

PLAN OF THE TOXICOLOGICAL ASSESSMENT FILE



CHARTER

1. PRODUCT DEFINITION

- **Manufacturing process**
- **Form:**
 - Physical presentation
 - Carrier or vehicle solvent: nature and proportions
- **Chemical structure:**
 - Chemical formula or structure of the most abundant identified ingredient
- **Specifications:**
 - Physical
 - Chemical
 - Microbiological
- **Nomenclature:**
 - INCI
 - and/or CAS
 - and/or EINECS

1.1 Specific cases of raw materials of plant origin

- **Name of the plant**
- **Part of the plant**
- **Manufacturing method:**
 - Process
 - Solvent(s)

1.2 Specific cases of raw-materials of animal origin

- **Animal species name**
- **Organ name**
- **Manufacturing method**
 - Extraction process or hydrolysis process
 - Solvent(s)

2. RECOMMENDED CONDITIONS OF USE

- Method of application
- Concentration
- Recommended use
- Frequency of use

3. HISTORICAL AND BIBLIOGRAPHICAL DATA IN TOXICOLOGY

- Review of existing literature up to a specified date.
- References in appendix

4. TOXICOLOGICAL TESTS

4.1. Local toxicity

- Primary skin irritation
- Ocular irritation

4.2. Allergenicity

- Sensitisation

4.3. Systemic toxicity

- Mutagenesis: Ames test
- Acute toxicity

5. SPECIFIC PRECAUTIONS KNOWN

6. RISK ASSESSMENT- CERTIFICATE