

Required documents for the Safety assessment and product information file

1. the (exact) formulation of the preparation, if required confidentiality agreement
2. material safety data sheets and specifications, certificates of analysis, microbiological status of the ingredients
3. physical and chemical data of the preparation, if applicable (pH, viscosity, color, superfatting of soaps, particle size is important for nano-materials)
4. description of the product, including amounts used (including labeling)
5. product stability (eg. B. 3 months at 40 ° C), bioburden test
6. (preservative) challenging test
7. skin tolerance tests (eg. B. Human Patch Test)
8. effectiveness tests (if claims are present)
9. INCI declaration, 26-allergens-list, IFRA certificates (if perfume oil available)
10. documents for packaging (EC declaration of conformity according to 1935/2004 and (EU) 10/2011 and SVHC Declaration)
11. information on microbiological contamination of the product (eg. bioburden testing of the last 3 batches)
12. GMP certificate
13. statistical complaint evaluation (if available)
14. product information file without safety report (if available)
15. information on animal experiments, concerning raw materials and product (confirmation "Cruelty Free")
16. Information on the manufacturing process (if available)
17. toxicological profiles of the raw materials by the manufacture (if available)
18. Labelling / others (if available)