

Input on substances nominated to the Office of the Report on Carcinogens for review. Information

The following information was submitted on 10/17/2013:

### Submission Form

- Input on substances nominated to the Office of the Report on Carcinogens for review.

### Respondent Information

- **Title**  
Dr.
- **First Name**  
Wolfgang
- **Last Name**  
Weber
- **Affiliation**  
Dr. Willmar Schwabe Pharmaceuticals, Germany

### Contact Information

- **Phone Number**  
+49 721 4005 665
- **E-mail Address**  
wolfgang.weber@schwabe.de

### Responses

**1. Please indicate substance on which you are providing information.**

Ginkgo biloba extract EGb 761

**2. What type of information are you providing?**

citationsOrStudies,expertsNominations

**3. If type of information is other, please provide a description**

Not provided.

**4. Input on substance indicated in Item 1.**

(1) Data on current production, use patterns, and human exposure Between 1989 and 2012 approximately 8.709 million defined daily doses (DDD) of the standardized Ginkgo biloba leaf extract EGb 761® (oral presentation forms) were placed on the international market worldwide (as based on the standard daily dose of 120 mg active substance), the vast majority thereof as active ingredient of medicinal (drug) products. (2) Scientific issues important for assessing carcinogenicity of the substance (all literature below is available in our files and can be provided on request) 1) Genotoxicity studies performed with EGb 761® Neumann W. (1984). Mutagenicity Study of PSc 44 in the Ames Salmonella/Microsome Plate Test (in vitro); LPT Report Allen J. A. (1989). An Assessment of the Mutagenic Potential of J-121 Using the Mouse Lymphoma TK Locus Assay; Huntingdon Report No. HYW5/881803 Brooker, P. C. (1988). J-121: Metaphase Chromosome Analysis of Human Lymphocytes Cultured in Vitro; Huntingdon Report No. HYW3/88866 Henderson I. M. (1988). Mouse Micronucleus Test on J-121; Huntingdon Report No. HYW2/88417 Kitching J. (1999). EGb 761: Bacterial Mutation Assay; Huntingdon Report No. SHB046/993358 Leuschner J (2008). Micronucleus Test of EGb 761 in Bone Marrow Cells of the Mouse by Oral Administration. LPT Report No. 22993 Leuschner J. (2009). Mutagenicity study of Ginkgo biloba extract 501282080/Ex. Ch. 249 in Mammalian Cells (V79) in the in Vitro Gene Mutation Assay (HPRT Test). LPT Report No. 21783 Leuschner J (2013). Micronucleus Test of Ginkgo biloba extract EGb 761 and Ginkgo biloba extract NTP in Bone Marrow Cells of the NMRI Mouse Following Oral Administration. LPT Report No. 29879 2) Carcinogenicity studies performed

Reference Number: 11975

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with EGb 761® Gazeley M. J. S. (1994). Ginkgo Extract EGb 761 (RH 44): Oral (Dietary Administration) Carcinogenicity Study in the Mouse; Hazleton Report No. 7488-690/10 Hill, R. E. (1989). RH 44: 52 Week Dietary Toxicity Study in the Rat. Toxicol. Lab. Report No. RHC/2/89 3) Statement on a Possible Genotoxic and Carcinogenic Potential of the Ginkgo biloba leaf Extract EGb 761® (3) Name of scientist with expertise or knowledge about the substance Dr. Egon Koch; Head of Preclinical Research; Dr. Willmar Schwabe GmbH & Co. KG, 76227 Karlsruhe, Germany; email: [egon.koch@schwabe.de](mailto:egon.koch@schwabe.de)

**Optional Files(s)**

- Not provided.