

PRODUCT INFORMATION FILE to the COSMETIC PRODUCT
(article 11, Regulation (EC) No. 1223/2009 on cosmetic products)

COSMETIC PRODUCT SAFETY REPORT

{article 10, par. 1, Regulation (EC) 1223/2009;
Annex I, Regulation (EC) 1223/2009;
Commission implementing decision of 25 November 2013 on
guidelines on Annex I to Regulation (EC) 1223/2009 -
2013/674/EU}

FURTHER DOCUMENTATION

(article 11, Regulation (EC) 1223/2009)

- description of the cosmetic product
- description of the method of manufacturing
- statement on compliance with good manufacturing practice
- proof of the effect claimed for the cosmetic product
- data on any animal testing

COSMETIC PRODUCT SAFETY INFORMATION

(part A of Annex I, Regulation (EC) 1223/2009)

- quantitative and qualitative composition of the cosmetic product
- physical/chemical characteristic of the cosmetic product
- microbiological quality
- impurities, traces, information about the packaging material
- normal and reasonably foreseeable use
- exposure to cosmetic product
- exposure to substances
- toxicological profile of substances
- undesirable effects and serious undesirable effects
- information on the cosmetic product

COSMETIC PRODUCT SAFETY ASSESSMENT

(part B of Annex I, Regulation (EC) 1223/2009)

- assessment conclusion
- labelled warnings and instructions of use
- reasoning ... based on information from Part A
- assessor's credentials and approval of Part B

