ASSURING THE SAFETY, QUALITY & EFFICACY
OF VETERINARY MEDICINES

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
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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].

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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 ºC (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 ºC	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, (*Oncorhynchus mykiss*) 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, (*Oncorhynchus mykiss*) 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) mg/l NOEC for mortality = 21 mg/l, LOEC 40 mg/l
Toxicity to Sheepshead minnow (*Cyprinodon variegatus)*, 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 (*Lepomis 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 *Daphnia magna*, 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 *Daphnia magna* 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 *Daphnia magna*, using Pyceze®, 21-day semi-static, nominal concentrations as 'Pyceze'	adult mortality 21-day LC_{50} = 0.57 (0.27 – 1.04) mg/l 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 magna*.	NOEC 0.048 mg/l
Toxicity of Myacide BT (95 % bronopol) to *Crangon crangon*, semi-static test	24-h LC_{50} = 565 mg/l 96-h LC_{50} = 121 mg/l
Acute toxicity Mysid shrimp (*Mysidopsis bahia)*, seawater, continuous flow, mean measured concentrations	24-h LC_{50} = 15.3 (6.1 – 39.9) mg/l 96-h LC_{50} = 5.9 (5.1 – 7.3) mg/l
Toxicity to embryos of Oyster larvae (*Crassostrea gigas*), seawater, static test, nominal concentrations	48-h LC_{50} = 1.7 (1.3 – 2.4) mg/l 48-h EC_{50} = 0.69 (0.56 – 1.0) mg/l
OECD 201, Green algae (*Scenedesmus subspicatus*) strain 86.81 SAG, nominal concentrations	72-h EC_{50} growth inhibition = 0.02 (0.01 – 0.03) mg/l 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* *Scenedesmus subspicatus* *Chlorella vulgaris* 1 *Chlorella vulgaris* 2	 NOEC 0.1 mg/l; E_bC_{50} 0.16 mg/l; E_rC_{50} 0.37 mg/l NOEC 0.1 mg/l; E_bC_{50} 0.15 mg/l; E_rC_{50} >1.0 mg/l NOEC 0.32 mg/l; E_bC_{50} 0.4 mg/l; E_rC_{50} 0.89 mg/l NOEC 0.32 mg/l; E_bC_{50} 0.82 mg/l; E_rC_{50} 2.84 mg/l
OECD 201, 72-h algal growth inhibition in 2 strains, static test, nominal concentrations *Scenedesmus subspicatus* CCAP 276/20 86:81 SAG	 NOEC 0.1 mg/l; E_bC_{50} 0.35 mg/l; E_rC_{50} >3.2 mg/l NOEC 0.032 mg/l; E_bC_{50} 0.06 mg/l; E_rC_{50} 0.19 mg/l
Growth inhibition of green algae (*Scenedesmus subspicatus)*, strain SAG 86:81, measured concentrations	NOEC 0.453 mg/l; 72-h E_bC_{50} 1.24 (1.11 – 1.38) mg/l; 72-h E_rC_{50} 2.61 (1.86 – 4.17) mg/l
Growth inhibition of *Scenedesmus subspicatus*, strain SAG 86:81, using Pyceze®, measured concentrations	NOEC 0.225 mg/l; 72-h E_bC_{50} 1.05 mg/l; 72-h E_rC_{50} 1.53 mg/l

Note data in shaded rows were generated with a formulated product