

HOMEOPATHIC MEDICINAL PRODUCT WORKING GROUP

(HMPWG)

STRUCTURE OF THE LIST OF FIRST SAFE DILUTIONS

DISCUSSION IN THE SUBGROUP	February - March 2009		
DISCUSSION IN THE HMPWG	29 April 2009		
ADOPTION FOR TRANSMISSION TO HMA for release for consultation	1 June 2009		
DEADLINE FOR COMMENTS	1 October 2009		
DISCUSSION IN THE SUBGROUP	October 2009		
DISCUSSION IN THE HMPWG FOR ADOPTION	8 December 2009		
ADOPTION BY THE HMPWG FOR TRANSMISSION TO THE HMA	January 2010		
ADOPTION BY THE HMA	10 May 2010		

Identity of the stock*/ raw/starting material**	Preparation	Constituents of toxicological concern	Acceptable amount mg/kg/day based on PDE/TTC/(LHRD/100)	First safe dilution	Toxicological comments
 Name Eur. Ph./Scientific name Name national Ph. Ref. to monograph Ref. to other published literature Synonyms Plant part Fresh/dried 	 Homeopathic Manufact. Method/ Method of preparation 	(international nomenclature, CAS #)		(as defined point 3.4 under the points to consider)	(e.g. target organs, major toxic concern, patients groups with special concern for which the use is not recommended)
		Known toxic or possibly toxic substances With max % in raw/starting material/stock (to be specified if possible Not known	Based on stock/raw/starting material (to be specified) Based on known or possible toxic constituent		

* As defined in the Eur. Ph.

** For information related to the identity, refer to "Guidance on module 3 of the homeopathic medicinal product dossier" (<u>http://www.hma.eu/uploads/media/HMPWG_dossier_guidance_mod3.pdf</u>)

List of used abbreviations

- FSD: First Safe Dilution
- LHRD: Lowest Human Recommended Dose
- PDE: Permitted Daily Exposure
- TTC:
- Threshold of Toxicological Concern German Homeopathic Pharmacopoeia GHP:
- Fr. Ph.: French Pharmacopoeia
- Eur. Ph.: European pharmacopoeia