

ASSURING THE SAFETY, QUALITY & EFFICACY OF VETERINARY MEDICINES

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ATI 310

Request

From: [Redacted under section 40 of the FOIA]

Sent: 3 September 2014

Subject: FOI request for ecotoxicological data

To Whom it may concern,

The Vim Spectrum Hungary Ltd Company would like to submit a request under the FOI act for the available ecotoxicological data concerning the active substance doxycycline, when used in powders for drinking water.

VMD Reply

Sent: 30 September 2014

To: [Redacted under section 40 of the FOIA] **Subject**: FOI request for ecotoxicological data

Your Request

Thank you for your email to the VMD, dated 3 September 2014.

We are dealing with your request under the Freedom of Information Act 2000 (FOIA).

You asked for the ecotoxicological data concerning the active substance doxycycline, when used in powders for drinking water.

Our Reply

We have placed the data we hold [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

Ecotoxicological information - Doxycycline

Study	Results ¹		
	Data set 1	Data set 2	Data set 3
n-octanol/water	OECD 107:	OECD 107:	-0.02 (EpiSuite
partition coefficient	Log Pow:	Log Pow:	database)
OECD 107, 117 or 123	pH2 = -0.16;	pH2.5 = -0.2;	
	pH7 = -0.12;	pH7 = -0.0;	
	pH10 = -1.65	pH9 = -1.6	
Soil	OECD 106	OECD 106	OECD 106
adsorption/desorption	Koc: 47246; 93926;	Koc: 137460; 74682;	Koc: 71177; 106087;
OECD 106	237225	175928; 99025;	221722
		315188	
Soil degradation OECD	OECD 307	OECD 307	OECD 307
307	DT ₅₀ :27 d ; 31 d	DT ₅₀ :69 d ; 50 d	DT50 <30 days in 2
		(indicative only)	soils
Nitrogen transformation	OECD 216	OECD 216	OECD 216
OECD 216	No effect 86.9 mg/kg	No effects >10 mg/kg	No effects 8.04 mg/kg
Terrestrial plants	OECD 208	OECD 208	OECD 208
OECD 208	EC ₅₀ >150 mg/kg ²	lowest EC ₅₀ 66.3 mg/kg	$EC_{50} > 1000 \text{ mg/kg}^2$
Earthworm	OECD 222	OECD 222	OECD 222
subacute/reproduction OECD 220/222	NOEC 925 mg/kg	NOEC 160 mg/kg	NOEC 1000 mg/kg
Algal growth inhibition	OECD 201 Anabaena	OECD 201	OECD 201
OECD 201	72 h EC ₅₀ 175 μg/l	Pseudokircheriella	Synechococcus
		72 h EC ₅₀ 87.74 μg/l	leopoliensis
			72 h EC ₅₀ 145 μg/l
Daphnia magna	OECD 202	OECD 202	OECD 202
immobilisation OECD 202	48 h EC ₅₀ >161 mg/l	48 h EC ₅₀ >100 mg/l	48 h EC ₅₀ >68.1 mg/l
Fish acute toxicity	OECD 203	OECD 203	OECD 203
OECD203	96 h LC ₅₀ >97.55 mg/l	96 h LC ₅₀ >129.8 mg/l	96 h LC ₅₀ >90.6 mg/l

¹ All applications for a Marketing Authorisation are required to provide their own environmental risk assessment which leads more than one set of data for some active substances. Different results in the same test will be due to a number of factors including inherent biological variation and inter laboratory differences.
² All species tested (n=3)

Fate and effects information - Amoxicillin

Study	Result
Soil adsorption/desorption OECD 106	OECD 106 Koc: 40.4; 237.8; 65.4; 217.1; 51.2
Soil degradation OECD 307	OECD 307 DT ₅₀ :0.41 hr; 0.85 hr; 1.49 hr; 1.26 hr

We hold no effects data for amoxicillin.