

II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) 2018/885

of 20 June 2018

amending Annex VI to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products ⁽¹⁾, and in particular Article 31(2) thereof,

Whereas:

- (1) 2,2'-Methylene-bis(6-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethyl-butyl)phenol)/Bisotrizole with the International Nomenclature of Cosmetic Ingredients name Methylene Bis-Benzotriazolyl Tetramethylbutylphenol (MBBT) is authorised for use as a UV-filter in cosmetic products under entry 23 of Annex VI to Regulation (EC) No 1223/2009. The use of MBBT (nano) as a UV-filter in cosmetic products is currently not regulated.
- (2) In its opinion of 25 March 2015 ⁽²⁾, the Scientific Committee on Consumer Safety (SCCS) concluded that the use of MBBT (nano) as a UV-filter, with the characteristics as indicated in the opinion and at a concentration up to 10 % w/w in dermally applied cosmetic products does not pose a risk to human health after application on healthy, intact skin and also damaged skin. The characteristics indicated by the SCCS in that opinion relate to the physico-chemical properties of the material (such as purity, median particle size, number size distribution).
- (3) The SCCS also considered that the conclusions of its opinion of 25 March 2015 do not apply to applications that might lead to the exposure of the end-user's lungs to MBBT (nano) by inhalation.
- (4) In light of the SCCS opinion and in order to take into account technical and scientific progress, the use of MBBT (nano) as a UV-filter in cosmetic products, according to the SCCS's specifications, should be authorised at a maximum concentration of 10 % w/w, except in applications that may lead to the exposure of the end-user's lungs to MBBT (nano) by inhalation.
- (5) Annex VI to Regulation (EC) No 1223/2009 should therefore be amended accordingly.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Cosmetic Products,

⁽¹⁾ OJ L 342, 22.12.2009, p. 59.

⁽²⁾ SCCS/1546/15, Revision of 25 June 2015: https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_168.pdf

HAS ADOPTED THIS REGULATION:

Article 1

Annex VI to Regulation (EC) No 1223/2009 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 20 June 2018.

For the Commission
The President
Jean-Claude JUNCKER

Annex VI to Regulation (EC) No 1223/2009 is amended as follows:

(1) entry 23 is replaced by the following entry:

| Reference Number | Substance identification | | | | Conditions | | | Wording of conditions of use and warnings |
|------------------|----------------------------------------------------------------------------------------------|-----------------------------------------------------|-------------|-----------|--------------------------|----------------------------------------------------|-------|-------------------------------------------|
| | 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 | |
| a | b | c | d | e | f | g | h | i |
| '23 | 2,2'-Methylene-bis(6-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol)/Bisoctrizole | Methylene Bis-Benzotriazolyl Tetramethylbutylphenol | 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.;

(2) entry 23a is inserted:

| Reference Number | Substance identification | | | | Conditions | | | Wording of conditions of use and warnings |
|------------------|----------------------------------------------------------------------------------------------|------------------------------------------------------------|-------------|-----------|--------------------------|----------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|
| | 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 | |
| a | b | c | d | e | f | g | h | i |
| '23a | 2,2'-Methylene-bis(6-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol)/Bisoctrizole | Methylene Bis-Benzotriazolyl Tetramethylbutylphenol (nano) | 103597-45-1 | 403-800-1 | | 10 % (*) | 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 \geq 98,5 %, with 2,2'-methylene-bis(6(2H-benzotriazol-2-yl)-4-(isooctyl)phenol) isomer fraction not exceeding 1,5 %; | |

| Reference Number | Substance identification | | | | Conditions | | | Wording of conditions of use and warnings |
|------------------|--------------------------|-------------------------------------|------------|-----------|--------------------------|----------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|
| | 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 | |
| a | b | c | d | e | f | g | h | i |
| | | | | | | | <ul style="list-style-type: none"> — 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. | |

(*). 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.'.