

## TEGO® Betain F 50

### 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
Akute orale Toxizität (Ratte) Acute oral toxicity (rat)	OECD 401	LD <sub>50</sub> = 2,335 mg/kg <sup>1)</sup>	09/1977
Akute dermale Toxizität (Ratte) Acute dermal toxicity (rat)	OECD 402	LD <sub>50</sub> > 620 mg/kg <sup>1)</sup>	09/1987
Dermale Penetration (menschliche Bauchdeckenhaut aus kosmetischen Operationen) Dermal penetration (human abdominal skin from cosmetic surgery)	OECD 428	The mean absorbed dose of Coco AAPB, sum of the amounts found in the viable epidermis, dermis and receptor medium was 0 % <sup>1)</sup>	04/2009
Grundlegende Toxikokinetik (Ratte) Basic Toxicokinetics (rat)	OECD 417	90% of test material excreted <sup>2)</sup> unchanged in faeces, 3% in urine, 2% in respired air	
Hautverträglichkeit (Kaninchen) Skin irritation / corrosion (rabbit)	OECD 404	nicht reizend not irritant	01/1990
Hautverträglichkeit (Kaninchen) Skin irritation / corrosion (rabbit)	OECD 404	nicht reizend not irritant	11/1991
Hautverträglichkeit (Kaninchen) Skin irritation / corrosion (rabbit)	OECD 404	nicht reizend <sup>3)</sup> not irritant	11/1986
Hautverträglichkeit (Kaninchen) Skin irritation / corrosion (rabbit)	OECD 404	nicht reizend <sup>4)</sup> not irritant	01/1995
Schleimhautverträglichkeit (Kaninchen) Acute Eye Irritation/Corrosion (rabbit)	OECD 405	84 % a.s. irreversible Effekte irreversible effects on the eye	12/1991
Schleimhautverträglichkeit (Kaninchen) Acute Eye Irritation/Corrosion (rabbit)	OECD 405	10 % a.s. in water, augenreizend <sup>5)</sup> eye irritant	05/1982
Schleimhautverträglichkeit (Kaninchen) Acute Eye Irritation/Corrosion (rabbit)	OECD 405	25 % a.s. in water, irreversible Effekte irreversible effects on the eye <sup>5)</sup>	09/1987
Schleimhautverträglichkeit (Kaninchen) Acute Eye Irritation/Corrosion (rabbit)	OECD 405	5 % a.s. in water, augenreizend <sup>5)</sup> eye irritant	06/1986
Schleimhautverträglichkeit (Kaninchen) Acute Eye Irritation/Corrosion (rabbit)	OECD 405	4.5 % a.s. in water, nicht <sup>5)</sup> augenreizend not an eye irritant	12/1965
Schleimhautverträglichkeit (Kaninchen) Acute Eye Irritation/Corrosion (rabbit)	OECD 405	35 % a.s. in water, irreversible Effekte irreversible effects on the eye <sup>5)</sup>	11/1986

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Schleimhautverträglichkeit (Kaninchen) Acute Eye Irritation/Corrosion (rabbit)	OECD 405	99.4 % dry solids, irreversible Effekte irreversible effects on the eye <sup>5)</sup>	01/1995
Hautsensibilisierung (Meerschweinchen) Skin Sensitization (guinea pig)	OECD 406	30 % a.s. in water nicht sensibilisierend not sensitizing <sup>5)</sup>	11/1980
Hautsensibilisierung (Meerschweinchen) Skin Sensitization (guinea pig)	OECD 406	30 % a.s. in water nicht sensibilisierend not sensitizing <sup>5)</sup>	05/1990
Toxizität bei wiederholter Verabreichung (Ratte) 90 day repeated dose toxicity (rat)	OECD 408	NOEL systemic toxic effects 300 mg a.s./kg bw LOEL (local effects, forestomach) 150 mg a.s./kg bw	04/1991
Toxizität bei wiederholter Verabreichung (Ratte) 90 day repeated dose toxicity (rat)	OECD 408	NOEL systemic toxic effects <sup>6)</sup> 247 mg a.s./kg bw LOEL (local effects, caecum and liver) 47 mg a.s./kg bw	05/1994
Säugetierzellen-Mutationsversuch Mammalian cell gene mutation assay	OECD 476	no significant dose dependent trend of the mutation frequency indicated by a probability value of <0.05 was determined in all experimental groups	02/2010
Gentoxizität (Ames) Gene Toxicity (Ames)	EU Method B.13/14	negativ negative <sup>7)</sup>	
Chromosomale Aberration Chromosomal aberration	OECD 474	nicht clastogen not clastogenic <sup>1)</sup>	03/1987
Entwicklungstoxizität/ Teratogenität Developmental toxicity/ teratogenicity	OECD 414	NOEL (maternal toxicity) 100 mg a.s./kg bw/day NOEL (developmental toxicity) 300 mg a.s./kg bw/day NOEL (external, skeletal or soft tissue malformations and variations) 1,000 mg a.s./kg bw/day	07/2004
Bioakkumulation in aquatischen Sedimenten Bioaccumulation in aquatic sediment	BCFWIN v2.15	Values in the range between 3 (C8 <sup>8)</sup> fatty acid derivate) and 71 L/kg (C10 - C18 and C18 unsaturated fatty acid derivates)	2004
Bioabbau aerob Biodegradation aerobic	EPA OPPTS 835.3120	Leicht abbaubar Readily biodegradable (87.2% 28 d)	08/2000
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Bioabbau aerob Biodegradation aerobic	OECD 301 B	Leicht abbaubar Readily biodegradable (91.6% 28 d)	06/2008
Bioabbau anaerob Biodegradation anaerobic	ECETOC (Technical Report No. 28)	Gut abbaubar Well biodegradable (68 % 62 d)	05/2000
Akute Fischtoxizität Acute fish toxicity	OECD 204	28 d NOEC: 0.16 mg a.s./L (nominal) 28 d LOEC: 0.5 mg a.s./L (nominal)	10/1995
Langzeit-Fischtoxizität Long-term fish toxicity	OECD 210	100 d NOEC: 0.135 mg a.s./L 100 d LOEC: 0.405 mg a.s./L	10/2008
Akute Daphnientoxizität Acute Daphnia Immobilisation	OECD 202	EC <sub>50</sub> (48 h): 6.5 mg a.s./L (nominal)	12/1991
Langzeit-Daphnientoxizität Long-term Daphnia reproduction	OECD 211	21 d NOEC: 0.03 mg a.s./L (nominal) <sup>9)</sup> 21 d LOEC: 0.1 mg a.s./L (nominal)	10/1995
Langzeit-Daphnientoxizität Long-term Daphnia reproduction	OECD 211	21 d NOEC: 0.932 mg a.s./L (nominal) <sup>9)</sup> 21 d LOEC: 2.98 mg a.s./L (nominal)	06/2006
Langzeit-Daphnientoxizität Long-term Daphnia reproduction	OECD 211	21 d NOEC: 0.9 mg a.s./L (nominal) <sup>9)</sup> 21 d LOEC: 3.6 mg a.s./L (nominal)	12/1991
Algeninhibierung Algae Growth Inhibition	ISO 10253 <sup>10)</sup>	ErC <sub>50</sub> (72h): 0.74 mg a.s./L <sup>5)</sup> NOEC (72h): 0.36 mg a.s./L	02/2008
Bakterientoxizität Bacteria Toxicity	EN ISO 10712	EC <sub>0</sub> (16h) > 3.000 mg a.s./L (nominal) <sup>5)</sup>	02/2004
Akute Regenwurmtoxizität Earthworm acute toxicity test	OECD 207	14 d LC <sub>0</sub> : >=380 mg a.s./kg soil dw (nominal) 14 d EC <sub>0</sub> : >=380 mg a.s./kg soil dw (nominal)	02/2004
Bioabbaubarkeit im Meerwasser Biodegradability in sea water	OECD 306	Leicht abbaubar <sup>5)</sup> Readily biodegradable (76% 28 d)	03/2007
Sediment-Toxizität Sediment toxicity	OSPARCOM (1995) <sup>11)</sup>	10 d NOEC: 5,129 mg a.s./kg sediment dw LC <sub>50</sub> : > 5,129 mg a.s./kg sediment dw (nominal) <sup>5)</sup>	02/2008
Toxizität gegenüber terrestrischen Pflanzen Toxicity to terrestrial plants	OECD 208	17 d NOEC: 84.6 mg a.s./kg soil dw Endpoint(s) Effected: emergence and growth <sup>5)</sup>	05/1995

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a.s. active substance

- 1) Read-Across from Coco Alkyl Amidopropylbetaine, 30% a.s.
- 2) Read-Across from C12 Alkyl Amidopropylbetaine
- 3) Read-Across from Coco Alkyl Amidopropylbetaine, 35% a.s.
- 4) Read-Across from Coco Alkyl Amidopropylbetaine, 99.4% a.s.
- 5) Read-Across from Coco Alkyl Amidopropylbetaine
- 6) Read-Across from Coco Alkyl Amidopropylbetaine, 33.8% a.s.
- 7) Read-Across from C8-18 and C18 unsaturated Alkyl Amidopropylbetaine
- 8) Based on the calculated BCFs a low potential for bioaccumulation is to be expected for Alkylamidopropyl Betaines
- 9) Weight of evidence
- 10) Water quality – Marine Algal Growth Inhibition Test with *Skeletonema costatum* and *Phaeodactylum tricorutum*
- 11) A sediment bioassay using an amphipod *Corophium volutator*

\* Full Robust Study Summaries can be checked under the ECHA Registered Substance website and with the following registration number: 01-2119488533-30

Video instruction for use:

<http://personal-care.evonik.com/product/personal-care/en/media-center/videos/reach-tox-data/pages/default.aspx>

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