

ASSURING THE SAFETY, QUALITY & EFFICACY OF VETERINARY MEDICINES

Copyright notice

The information below was supplied in response to an Access to Information (ATI) request. It is the copyright of the Veterinary Medicines Directorate. You are free to use it for your own purposes, including for private study and non-commercial research, and for any other purpose authorised by an exception in current copyright law. Documents (except photographs or logos) can be also used in the UK without requiring permission for the purposes of news reporting. Any other re-use, for example commercial publication, would require the permission of the copyright holder.

ATI 307

Request

From: [Redacted under section 40 of the FOIA]

Sent: 14 July 2014

Subject: FOI Request: Environmental Fate and Effects

I would like to request for information relating to the environmental fate and effect data you may hold regarding the following substances:

Tricaine (tricaine methane sulphonate) Bronopol

VMD Reply

Sent: 23 July 2014

To: [Redacted under section 40 of the FOIA]

Subject: FOI Request: Environmental Fate and Effects

We are dealing with it under the Freedom of Information Act 2000.

You asked for information relating to the environmental fate and effect data the VMD hold regarding the following substances:

Tricaine (tricaine methane sulphonate)
Bronopol

Our Reply

We do not hold any data for Tricaine (tricaine methane sulphonate).

We have placed the data we do hold for Bronopol [below].

Copyright

The information supplied to you is Crown copyright, unless otherwise stated, and is protected by the Copyright, Designs and Patents Act 1988. You are free to use it for your own purposes, including any non-commercial research. Documents (except photographs or logos) can be also used in the UK without requiring permission for the purposes of news reporting. Any other re-use, for example commercial publication, will require permission. You can find details on the arrangements for re-using Crown copyright information at: http://www.nationalarchives.gov.uk/doc/open-government-licence.htm

Information you receive which is **not** subject to Crown Copyright continues to be protected by the copyright of the person, or organisation, from which the information originated. You must ensure that you gain their permission before reproducing any third party (non-Crown Copyright) information.

Our Service

If you are unhappy with the service you have received in relation to your request and wish to make a complaint, you may request an internal review within two calendar months of the date of this e-mail. If you would like to request an internal review please write to [Redacted under section 40 of the FOIA] at the VMD via ati@vmd.defra.gsi.gov.uk. If you are not content with the outcome of the internal review you have the right to apply directly to the Information Commissioner for a decision. The Information Commissioner can be contacted at: Information Commissioner's Office

Wycliffe House

Water Lane

Wilmslow

Cheshire

SK9 5AF

ATI 307: Environmental fate and effect data regarding the following substances:

Tricaine methane sulphonate Bronopol

Fate and effects information - Tricaine methane sulphonate

The VMD hold no data on the fate and effects of Tricaine methane sulphonate..

Fate and effects information - bronopol

Study	Results
OECD 107: Octanol/water partition coefficient	1.5 @ 20 °C (Log P _{ow} 0.18)
OECD 301D: Ready biodegradability, closed bottle test	Not readily biodegradable
Adsorption/desorption in soil	K _d : 0.28 - 3.546. K _{oc} : 37 - 1416.
Photolysis in pH 4 buffer @ 25 °C	Half-life of bronopol about 24 hours.
OECD 302B: modified Zahn-Wellens inherent biodegradability	50 % degradation by day 45
Aerobic aquatic biodegradation based on modified OECD 304A & 302B	Bronopol was rapidly degraded by activated sludge micro-organisms in aerobic aquatic system.
Hydrolysis as a function of pH (OECD test guideline 1, OJ 1984)	Hydrolysis > 10 % after 120 hours @ pH 4. Half-life < 2.4 hours @ pH's 7 & 9.
OECD 301B: Ready biodegradability	Did not pass biodegradability criteria according to OECD 301B.
Toxicity of Myacide BT (98 % bronopol) to rainbow trout, (<i>Oncorhynchus mykiss</i>) static test, nominal concentrations	24-h LC ₅₀ = 33 (28.5 – 38.3) mg/l 96-h LC ₅₀ = 20.0 (18.5 – 21.7) mg/l NOEC 10 mg/l
Toxicity to rainbow trout, (<i>Oncorhynchus mykiss</i>) flow-through test, mean measured concentrations	24-h LC ₅₀ = 90.5 (80.3 – 106.7) mg/l 96-h LC ₅₀ = 41.2 (36.1 – 45.3) mg/l
Early-life stage test rainbow trout, (Oncorhynchus mykiss) continuous-flow 49 days, nominal concentrations	49-day $LC_{50} = 30 (36 - 45) \text{ mg/l}$ NOEC for mortality = 21 mg/l, LOEC 40 mg/l
Toxicity to Sheepshead minnow (<i>Cyprinodon variegatus</i>), seawater, flow-through test, mean measured concentrations	24-h LC ₅₀ = 101 (88 – 114) mg/l 96-h LC ₅₀ = 57.6 (31 – 164) mg/l
Toxicity to Blue gill sunfish (<i>Lepomis</i> machrochirus), flow-through test, mean measured concentrations	24-h LC ₅₀ = 51.6 (48 – 65) mg/l 96-h LC ₅₀ = 35.7 (31 – 40) mg/l
Toxicity of Myacide BT (98 % bronopol) to Daphnia magna, static test, 20°C nominal concentrations	24-h EC ₅₀ = 2.9 (2.3 – 3.5) mg/l 48-h EC ₅₀ = 1.4 (0.7 – 2.8) mg/l
OECD 202 (now OECD 211): reproduction test with <i>Daphnia magna</i> , flow-through, measured concentrations	EC_{50} parental immobility = 0.27 - 0.88 mg/l EC_{50} for reproduction = 0.27 - 0.88 mg/l LOEC for parental immobility = 0.88 mg/l Overall NOEC = 0.27 mg/l
OECD 202 (now OECD 211): reproduction test with <i>Daphnia magna</i> using Myacide S1 ² , flow through measured concentration	14-day EC $_{50}$ immobility 1.42 (0.9 $-$ 2.14) mg/l 22-day EC $_{50}$ immobility 0.83 (0.67 $-$ 1.03) mg/l 22-day EC $_{50}$ reproduction 0.43< x <1.33 mg/l Overall LOEC 22 days 1.33 mg/l Overall NOEC 0.43 mg/l

Study	Results
OECD 211: reproduction test with <i>Daphnia</i>	adult mortality
magna, using Pyceze®, 21-day semi-static,	21-day LC ₅₀ = 0.57 (0.27 – 1.04) mg/l
nominal concentrations as 'Pyceze'	NOEC – could not be determined, LOEC 0.32 mg/l
	reproduction 21-day EC ₅₀ = 0.798 mg/l
	NOEC = 0.63 mg/l, LOEC = 1.25 mg Pyceze/l
'Pyceze': Field monitoring study with Daphnia	NOEC 0.048 mg/l
magna.	11020 0.0 to mg/i
Toxicity of Myacide BT (95 % bronopol) to	24-h LC ₅₀ = 565 mg/l
Crangon crangon, semi-static test	96-h LC ₅₀ = 121 mg/l
Acute toxicity Mysid shrimp (Mysidopsis	24-h LC ₅₀ = 15.3 (6.1 – 39.9) mg/l
bahia), seawater, continuous flow, mean	96-h $LC_{50} = 5.9 (5.1 - 7.3) \text{ mg/l}$
measured concentrations	
Toxicity to embryos of Oyster larvae	$48-h LC_{50} = 1.7 (1.3 - 2.4) \text{ mg/l}$
(Crassostrea gigas), seawater, static test,	48-h $EC_{50} = 0.69 (0.56 - 1.0) \text{ mg/l}$
nominal concentrations	70 50 11 12 13 13 14 15 15 15 15 15 15 15
OECD 201, Green algae (Scenedesmus	72-h EC ₅₀ growth inhibition = 0.02 (0.01 – 0.03) mg/l
subspicatus) strain 86.81 SAG, nominal concentrations	72-h EC ₅₀ growth rate = 0.05 (0.04 – 0.1) mg/l
OECD 201: growth inhibition in 3 species of	
algae, 72-hour effects, static test, nominal	
concentrations	
Selenastrum capricornutum	NOEC 0.1 mg/l; E_bC_{50} 0.16 mg/l; E_rC_{50} 0.37 mg/l
Scenedesmus subspicatus	NOEC 0.1 mg/l; E_bC_{50} 0.15 mg/l; E_rC_{50} >1.0 mg/l
Oldered the series of	NOTO 0.00
Chlorella vulgaris 1	NOEC 0.32 mg/l; E_bC_{50} 0.4 mg/l; E_rC_{50} 0.89 mg/l
Chlorella vulgaris 2	NOEC 0.32 mg/l; E _b C ₅₀ 0.82 mg/l; E _r C ₅₀ 2.84 mg/l
Omorona vargano 2	11020 0.02 mg/i, L ₀ 050 0.02 mg/i, L ₀ 050 2.04 mg/i
OECD 201, 72-h algal growth inhibition in	
2 strains, static test, nominal concentrations	
Scenedesmus subspicatus	
CCAP 276/20	NOEC 0.1 mg/l; E_bC_{50} 0.35 mg/l; E_rC_{50} >3.2 mg/l
86:81 SAG	NOEC 0.032 mg/l; E_bC_{50} 0.06 mg/l; E_rC_{50} 0.19 mg/l
Growth inhibition of green algae	NOEC 0.453 mg/l;
(Scenedesmus subspicatus), strain SAG	72-h E_bC_{50} 1.24 (1.11 – 1.38) mg/l;
86:81, measured concentrations	72-h E _r C ₅₀ 2.61 (1.86 – 4.17) mg/l
Growth inhibition of Scenedesmus	NOEC 0.225 mg/l;
subspicatus, strain SAG 86:81, using	72-h E_bC_{50} 1.05 mg/l;
Pyceze®, measured concentrations	72-h E _r C ₅₀ 1.53 mg/l

Note data in shaded rows were generated with a formulated product