TEGO® Natural Betaine

Zusammenfassung der Produktdaten zur Toxikologie und Ökologie* / Summary of Product Data with Reference to Toxicology and Ecology*

Prüfung Test	Methode Method	Ergebnis Result	Datum Date
Grundlegende Toxikokinetik Basic toxicokinetics	No guideline followed [1)]	No bioaccumulation potential based on study results and expert judgement	2006
Akute orale Toxizität (Ratte) Acute Oral Toxicity (rat)	OECD 423	LD_{50} > 11,204 mg/kg bw	06/1990
Hautverträglichkeit (Kaninchen) Acute Dermal Irritation/Corrosion (rabbit)	OECD 404	nicht reizend not irritating	04/1989
In-vitro Hautabsorptionsstudie Percutaneous absorption study	OECD 428	< 0.1% of the initial dose regardless formulation	02/2007
Schleimhautverträglichkeit (Kaninchen) Acute Eye Irritation/Corrosion (rabbit)	OECD 405	nicht reizend not irritating	01/1992
Hautsensibilisierung (Meerschweinchen) Skin Sensitisation (guinea pig)	OECD 406	nicht sensibilisierend not sensitising	03/1989
Toxizität bei wiederholter Verabreichung (Ratte) Repeated dose toxicity (rat)	OECD 407	NOAEL (28 d) > 5,771 mg/kg bw/day	07/2001
Gentoxizität (Ames) Gene Toxicity (Ames)	EU method B.13/14	nicht mutagen not mutagenic	04/1989
Chromosomen-Aberrationstest Chromosomal aberration	EU method B.10	nicht clastogen not clastogenic	09/1989
Kombinierte chronische Toxizität / Karzinogenität Combined Chronic Toxicity / Carcinogenicity	OECD 453 [2)]	no effect level determined up to 5% in oral feed, betaine is not carcinogenic	03/2002
Reproduktionstoxizität Toxicity to reproduction	No guideline followed [2,3)]	log(ER-RBA) = -13.38 betaine does not bind Estrogen receptor B.	01/2010
Bioabbau aerob Biodegradation aerob	OECD 301 B	<= 88% (28 d) readily biodegradable	11/1997
Akute Daphnientoxizität Acute Daphnia Immobilisation	OECD 202	EC_{50} (48 h) <= 4,335 mg/L	04/2010
Algenwachstumshemmtest Alga growth inhibition test	OECD 201	EC_{50} (72 h) <= 1,199 mg/L	04/2010

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1) Pharmacokinetic studies, as well as nutritional studies have been done with orally administered betaine in healthy and homocystinuria patients. Different variations, from single administration of 50 mg to continuous intake of twice daily.
2) Supporting study
3) QSAR-modelling following QMRF reported as QPRF

* Full Robust Study Summaries can be checked under the ECHA Registered Substance website and with the following registration number: 01-2119520508-42

Video instruction for use:
http://personal-care.evonik.com/product/personal-care/en/media-center/videos/reach-tox-data/pages/default.aspx