



Council of the  
European Union

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ADD 1

MI 126  
ENT 46  
CONSOM 51  
SAN 81  
ECO 21  
ENV 141  
CHIMIE 9

#### COVER NOTE

|                  |                                                                                                                                                                             |
|------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| From:            | European Commission                                                                                                                                                         |
| date of receipt: | 19 February 2016                                                                                                                                                            |
| To:              | General Secretariat of the Council                                                                                                                                          |
| No. Cion doc.:   | D041818/04 ANNEX 1                                                                                                                                                          |
| Subject:         | ANNEX to the Commission Regulation (EU) .../... of XXX amending Annex VI to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products |

Delegations will find attached document D041818/04 ANNEX 1.

Encl.: D041818/04 ANNEX 1



EUROPEAN  
COMMISSION

Brussels, XXX  
[...] (2015) XXX draft

ANNEX 1

**ANNEX**

**to the**

**Commission Regulation (EU) .../... of XXX**

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

ANNEX

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

(1) entry 27 is replaced by the following entry:

| Substance Identification |                       |                                     |            | Conditions |                          |                                                    |       |                                           |
|--------------------------|-----------------------|-------------------------------------|------------|------------|--------------------------|----------------------------------------------------|-------|-------------------------------------------|
| Reference number         | 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 | Wording of conditions of use and warnings |
| a                        | b                     | c                                   | d          | e          | f                        | g                                                  | h     | i                                         |

|     |                                 |                  |                                        |                                        |  |                     |  |  |
|-----|---------------------------------|------------------|----------------------------------------|----------------------------------------|--|---------------------|--|--|
| '27 | Titanium dioxide <sup>(2)</sup> | Titanium Dioxide | 13463-67-7/<br>1317-70-0/<br>1317-80-2 | 236-675-5/<br>205-280-1 /<br>215-282-2 |  | 25 % <sup>(*)</sup> |  |  |
|-----|---------------------------------|------------------|----------------------------------------|----------------------------------------|--|---------------------|--|--|

<sup>(2)</sup> For use as a colorant, see Annex IV, No. 143.

(2) entry 27a is inserted:

|                  | Substance Identification |                                     |            |           | Conditions               |                                                    |       |                                           |
|------------------|--------------------------|-------------------------------------|------------|-----------|--------------------------|----------------------------------------------------|-------|-------------------------------------------|
| Reference number | 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 | Wording of conditions of use and warnings |
| a                | b                        | c                                   | d          | e         | f                        | g                                                  | h     | i                                         |

|      |                                   |                         |                                        |                                       |  |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |  |
|------|-----------------------------------|-------------------------|----------------------------------------|---------------------------------------|--|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| '27a | Titanium dioxide ( <sup>2</sup> ) | Titanium Dioxide (nano) | 13463-67-7/<br>1317-70-0/<br>1317-80-2 | 236-675-5/<br>205-280-1/<br>215-282-2 |  | 25 % ( <sup>x</sup> ) | <p>Not to be used in applications that may lead to exposure of the end user's lungs by inhalation</p> <p>Only nanomaterials having the following characteristics are allowed:</p> <ul style="list-style-type: none"> <li>- Purity <math>\geq 99</math> %;</li> <li>- Rutile form, or rutile with up to 5 % anatase, with crystalline structure and physical appearance as clusters of spherical, needle, or lanceolate shapes;</li> <li>- Median particle size based on number size distribution <math>\geq 30</math> nm;</li> <li>- Aspect ratio from 1 to 4,5, and volume specific surface area <math>\leq 460</math> m<sup>2</sup>/cm<sup>3</sup>;</li> <li>- Coated with Silica, Hydrated Silica, Alumina, Aluminium Hydroxide, Aluminium Stearate, Stearic Acid, Trimethoxycaprylylsilane,</li> </ul> |  |
|------|-----------------------------------|-------------------------|----------------------------------------|---------------------------------------|--|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|

