List of required documents for compilation of Product Information File (PIF)

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LIST OF REQUESTED DOCUMENTS FOR COMPILATION OF PRODUCT INFORMATION FILE (PIF)

01

Qualitative and Quantitative Formulas:

Please make sure you include the trade names of the raw material used, the ingredients and the percentage breakdown, adding up to 100%.

Template already provided in folder "Product Formula"

02

Raw material specifications:

Please send the MSDS and the CoA of all raw materials.
Please, make sure that:

- The MSDS of each raw material includes its precise composition, together with the percentages of ingredients in it;
- The physic-chemical, microbiological and toxicological specifications are provided;
- The CoAs for the corresponding MSDSs are issued by the same supplier.

To be placed in folder "Raw material specifications"

03

Physic-chemical and Microbiological specifications of final product:

Please send the COAs of the finished products with physic-chemical specifications and results (e.g. color, odor, appearance, pH, viscosity, density, etc.).
The COAs should also have the determination of the bacterial total plate count (cfu/ml), the determination of yeasts & moulds and the detection of the pathogens Pseudomonas aeruginosa, Staphylococcus aureus and Candida albicans.

To be placed in folder "Finished Product Specifications"

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04 Stability test report

Commonly accepted Stability Test Protocol:

- Lab and product identification (Lab name and contact information, Product name, Product reference number, Batch number, Manufacturer's name etc.);
- Performed on minimum 90 days (accelerated); indicate the test's starting and ending dates;
- Measured at different times (T0, 30 days, 60 days, 90 days);
- Measured at different temperatures (-5, 25 and 45 °C);
- Physical observations - pH color, odor, appearance, viscosity, density, etc.;
- A light/no light condition should be included only for transparent packaging;
- Microbiological quality (Pseudomonas aeruginosa, Staphylococcus aureus and Candida albicans);
- Thorough conclusion including PAO or EXPIRY DATE;
- Signed by a lab technician

This is commonly accepted protocol. Other protocols can be accepted if a justification is provided as well.

To be placed in folder "Finished Product Specifications"

05 Challenge test

Please make sure that the Challenge Test includes:

- Lab and production identificaition;
- Inoculum: 10 / 10 ;
- Performed on 28 days; indicate the test's starting and ending dates;
- Protocol used (parameters measured, time of measurement, results at different times);
- Log reduction information;
- Measured for – Pseudomonas aeruginosa, Staphylococcus aureus, Candida albicans, Aspergillus brasiliensis, E. Coli;
- Conclusion
- Signature by a lab technician

To be placed in folder "Challenge Test with Method"

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06

Detailed packaging specifications

- Identification and brief description of the packaging material – the one that comes in direct contact with th product (inner container) and of the closure system – with information about common uses, composition and impurities.
- Please specify the exact material, e.g. PET, PP, glass, etc.
- If possible, please provide a Food Grade Certificate.

To be placed in folder "Packaging Specifications"

07

Compatibility Report

Can be run along the Stability Test, with the product being tested in its final packaging (the one that is in direct contact with the product). In the Compatibility Test, the possible interaction between the product and the packaging is studied.
Please make sure that the Compatibility Report includes:

- Packaging material identification/description;
- Physical observations – color change, weight loss, leakage, distortion, appearance, etc.;
- If product comes in PVC, PET, TPEE, PETG plastic containers, a phtalates test should be run, due to the possibility of migration between the container and the content;
- If product comes in metal or metal cup, heavy metals testing should be run;
- If product comes in glass no further investigation is needed;
- Testing conclusions.

» To be placed in folder "Compatibility Report"

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LIST OF REQUESTED DOCUMENTS FOR COMPILATION OF PRODUCT INFORMATION FILE (PIF)

08 Method of Manufacture:

Per product or type of products – flowchart or description with the main manufacturing steps and quality control points.

To be placed in folder "Declaration"

09 IFRA Certificate according to the 49th Amendment:

For any frangrances and botanical essential oils used in the formulations of the products.

To be placed in folder "IFRA &Allergens'"

10 Allergens list with the % of the allergens in the fragrance:

For any frangrances and botanical essential oils used in the formulations of the products.

To be placed in folder "IFRA &Allergens'"

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11 Data on any reported undesirable effects or serious undesirable effects associated with the use of these products:

To be placed in folder "Declarations"

12 Labels (artworks)

Pease, be informed that we will check the labels as a final step, since we first need a Safety Assessment issued.
Kindly add any proof of claim should you have (tests etc.).

To be placed in folder "Labels'"

13 Declarations

Please fill in and sign the Obelis declarations regarding UE&SUE and Labelling Compliancy.

- The rest of the declarations must be reviewed and signed by your producer.
- Please provide GMP certificate according to ISO:22716 (Cosmetics Good Manufacturing Practice) if available.

To be placed in folder "Declarations"

14 Patch test

If applicable / if available

15 Safety assessement

If available