commission and the Member States is drawn to this.

3. CLARIFICATION 2009

The SCCP considers that on basis of the dossier reviewed in 2003 the use of ZnO in its non-nano form (pigment grade, with particle sizes above 100 nm) is considered safe. The concern expressed in the SCCNFP opinion 0693/03 with regard to phototoxicity is not relevant for this form of ZnO due to the absence of dermal penetration.

4. CONCLUSION 2013

The SCCS concludes that ZnO nanomaterials with the following characteristics can be considered similar to the ZnO nanomaterials as evaluated in opinion SCCS/1489/12 and thus pose no or limited risk for use on the skin as UV filter in sunscreen formulations:

1. *ZnO nanoparticles of purity ≥96%, with wurtzite crystalline structure and physical appearance as clusters that are rod-like, star-like and/or isometric shapes, with impurities consisting only of carbon dioxide and water, whilst any other impurities are less than 1% in total.*

2. *ZnO nanoparticles with a median diameter (D50: 50% of the number below this diameter) of the particle number size distribution above 30 nm, and the D1 (1% below this size) above 20nm.*

3. *ZnO nanoparticles that are either uncoated or coated with triethoxycaprylylsilane, dimethicone, dimethoxydiphenylsilanetriethoxycaprylylsilane cross-polymer, or octyl triethoxy silane. Other cosmetic ingredients can be used as coatings as long as they are demonstrated to the SCCS to be safe and do not affect the particle properties related to behaviour and/or effects, compared to the nanomaterials covered in the current opinion.*

4. *ZnO nanoparticles that have a comparable solubility to that reported in the dossier, i.e. below 50 mg/L (approximately the maximum solubility of the ZnO nanomaterials for which data are provided in the dossier).*

The submitted 90 days inhalation study resulted in a NOAEL of 0.3 mg/m^3.
However these new data do not address the concerns relating to the lung exposure and the potential manifestation of harmful effects.

Panoramica filtri Allegato VI

Proposed Order 2021 GRASE Status

	Active Ingredient	Category
	Aminobenzoic acid (PABA)	Not GRASE and/or misbranded
	Trolamine salicylate	
	Zinc Oxide	Generally regarded as safe and effective (GRASE) and not misbranded
	Titanium dioxide	
Supportati PCPC	Avobenzone	Insufficient data to classify as either «not GRASE OR MISBRANDED» OR «GENERALLY REGARDED AS EFFECTIVE (grase) AND NOT MISBRANDED»
Supportati PCPC	Ensulizole	
Supportati PCPC	Homosalate	
Supportati PCPC	Octinoxate	
Supportati PCPC	Octisalate	
Supportati PCPC	Octocrylene	
Supportati PCPC	Oxybenzone	
Supportati da enti indipendenti	Meradimate	
Non commercializzati e non supportati da industrie	Sulisobenzone – BZ-4	
Non commercializzati e non supportati da industrie	Dioxybenzone – BZ-8	
Non commercializzati e non supportati da industrie	Cinoxate	

GRAZIE PER L'ATTENZIONE!

Giovanna Ecclesia

Product Specialist and Technical Support

giovanna.ecclesia@acef.it

Bibliografia

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4. *https://youtu.be/hMhBviDRq_k*
5. *CosIng - Cosmetics - GROWTH - European Commission (europa.eu)*
6. *https://sunscreensimulator.basf.com/*