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| GUIDE FOR PLANTS (AND PARTS OF PLANTS) NOT INCLUDED IN THE ANNEX  OF THE ROYAL DECREE OF the 29th AUGUST 1997 |

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| **1. General** | | |
| 1.1 | Binomial scientific name of plant | Genus, species, variety, cultivar, author and chemotype (where applicable)  Referred botanical name & synonyms |
| 1.2 | Other names | Original name, Dutch, French, German, English,  Trade name |
| 1.3 | Parts of the plant | Specification of areal and/or non areal  Fresh and/of dried |
| 1.4 | Description of the constituents | Primary and secondary metabolites  Percentages and usual amounts  Chemical formulae |
| 1.5 | Tradtional use | Ethnopharmacology of plant species and preparations thereof  Recent developments |
| **2. Toxicity & safety** | | |
| 2.1 | Possible toxicity of the herbal substance as such | Experimental data and case studies  GRAS status |
| 2.2 | Possible toxicity of certain constituents | Experimental data about acute, subacute and chronic toxicity, genotoxicity and carcinogenicity |
| 2.3 | Possible toxicity of certain parts | Experimental data and case studies  GRAS status |
| 2.4 | Possible toxicity of certain preparations | Preparations should be specified (parts of the plant, extraction solvent, specification of constituents, doses, concentrations, way and duration of administration, reversibility of the outcomes) |
| 2.5 | Possible toxicity of certain contaminants | Specification of contaminants and concentrations |
| 2.6 | Mentioned in EFSA compendium ? | Specified compounds of concern |
| **3. Conclusions** | | |
|  |  | Proposed conditions for safe use |