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NEW DATA REQUIREMENTS

This LOEP template reflects the new data requirements for active substances and plant protection products as set out in Commission Regulations (EU) No 283/2013 and 284/2013 of 1 March 2013, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.

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AT	**July 2018**	**Triticonazole**

Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Identity, Physical and Chemical Properties, Details of Uses, Further Information (Regulation (EU) N° 283/2013, Annex Part A, points 1.3 and 3.2)

Active substance (ISO Common Name)	Triticonazole (ISO)
Function	Fungicide

Rapporteur Member State	Austria
Co-rapporteur Member State	United Kingdom

Identity (Regulation (EU) N° 283/2013, Annex Part A, point 1)

Chemical name (IUPAC)	(*RS*)-(*E*)-5-(4-chlorobenzylidene)-2,2-dimethyl-1-(1*H*-1,2,4-triazol-1-ylmethyl)cyclopentanol
Chemical name (CA)	(5*E*)-5-[(4-chlorophenyl)methylene]-2,2-dimethyl-1-(1*H*-1,2,4-triazol-1-ylmethyl)cyclopentanol
CIPAC No	652
CAS No	131983-72-7 138182-18-0
EC No (EINECS or ELINCS)	603-543-7
FAO Specification (including year of publication)	No FAO specification exists
Minimum purity of the active substance as manufactured	Triticonazole is a racemic mixture 950 g/kg (dry compound) TC 874 g/kg (damp product, specification in the Annex I Registration process) 890 g/kg TK
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	Methanol max. 3 g/kg (damp product) TK
Molecular formula	$C_{17}H_{20}ClN_3O$
Molar mass	317.82 u

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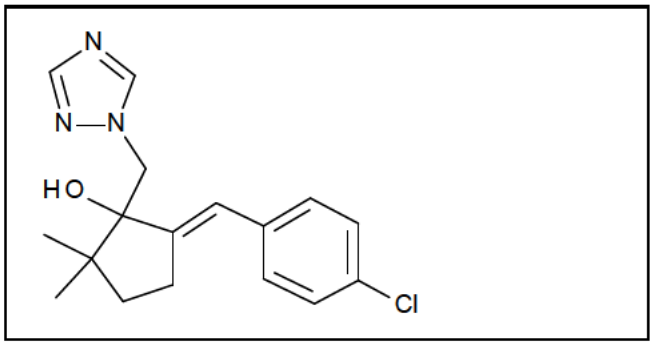
Structural formula



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Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Physical and chemical properties (Regulation (EU) N° 283/2013, Annex Part A, point 2)

Melting point (state purity)	First crystalline form: 137 °C second crystalline form: 141 °C (998.5 g/kg)
Boiling point (state purity)	Not measurable
Temperature of decomposition (state purity)	Starts slightly decomposing after melting Significant decomposition above 180 °C (998.5 g/kg)
Appearance (state purity)	White powder (998.5 g/kg) White powder with or without agglutinated mass (959 and 957 g/kg)
Vapour pressure (state temperature, state purity)	9.0×10^{-8} Pa at 25 °C (996 g/kg)
Henry's law constant	1.2×10^{-6} Pa m^3 mol^{-1} at 20 °C
Solubility in water (state temperature, state purity and pH)	Distilled water (pH 7.3 – 8.7; 20°C) 9.3 mg/L Buffer solution pH 5 (20°C) 7.7 mg/L Buffer solution pH 9 (20°C) 8.3 mg/L
Solubility in organic solvents (state temperature, state purity)	at 20 °C (g/L) Hexane 0.12 Toluene 12.6 Methanol 18.2 2-Propanol 7.6 1-Octanol 6.2 Dichloromethane 191.0 Acetone 74.5 Ethyl acetate 48.6
Surface tension (state concentration and temperature, state purity)	72.0 mN/m at 20 °C (90 % saturated solution)(986 g/kg)
Partition coefficient (state temperature, pH and purity)	Log Pow = 3.29 ± 0.04 at 20 °C (993 g/kg) No dissociation is expected in aqueous solution based on the molecular structure.
Dissociation constant (state purity)	No dissociation is expected in aqueous solution. The examination of the chemical structure shows that there is no substituent which could be easily ionised and make the substance ionisable over the range of pH 3-9.

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UV/VIS absorption (max.) incl. ε (state purity, pH)	Neutral medium (MeOH/Water 100:10) (993 g/kg) Wavelength (nm) ε (L x mol^{-1} x cm^{-1}) 212 23879 263 25731 No significant modifications were observed between the spectrum obtained in neutral, acidic or alkaline media. UV absorption at 290 nm: (994 g/kg) ε (L x mol^{-1} x cm^{-1}) in methanol: 1555 in water: 1884 in water (acidic conditions): 1734 in water (basic conditions): 1869 The absorption between 310 nm - 320 nm is negligible (<< 10 L x mol^{-1} x cm^{-1}) in all tested solutions.
Flammability (state purity)	Not highly flammable (968 g/kg)
Explosive properties (state purity)	No explosive properties (911 g/kg)
Oxidising properties (state purity)	No oxidising properties (968 g/kg)

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Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Summary of representative uses evaluated, for which all risk assessments needed to be completed (*Triticonazole*) (Regulation (EU) N° 284/2013, Annex Part A, points 3, 4)

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s /hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
winter wheat (TRZAW), spring wheat (TRZAS), winter barley (HORVX), spring barley (HORVS), rye (SECCW), triticale (TTLWI), oats (AVESA)	*BE, BG, CZ, EE, ES, FR, HU, IE, IT, LT, LV, PL, RO, UK,*	*BAS 595 01 F, Premis*	*F*	*Fusarium spp.* (FUSASP), *Tilletia caries/Tilletia tritici* (TILLCA), *Ustilago nuda tritici* (USTINT), *Ustilago nuda* (USTINH), *Ustilago hordei* (USTINHO), *Ustilago avenae* (USTIAV), *Urocystis occulta* (UROCOC)	*FS*	*25 g/L*	*Seed treatment (slurry)*	*BBCH 00 / spring or autumn*	*1*	-	*n.a.*	*Used undiluted or diluted with water at max ratio of 1:5 (prod:water)*	*0.0125*	*n.a.*	*Maximum seeding rate is 250 kg/ha*

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and sucking insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
(j) Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of applications possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

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Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Summary of additional intended uses for which MRL applications have been made, that in addition to the uses above, have also been considered in the consumer risk assessment (*Triticonazole*)
Regulation (EC) N° 1107/2009 Article 8.1(g))

Important note: efficacy, environmental risk and risk to humans by exposure other than via their diet have not been assessed for these uses

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s /hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
MRL Application (according to Article 8.1(g) of Regulation (EC) No 1107/2009)															

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and sucking insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
(j) Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of applications possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

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Section 1 Identity, Physical/ Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Further information, Efficacy

Effectiveness (Regulation (EU) N° 284/2013, Annex Part A, point 6.2)

The GAP for the representative use is supported.

Adverse effects on field crops (Regulation (EU) N° 284/2013, Annex Part A, point 6.4)

The GAP for the representative use is supported. No adverse effects are to be expected.

Observations on other undesirable or unintended side-effects (Regulation (EU) N° 284/2013, Annex Part A, point 6.5)

The GAP for the representative use is supported. No undesirable or unintended side-effect are to be expected.

Groundwater metabolites: Screening for biological activity (SANCO/221/2000-rev.10-final Step 3 a Stage 1)

	Met1	*Met2*	*Met3*
Activity against target organism	*no*	*no*	*no*

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Section 1 Identity, Physical/ Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Methods of Analysis

Analytical methods for the active substance (Regulation (EU) N° 283/2013, Annex Part A, point 4.1 and Regulation (EU) N° 284/2013, Annex Part A, point 5.2)

Technical a.s. (analytical technique)	HPLC-UV
Impurities in technical a.s. (analytical technique)	HPLC-UV, GC-FID, CIPAC MT 30.5
Plant protection product (analytical technique)	HPLC-UV

Analytical methods for residues (Regulation (EU) N° 283/2013, Annex Part A, point 4.2 & point 7.4.2)

Residue definitions for monitoring purposes

Food of plant origin		Triticonazole
Food of animal origin		Not relevant at the time being
Soil		Triticonazole
Sediment		Triticonazole
Water	surface	Triticonazole
	drinking/ground	Triticonazole
Air		Triticonazole
Body fluids and tissues		Triticonazole

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	**Stanislowski T., 2014c** **Jarrett H., 2014a (ILV)** LC-MS/MS two transitions LOQ: 0.01 mg/kg Analyte: Triticonazole Matrices: Wheat grain, Tomato, Rape seed, Orange fruit
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	**Stanislowski T., 2014d** **Chambers J.G. et al., 2014a (ILV)** LC-MS/MS two transitions LOQ: 0.01 mg/kg Analyte: Triticonazole Matrices: Bovine Meat, Bovine Liver, Whole Milk, Egg, Fat

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Soil (analytical technique and LOQ)	**Obermann M., Langenbach S., 2016** LC-MS/MS two transitions LOQ: 0.002 mg/kg, each Analyte: Triticonazole, M595F001, M595F002, M595F014 Matrix: Soil, LUFA 2.2 and LUFA 2.4
Water (analytical technique and LOQ)	**Class T., 2014d and 2015b** **Chambers J. et al., 2014b and 2015 a (ILV)** LC-MS/MS two transitions LOQ: 0.05 µg/L Analyte: Triticonazole Matrices: Drinking and surface water
Air (analytical technique and LOQ)	**Stanislowski T., 2014b** LC-MS/MS two transitions LOQ: 7.5 µg/m^3 Analyte: Triticonazole
Body fluids and tissues (analytical technique and LOQ)	**Richter S., 2016** LC-MS/MS two transitions LOQ: 0.01 mg/kg Analyte: Triticonazole Matrices: Urine, blood Tissues are covered by animal matrices LOQ: 0.01 mg/kg

Classification and labelling with regard to physical and chemical data (Regulation (EU) N° 283/2013, Annex Part A, point 10)

Substance	Triticonazole
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended][1]:	No classification regarding physical and chemical data
Peer review proposal [2] for harmonised classification according to Regulation (EC) No 1272/2008:	No classification regarding physical and chemical data

[1] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

[2] It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

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Section 2 Mammalian Toxicology

Impact on Human and Animal Health

Absorption, distribution, metabolism and excretion (toxicokinetics) (Regulation (EU) N° 283/2013, Annex Part A, point 5.1)

Rate and extent of oral absorption/systemic bioavailability	> 98 % (based on mostly faecal and bile excretion after single and repeated low dose administration) Correction of AOEL for oral absorption not considered necessary
Toxicokinetics	$\underline{C_{max}}$ (µg/g) Single high dose (500 mg/kg bw), whole blood 25.38 (males) and 19.28 (females) Single high dose (500 mg/kg bw), plasma 33.24 (males) and 23.52 (females) Single low dose (5 mg/kg bw), whole blood 1.58 (males) and 0.58 (females) Single low dose (5 mg/kg bw), plasma 2.37 (males) and 0.86 (females) $\underline{T_{max}}$ (h) Single high dose (500 mg/kg bw), whole blood 2 (males) and 1.8 (females) Single high dose (500 mg/kg bw), plasma 2 (males) and 1.6 (females) Single low dose (5 mg/kg bw), whole blood 0.6 (males and females) Single low dose (5 mg/kg bw), plasma 0.6 (males and females) $\underline{t_{0.5}}$ (h) Single high dose (500 mg/kg bw), whole blood 95.6 (males) and 106.3 (females) Single high dose (500 mg/kg bw), plasma 82.7 (males) and 99.9 (females) Single low dose (5 mg/kg bw), whole blood 119.4 (males) and 116.4 (females) Single low dose (5 mg/kg bw), plasma 109.7 (males) and 113.0 (females)
Distribution	Widely distributed (highest levels found in skin and fur, liver, plasma and adrenals)
Potential for bioaccumulation	No evidence for accumulation
Rate and extent of excretion	Rapid; > 98%; urinary (>10 %) and biliary (>80 %) after single low dose and > 89 % (multiple low dose), within 72 hours; mainly via faeces (bile). Nearly 100 % after

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	168 hours after repeat dose.
Metabolism in animals	Extensively metabolized in rats after single and repeated low dose (only < 1.5 % of dose as parent compound in faeces) via hydroxylation at different positions of the molecule
In vitro metabolism	No indication for a UHM from the comparative (human:rat) *in vitro* metabolism study and literature data
Toxicologically relevant compounds (animals and plants)	Parent
Toxicologically relevant compounds (environment)	Parent

Acute toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.2)

Rat LD_{50} oral	> 2000 mg/kg bw	
Rat LD_{50} dermal	> 2000 mg/kg bw	
Rat LC_{50} inhalation	> 5.61 mg/L air /4h (nose only)	
Skin irritation	Non-irritant	
Eye irritation	Non-irritant	
Skin sensitisation	not sensitizing (M & K test, Buehler test, modified Buehler test)	
Phototoxicity	Not phototoxic in 3T3 NRU-PT test*	

* The 3T3 NRU-PT test is not appropriate test for UVB absorbers like triticonazole

Short-term toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.3)

Target organ / critical effect	Rat: liver (weight; hypertrophy, vacuolation), adrenals (cortical fatty vacuolation and degeneration of *zona reticularis*), Dog: adrenals (cortical fatty vacuolation and degeneration of *zona reticularis*), eyes (cataract) Mouse: liver (weight; hypertrophy, fatty vacuolation, necrosis, and increased mitotic activity)	
Relevant oral NOAEL	90-day rat: 19.8 mg/kg bw per day 90-day mouse: no NOAEL derived 1-year dog: 2.5 mg/kg bw per day	
Relevant dermal NOAEL	21-day, rat: 1000 mg/kg bw per day	
Relevant inhalation NOAEL	No data - not required	

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Genotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.4)

In vitro studies	Two Reverse mutation assays in bacterial cells: negative Chinese Hamster V79 cell/HGPRT locus gene mutation assay: negative Two Chromosomal aberration assays in cultured human lymphocytes: negative Unscheduled DNA synthesis assay in rat hepatocytes: negative GreenScreen HC GADD45a-GFP, CellCiphr p53, CellSensor p53 RE-bla (non-standard tests): negative	
In vivo studies	Micronucleus test in CD-1 mice: negative	
Photomutagenicity	No appropriate photo-mutagenicity test available	
Potential for genotoxicity	Triticonazole is unlikely to be genotoxic	-

Long-term toxicity and carcinogenicity (Regulation (EU) N°283/2013, Annex Part A, point 5.5)

Long-term effects (target organ/critical effect)	Rat: adrenals, liver (weight and histopathology) Mouse: liver (weight and histopathology)	
Relevant long-term NOAEL	2-year, rat: 29.4 mg/kg bw per day 18-month, mouse: 17.4 mg/kg bw per day	
Carcinogenicity (target organ, tumour type)	Rat: no tumours Mouse: no tumours Triticonazole is unlikely to pose a hazard to humans	
Relevant NOAEL for carcinogenicity	2-year, rat: 203.6 mg/kg bw per day; 18-month, mouse: 202.2 mg/kg bw per day	

Reproductive toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.6)

Reproduction toxicity

Reproduction target / critical effect	Parental toxicity: maternal mortality, significantly reduced body weight in both sexes and necropsy findings (histopathology and organ weights) in adrenals, liver and ovaries Reproductive toxicity: reduced mating and fertility index in F_1 generation (above MTD) Offspring's toxicity: Reduced survival and growth	

	CHEST assay: no effects on mortality, blood vessels development and blood vessels discoloration, slight effect on embryo development Public literature: Zebrafish developmental screening assay: toxic to embryo/larvae > 20 µM, no malformations Modified zebrafish developmental screening assay: benchmark concentrations of 80.5 µM and 40 µM for general morphology and teratogenicity (highest concentration tested), the least potent triazole tested Slight decrease in retinol metabolism pathway, but higher steroid biosynthesis regulation and Cyp51 expression than for other tested triazoles	
Relevant parental NOAEL	48.4 mg/kg bw per day	
Relevant reproductive NOAEL	48.4 mg/kg bw per day	
Relevant offspring NOAEL	48.4 mg/kg bw per day	

Developmental toxicity

Developmental target / critical effect	Rat: Maternal toxicity: reduced body weight gain. Developmental toxicity: increased incidence of skeletal findings at maternal toxic dose Rabbit: Maternal toxicity: (slight) body weight loss (days 6 to 8) and reduced food intake (days 6 to 12) Developmental toxicity: increased incidence of skeletal findings at maternal toxic dose At 75 and 50 mg/kg bw per day treatment related mortality in rabbit dams (main study), warranting classification for STOT RE 2. In the range finding study all 8 rabbit dams at 150 mg/kg bw per day sacrificed in extremis, warranting classification for STOT RE 2	STOT RE 2
Relevant maternal NOAEL	Rat: 200 mg/kg bw per day Rabbit: 5 mg/kg bw per day	

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Relevant developmental NOAEL	Rat: 200 mg/kg bw per day Rabbit: 5 mg/kg bw per day	

Neurotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.7)

Acute neurotoxicity	NOAEL > 2000 mg/kg bw No neurotoxic effects in rats	
Repeated neurotoxicity	NOAEL > 10000 ppm (695.1 mg/kg bw per day for males and 820.3 mg/kg bw per day for females) No neurotoxic effects in rats	
Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity)	No additional studies, not necessary	

Other toxicological studies (Regulation (EU) N° 283/2013, Annex Part A, point 5.8)

Supplementary studies on the active substance	Immunotoxicity (28 days rat): NOAEL > 462 mg/kg bw per day) No immunotoxic effects in rats In the general pharmacology study no effects on general behaviour of mice and rats, no effects on respiratory parameters in rats. Blood pressure was elevated transitory in rats treated with 2000 mg triticonazole/kg bw Triticonazole may induce expression of mRNA that is mediated by the CAR/PXR or AhR receptors. Triticonazole may bind to the human and the chimpanzee AR receptor although no transactivation through the AR receptor was detected

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Endocrine disrupting properties	ACTH challenge assay: animals treated with triticonazole and suffering morphological changes in zona fasciculata of adrenals were still able to excrete corticosterone after a successful ACTH challenge and therefore the functional capacity of adrenals was demonstrated, although in the high dose females the level of excreted corticosterone was slightly lower than in controls YAS assay *(Saccharomyces cerevisiae)* – no androgenic or antiandrogenic activity YES assay *(Saccharomyces cerevisiae)* – no estrogenic or antiestrogenic activity Modified aromatase inhibition assay (*in vitro*): weak positive; human aromatase inhibition: IC_{50} of 4.40 x 10^{-5} M, rat aromatase inhibition: 1.8 x 10^{-6} M. The aromatase inhibition observed *in vitro* was not confirmed in parameters measured in the *in vivo* studies or in the steroidogenesis assay (ToxCast) Public literature: No interaction for the oestrogen receptor binding group, agonist group, antagonist group, growth group and the oestrogen receptor Interaction Score in the high-throughput screening (HTS) assays Inactive in all assays for the ER and thyroid hormone receptor (ThR), responsive for human and chimpanzee androgen receptor (AR) No indication of ROS formation in murine Leydig cells (MA-10) Inhibition of testosterone secretion in murine Leydig cells (MA-10) Androgen receptor inhibition in human T47D-ARE cells Slight decrease in progesterone, deoxycorticosterone and cortisol in modified H295R steroidogenesis assay, for last two only above cytotoxic concentration. No effects on estradiol No TPO (thyroperoxidase) inhibition in the AUR-TPO assay No inhibition of DIO1 (deiodinase type 1 enzyme) activity
Studies performed on metabolites or impurities	*Metabolites:* M595F001 (Reg. 5079285, RPA 404766): - CaseUltra AMES: negative - CaseUltra MNT: negative - Toxtree: negative TTC (Cramer Class III) for acute and chronic exposure: not exceeded

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M595F002 (Reg. 5059144, RPA 406341):

- Acute oral LD_{50} > 2000 mg/kg bw
- Negative AMES test
- CaseUltra AMES: negative
- CaseUltra MNT: negative
- Toxtree: negative

TTC (Cramer Class III) for acute and chronic exposure: not exceeded

M595F004-1 and M595F004-2:

- CaseUltra AMES: negative
- CaseUltra MNT: negative
- Toxtree: positive

TTC for genotoxicity (0.0000025 mg/kg bw/): not exceeded

TTC (Cramer Class III) for acute and chronic exposure: not exceeded

M595F005 (Reg. 5079247, RPA 404886):

- CaseUltra AMES: negative
- CaseUltra MNT: negative
- Toxtree: negative

TTC (Cramer Class III) for acute and chronic exposure: not exceeded

M595F006 (Reg. 5079450, RPA 406972):

- CaseUltra AMES: negative
- CaseUltra MNT: negative
- Toxtree: negative

Considered to be covered by parent triticonazole (> 10% of absorbed dose)

M595F007 (Reg. 5079286, RPA 406780):

- CaseUltra AMES: negative
- CaseUltra MNT: negative
- Toxtree: negative

TTC (Cramer Class III) for acute and chronic exposure: not exceeded

M595F010:

- CaseUltra AMES: negative
- CaseUltra MNT: negative
- Toxtree: negative

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Section 2 Mammalian Toxicology

Considered to be covered by parent triticonazole and M595F006 (glucuronide)

M595F013 (Reg. 5079288, RPA 407922):

- CaseUltra AMES: negative
- CaseUltra MNT: negative
- Toxtree: negative

TTC (Cramer Class III) for acute and chronic exposure: not exceeded

M595F014 (Z-isomer, Reg. 5079359, RPA 406203)

- Acute oral LD_{50} > 2000 mg/kg bw
- Negative AMES test
- Negative mouse micronucleous assay *in vitro*
- CaseUltra AMES: negative
- CaseUltra MNT: negative
- Toxtree: negative

TTC (Cramer Class III) for acute and chronic exposure: not exceeded

M595F015-1 and M595F015-2:

- CaseUltra AMES: negative
- CaseUltra MNT: negative
- Toxtree: negative

TTC (Cramer Class III) for acute and chronic exposure: not exceeded

[redacted]:

- CaseUltra AMES: negative
- CaseUltra MNT: negative
- Toxtree: negative

TTC (Cramer Class III) for acute and chronic exposure: not exceeded

Non-identified fraction "MET 6 (MWT 333)", > 0.1 µg/l and < 0.75 µg/l in groundwater :

- Based on molecular weight strongly assumed to be mono-hydroxylated metabolite(s) of triticonazole
- Absence of genotoxic properties should be substantiated by data after identification has been conducted

Impurities:

List of end points

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Section 2 Mammalian Toxicology

[redacted]	Acute oral LD_{50} > 2000 mg/kg bw Acute dermal LD_{50} > 2000 mg/kg bw Two negative AMES tests Positive Mouse lymphoma assay, L5178Y cell line (increase in small colonies) Negative human lymphoblastoid TK6 assay Negative mouse micronucleous assay *in vitro* CaseUltra AMES: negative CaseUltra MNT: negative NOAEL in 14 days comparative study (triticonazole and [redacted] = 100 mg/kg bw per day (for both)
[redacted]	Two negative AMES tests CaseUltra AMES: negative CaseUltra MNT: negative
[redacted]	Negative AMES test CaseUltra AMES: negative CaseUltra MNT: negative
[redacted]	Negative AMES test CaseUltra AMES: negative CaseUltra MNT: negative
[redacted]	Acute oral LD50 > 2000 mg/kg bw Acute dermal LD50 > 2000 mg/kg bw Not eye or skin irritant Not skin sensitizer Negative AMES test Negative chromosome aberration (human lymphocytes) CaseUltra AMES: negative CaseUltra MNT: negative NOAEL in 4 weeks rat study could not be determined (LOAEL = 50 mg/kg bw per day)

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Section 2 Mammalian Toxicology

Medical data (Regulation (EU) N° 283/2013, Annex Part A, point 5.9)

Limited. No adverse effects in manufacturing personnel reported

Summary[3] (Regulation (EU) N°1107/2009, Annex II, point 3.1 and 3.6)

	Value (mg/kg bw (per day))	Study	Uncertainty factor
Acceptable Daily Intake (ADI)	0.025	dog, 1-year	100
Acute Reference Dose (ARfD)	0.05	rabbit, developmental	100
Acceptable Operator Exposure Level (AOEL)	0.025	dog, 1-year	100
Acute Acceptable Operator Exposure Level (AAOEL)	0.05	rabbit, developmental	100

Dermal absorption (Regulation (EU) N° 284/2013, Annex Part A, point 7.3)

Representative formulation: Premis 25 FS (flowable concentrate for seed treatment), code: BAS 595 01 F, 25 g/L	Concentrate: 1 % Spray dilution (1:5 in use dilution): 3 % *in vitro* human skin study with the representative formulation

Exposure scenarios (Regulation (EU) N° 284/2013, Annex Part A, point 7.2)

Operators	Application rate = 12.5 g/ha (5 g as/100 kg cereal seed, 250 kg seed/ha) *Operator exposure to triticonazole from use of BAS 595 01 F during seed treatment:* <u>Exposure estimates</u> (model): <u>% of AOEL</u> UK SeedTropex Model, 60 kg operator (Gloves and coveralls worn during mixing/loading, calibration and cleaning. Coveralls worn during bagging): undiluted: 39 diluted: 24 France SeedTropex Model, 70 kg operator (Gloves and coveralls worn during mixing/loading, calibration and cleaning. Coveralls worn during bagging. RPE worn during cleaning) undiluted: 55 diluted: 69

[3] If available include also reference values for metabolites

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	Higher tier data (field study): Static seed treatment (Cotton/polyester work clothing for mixing/loading, calibration and bagging. An impermeable coverall is worn over work clothing with suitable protective gloves during cleaning operations) 0.25 Mobile seed treatment (Cotton/polyester work clothing and suitable protective gloves for mixing/loading, calibration and bagging) 0.32 Updated SeedTropex model approach (2014 V15): Static seed treatment (Cotton/polyester work clothing for mixing/loading, calibration and bagging. An impermeable coverall is worn over work clothing with suitable protective gloves during cleaning operations) Long-term exposure (75th percentile) 4.7 Acute exposure (95th percentile) 7.9 Mobile seed treatment (Cotton/polyester work clothing for mixing/loading, calibration and bagging): Long-term exposure (75th percentile) 3.1 Acute exposure (95th percentile) 15.5 *Operator exposure to triticonazole from sowing seed treated with BAS 595 01 F (protective clothing (coveralls)):* UK SeedTropex Model: 28 Updated SeedTropex model (2014 V15) (long-term and acute): 15
Workers	Not relevant since re-entry is not considered necessary
Bystanders and residents	UK SeedTropex Model (forklift operators): 4 %

Classification with regard to toxicological data (Regulation (EU) N° 283/2013, Annex Part A, Section 10)

Substance :	name
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended][4] :	None for human health (discussed at ECB Ispra, 22 August 2007; ECBI/90/06 Rev. 8)

[4] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

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Section 2 Mammalian Toxicology

Peer review proposal [5] for harmonised classification according to Regulation (EC) No 1272/2008:	STOT RE 2, H373

[5] It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

List of end points

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Section 3 Residues

Residues in or on treated products food and feed

Metabolism in plants (Regulation (EU) N° 283/2013, Annex Part A, points 6.2.1, 6.5.1, 6.6.1 and 6.7.1)

Primary crops (Plant groups covered)
OECD Guideline 501

Crop groups	Crop(s)	Application(s)	DAT (days)
Fruit crops			
Root crops			
Leafy crops			
Cereals/grass crops	Wheat, Barley	Seed treatment	Forage 50 Hay 65 Plant 136-211 Straw 134-240 Grain 134-240
Pulses/Oilseeds			
Miscellaneous			

Two of the four metabolism studies are overdosed to 9-39 N use rate (intention: achieving residue levels for characterisation and identification of metabolites).

Triticonazole is metabolised in growing cereal plants via hydroxylation following separation and destruction of the triazole moiety with incorporation of triazole derived material into natural products to form polar residues.

Rotational crops (metabolic pattern)
OECD Guideline 502

Crop groups	Crop(s)	PBI (days)	Comments
Root/tuber crops	radish	30, 149, 366	29 N use rate
Leafy crops	lettuce	30, 149, 366	
Cereal (small grain)	wheat	30, 149, 366	
Other			

Rotational crop and primary crop metabolism similar?

On the basis of the results of the study it can be concluded that the metabolism of [^{14}C]-triticonazole in confined rotational crops follows the same metabolic path as primary crops.

Processed commodities (standard hydrolysis study)
OECD Guideline 507

Conditions	triticonazole			
20 min, 90°C, pH 4	95.3 %			
60 min, 100°C, pH 5	101.7 %			
20 min, 120°C, pH 6	99.3 %			

Residue pattern in processed commodities similar to residue pattern in raw commodities?

Hydrolysis products were detected in a range between 2.8 and 3.2 % of applied radioactivity. They were not further investigated, due to their low amount in the test solutions.

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Section 3 Residues

Plant residue definition for monitoring (RD-Mo) **OECD Guidance, series on pesticides No 31**	Triticonazole limited to seed dressing on cereals
Plant residue definition for risk assessment (RD-RA)	Triticonazole limited to seed dressing on cereals
Conversion factor (monitoring to risk assessment)	1

Metabolism in livestock (Regulation (EU) N° 283/2013, Annex Part A, points 6.2.2, 6.2.3, 6.2.4, 6.2.5 6.7.1)

OECD Guideline 503 and **SANCO/11187/2013 rev. 3** (fish) **Animals covered**	**Animal**	**Dose** (mg/kg bw per day)	**Duration** (days)	**N rate/comment**
	Laying hen			
	Goat/Cow	Goat: 0.32	7	Approximately: 320 N for beef cattle 160 N for dairy cattle 107 N for sheep (ram/ewe) 80 N for lamb
	Pig			
	Fish	mg/kg DM		
	The study was not triggered by dietary burden calculations although cereal green forage is used in the OECD animal diet. However, it is considered valid and adequate for proposing an animal residue definition if needed.			

Time needed to reach a plateau concentration in milk and eggs (days)	Milk: 5 days
Animal residue definition for monitoring (RD-Mo) **OECD Guidance, series on pesticides No 31**	Not relevant at the time being.
Animal residue definition for risk assessment (RD-RA)	Not relevant at the time being
Conversion factor (monitoring to risk assessment)	Not applicable.
Metabolism in rat and ruminant similar (Yes/No)	Yes
Fat soluble residues (Yes/No) **(FAO, 2009)**	Yes (log P_{ow} = 3.29 ± 0.04 at 20 °C), but no accumulation was observed in the goat metabolism study.

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Section 3 Residues

Residues in succeeding crops (Regulation (EU) N° 283/2013, Annex Part A, point 6.6.2)

Confined rotational crop study (Quantitative aspect) **OECD Guideline 502**	A confined rotational crop study on radish, lettuce and wheat was already evaluated (soil treatment at approx. 20 N rate, PBI: 30, 149, 366 days). It was concluded that metabolic patterns in primary and succeeding crops are similar, no detectable residues in succeeding crops to be expected
Field rotational crop study **OECD Guideline 504**	In five already evaluated field rotational crop studies no detectable triticonazole residues in crops planted after harvest of seed treated wheat (protein peas, sugar beet root, sunflower seed, oilseed rape and grains of wheat) were found.

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Section 3 Residues

Stability of residues (Regulation (EU) N° 283/2013, Annex Part A, point 6.1)

OECD Guideline 506

Plant products (Category)	**Commodity**	**T** (°C)	**Stability** (Month/Year)			
			Triticonazole			
High water content						
High oil content						
High protein content						
High starch content	Cereal grain and straw	≤ -20	12 months			
High acid content						
In the DAR, the storage stability of triticonazole was assessed for maize grain, and for wheat grain and straw. Stable for 12 months						

Animal	**Animal commodity**	**T** (°C)	**Stability** (Month/Year)			
	Muscle					
	Liver					
	Kidney					
	Milk					
	Egg					

List of end points

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Section 3 Residues

Summary of residues data from the supervised residue trials (Regulation (EU) N° 283/2013, Annex Part A, point 6.3) OECD Guideline 509, OECD Guidance, series on pesticides No 66 and OECD MRL calculator

Crop	**Region/ Indoor** (a)	**Residue levels** (mg/kg) **observed in the supervised residue trials relevant to the supported GAPs** (b)	**Recommendations/comments** (OECD calculations)	**MRL** proposals (mg/kg)	**HR** (mg/kg) (c)	**STMR** (mg/kg) (d)
Representative use: Wheat (spring and winter), seed treatment						
Wheat grain Barley grain Rye grain	NEU	27 x <0.01 Combined dataset on barley (10), rye (2) and wheat (15) with application rates of 50 g a.s./ton.	Triticonazole (MO and RA)	0.01	0.01	0.01
	SEU	28 x <0.01 Combined dataset on barley (7) and wheat (21) with application rates of 50 g a.s./ton.				
Livestock feed						
Wheat straw Barley grain Rye grain	NEU	20 x <0.05, 7 x <0.01	Triticonazole (MO and RA)	Not applicable	0.05	0.05
	SEU	20 x <0.05, 8 x <0.01				
Wheat forage Barley forage Rye forage	NEU	6 x <0.05, 8 x <0.01	Triticonazole (MO and RA) BBCH 49 to BBCH 85 for shoots/whole plant without roots was taken into account.	Not applicable	0.05	0.01
	SEU	8 x <0.01				

Summary of the data on formulation equivalence OECD Guideline 509

Crop	**Region**	**Residue data** (mg/kg)	**Recommendations/comments**			
Wheat		No data available.	Not relevant: Triticonazole is applied as seed treatment use.			

Summary of data on residues in pollen and bee products (Regulation (EU) No 283/2013, Annex Part A, point 6.10.1)

Product(s)	**Region**	**Residue data** (mg/kg)	**Recommendations/comments**			
Wheat		No data available.	Cereal crops are regarded as having no melliferous potential.			

(a): **NEU** or **SEU** for northern or southern **outdoor** trials in EU member states (**N+SEU** if both zones), **Indoor** for glasshouse/protected crops, **Country** if non-EU location.

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Section 3 Residues

(b): Residue levels in trials conducted according to GAP reported in ascending order (*e.g.* 3x <0.01, 0.01, 6x 0.02, 0.04, 0.08, 3x 0.10, 2x 0.15, 0.17). When residue definition for monitoring and risk assessment differs, use **Mo/RA** to differentiate data expressed according to the residue definition for **Mo**nitoring and **R**isk **A**ssessment.
(c): **HR**: Highest residue. When residue definition for monitoring and risk assessment differs, HR according to residue definition for monitoring reported in brackets (HR_{Mo}).
(d): **STMR:** Supervised Trials Median Residue. When residue definition for monitoring and risk assessment differs, STMR according to definition for monitoring reported in brackets ($STMR_{Mo}$).

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Section 3 Residues

Inputs for animal burden calculations

Feed commodity	Median dietary burden		Maximum dietary burden	
	(mg/kg)	**Comment**	(mg/kg)	**Comment**
Representative uses: Wheat (spring and winter), seed treatment				
Barley grain	0.01	STMR	0.01	HR
Oats grain	0.01	STMR	0.01	HR
Rye grain	0.01	STMR	0.01	HR
Wheat grain	0.01	STMR	0.01	HR
Barley straw	0.05	STMR	0.05	HR
Oats straw	0.05	STMR	0.05	HR
Rye straw	0.05	STMR	0.05	HR
Wheat straw	0.05	STMR	0.05	HR
Barley forage	0.01	STMR	0.05	HR

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Section 3 Residues

Residues from livestock feeding studies (Regulation (EU) N° 283/2013, Annex Part A, points 6.4.1, 6.4.2, 6.4.3 and 6.4.4)

OECD Guideline 505 and OECD Guidance, series on pesticides No 73

MRL calculations	**Ruminant**				**Pig/Swine**		**Poultry**		**Fish**	
Highest expected intake (mg/kg bw per day) (mg/kg DM for fish)	Beef cattle	0.001	Ram/Ewe	0.003	Breeding	0.000	Broiler	0.001	Carp	
	Dairy cattle	0.002	Lamb	0.004	Finishing	0.000	Layer	0.001	Trout	
							Turkey	0.000	Fish intake >0.1 mg/kg DM	
Intake >0.004 mg/kg bw	No		No		No		No		No	
Feeding study submitted	No		No		No		No		No	
Representative feeding level (mg/kg bw per day, mg/kg DM for fish) and **N rates**	Level	Beef: N Dairy: N	Level	Lamb: N Ewe: N	Level	N rate Breed/Finish	Level	B or T: N Layer: N	Level	N rate Carp/Trout
	Estimated HR[(a)] at 1N	**MRL** proposals	Estimated HR[(a)] at 1N	**MRL** proposals	Estimated HR[(a)] at 1N	**MRL** proposals	Estimated HR[(a)] at 1N	**MRL** proposals	Estimated HR[(a)] at 1N	**MRL** proposals
Muscle										
Fat										
Meat[(b)]										
Liver										
Kidney										
Milk[(a)]										
Eggs										
Method of calculation[(c)]										

[(a)]: Estimated HR calculated at 1N level (**estimated mean level for milk**).
[(b)]: HR in meat calculated for mammalian on the basis of 20% fat + 80% muscle and 10% fat + 90% muscle for poultry
[(c)]: The OECD guidance document on residues in livestock (series on pesticides 73) recommends three different approaches to derive MRLs for animal products; by applying a transfer factor (Tf), by intrapolation (It) or by linear regression (Ln). Fill in method(s) considered to derive the MRL proposals.

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Section 3 Residues

STMR calculations	**Ruminant**				**Pig/Swine**		**Poultry**		**Fish**	
Median expected intake (mg/kg bw per day) (mg/kg DM for fish)	Beef cattle	0.0006	Ram/Ewe	0.0013	Breeding	0.000	Broiler	0.001	Carp	
	Dairy cattle	0.0008	Lamb	0.0016	Finishing	0.000	Layer	0.001	Trout	
							Turkey	0.000		
Representative feeding level (mg/kg bw per day, mg/kg DM for fish) and **N rates**	Level	Beef: N Dairy: N	Level	Lamb : N Ewe: N	Level	N rate Breed/Finish	Level	B or T: N Layer: N	Level	N rate Carp/Trout
	Mean level in feeding level	Estimated **STMR**[(b)] at 1N	Mean level in feeding level	Estimated **STMR**[(b)] at 1N	Mean level in feeding level	Estimated **STMR**[(b)] at 1N	Mean level in feeding level	Estimated **STMR**[(b)] at 1N	Mean level in feeding level	Estimated **STMR**[(b)] at 1N
Muscle										
Fat										
Meat[(a)]										
Liver										
Kidney										
Milk										
Eggs										
Method of calculation[(c)]										

[(a)]: STMR in meat calculated for mammalian on the basis of 20% fat + 80% muscle and 10% fat + 90% muscle for poultry
[(b)]: When the mean level is set at the LOQ, the STMR is set at the LOQ.
[(c)]: The OECD guidance document on residues in livestock (series on pesticide 73) recommends three different approaches to derive MRLs for animal products; by applying a transfer factor (Tf), by intrapolation (It) or by linear regression (Ln). Fill in method(s) considered to derive the MRL proposals.

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Section 3 Residues

Conversion Factors (CF) for monitoring to risk assessment

Not relevant (RD-Mo = RD-RA

Processing factors (Regulation (EU) N° 283/2013, Annex Part A, points 6.5.2 and 6.5.3)

Not relevant: As hydrolysis products were not further investigated, due to their low amount in the test solutions, processing studies were not considered necessary.

Consumer risk assessment (Regulation (EU) N° 283/2013, Annex Part A, point 6.9)
Consumer risk assessment limited to the representative uses

ADI	mg/kg bw per day
TMDI according to EFSA PRIMo	Highest TMDI: 0.4 % ADI (DK child, wheat)
ARfD	mg/kg bw
IESTI (% ARfD), according to EFSA PRIMo	Highest IESTI: 0.3 % ARfD (wheat)

Proposed MRLs (Regulation (EU) No 283/2013, Annex Part A, points 6.7.2 and 6.7.3)

Code[(a)]	Commodity/Group	MRL/Import tolerance[(b)] (mg/kg) and Comments	
Plant commodities			
Representative uses			
0500010	Barley	0.01*	
0500050	Oat	0.01*	
0500070	Rye	0.01*	
0500090	Wheat	0.01*	
Animal commodities			
			No residues above 0.01 mg/kg are expected in animal tissues

(a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005
(b): MRLs proposed at the LOQ, should be annotated by an asterisk (*) after the figure.

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Section 4 Environmental fate and behaviour

Environmental fate and behaviour

Route of degradation (aerobic) in soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.1)

Mineralisation after 100 days	20 - 25 °C: 1.5 - 8.1 % after 100 - 140 d, [^{14}C-phenyl]-label (n[6] = 9) 0.1 - 0.4 % after 100 - 120 d, [^{14}C-triazol]-label (n = 5) 10 °C: 0.6 - 1.4 % after 99 - 112 d, [^{14}C-phenyl]-label (n = 5) 22 °C, sterile: 0.0 % after 100 d, [^{14}C-phenyl]-label (n = 1)
Non-extractable residues after 100 days	20 - 25 °C: 4.5 - 21.0 % after 100 - 140 d, [^{14}C-phenyl]-label (n = 9) 8.3 - 27.3 % after 100 - 120 d, [^{14}C-triazol]-label (n = 5) 10 °C: 2.4 - 4.1 % at 99 - 112 d, [^{14}C-phenyl]-label (n = 5) 22 °C, sterile: 2.6 % after 100 d, [^{14}C-phenyl]-label (n = 1)
Metabolites requiring further consideration - name and/or code, % of applied (range and maximum)	**RPA 406341 (Trans-diol)** 20 - 25 °C: 5.9 - **20.2** % at 56 - 365 d (n = 14) [^{14}C-phenyl] & [^{14}C-triazol] labels 10 °C: 9.2 - 16.1 % at 56 - 365 d, [^{14}C-phenyl]-label (n = 5) 22 °C, sterile: 8.9 % at 77 d, [^{14}C-phenyl]-label (n = 1) **RPA 404766 (Cis-diol)** 20 - 25 °C: 6.3 - 9.9 % at 28 - 365 d (n = 14) [^{14}C-phenyl] & [^{14}C-triazol] labels 10 °C: 6.5 - **13.9** % at 28 - 365 d, [^{14}C-phenyl]-label (n = 5) 22 °C, sterile: 3.2 % at 50 d, [^{14}C-phenyl]-label (n = 1) Two tentatively identified metabolite fractions observed > 5 % at two consecutive sampling points in *Ayliffe & Austin* (1993): **'Met 6 (MWT 333)'** 20 - 25 °C: 1.6 - **12.8** % at 266 - 363 d, [^{14}C-phenyl]-label (n = 4) **'Met 7 (MWT 315)'** 20 - 25 °C: 0.9 - **6.5** % at 245 - 363 d, [^{14}C-phenyl]-label (n = 4)

[6] n corresponds to the number of soils.

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Section 4 Environmental fate and behaviour

Route of degradation (anaerobic) in soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.2)

Mineralisation after 100 days	0.8 % after 100 d, [^{14}C-phenyl]-label (n = 1)
Non-extractable residues after 100 days	17.0 % after 100 d, [^{14}C- phenyl]-label (n = 1)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	None above 5 %

Route of degradation (photolysis) on soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3)

Mineralisation at study end	1.3 % after 30 d, [^{14}C-phenyl]-label (n = 1)
Non-extractable residues at study end	4.1 % after 30 d, [^{14}C-phenyl]-label (n = 1)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	**RPA 406203 (Z-isomer)** **11.0** % at 30 d, [^{14}C-phenyl]-label (n = 1)

Rate of degradation in soil (aerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Triticonazole	Dark aerobic conditions, **20 - 25 °C**						
Soil type	Label	pH[a)]	t. °C / MC	$DegT_{50}$ / $DegT_{90}$ (d)	$DegT_{50}$ (d) 20 °C pF2/10kPa[b)]	St. (χ^2)	Method of calculation
Sandy loam[c)]	Ph	6.4[d)]	22 / 75 % 33 kPa	289 / > 1000	280[e)]	5.0	HS
Clay loam[c)]	Ph	6.2[d)]	22 / 75 % 33 kPa	137 / 455	148	4.4	SFO
Loamy sand[c)]	Ph	6.8[d)]	22 / 75 % 33 kPa	233 / 986	360[e)]	5.0	HS
Loamy sand[c)]	Ph	6.3[d)]	22 / 75 % 33 kPa	290 / > 1000	565[e)]	4.2	HS
Clay	T	5.7	25 / 75 % 33 kPa	495 / > 1000	376	5.7	SFO
Sandy loam, std.	Ph	6.1	25 / 50 % FC	183 / 702	312[e)]	3.3	HS
Sandy loam, red. rate	Ph	6.1	25 / 50 % FC	221 / 816	358[e)]	6.5	HS
Sand	T	8.1[g)]	20 / 50 % MWHC	305 / > 1000	262	3.1	SFO
Loam	Ph & T	6.8[g)]	20 / 50 % MWHC	78.8 / 661	230[e)]	2.4	DFOP
Sandy loam	T	6.0[g)]	20 / 50 % MWHC	128 / 664	199[e)]	3.2	DFOP
Loamy sand	Ph & T	6.3	20 / 50 % MWHC	148 / 633	178[e)]	1.0	DFOP
Loamy sand	-	5.5	20 / 50 % MWHC	317 / > 1000	298	7.3	SFO
Sandy loam	-	6.9	20 / 50 % MWHC	115 / 381	109	5.9	SFO

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Sandy loam	-	7.4	20 / 50 % MWHC	114 / 521	161[e)]	6.3	HS
Geometric mean (if not pH dependent)					**246[f)]**		
Maximum				**495 / 1000**			SFO
pH dependence					No		

[a)] Measured in calcium chloride solution
[b)] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
[c)] Soil texture classification not specified
[d)] Matrix not specified
[e)] On basis of slow phase DegT50 (DFOP or HS)
[f)] Two experiments with sandy loam (standard and reduced rate) averaged (geometric mean)
[g)] In water

Triticonazole	Dark aerobic conditions, **10 °C or reduced soil moisture**						
Soil type	Label	pH[a)]	t. °C / MC	$DegT_{50}$ / $DegT_{90}$ (d)	$DegT_{50}$ (d) 20 °C pF2/10kPa[b)]	St. (χ^2)	Method of calculation
Sandy loam[c)]	Ph	6.3[d)]	10 / 75 % 33 kPa	341 / > 1000	nc	3.5	DFOP
Clay loam[c)]	Ph	6.1[d)]	10 / 75 % 33 kPa	176 / 892	nc	5.0	HS
Loamy sand[c)]	Ph	6.3[d)]	10 / 75 % 33 kPa	> 1000 / > 1000	nc	2.6	HS
Loamy sand[c)]	Ph	6.2[d)]	10 / 75 % 33 kPa	862 / > 1000	nc	3.9	HS
Sandy loam	Ph	6.1	10 / 50 % FC	584 / > 1000	nc	4.5	SFO
Sandy loam	Ph	6.1	25 / 20 % FC	259 / > 1000	nc	13.1	DFOP
Geometric mean (if not pH dependent)					**nc**		
pH dependence					No		

[a)] Measured in calcium chloride solution
[b)] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
[c)] Soil texture classification not specified
[d)] Matrix not specified
[e)] On basis of slow phase DegT50 (DFOP or HS)

Rate of degradation in soil (aerobic) laboratory studies transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

RPA 406341 (Trans-diol)	Dark aerobic conditions, **20 - 25 °C**, metabolite dosed or the precursor from which the f.f. was derived was triticonazole							
Soil type	Label	pH[a)]	t. °C / MC	$DegT_{50}$/ $DegT_{90}$ (d)	f. f. k_f / k_{dp}	$DegT_{50}$ (d) 20 °C pF2/ 10kPa[b)]	St. (χ^2)	Method of calculation
Sandy loam[c)]	Ph	6.4[d)]	22 / 75 % 33 kPa	80.1 / 266	0.426	56.1	13.2	HS-SFO
Clay loam[c)]	Ph	6.2[d)]	22 / 75 % 33 kPa	68.5 / 228	0.372	74.0	17.3	SFO-SFO

Loamy sand[c)]	Ph	6.8[d)]	22 / 75 % 33 kPa	405 / > 1000	0.390	450	7.5	HS-SFO
Loamy sand[c)]	Ph	6.3[d)]	22 / 75 % 33 kPa	105 / 349	0.473	127	21.3	HS-SFO
Clay	T	5.7	25 / 75 % 33 kPa	170 / 566	0.583	139	17.4	SFO-SFO
Sandy loam, std.	Ph	6.1	25 / 50 % FC	188 / 623	0.510	263	7.1	HS-SFO
Sandy loam, red. rate	Ph	6.1	25 / 50 % FC	207 / 686	0.607	290	5.9	HS-SFO
Sand	T	8.1[h)]	20 / 50 % MWHC	462 / > 1000	0.207	397	10.1	SFO-SFO
Loam	Ph & T	6.8[h)]	20 / 50 % MWHC	208 / 692	0.118	185	7.8	DFOP-SFO
Sandy loam	T	6.0[h)]	20 / 50 % MWHC	176 / 584	0.160	151	6.3	DFOP-SFO
Loamy sand	Ph & T	6.3	20 / 50 % MWHC	202 / 670	0.178	172	5.8	DFOP-SFO
Loamy sand	-	5.5	20 / 50 % MWHC	165 / 549	na	102	2.0	SFO[e)]
Sandy loam	-	6.9	20 / 50 % MWHC	199 / 661	na	143	2.3	SFO[e)]
Sandy loam	-	7.4	20 / 50 % MWHC	346 / > 1000	na	232	3.5	SFO[e)]
Geometric mean (if not pH dependent)						**163[f)]**		
Arithmetic mean					**0.347[g)]**			
Maximum				**462 / > 1000**				SFO
pH dependence						No		

[a)] Measured in calcium chloride solution
[b)] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
[c)] Soil texture classification not specified
[d)] Matrix not specified
[e)] Metabolite dosed study
[f)] Two experiments with sandy loam (standard and reduced rate) averaged (geometric mean)
[g)] Two experiments with sandy loam (standard and reduced rate) averaged (arithmetic mean)
[h)] In water

RPA 406341 (Trans-diol)	Dark aerobic conditions, **10 °C**, metabolite dosed or the precursor from which the f.f. was derived was triticonazole							
Soil type	Label	pH[a)]	t. °C / MC	$DegT_{50}$/ $DegT_{90}$ (d)	f. f. k_f / k_{dp}	$DegT_{50}$ (d) 20 °C pF2/ 10kPa[b)]	St. (χ^2)	Method of calculation
Clay loam[c)]	Ph	6.1[d)]	10 / 75 % 33 kPa	309 / > 1000	0.370	nc	12.5	HS-SFO
Sandy loam	Ph	6.1	10 / 50 % FC	393 / > 1000	0.736	nc	18.5	SFO-SFO
Geometric mean (if not pH dependent)						**nc**		
Arithmetic mean					**nc**			
pH dependence						na		

[a)] Measured in calcium chloride solution
[b)] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

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[c] Soil texture classification not specified
[d] Matrix not specified

RPA 404766 (Cis-diol)	Dark aerobic conditions, **20 - 25 °C**, metabolite dosed or the precursor from which the f.f. was derived was triticonazole							
Soil type	Label	pH[a]	t. °C / MC	$DegT_{50}$/ $DegT_{90}$ (d)	f. f. k_f / k_{dp}	$DegT_{50}$ (d) 20 °C pF2/ 10kPa[b]	St. (χ^2)	Method of calculation
Clay loam[c]	Ph	6.2[d]	22 / 75 % 33 kPa	22.7 / 75.5	0.628	24.5	19.1	SFO-SFO
Loamy sand[c]	Ph	6.8[d]	22 / 75 % 33 kPa	155 / 516	0.365	172	9.5	DFOP-SFO
Loamy sand[c]	Ph	6.3[d]	22 / 75 % 33 kPa	42.0 / 141	0.448	50.8	29.1	DFOP-SFO
Clay	T	5.7	25 / 75 % 33 kPa	213 / 707	0.418	175	22.6	SFO-SFO
Sandy loam, std.	Ph	6.1	25 / 50 % FC	95.0 / 315	0.354	133	12.4	DFOP-SFO
Sandy loam, red. rate	Ph	6.1	25 / 50 % FC	98.2 / 326	0.393	137	6.2	HS-SFO
Sand	T	8.1[h]	20 / 50 % MWHC	170 / 566	0.305	146	9.9	SFO-SFO
Loam	Ph & T	6.8[h]	20 / 50 % MWHC	139 / 461	0.181	124	4.2	DFOP-SFO
Sandy loam	T	6.0[h]	20 / 50 % MWHC	148 / 493	0.214	127	4.8	DFOP-SFO
Loamy sand	Ph & T	6.3	20 / 50 % MWHC	93.5 / 311	0.243	79.5	4.5	DFOP-SFO
Loamy sand	-	5.5	20 / 50 % MWHC	30.9 / 103	na	30.9	7.2	SFO[e]
Sandy loam	-	6.9	20 / 50 % MWHC	20.8 / 69.0	na	20.8	15.8	SFO[e]
Sandy loam	-	7.4	20 / 50 % MWHC	56.1 / 187	na	56.1	9.1	SFO[e]
Geometric mean (if not pH dependent)						**75.3**[f]		
Arithmetic mean					**0.353**[g]			
Maximum				**213 / 707**				SFO
pH dependence						No		

[a] Measured in calcium chloride solution
[b] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
[c] Soil texture classification not specified
[d] Matrix not specified
[e] Metabolite dosed study
[f] Two experiments with sandy loam (standard and reduced rate) averaged (geometric mean)
[g] Two experiments with sandy loam (standard and reduced rate) averaged (arithmetic mean)
[h] In water

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RPA 404766 (Cis-diol)	Dark aerobic conditions, **10 °C or reduced soil moisture**, metabolite dosed or the precursor from which the f.f. was derived was triticonazole							
Soil type	Label	pH[a)]	t. °C / MC	$DegT_{50}$/ $DegT_{90}$ (d)	f. f. k_f / k_{dp}	$DegT_{50}$ (d) 20 °C pF2/ 10kPa[b)]	St. (χ^2)	Method of calculation
Clay loam[c)]	Ph	6.1[d)]	10 / 75 % 33 kPa	140 / 464	0.405	nc	21.2	HS-SFO
Sandy loam	Ph	6.1	25 / 20 % FC	296 / 983	0.209	nc	7.0	DFOP-SFO
Geometric mean (if not pH dependent)						**nc**		
Arithmetic mean					**nc**			
pH dependence						na		

[a)] Measured in calcium chloride solution
[b)] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
[c)] Soil texture classification not specified
[d)] Matrix not specified

Rate of degradation field soil dissipation studies (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.1)

Triticonazole	Aerobic conditions - **non-normalized data**							
Soil type (indicate if bare or cropped soil was used)	Location (country or USA state).		pH[a)]	Depth (cm)	$DissT_{50}$ (d)	$DissT_{90}$ (d)	St. (χ^2)	$DegT_{50}$ (d) Norm.[b)]	Method of calculation
Bologna, cropped	IT		8.4[c)]	90	169	563	20.7	nc	SFO
Goch, cropped	DE		6.6[c)]	90	183	609	28.7	nc	SFO
Manningtree, spray, cropped	UK		5.3[c)]	90	55.0	633	13.0	nc	DFOP
Manningtree, seed treatment, cropped	UK		5.3[c)]	90	223	741	33.2	nc	SFO
Mereville, cropped	FR		7.8[c)]	90	204	678	13.5	nc	SFO
Brentwood, cropped	UK		7.3	90	242	803	30.3	nc	SFO
Saint Trivier sur Moignans, cropped	FR		7.1	90	118	392	16.9	nc	SFO
Balaguer, cropped	ES		7.4	90	99.1	329	28.5	nc	SFO
Goch, cropped	DE		6.7	90	36.1	477	9.4	nc	DFOP
Geometric mean (if not pH dependent)								**nc**	
Maximum					**242**	**803**			SFO
pH dependence					No				

[a)] Measured in calcium chloride solution
[b)] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7, values are DegT50matrix
[c)] Matrix unknown

[d] On basis of DFOP- or HS- DegT90 divided by 3.32 (residues at study termination < 10 % of initial dose)

Triticonazole	Aerobic conditions - **time-step normalized data (20 °C, pF2, Q_{10} = 2.58)**								
Soil type (indicate if bare or cropped soil was used)	Location (country or USA state).		pH[a]	Depth (cm)	$DegT_{50}$ (d) norm.[b]	$DegT_{90}$ (d) norm.[b]	St. (χ^2)	$DegT_{50}$ (d) norm.[b]	Method of calculation
Bologna, cropped	IT		8.4[c]	90	78.9	262	20.7	78.9	SFO
Goch, cropped	DE		6.6[c]	90	66.9	222	28.7	66.9	SFO
Manningtree, spray, cropped	UK		5.3[c]	90	15.4	281	13.0	84.6[d]	DFOP
Manningtree, seed treatment, cropped	UK		5.3[c]	90	90.4	300	33.2	90.4	SFO
Mereville, cropped	FR		7.8[c]	90	35.7	441	13.5	133[d]	HS
Brentwood, cropped	UK		7.3	90	101	337	30.3	101	SFO
Saint Trivier sur Moignans, cropped	FR		7.1	90	51.2	170	16.9	51.2	SFO
Balaguer, cropped	ES		7.4	90	15.2	245	28.5	73.8[d]	HS
Goch, cropped	DE		6.7	90	12.2	208	9.4	62.7[d]	DFOP
Geometric mean (if not pH dependent)								**78.7**[e]	
pH dependence					No				

[a] Measured in calcium chloride solution
[b] Time-step normalised, values are DegT50matrix and DegT90matrix, respectively
[c] Matrix unknown
[d] On basis of DFOP- or HS-DegT90 divided by 3.32 (residues at study termination < 10 % of initial dose)
[e] Different experiments from Manningtree field site (spray and seed treatment) averaged (geometric mean) before averaging data from different field sites

RPA 406341 (Trans-diol)	Aerobic conditions - **non-normalized data**, metabolite dosed									
Soil type	Location		pH[a]	Depth (cm)	$DissT_{50}$ (d) actual	$DissT_{90}$ (d) actual	St. (χ^2)	$DegT_{50}$ (d) norm[b].	f. f. k_f / k_{dp}	Method of calculation
Goch-Nierswalde	DE		4.7	50	58.2	193	13.8	nc	na	SFO
Rummen	BE		5.1	50	78.9	262	20.7	nc	na	SFO
Meauzac	FR		5.4	50	123	407	16.3	nc	na	SFO
Alberic/Valencia	ES		7.6	50	25.5	84.7	28.8	nc	na	SFO
Geometric mean (if not pH dependent)								**nc**		
Arithmetic mean									**nc**	
Maximum					123	407				SFO
pH dependence						No				

[a] Measured in calcium chloride solution

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[b] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7 values are DegT50matrix

RPA 406341 (Trans-diol)		Aerobic conditions - **time-step normalized data (20 °C, pF2, Q_{10} = 2.58)**, metabolite dosed							
Soil type	Location	pH[a]	Depth (cm)	$DegT_{50}$ (d) norm.[b]	$DegT_{90}$ (d) norm.[b]	St. (χ^2)	$DegT_{50}$ (d) norm.[b]	f. f. k_f / k_{dp}	Method of calculation
Goch-Nierswalde	DE	4.7	50	34.8	116	10.9	34.8	na	SFO
Rummen	BE	5.1	50	32.7	109	23.5	32.7	na	SFO
Meauzac	FR	5.4	50	55.8	186	12.8	55.8	na	SFO
Alberic/Valencia	ES	7.6	50	42.6	142	18.4	42.6	na	SFO
Geometric mean (if not pH dependent)							**40.6**		
Arithmetic mean								**nc**	
pH dependence					No				

[a] Measured in calcium chloride solution
[b] Time-step normalised, values are DegT50matrix and DegT90matrix, respectively

Combined laboratory and field kinetic endpoints for modelling (when not from different populations)

	Field kinetic endpoints used for modelling (different population)	
Rate of degradation in soil active substance, normalised geometric mean (if not pH dependent)		
Rate of degradation in soil transformation products, normalised geometric mean (if not pH dependent)	**RPA 406341 (Trans diol)** - Field kinetic endpoints used for modelling (different population)	na
Kinetic formation fraction (f. f. k_f / k_{dp}) of transformation products, arithmetic mean	na	na

Soil accumulation (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.2)

Soil accumulation and plateau concentration	**Triticonazole:** Plateau concentration of 0.0023 mg/kg reached after approx. 6 years (based on calculation) **RPA 406341 (Trans-diol):** Plateau concentration of 0.0001 mg/kg reached after approx. 2 years (based on calculation)

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Rate of degradation in soil (anaerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Parent	Dark anaerobic conditions						
Soil type	Label	pH[a)]	t. °C / MC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C[b)]	St. (χ^2)	Method of calculation
Sandy loam	Ph	7.6	25 / flooded	Stable	nc	na	na
Geometric mean (if not pH dependent)					**nc**		

[a)] Measured in potassium chloride
[b)] Normalised using a Q10 of 2.58

Rate of degradation in soil (anaerobic) laboratory studies transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.4 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Met 1	Dark anaerobic conditions Metabolite dosed or the precursor from which the f.f. was derived was *xxx.*							
Soil type	*X[10]*	pH[a)]	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_f / k_{dp}	DT_{50} (d) 20°C[b)]	St. (χ^2)	Method of calculation
No data								
Geometric mean (if not pH dependent)								
Arithmetic mean								

[a)] Measured in [medium to be stated, usually calcium chloride solution or water]
[b)] Normalised using a Q10 of 2.58

Rate of degradation on soil (photolysis) laboratory active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3

Parent	Soil photolysis					
Soil type	Label	pH[a)]	t. °C / % MWHC	DT_{50} / DT_{90} (d) calculated at 50 °N	St. (χ^2)	Method of calculation
Sandy loam	Ph	5.1	20 / 75 % 33 kPa	65.3 / 217	0.5	SFO

[a)] Measured in calcium chloride solution

Soil adsorption active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

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Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Silt loam	1.85	5.7	na	na	11.8	636	0.92

Sandy loam	0.99	6.7	na	na	3.67	370	0.89
Sand	0.60	5.6	na	na	5.23	871	0.93
Loamy sand	0.95	6.2	na	na	4.79	504	0.91
Sandy clay loam	1.22	7.4	na	na	3.97	325	0.94
Silt loam	2.01	5.8	na	na	13.4	665	0.893
Sandy loam	0.66	5.3	na	na	4.52	685	0.898
Sand	0.72	5.6	na	na	5.60	778	0.889
Loamy sand	0.89	6.1	na	na	5.11	574	0.888
Silty clay loam	1.92	7.1	na	na	5.56	290	0.848
Geometric mean (if not pH dependent)					**na**	**na**	
Arithmetic mean (if not pH dependent)							**0.90**
Minimum[b)]						**307**	
Maximum[c)]						**823**	
pH dependence			Yes				

[a)] Measured in calcium chloride solution
[b)] Geometric mean of the two silty clay loam soils (considered to represent identical soils)
[c)] Geometric mean of the two sand soils (considered to represent identical soils)

Soil adsorption transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

RPA 406341 (Trans-diol)							
Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Clay silt	1.97	5.8	na	na	2.59	132	0.95
Loamy sand	0.7	7.1	na	na	0.80	114	0.96
Sand	0.6	6.0	na	na	0.68	114	0.98
Silty clay	0.6	5.5	na	na	1.94	324	1.00
Silty clay loam	1.3	7.7	na	na	1.38	106	0.94
Silt loam	2.01	5.8	na	na	3.72	185	0.919
Sandy loam	0.66	5.3	na	na	1.02	154	0.945
Sand	0.72	5.6	na	na	1.35	188	0.937
Loamy sand	0.89	6.1	na	na	1.31	148	0.932
Silty clay loam	1.92	7.1	na	na	1.57	81.6	0.839
Geometric mean (if not pH dependent)					**1.45**	**144**	
Arithmetic mean (if not pH dependent)							**0.94**
pH dependence			No				

[a)] Measured in calcium chloride solution

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RPA 404766 (Cis-diol)							
Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Clay silt	1.97	5.8	na	na	0.68	161	0.95
Loamy sand	0.7	7.1	na	na	0.83	49.0	0.90
Sand	0.6	6.0	na	na	0.28	46.1	0.97
Silty sand	0.6	5.5	na	na	0.34	139	0.98
Silty clay loam	1.3	7.7	na	na	3.17	52.6	0.99
Silt loam	2.01	5.8	na	na	1.71	85.3	0.889
Sandy loam	0.66	5.3	na	na	0.48	72.6	0.920
Sand	0.72	5.6	na	na	0.68	94.0	0.946
Loamy sand	0.89	6.1	na	na	0.67	74.8	0.922
Silty clay loam	1.92	7.1	na	na	1.03	53.6	0.868
Geometric mean (if not pH dependent)					**0.76**	**75.7**	
Arithmetic mean (if not pH dependent)							**0.93**
pH dependence			No				

[b)] Measured in calcium chloride solution

'Met 6 (MWT 333)'							
Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
na	na	na	na	na	na	278[a)]	1.00

[a)] Estimated on basis of HPLC retention time observed in *Ayliffe & Austin (1993)* (K_{foc} (mL/g) = 697 × rRT - 161, r^2 = 0.999)

'Met 7 (MWT 315)'							
Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
na	na	na	na	na	na	327[a)]	1.00

[a)] Estimated on basis of HPLC retention time observed in *Ayliffe & Austin (1993)* (K_{foc} (mL/g) = 697 × rRT - 161, r^2 = 0.999)

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Mobility in soil column leaching active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Column leaching	Elution (mm): 1040 mm Time period (d): 3 - 12 d (n = 5)
	Non-aged: Leachate: 0.1 - 70.6 % total radioactivity in leachate (n = 5, above 0.6 % in one sand soil only) Predominately active substance 3.2 - 101.3 % total radioactivity retained in top 6 cm (n = 5) Aged (30 days): Leachate: 0.5 - 27.1 % total radioactivity in leachate (n = 5,above 1.8 % in one sand soil only) Predominately active substance with unspecified amounts of RPA 406341 (Trans-diol) and RPA 404766 (Cis-diol) 19.0 - 89.1 % total radioactivity retained in top 6 cm (n = 5)

Mobility in soil column leaching transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Column leaching	No reliable study
	No reliable study

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Lysimeter / field leaching studies (Regulation (EU) N° 283/2013, Annex Part A, points 7.1.4.2 / 7.1.4.3 and Regulation (EU) N° 284/2013, Annex Part A, points 9.1.2.2 / 9.1.2.3)

Lysimeter/ field leaching studies	**[^{14}C-phenyl]-label:** Location: Münster, Germany Study type (e.g. lysimeter, field): lysimeter Soil properties (top soil): silty sand, pH ($CaCl_2$) = 5.6, OC = 1.32 % Dates of application: 1st yr: 16th of November 2000 (lys56/lys57) 2nd yr: 9th of November 2001 (lys57) Crop: 1st yr: Winter cereals (seed treatment) 2nd yr: Winter barley (seed treatment), *Phacelia* Interception estimated: 0 % Number of applications: **2** years, **1** applications per year Duration: **2** years Application rate: 1st yr: **12.4** g/ha/year (lys56/lys57) 2nd yr: **13.1** g/ha/year (lys57) Average annual rainfall + irrigation (mm): 1st yr: **907** 2nd yr: **929** Average annual leachate volume (mm): 1st yr: **413 / 356** (lys56/lys57) 2nd yr: **554 / 505** (lys56/lys57) % radioactivity in leachate (maximum/year): 1st yr: **<LOD / <LOD** (lys56/lys57) 2nd yr: **0.93 / 0.99 % AR** (lys56/lys57) **Parent equivalents:** Individual annual maximum concentrations: 1st yr: **nd / nd** (lys56/lys57) 2nd yr: **0.073 / 0.051 µg/L** (lys56/lys57) Individual annual average concentrations: 1st yr: **nd / nd** (lys56/lys57) 2nd yr: **0.022 / 0.026 µg/L** (lys56/lys57) Radioactivity detected was slightly more polar than the most polar reference metabolite RPA 404766 (Cis-diol). Neither triticonazole, nor RPA 406341 (Trans-diol) and RPA 404766 (Cis-diol) were detectable in any of the leachates water samples (LOD = 0.008 - 0.010 µg/L) Amount of radioactivity in the soils at the end of the study = **53.6 / 64.8 % AR** (lys56/lys57) with traces of parent, RPA 406341 (Trans-diol) and RPA 404766 (Cis-diol) Amount of radioactivity in the crops:

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1st yr: **0.89 / 0.85 % AR** (lys56/lys57) 2nd yr: **0.06 / 0.49 % AR** (lys56/lys57)
[^{14}C-triazole]-label: Location: Münster, Germany Study type (e.g. lysimeter, field): lysimeter Soil properties (top soil): silty sand, pH ($CaCl_2$) = 5.6, OC = 1.32 % Dates of application : 1st yr: 17th of November 2000 (lys54/lys55) 2nd yr: 26nd of October, 2001 (lys54) Crop: 1st yr: Winter cereals (seed treatment) 2nd yr: Winter barley (seed treatment) 3rd yr: Oil seed rape Interception estimated: 0 Number of applications: **2** years, **1** applications per year Duration: **3** years Application rate: 1st yr: **12.4** g/ha/year (lys54 & lys55) 2nd yr: **13.1** g/ha/year (lys54) Average annual rainfall + irrigation (mm): 1st yr: **905** 2nd yr: **935** 3rd yr: **820** Average annual leachate volume (mm): 1st yr: **403 / 421** (lys54/lys55) 2nd yr: **583 / 590** (lys54/lys55) 3rd yr: **303 / 295** (lys54/lys55) % radioactivity in leachate (maximum/year): 1st yr: **0.02 %AR / <LOD** (lys54/lys55) 2nd yr: **1.89 / 1.99 % AR** (lys54/lys55) 3rd yr: **2.15 / 1.99 % AR** (lys54/lys55) **Parent equivalents:** Individual annual maximum concentrations: 1st yr: **0.016 µg/L / nd** (lys54/lys55) 2nd yr: **0.159 / 0.077 µg/L** (lys54/lys55) 3rd yr: **0.231 / 0.098 µg/L** (lys54/lys55) Individual annual average concentrations: 1st yr: **0.002 µg/L / nd** (lys54/lys55) 2nd yr: **0.089 / 0.042 µg/L** (lys54/lys55) 3rd yr: **0.180 / 0.084 µg/L** (lys54/lys55) The vast majority of parent equivalents was unidentified polar material (max. 0.198 µg/L, on average 0.150 µg/L, 3 - 5 peaks) eluting within the first five minutes of the HPLC runs. Neither triticonazole, nor RPA 406341 (Trans-diol) and RPA 404766 (Cis-diol) were detectable in any of the leachates water samples

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	(LOD = 0.008 - 0.010 µg/L) Amount of radioactivity in the soils at the end of the study = **52.7 / 51.3 % AR** (lys54/lys55) with traces of parent, RPA 406341 (Trans-diol) and RPA 404766 (Cis-diol) Amount of radioactivity in the crops: 1st yr: **1.25 / 2.21 % AR** (lys54/lys55) 2nd yr: **1.32 / 0.85 % AR** (lys54/lys55) 3rd yr: **1.06 / 0.77 % AR** (lys54/lys55)

Hydrolytic degradation (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.1.1

Hydrolytic degradation of the active substance and metabolites > 10 %	Stable at pH 4, 5, 7 and 9 (25 °C)

Aqueous photochemical degradation (Regulation (EU) N° 283/2013, Annex Part A, points 7.2.1.2 / 7.2.1.3)

Photolytic degradation of active substance and metabolites above 10 %	DT_{50}: 7.4 - 32.7 days (two studies) after reaching equilibrium with RPA 406203 (Z-isomer) Natural light, 52 °N; DT_{50} 14 - 167 days **RPA 406203 (Z-isomer): 42.3 % AR** (3 d) Conversation from triticonazole (E-isomer) to RPA 406203 (Z-isomer) reversible approaching equilibrium by approx. 1 - 2 days
Quantum yield of direct phototransformation in water at Σ > 290 nm	0.05 mol · Einstein $^{-1}$

'Ready biodegradability' (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.1)

Readily biodegradable (yes/no)	No

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Aerobic mineralisation in surface water (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.1)

Parent										
System identifier (indicate fresh, estuarine or marine)	pH water phase	pH sed[a)]	t. °C[b)]	DT_{50}/DT_{90} whole sys. (suspended sediment test)		St. (χ^2)	DT_{50} /DT_{90} Water (pelagic test)		St. (χ^2)	Method of calculation
				At study temp	Normalised to *x* °C[c)]		At study temp	Normalised to x °C[c)]		
Fröschweiher (fresh) - low dose	8.0	na	21.2	Stable	na	na	na	na	na	na
Fröschweiher (fresh) - high dose	8.0	na	21.2	Stable	na	na	na	na	na	na

[a)] Measured in [medium to be stated, usually calcium chloride solution or water]
[b)] Temperature of incubation = temperature that the environmental media was collected or std. temperature of 20 °C
[c)] Normalised using a Q10 of 2.58 to the temperature of the environmental media at the point of sampling. (note temp of x should be stated).

Metabolite *X*	Max in total system *x* % after *n* days									
System identifier (indicate fresh, estuarine or marine)	pH water phase	pH sed [a)]	t. °C[b)]	DT_{50} /DT_{90} whole sys. (suspended sediment test)		St. (χ^2)	DT_{50} /DT_{90} Water (pelagic test)		St. (χ^2)	Method of calculation
				At study temp	Normalised to x °C[c)]		At study temp	Normalised to x °C[c)]		
No data										

[a)] Measured in [medium to be stated, usually calcium chloride solution or water]
[b)] Temperature of incubation=temperature that the environmental media was collected or std temperature of 20°C
[c)] Normalised using a Q10 of 2.58 to the temperature of the environmental media at the point of sampling. (note temp of x should be stated).

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Mineralisation and non extractable residues (for parent dosed experiments)					
System identifier (indicate fresh, estuarine or marine)	pH water phase	pH sed	Mineralisation *x* % after *n* d (end of the study)	Non-extractable residues. max *x* % after *n* d (suspended sediment test)	Non-extractable residues. max *x* % after *n* d (end of the study) (suspended sediment test)
Fröschweiher (fresh) - low dose	8.0	na	3.1 / < 0.1 % after 59 d [^{14}C-phenyl / ^{14}C-triazole]	na	na
Fröschweiher (fresh) - high dose	8.0	na	1.0 / 0.3 % after 59 d [^{14}C-phenyl / ^{14}C-triazole]	na	na

Water / sediment study (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.2)

Triticonazole	Max. in sediment: 76.0 % after 63 d									
Water / sediment system	pH water phase	pH sed[a)]	t. °C	$DegT_{50}$ / $DegT_{90}$ whole sys.	St. (χ^2)	$DissT_{50}$ / $DissT_{90}$ water	St. (χ^2)	$DissT_{50}$ / $DissT_{90}$ sed.	St. (χ^2)	Method of calculation
River	7.7	6.9	20	399 / 1325	1.5	5.3 / 97.8	6.6	nc	na	SFO
Pond	8.0	6.9	20	225 / 748	1.6	9.5 / 125	3.3	nc	na	SFO
Geometric mean at 20 °C[b)]				**300 / 996**		nc		nc		

[a)] Matrix unknown
[b)] Normalised using a Q10 of 2.58

Mineralisation and non-extractable residues (from parent dosed experiments)					
Water / sediment system	pH water phase	pH sed[a)]	Mineralisation x % after n d (end of the study)	Non-extractable residues in sed. max x % after n d	Non-extractable residues in sed. max x % after n d (end of the study)
River	7.7	6.9	1.3 % after 105 d	14.5 after 105 d	14.5 after 105 d
Pond	8.0	6.9	1.7 % after 105 d	25.0 after 105 d	25.0 after 105 d

[a)] Matrix unknown

Fate and behaviour in air (Regulation (EU) N° 283/2013, Annex Part A, point 7.3.1)

Direct photolysis in air	No data
Photochemical oxidative degradation in air	DT_{50} of 0.114 days derived by the Atkinson model (version 1.92). OH (12 h) concentration assumed = 1.5e6 OH/cm^3
Volatilisation	From plant surfaces (BBA guideline): no data
	From soil surfaces (BBA guideline): no data
Metabolites	No data

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Residues requiring further assessment (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.1)

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure	Soil: Triticonazole, RPA 406341 (Trans-diol), RPA 404766 (Cis-diol), RPA 406203 (Z-isomer)[(a)], 'Met 6 (MWT 333)'[(b)], 'Met 7 (MWT 315)'[(b)] Surface water: Triticonazole, RPA 406341 (Trans-diol), RPA 404766 (Cis-diol), RPA 406203 (Z-isomer), 'Met 6 (MWT 333)'[(b)], 'Met 7 (MWT 315)'[(b)] Sediment: triticonazole, RPA 406341 (Trans-diol), RPA 404766 (Cis-diol), RPA 406203 (Z-isomer), 'Met 6 (MWT 333)'[(b)], 'Met 7 (MWT 315)'[(b)] Ground water: triticonazole, RPA 406341 (Trans-diol), RPA 404766 (Cis-diol), RPA 406203 (Z-isomer)[(a)], 'Met 6 (MWT 333)'[(b)], 'Met 7 (MWT 315)'[(b)] Air: Triticonazole (a) Soil photolysis metabolite: Exposure assessment triggered only in case of soil surface applications (e.g. spraying) (b) Unknown metabolite fractions observed > 5 % at two consecutive sampling points in *Ayliffe & Austin (1993)*

Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2)

See section 5, Ecotoxicology

Monitoring data, if available (Regulation (EU) N° 283/2013, Annex Part A, point 7.5

Soil (indicate location and type of study)	No data
Surface water (indicate location and type of study)	Triticonazole in public monitoring: **France, 2008 - 2012:** Number of sites sampled per year: 311 - 1471 Number of analyses per year: 1567 - 9815 Number of detections > LOD µg/L per year: 15 - 52 Number of detections > 0.1 µg/L pear year: 1 - 2 **US:** Water samples from streams, ponds, and shallow groundwater in areas of intense fungicide use within three geographic areas across the United States. Triticonazole was detected in 2 of 72 surface water samples with a maximum concentration of 66.8 ng/L
Ground water (indicate location and type of study)	Triticonazole in public monitoring: **France, 2007 - 2011:** Number of well sampled per year: 52 - 1655 Number of analyses per year: 75 - 4448 Number of detections > LOD µg/L per year: 0 - 2

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	Number of detections > 0.1 µg/L per year: 0 **Czech Republic, 2009 - 2012:** Number of well sampled per year: 651 - 653 Number of analyses per year: 653 - 1265 Number of detections > LOD µg/L per year: 1 - 5 Number of detections > 0.1 µg/L per year: 0 **Italy, 2009 - 2010:** Number of well sampled per year: 1 - 12 Number of analyses per year: 2 - 25 Number of detections > LOD µg/L per year: 0 Number of detections > 0.1 µg/L per year: 0 **US:** Water samples from streams, ponds, and shallow groundwater in areas of intense fungicide use within three geographic areas across the United States. Triticonazole was detected in 2 of 72 surface water samples with a maximum concentration of 66.8 ng/L
Air (indicate location and type of study)	No data

PEC soil (Regulation (EU) N° 284/2013, Annex Part A, points 9.1.3 / 9.3.1)

Triticonazole Method of calculation	DT_{50} (d): 242 days Kinetics: SFO Field or Lab: representative non-normalized worst case from field studies
Application data	Crop: Winter cereals (seed treatment) Depth of soil layer: 5 cm (20 cm tillage each year) Soil bulk density: 1.5 g/cm^3 % plant interception: 0 Number of applications: 1 Interval (d): na Application rate(s): 12.5 g a.s./ha

$PEC_{(s)}$ (mg/kg)		Single application Actual[a)]	Single application Time weighted average [a)]	Multiple application Actual	Multiple application Time weighted average
Initial		0.0189	-	na	
Short term	24h	0.0189	0.0189	na	na
	2d	0.0188	0.0189	na	na
	4d	0.0187	0.0188	na	na
Long term	7d	0.0186	0.0188	na	na
	28d	0.0176	0.0183	na	na

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PEC$_{(s)}$ (mg/kg)		Single application Actual[a)]	Single application Time weighted average[a)]	Multiple application Actual	Multiple application Time weighted average
	50d	0.0167	0.0178	na	na
	100d	0.0148	0.0168	na	na
Plateau concentration		0.0023 mg/kg after ~ 6 yrs			

a) Including plateau concentration

RPA 406341 (Trans-diol) Method of calculation	Molecular weight relative to the parent: 1.05 DT$_{50}$ (d): 123 days Kinetics: SFO Field or Lab: representative non-normalized worst case from field studies
Application data	Application rate assumed: 2.65 g/ha (assumed RPA 406341 (Trans-diol) is formed at a maximum of 20.2 % of the applied dose)

PEC$_{(s)}$ (mg/kg)		Single application Actual[a)]	Single application Time weighted average[a)]	Multiple application Actual	Multiple application Time weighted average
Initial		**0.0037**	-	na	
Short term	24h	0.0036	0.0037	na	na
	2d	0.0036	0.0036	na	na
	4d	0.0036	0.0036	na	na
Long term	7d	0.0035	0.0036	na	na
	28d	0.0031	0.0034	na	na
	50d	0.0028	0.0032	na	na
	100d	0.0021	0.0028	na	na
Plateau concentration		0.0001 mg/kg after ~ 2 yrs			

a) Including plateau concentration

RPA 404766 (Cis-diol) Method of calculation	Molecular weight relative to the parent: 1.05 DT$_{50}$ (d): 213 days Kinetics: SFO Field or Lab: representative non-normalized worst case from lab studies

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Application data		Application rate assumed: 1.82 g/ha (assumed RPA 404766 (Cis-diol) is formed at a maximum of 13.9 % of the applied dose)			
$PEC_{(s)}$ (mg/kg)		Single application Actual[a)]	Single application Time weighted average[a)]	Multiple application Actual	Multiple application Time weighted average
Initial		**0.0027**	-	na	
Short term	24h	0.0027	0.0027	na	na
	2d	0.0027	0.0027	na	na
	4d	0.0027	0.0027	na	na
Long term	7d	0.0026	0.0027	na	na
	28d	0.0025	0.0026	na	na
	50d	0.0023	0.0025	na	na
	100d	0.002	0.0023	na	na
Plateau concentration		0.0003 mg/kg after ~ 4 yrs			

a) Including plateau concentration

'Met 6 (MWT 333)' Method of calculation		Molecular weight relative to the parent: 1.05 (indicative) DT_{50} (d): 1000 days Kinetics: SFO Field or Lab: Default			
Application data		Application rate assumed: 1.68 g/ha (assumed 'Met 6 (MWT 333)' is formed at a maximum of 12.8 % of the applied dose)			
$PEC_{(s)}$ (mg/kg)		Single application Actual[a)]	Single application Time weighted average[a)]	Multiple application Actual	Multiple application Time weighted average
Initial		0.0042	-	na	
Short term	24h	nc	nc	na	na
	2d	nc	nc	na	na
	4d	nc	nc	na	na
Long term	7d	nc	nc	na	na
	28d	nc	nc	na	na
	50d	nc	nc	na	na
	100d	nc	nc	na	na
Plateau concentration		0.0019 mg/kg after ~ 20 yrs			

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'Met 7 (MWT 315)' Method of calculation	Molecular weight relative to the parent: 0.994 (indicative) DT_{50} (d): 1000 days Kinetics: SFO Field or Lab: Default
Application data	Application rate assumed: 0.81 g/ha (assumed RPA 404766 (Cis-diol) is formed at a maximum of 6.5 % of the applied dose)

$PEC_{(s)}$ (mg/kg)		Single application Actual[a)]	Single application Time weighted average[a)]	Multiple application Actual	Multiple application Time weighted average
Initial		0.0019	-	na	
Short term	24h	nc	nc	na	na
	2d	nc	nc	na	na
	4d	nc	nc	na	na
Long term	7d	nc	nc	na	na
	28d	nc	nc	na	na
	50d	nc	nc	na	na
	100d	nc	nc	na	na
Plateau concentration		0.0010 mg/kg after ~ 20 yrs			

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PEC ground water (Regulation (EU) N° 284/2013, Annex Part A, point 9.2.4.1)

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance. Model(s) used: PEARL 4.4.4, PELMO 5.5.3, MACRO 5.5.4 Crop: Winter & spring cereals **Triticonazole:** Mol mass (g/mol): 317.8 Water solubility (mg/L): 9.3 at pH 7 and 20 °C Vapour pressure: 9E-8 Pa at 25 °C Geometric mean $DegT_{50field}$: 78.7 d (time-step normalisation to 10kPa or pF2, 20 °C with Q_{10} of 2.58 and Walker equation coefficient 0.7) K_{foc}: minimum 307 mL/g (pH dependent sorption), arithmetic mean $^1/_n = 0.90$ Crop uptake factor: 0 **RPA 406341 (Trans-diol):** Mol mass (g/mol): 333.8 Water solubility (mg/L): 9.3 at pH 7 and 20 °C (parent data used) Vapour pressure: 0 Pa at 25 °C Geometric mean $DegT_{50field}$: 40.6 d (time-step normalisation to 10kPa or pF2, 20 °C with Q_{10} of 2.58 and Walker equation coefficient 0.7) K_{foc}: geometric mean 144 mL/g, arithmetic mean $^1/_n = 0.94$ Crop uptake factor: 0 Formation fraction (from parent): 0.347 **RPA 404766 (Cis-diol):** Mol mass (g/mol): 333.8 Water solubility (mg/L): 9.3 at pH 7 and 20 °C (parent data used) Vapour pressure: 0 Pa at 25 °C Geometric mean $\underline{DegT_{50lab}}$: 75.3 d (no refinement) (time-step normalisation to 10kPa or pF2, 20 °C with Q_{10} of 2.58 and Walker equation coefficient 0.7) Geometric mean $\underline{DegT_{50field}}$: 40.6 d (refinement) ($DegT50_{field}$ of RPA 406341 (Trans-diol) used as a conservative estimate) K_{foc}: geometric mean 75.7 mL/g, arithmetic mean $^1/_n = 0.93$ Formation fraction (from parent): 0.353 **'Met 6 (MWT 333)'[(a)]:** Mol mass (g/mol): 333.8 (indicative) Water solubility (mg/L): 9.3 at pH 7 and 20 °C (parent data used)

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	Vapour pressure: 0 Pa at 25 °C Geometric mean $DegT_{50lab}$: 1000 d (default) K_{oc}: 278 mL/g (estimated on basis of HPLC retention time), $^1/_n$ = 0.94 (value from RPA 406341 (Trans-diol) used)) Crop uptake factor: 0 Formation fraction (from parent): 0.077 **'Met 7 (MWT 315)'[(a)]:** Mol mass (g/mol): 315.8 (indicative) Water solubility (mg/L): 9.3 at pH 7 and 20 °C (parent data used) Vapour pressure: 0 Pa at 25 °C Geometric mean $DegT_{50lab}$: 1000 d (default) K_{oc}: 327 mL/g (estimated on basis of HPLC retention time), $^1/_n$ = 0.94 (value from RPA 406341 (Trans-diol) used)) Crop uptake factor: 0 Formation fraction (from parent): 0.051 (a) Indicative identified metabolite fractions observed > 5 % AR at two consecutive sampling points in *Ayliffe & Austin* (1993)
Application rate	Gross application rate: 12.5 g/ha Crop growth stage: At seeding (seed treatment) Canopy interception: 0 % Application rate net of interception: 12.5 g/ha No. of applications: 1 Time of application (relative application dates): 14 days pre-emergence

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PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1m)

	Scenario	Triticonazole (µg/L)	Metabolite (µg/L)				
			RPA 406341 (Trans-diol)	RPA 404766 (Cis-diol), DegT50 = 75.3 d[(a)]	RPA 404766 (Cis-diol), DegT50 = 40.6 d[(b)]	'Met 6 (MWT 333)'	'Met 7 (MWT (315)'
PEARL 4.4.4 /Winter cereals	Chateaudun	< 0.001	< 0.001	0.047	0.004	0.141	0.058
	Hamburg	< 0.001	0.005	0.134	0.029	0.161	0.083
	Jokioinen	< 0.001	0.001	0.070	0.009	0.047	0.011
	Kremsmünster	< 0.001	0.003	0.093	0.019	0.118	0.062
	Okehampton	< 0.001	0.006	0.120	0.029	0.123	0.067
	Piacenza	< 0.001	0.002	0.071	0.013	0.130	0.066
	Porto	< 0.001	0.002	0.070	0.016	0.089	0.048
	Sevilla	< 0.001	< 0.001	< 0.001	< 0.001	0.005	0.001
	Thiva	< 0.001	< 0.001	0.036	0.002	0.131	0.037

(a) No refinement: Lab DegT50 used
(b) Refinement: Field DegT50 of RPA 406341 (Trans-diol) used as a conservative estimate of the field DegT50 of RPA 404766 (Cis-diol)

	Scenario	Triticonazole (µg/L)	Metabolite (µg/L)				
			RPA 406341 (Trans-diol)	RPA 404766 (Cis-diol), DegT50 = 75.3 d[(a)]	RPA 404766 (Cis-diol), DegT50 = 40.6 d[(b)]	'Met 6 (MWT 333)'	'Met 7 (MWT (315)'
PEARL 4.4.4 /Spring cereals	Chateaudun	< 0.001	< 0.001	0.036	0.002	0.112	0.045
	Hamburg	< 0.001	0.005	0.147	0.030	0.187	0.094
	Jokioinen	< 0.001	0.000	0.065	0.008	0.034	0.007
	Kremsmünster	< 0.001	0.003	0.093	0.018	0.129	0.067
	Okehampton	< 0.001	0.004	0.109	0.023	0.125	0.068
	Piacenza	No crop	No crop	No crop	No crop	No crop	No crop
	Porto	< 0.001	0.001	0.063	0.013	0.083	0.045
	Sevilla	No crop	No crop	No crop	No crop	No crop	No crop
	Thiva	No crop	No crop	No crop	No crop	No crop	No crop

(a) No refinement: Lab DegT50 used
(b) Refinement: Field DegT50 of RPA 406341 (Trans-diol) used as a conservative estimate of the field DegT50 of RPA 404766 (Cis-diol)

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	Scenario	Triticonazole (µg/L)	Metabolite (µg/L)				
			RPA 406341 (Trans-diol)	RPA 404766 (Cis-diol), DegT50 = 75.3 d[(a)]	RPA 404766 (Cis-diol), DegT50 = 40.6 d[(b)]	'Met 6 (MWT 333)'	'Met 7 (MWT (315)'
PELMO 5.5.3 /Winter cereals	Chateaudun	< 0.001	< 0.001	0.033	0.002	0.113	0.037
	Hamburg	< 0.001	0.004	0.124	0.026	0.173	0.087
	Jokioinen	< 0.001	0.001	0.071	0.010	0.031	0.006
	Kremsmünster	< 0.001	0.002	0.085	0.016	0.138	0.071
	Okehampton	< 0.001	0.005	0.110	0.025	0.128	0.070
	Piacenza	< 0.001	0.002	0.077	0.014	0.149	0.076
	Porto	< 0.001	0.003	0.087	0.024	0.091	0.050
	Sevilla	< 0.001	< 0.001	0.002	0.000	0.008	0.001
	Thiva	< 0.001	< 0.001	0.018	0.001	0.095	0.024

(a) No refinement: Lab DegT50 used
(b) Refinement: Field DegT50 of RPA 406341 (Trans-diol) used as a conservative estimate of the field DegT50 of RPA 404766 (Cis-diol)

	Scenario	Triticonazole (µg/L)	Metabolite (µg/L)				
			RPA 406341 (Trans-diol)	RPA 404766 (Cis-diol), DegT50 = 75.3 d[(a)]	RPA 404766 (Cis-diol), DegT50 = 40.6 d[(b)]	'Met 6 (MWT 333)'	'Met 7 (MWT (315)'
PELMO 5.5.3 /Spring cereals	Chateaudun	< 0.001	< 0.001	0.021	0.001	0.097	0.034
	Hamburg	< 0.001	0.003	0.107	0.021	0.157	0.080
	Jokioinen	< 0.001	< 0.001	0.050	0.006	0.028	0.006
	Kremsmünster	< 0.001	0.002	0.078	0.014	0.126	0.065
	Okehampton	< 0.001	0.003	0.090	0.018	0.117	0.064
	Piacenza	No crop	No crop	No crop	No crop	No crop	No crop
	Porto	< 0.001	0.002	0.062	0.014	0.083	0.044
	Sevilla	No crop	No crop	No crop	No crop	No crop	No crop
	Thiva	No crop	No crop	No crop	No crop	No crop	No crop

(a) No refinement: Lab DegT50 used
(b) Refinement: Field DegT50 of RPA 406341 (Trans-diol) used as a conservative estimate of the field DegT50 of RPA 404766 (Cis-diol)

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	Scenario	Triticonazole (µg/L)	Metabolite (µg/L)				
			RPA 406341 (Trans-diol)	RPA 404766 (Cis-diol), DegT50 = 75.3 d	RPA 404766 (Cis-diol), DegT50 = 40.6 d	'Met 6 (MWT 333)'	'Met 7 (MWT (315)'
MACRO 5.5.4 /winter & spring cereals	Chateaudun	< 0.001	< 0.001	0.048	nc	nc	nc
	Hamburg	< 0.001	< 0.001	0.035	nc	nc	nc

PEC$_{(gw)}$ from lysimeter

Parent	1st year	2nd year	3rd year
Annual average (µg/L)	< LOD (0.008 - 0.010 µg/L)	< LOD (0.008 - 0.010 µg/L)	< LOD (0.008 - 0.010 µg/L)

RPA 406341 (Trans-diol)	1st year	2nd year	3rd year
Annual average (µg/L)	< LOD (0.008 - 0.010 µg/L)	< LOD (0.008 - 0.010 µg/L)	< LOD (0.008 - 0.010 µg/L)

RPA 404766 (Cis-diol)	1st year	2nd year	3rd year
Annual average (µg/L)	< LOD (0.008 - 0.010 µg/L)	< LOD (0.008 - 0.010 µg/L)	< LOD (0.008 - 0.010 µg/L)

PEC surface water and PEC sediment (Regulation (EU) N° 284/2013, Annex Part A, points 9.2.5 / 9.3.1)

Parent Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: 3.2 Molecular weight (g/mol): 317.8 K_{oc} / K_{om} (mL/g): pH dependent sorption PEC_{sw}: 307 (minimum) PEC_{sed}: 823 (maximum) DT_{50} soil (d): 78.7 (field, in accordance with FOCUS SFO) DT_{50} water/sediment system (d): 300 (geomean from water/sediment studies) DT_{50} water (d): 1000 DT_{50} sediment (d): 300 Crop interception (%): 0
Parameters used in FOCUSsw step 3 (if performed)	Version control no.'s of FOCUS software: 5.3 Water solubility (mg/L) at 20 °C: 9.3 Vapour pressure (Pa) at 25 °C: 9E-8 K_{foc} (mL/g): pH dependent sorption: drainage scenarios: 307 (minimum)

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	runoff scenarios: 307 or 823 (minimum/maximum) 1/n: 0.90 (Freundlich exponent general) Q10 = 2.58, Walker equation coefficient 0.7 Crop uptake factor: 0
Application rate	Crop and growth stage: Winter & spring cereals at seeding Number of applications: 1 Interval (d): - Application rate(s): 12.5 g a.s./ha Application method (CAM): granular application, CAM 6 (incorporation soil linear decrease), std. incorporation depth of 4 cm Start of application window: 14 days pre-emergence

FOCUS STEP 1	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Winter & spring cereals	0 h	3.07		16.76	

FOCUS STEP 2	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Winter cereals, North-EU, Oct.-Feb.	0 h	1.52		8.32	
Winter cereals, South-EU, Oct.-Feb.	0 h	1.23		6.75	
Spring cereals, North-EU, Mar.-May	0 h	0.66		3.60	
Spring cereals, South-EU, Mar.-May	0 h	1.23		6.75	

FOCUS STEP 3	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
Winter cereals	D1-ditch	0 h	0.600		2.793	
	D1-stream	0 h	0.375		1.566	
	D2-ditch	0 h	0.915		2.325	
	D2-stream	0 h	0.571		1.381	
	D3-ditch	0 h	< 0.001		< 0.001	
	D4-pond	0 h	0.098		0.471	
	D4-stream	0 h	0.100		0.185	
	D5-pond	0 h	0.082		0.392	

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FOCUS STEP 3	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
	D5-stream	0 h	0.101		0.113	
	D6-ditch	0 h	0.326		0.262	
	R1-pond	0 h	0.009		0.073[(a)]	
	R1-stream	0 h	0.208		0.056	
	R3-stream	0 h	0.272		2.108[(a)]	
	R4-stream	0 h	0.188		0.068[(a)]	
Spring cereals	D1-ditch	0 h	0.235		1.212	
	D1-stream	0 h	0.147		0.715	
	D3-ditch	0 h	< 0.001		< 0.001	
	D4-pond	0 h	0.037		0.192	
	D4-stream	0 h	0.037		0.074	
	D5-pond	0 h	0.012		0.093	
	D5-stream	0 h	0.014		0.020	
	R4-stream	0 h	0.073[(a)]		0.074[(a)]	

(a) Worst case on basis of maximum K_{foc} of 823 mL/g

RPA 406341 (Trans-diol)	
Parameters used in FOCUSsw step 1 and 2	Molecular weight (g/mol): 333.8 Soil or water metabolite: Soil K_{oc} / K_{om} (mL/g): 144 / 83.5 DT_{50} soil (d): 40.6 (field, in accordance with FOCUS SFO) DT_{50} water/sediment system (d): 1000 (default) DT_{50} water (d): 1000 (default) DT_{50} sediment (d): 1000 (default) Maximum occurrence observed (% molar basis with respect to the parent) Total Water and Sediment: 0 Soil: 20.2
Main routes of entry	Soil runoff/drainage

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RPA 404766 (Cis-diol) Parameters used in FOCUSsw step 1 and 2	Molecular weight (g/mol): 333.8 Soil or water metabolite: Soil K_{oc} / K_{om} (mL/g): 75.7 / 43.9 DT_{50} soil (d): 75.3 (lab, in accordance with FOCUS SFO) DT_{50} water/sediment system (d): 1000 (default) DT_{50} water (d): 1000 (default) DT_{50} sediment (d): 1000 (default) Maximum occurrence observed (% molar basis with respect to the parent) Total Water and Sediment: 0 Soil: 13.9
Main routes of entry	Soil runoff/drainage
RPA 406203 (Z-isomer) Parameters used in FOCUSsw step 1 and 2	Molecular weight (g/mol): 333.8 Soil or water metabolite: Water K_{oc} / K_{om} (mL/g): 0 / 0 (PEC water) and 1000/580 (PEC sediment) DT_{50} soil (d): 1000 (default) DT_{50} water/sediment system (d): 1000 (default) DT_{50} water (d): 1000 (default) DT_{50} sediment (d): 1000 (default) Maximum occurrence observed (% molar basis with respect to the parent) Total Water and Sediment: 42.3 Soil: 4.4
Main routes of entry	Aquatic photolysis
'Met 6 (MWT 333)' Parameters used in FOCUSsw step 1 and 2	Molecular weight (g/mol): 333.8 (indicative) Soil or water metabolite: Soil K_{oc} / K_{om} (mL/g): 278 / 161 (estimated on basis of HPLC retention time) DT_{50} soil (d): 1000 (default) DT_{50} water/sediment system (d): 1000 (default) DT_{50} water (d): 1000 (default) DT_{50} sediment (d): 1000 (default) Maximum occurrence observed (% molar basis with respect to the parent) Total Water and Sediment: 0 Soil: 12.8
Main routes of entry	Soil runoff/drainage

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'Met 7 (MWT 315)' Parameters used in FOCUSsw step 1 and 2	Molecular weight (g/mol): 315.8 (indicative) Soil or water metabolite: Soil K_{oc} / K_{om} (mL/g): 327 / 190 (estimated on basis of HPLC retention time) DT_{50} soil (d): 1000 (default) DT_{50} water/sediment system (d): 1000 (default) DT_{50} water (d): 1000 (default) DT_{50} sediment (d): 1000 (default) Maximum occurrence observed (% molar basis with respect to the parent) Total Water and Sediment: 0 Soil: 6.5
Main routes of entry	Soil runoff/drainage
Application rate	Crop and growth stage: Winter & spring cereals (seed treatment) Number of applications: 1 Interval (d): - Application rate(s): 12.5 g a.s./ha Crop interception (%): No Application window: North EU, October - February South EU, October - February North EU, March - May South EU, March - May

FOCUS STEP 1 Scenario	Metabolite	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
Winter & spring cereals	RPA 406341 (Trans-diol)	0h	0.74		1.07	
	RPA 404766 (Cis-diol)	0h	0.55		0.42	
	RPA 406203 (Z-isomer)	0h	1.99		8.54	
	'Met 6 (MWT 333)'	0h	0.41		1.14	
	'Met 7 (MWT 315)'	0h	0.19		0.61	

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FOCUS STEP 2 Scenario	Metabolite	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
Winter cereals, North-EU, Oct.-Feb.	RPA 406341 (Trans-diol)	0h	0.35		0.50	
	RPA 404766 (Cis-diol)	0h	0.27		0.20	
	RPA 406203 (Z-isomer)	0h	0.99		4.24	
	'Met 6 (MWT 333)'	0h	0.20		0.57	
	'Met 7 (MWT 315)'	0h	0.09		0.31	
Winter cereals, South-EU, Oct.-Feb.	RPA 406341 (Trans-diol)	0h	0.28		0.40	
	RPA 404766 (Cis-diol)	0h	0.21		0.16	
	RPA 406203 (Z-isomer)	0h	0.80		3.44	
	'Met 6 (MWT 333)'	0h	0.16		0.45	
	'Met 7 (MWT 315)'	0h	0.07		0.24	
Spring cereals, North-EU, Mar.-May	RPA 406341 (Trans-diol)	0h	0.14		0.20	
	RPA 404766 (Cis-diol)	0h	0.11		0.08	
	RPA 406203 (Z-isomer)	0h	0.43		1.82	
	'Met 6 (MWT 333)'	0h	0.08		0.23	
	'Met 7 (MWT 315)'	0h	0.04		0.12	
Spring cereals, South-EU, Mar.-May	RPA 406341 (Trans-diol)	0h	0.28		0.40	
	RPA 404766 (Cis-diol)	0h	0.21		0.16	
	RPA 406203 (Z-isomer)	0h	0.80		3.44	
	'Met 6 (MWT 333)'	0h	0.16		0.45	
	'Met 7 (MWT 315)'	0h	0.07		0.24	

Estimation of concentrations from other routes of exposure (Regulation (EU) N° 284/2013, Annex Part A, point 9.4)

Method of calculation

Dust drift (pneumatic seeder, cereals):
Normalized exposure: 0.33 % (2-D dust drift)[a)]

a) EU Commission (2012): Guidance document on the authorisation of plant protection products for seed treatment. SANCO/10553/2012 rev. 0

PEC

Maximum concentration

PEC_{sw} from dust drift:
Triticonazole: 0.014 µg/L
RPA 406203 (Z-isomer): 0.007 µg/L

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Section 5 Ecotoxicology

Ecotoxicology

Effects on birds and other terrestrial vertebrates (Regulation (EU) N° 283/2013, Annex Part A, point 8.1 and Regulation (EU) N° 284/2013, Annex Part A, point 10.1)

Species	Test substance	Time scale	End point	Toxicity (mg/kg bw per day)
Birds				
Colinus virginianus	a.s.	Acute	LD_{50} $LD_{50extrapolated}$	> 2000 3776[a]
Anas platyrhynchos	a.s.	Acute	LD_{50}	> 2000 3776[a]
Perdix perdix	a.s.	Acute	LD_{50}	> 2000 3776[a]
Alectoris rufa	a.s.	Acute	LD_{50}	> 2000 3776[a]
Columba livia	a.s.	Acute	LD_{50}	> 2000* 3776[a]
Phasianus colchicus	a.s.	Acute	LD_{50}	> 2000* 3776[a]
Based on geometric mean of the endpoints from the studies with Bobwhite quail ([redacted], 1991a), Grey partridge ([redacted], 1992a) and Red-legged partridge ([redacted], 1992b)		Acute	LD_{50}	**3776**
Colinus virginianus	Metabolite RPA 406341	Acute	LD_{50}	> 2250
	a.s.	Long-term	LD_{50}/10	377.6
Colinus virginianus	a.s.	Long-term	NOEL	10.98[c]**
Colinus virginianus	a.s.	Long-term	NOAEL	**19.5**[c]
Colinus virginianus	a.s.	Long-term	NOAEL	12.4**
Anas platyrhynchos	a.s.	Long-term	NOEL	108.15
Colinus virginianus	a.s.	Long-term (shortened exposure	NOEL	24.7***
Mammals				
Rat	a.s.	Acute	LD_{50}	**> 2000**
Rat	Preparation Premis 25 FS	Acute	LD_{50}	**> 2000**

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Rat	Metabolite RPA 406341	Acute	LD_{50}	**> 2000**
Rat	a.s.	Long-term	NOAEL Developmental toxicity	200
Rabbit	a.s.	Long-term	NOAEL Developmental toxicity	**25**[bc]
Endocrine disrupting properties (Annex Part A, points 8.1.5) Triticonazole has been shown to inhibit the aromatase enzyme in vitro like other members of the azole class of fungicides, with 20-times lower IC for rat than for human aromatase. However, in vitro activity did not translate into any specific endocrine-related effect in vivo. This observation is supported by the lack of treatment-related carcinogenic effects in two lifetime cancer bioassays conducted in rats and mice, as well as the absence of specific reproductive or developmental toxicity in a 2-generation reproduction study and two developmental toxicity studies. The observed morphological changes in adrenals in all species and almost all studies, always accompanied by marked general toxicity, did not prove to impair the functional capacity of adrenals since corticosterone was successfully excreted after ACTH challenge. It is concluded that no evidence is available that effects observed in studies with triticonazole have an endocrine MoA.				
Additional higher tier studies (Annex Part A, points 10.1.1.2): One-generation reproduction study on bobwhite quail with shortened exposure duration to 4 weeks (Zok, 2008); Two degradation studies (Scrimshaw, 2006 and Moreno 2008); Two residue studies on spring wheat seeds (Plier, 2006) and winter wheat seeds 8Plier & Elze, 2017) with separate reports reviewing the degradation kinetics for the calculation of DT_{50} dissipation times (Szegedi, 2017a & b); Five studies to determine the focal species and to refine PD and PT values respectively (Moosmayer, 2008a, Barfknecht, 2006a, Sadowski *et al*, 2014a, Dittrich & Benito, 2017a; Erni *et al*., 2017a)				
Terrestrial vertebrate wildlife (birds, mammals, reptile and amphibians) (Annex Part A, points 8.1.4, 10.1.3): Two degradation studies (Scrimshaw, 2006 and Moreno 2008); Two residue studies on spring wheat seeds (Plier, 2006) and winter wheat seeds 8Plier & Elze, 2017) with separate reports reviewing the degradation kinetics for the calculation of DT_{50} dissipation times (Szegedi, 2017a & b); Four studies to refine PT values of wood mice (Fülling & Miersch, 2016, Barfknecht, 2008a, Fülling & Sainz-Elipe, 2017, Barfknecht, 2006)				

Bold written values are used for the risk assessment.

[a]LD_{50} extrapolated according to the EFSA Guidance Document on Birds and Mammals (2009). 10 birds per group were tested without any mortality during the study. An extrapolation factor of 1.888 was used for the calculation of the extrapolated LD_{50}

[b]Population-relevant ecotoxicological endpoint: The toxicological endpoint is considered to be 5 mg ai/kg bw as at ≥ 25 mg ai/kg bw a slight body weight loss at days 6 to 8 and reduced food intake occurred. Furthermore one precocious ossification of acromiom process was noted at ≥ 25 mg ai/kg/d. However, the body weight loss and the reduced food intake were < 10% and not statistically significant and the precocious ossification is not considered ecotoxicologically relevant (for details please refer to the RAR)

[c]Endpoint in discussion

*As a screening test the study can be used as additional information

**The reliability of this study and its inclusion in the list of endpoint should be discussed in the peer review

***The validity, reliability, and the usefullness of this study with shortened exposure to 4 weeks should be discussed in the peer review

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Section 5 Ecotoxicology

Toxicity/exposure ratios for terrestrial vertebrates (Regulation (EU) N° 284/2013, Part A, Annex point 10.1)

Cereals at 12.5 g a.s./ha [single application]

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Screening Step (Birds)					
Not required for seed treatments					
Tier 1 (Birds)					
BBCH 00	Small granivorous bird	Acute	15	252	10
Seedlings	Small omnivorous bird	Acute	5	755.2	10
Seedlings	Large herbivorous bird	Acute	3	1259	10
BBCH 00	Small granivorous bird	Long-term[a]	10.8	**1.80**	5
			9.6	**2.03**	
			7.95	**2.45**	
Seedlings	Small omnivorous bird	Long-term	2.65	7.36	5
Seedlings	Large herbivorous bird	Long-term	1.59	12.26	5

Higher tier (birds):
Initial residues on cereal seeds on the soil surface – worst case value of all submitted studies: 91.88%
Decline of residues on cereals seeds on the soil surface: DT_{50} = 5.5 days refinement of f_{twa} (0.351;0.568; 0.470)[a]
Focal species: Skylark, Yellowhammer, Chaffinch, woodpigeon, Rook/Carrion Crow, Pheasant, Linnet[b]
PT refinement[c]:
90th percentile PT consumer only for Skylark – spring cereals: 0.83; winter cereals: 0.76
90th percentile PT consumer only for Yellowhammer– spring cereals: 0.2; winter cereals: 0.35
90th percentile PT consumer only for Chaffinch– spring cereals: 0.63; winter cereals: 0.06

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Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Spring cereals BBCH 00	Skylark	Long-term[a]	5.769	**3.4**	5
			4.773	**4.1**	
			3.822	5.1	
Spring cereals BBCH 00	Yellowhammer	Long-term[a]	1.547	12.6	5
			1.280	15.2	
			0.956	20.4	
Spring cereals BBCH 00	Chaffinch	Long-term[a]	5.267	**3.7**	5
			4.359	**4.5**	
			3.255	5.9	
Spring cereals BBCH 00	Linnet[b]	Long-term[a]	9.250	**2.11**	5
			7.653	**2.55**	
			5.716	**3.41**	
Winter cereals BBCH 00	Skylark	Long-term[a]	5.282	**3.7**	5
			4.371	**4.5**	
			3.264	6.0	
Winter cereals BBCH 00	Yellowhammer	Long-term[a]	2.707	7.2	5
			2.240	8.7	
			1.673	11.7	
Winter cereals BBCH 00	Chaffinch	Long-term[a]	0.502	38.8	5
			0.415	47	
			0.310	62.9	
Winter cereals BBCH 00	Linnet[b]	Long-term[a]	9.25	**2.11**	5
			7.65	**2.55**	
			5.72	**3.41**	
Screening Step (Mammals)					
Not required for seed treatments					
Tier 1 (Mammals)					
BBCH 00	Small omnivorous mammal	Acute	12	> 167	10
Seedlings	Small omnivorous mammal	Acute	2.4	> 834	10
Seedlings	Large herbivorous mammal	Acute	4	> 500	10
BBCH 00	Small omnivorous mammal	Long-term[a]	8.64	**2.89**	5
			7.68	**3.26**	
			6.36	**3.93**	
Seedlings	Small omnivorous mammal	Long-term	1.27	19.7	5
Seedlings	Large herbivorous mammal	Long-term	2.12	11.7	5
Higher tier (Mammals): **Initial residues on cereal seeds on the soil surface** – worst case value of all submitted studies: 91.88% **Decline of residues on cereals seeds on the soil surface:** DT_{50} = 5.5 days refinement of f_{twa} (0.351;0.568; 0.470)[a] **Focal species:** Wood mouse **PD refinement[c] -** worst-case value of all submitted studies: 0.5					
BBCH 00	Wood mouse	Long-term[a]	3.135	7.97	5
			2.594	9.64	
			1.938	12.90	

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Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Risk from bioaccumulation and food chain behaviour					
Indicator or focal species		Time scale	DDD (mg/kg bw per day)	TER	Trigger
Earthworm-eating birds		Long-term	0.836	23	5
Earthworm-eating mammals		Long-term	1.019	24	5
Fish-eating birds		Long-term	0.036	542	5
Fish-eating mammals		Long-term	0.032	609	5
Higher tier : Not required					
Risk from consumption of contaminated water					
Not required for seed treatments					

[a]The averaging time of 21 days is under debate for seed treatments as the time from sowing to germination usually is shorter, for cereals 10 to 14 days can be assumed. To enable expert discussion, the risk assessment is presented with a worst case germination time of 10 days, with a more realistic value of 14 days and with 21 days as used for spray applications.
[b]It should be noted, that the studies for PD and PT refinement have all been conducted in Germany. Therefore it is not ascertained that these refinement options account for other than the central zones.
[c]The relevance of the linnet as a focal species in cereals is under discussion. A decision should be made in the peer review.
Bold values do not meet the trigger.

Toxicity data for all aquatic tested species (Regulation (EU) N° 283/2013, Annex Part A, points 8.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.2)

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
Laboratory tests				
Fish				
Oncorhynchus mykiss	a.s.	Acute 96 hr (flow-through)	Mortality, LC_{50}	> 10 mg ai/$L_{(nom)}$
Oncorhynchus mykiss	a.s.	Acute 96 hr (flow-through)	Mortality, LC_{50}	**> 3.6** mg ai/$L_{(mm)}$
Oncorhynchus mykiss	a.s.	Acute 96 hr (static)	Mortality, LC_{50}	> 12.4 mg ai/$L_{(mm)}$
Lepomis macrochirus	a.s.	Acute 96 hr (flow-through)	Mortality, LC_{50}	> 8.9 mg ai/$L_{(mm)}$
Lepomis macrochirus	a.s.	Acute 96 hr (static)	Mortality, LC_{50}	> 10.1 mg ai/$L_{(mm)}$
Cyprinodon variegatus	a.s.	Acute 96 hr (flow-through)	Mortality, LC_{50}	> 9.1 mg ai/$L_{(mm)}$
Cyprinus carpio	a.s.	Acute 96 hr (static)	Mortality, LC_{50}	> 18 mg ai/$L_{(mm)}$

List of end points

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Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
Pimephales promelas	a.s.	Chronic (flow-through) FFLC	Growth, NOEC	**0.0114** mg ai/$L_{(mm)}$
Pimephales promelas	a.s.	Chronic (flow-through) FFLC	Growth, NOEC	0.0473 mg ai/$L_{(mm)}$
Pimephales promelas	a.s.	Chronic (flow-through) ELS	Growth, NOEC	< 0.024 mg ai/$L_{(nom)}$
Pimephales promelas	a.s.	Chronic (flow-through) ELS	Growth, NOEC	0.021 mg ai/$L_{(nom)}$
Cyprinodon variegatus	a.s.	Chronic (flow-through) ELS	Growth, NOEC	0.12 mg ai/$L_{(nom)}$
Aquatic invertebrates				
Daphnia magna	a.s.	48 h (static)	Mortality, EC_{50}	**7.85** mg ai/$L_{(nom)}$
Mysidopsis bahia (Americamysis bahia)	a.s.	96 h (flow-through)	Mortality, LC_{50}	**1.9** mg ai/$L_{(mm)}$
Crasssostrea virginica	a.s.	96 h (flow-through)	Mortality, EC_{50}	**8.9** mg ai/$L_{(mm)}$
Daphnia magna	Preparation Premis 25 FS	48 h (static)	Mortality, EC_{50}	**> 100** mg prep./L (**2.5** mg ai/$L_{(nom)}$)
Daphnia magna	a.s.	21 d (semi-static)	Reproduction, NOEC	0.19 mg ai/$L_{(mm)}$
Daphnia magna	a.s.	21 d (semi-static)	Reproduction, NOEC	**0.11** mg ai/$L_{(mm)}$
Americamysis bahia	a.s.	28 d (flow-through)	Reproduction, NOEC	**0.041** mg ai/$L_{(mm)}$
Daphnia magna	Metabolite RPA 404766	48 h (semi-static)	Mortality, EC_{50}	**> 100** mg/$L_{(nom)}$
Daphnia magna	Metabolite RPA 407922	48 h (semi-static)	Mortality, EC_{50}	**> 100** mg/$L_{(nom)}$
Daphnia magna	Metabolite RPA 406341	48 h (semi-static)	Mortality, EC_{50}	**51.78** mg/$L_{(nom)}$
Daphnia magna	Metabolite RPA 406203	48 h (semi-static)	Mortality, EC_{50}	**3.4** mg/$L_{(mm)}$

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (**Name**)
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Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
Daphnia magna	Metabolite RPA 406203	48 h (static)	Mortality, EC_{50}	> 10 mg/$L_{(nom)}$
Sediment-dwelling organisms				
Chironomus riparius	a.s.	28 d (static)	NOEC	0.0777 mg ai/L*$_{(imm)}$
Algae				
Pseudokirchneriella subcapitata	a.s.	72 h (static)	Growth rate: E_rC_{50} NOEC Yield: E_yC_{50} NOEC	> 10 mg ai/$L_{(nom)}$ 1.0 mg ai/L > 10 mg ai/$L_{(nom)}$ 1.0 mg ai/L
Skeletonema costatum	a.s.	120 h (static)	72 h Growth rate: E_rC_{50} 120 h NOEC 72h Yield: E_yC_{50} 120 h NOEC	**0.46** mg ai/$L_{(mm)}$ 0.031 mg ai/L 0.33 mg ai/$L_{(mm)}$ 0.031 mg ai/L
Pseudokirchneriella subcapitata	Preparation Premis 25 FS	72 h (static)	Growth rate: E_rC_{50} Yield: E_yC_{50} NOEC	79.4 mg prep./L (2.04 mg ai/$L_{(nom)}$) 19.02 mg prep./L (0.49 mg ai/$L_{(nom)}$) 3.3 mg prep./L (0.08 mg ai/$L_{(nom)}$)
Pseudokirchneriella subcapitata	Metabolite RPA 406203	72 h (static)	Growth rate: E_rC_{50} Yield: E_yC_{50} NOEC	64.83 mg/$L_{(mm)}$ 8.57 mg/$L_{(mm)}$ 1.4 mg ai/L
Higher plant				
No valid studies provided				
Further testing on aquatic organisms Not required				

List of end points

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Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
Potential endocrine disrupting properties (Annex Part A, point 8.2.3) Population relevant effects of triticonazole on fish were studied in an early life-stage tests (ELS) with Fathead minnow (*Pimephales promelas*) and Sheepshead minnow (*Cyprinodon variegatus*) and in fish full life-cycle tests (FFLC) with Fathead minnow (*Pimephales promelas*). Growth of the fish larvae was affected in the ELS tests at 0.021 mg ai/L for Fathead minnow and at 0.12 mg ai/L for Sheepshead minnow. All other endpoints were affected only at higher concentrations. In the FFLC with Fathead minnow growth of F2 generation was the most sensitive parameter with slight effects at concentrations above 0.0114 mg ai/L. Slight effects on weight of the filial generation at the end were observed at a concentration of 0.0229 mg ai/L but not in the highest tested concentration of 0.0462 mg ai/L. The second FFLC study showed effects on growth for the F1 generation in at the highest concentration of 0.0937 mg ai/L but no clear dose response effect. Neither sex ratio nor reproduction of parental fish was affected at concentrations up to 0.0937 mg ai/L. Hatch of larvae of parental and filial generation was not affected up to concentration levels of 0.0462 and 0.0937 mg ai/L, respectively. While some slight growth effects were seen, a fish population is not likely to be adversely affected by these effects. Furthermore, since there is no indication from toxicology of a potential effect on the thyroid or other endocrine organs, it can be ruled out that these effects on growth are endocrine mediated. However, at the current state as not guidance is available, a final conclusion on the potential of triticonazole on endocrine disrupting properties is not possible.				

[1] ($_{nom}$) nominal concentration; ($_{mm}$) mean measured concentration; (imm) initial mean measured concentration; prep.: preparation; a.s.: active substance

*The validity/reliability of the study is questionable

Bold written values were used for the risk assessment.

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Bioconcentration in fish (Annex Part A, point 8.2.2.3)

	Active substance	Metabolite RPA 406203	Metabolite RPA 404766
$logP_{O/W}$	3.3	3.5	1.6
$BCF_{Kwhole\ fish}$	**72.55***	72.55**	Not required
Steady-state bioconcentration factor (BCF) (total wet weight/normalised to 5% lipid content)	-***	-	-
Uptake/depuration kinetics BCF (total wet weight/normalised to 5% lipid content)	-	-	-
Annex VI Trigger for the bioconcentration factor	100		
Clearance time (days) (CT_{50})	< 1day	-	-
(CT_{90})	< 3 days		
Level and nature of residues (%) in organisms after the 14 day depuration phase	-		
Higher tier study			
None			

*the validity of the study is questionable due to uncertain results and missing information. However the results have been used to be able to do a risk assessment

**no information is given for the Z-isomer of triticonazole (RPA 406203), an approach assuming that the BCF is the same as for triticonazole (E-isomer) is used here.

*** based on total ^{14}C or on specific compounds

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PEC/RAC comparisons for the most sensitive aquatic organisms (Regulation (EU) N° 284/2013, Annex Part A, point 10.2)

$FOCUS_{sw}$ step 1-3 – PEC/RAC comparisons for triticonazole – Winter Cereals (BBCH 00) at 12.5 g ai/ha

Scenario	PEC global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Sed. dweller prolonged
		Oncrhynchus mykiss	*Pimephales promelas*	*Americamysis bahia*	*Americamysis bahia*	*Skeletonema costatum*	*Chironomus riparius*
		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	NOEC
		> 3600 µg/L	11.4 µg/L	1900 µg/L	41 µg/L	460 µg/L	77.7 µg/L
RAC		**36 µg/L**	**1.14 µg/L**	**19 µg/L**	**4.1 µg/L**	**46 µg/L**	**7.77 µg/L**
Asessment factor**		100	10	100	10	10	10
FOCUS Step 1	3.07	3.07	**3.07**	3.07	3.07	3.07	3.07
FOCUS Step 2							
North Europe	1.52	1.52	**1.52**	1.52	1.52	1.52	1.52
South Europe	1.23	1.23	**1.23**	1.23	1.23	1.23	1.23
FOCUS Step 3*							
D1 / ditch	0.600	-	0.600	-	-	-	-
D1 / stream	0.375	-	0.375	-	-	-	-
D2 / ditch	0.915	-	0.915	-	-	-	-
D2 / stream	0.571	-	0.571	-	-	-	-
D3 / ditch	< 0.001	-	< 0.001	-	-	-	-
D4 / pond	0.098	-	0.098	-	-	-	-
D4 / stream	0.100	-	0.100	-	-	-	-
D5 / pond	0.082	-	0.082	-	-	-	-
D5 / stream	0.101	-	0.101	-	-	-	-
D6 / ditch	0.326	-	0.326	-	-	-	-
R1 / pond	0.009	-	0.009	-	-	-	-
R1 / stream	0.208	-	0.208	-	-	-	-
R3 / stream	0.272	-	0.272	-	-	-	-
R4 / stream	0.188	-	0.188	-	-	-	-

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*[Only scenarios where the trigger is not met at FOCUSsw step 1-2 should be included in step 3.]
**[If the Trigger value has been adjusted during the risk assessment, it should always be clear on what basis the risk assessment has been performed, i.e. what the AF value is and for which organism and endpoint it refers.]
values in **bold** exceed the relevant RAC, indicating an unacceptable risk

$FOCUS_{sw}$ step 1-3 – PEC/RAC comparisons for triticonazole – Spring Cereals (BBCH 00) at 12.5 g ai/ha

Scenario	PEC global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Sed. dweller prolonged
		Oncrhynchus mykiss	*Pimephales promelas*	*Americamysis bahia*	*Americamysis bahia*	*Skeletonema costatum*	*Chironomus riparius*
		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	NOEC
		> 3600 µg/L	11.4 µg/L	> 1900 µg/L	41 µg/L	460 µg/L	77.7 µg/L
RAC		**36 µg/L**	**1.14 µg/L**	**19 µg/L**	**4.1 µg/L**	**46 µg/L**	**7.77 µg/L**
Asessment factor**		100	10	100	10	10	10
FOCUS Step 1	3.07	3.07	**3.07**	3.07	3.07	3.07	3.07
FOCUS Step 2							
North Europe	0.66	0.66	**0.66**	0.66	0.66	0.66	0.66
South Europe	1.23	1.23	**1.23**	1.23	1.23	1.23	1.23
FOCUS Step 3*							
D1 / ditch	0.235	-	0.235	-	-	-	-
D1 / stream	0.147	-	0.147	-	-	-	-
D3 / ditch	< 0.001	-	< 0.001	-	-	-	-
D4 / pond	0.037	-	0.037	-	-	-	-
D4 / stream	0.037	-	0.037	-	-	-	-
D5 / pond	0.012	-	0.012	-	-	-	-
D5 / stream	0.014	-	0.014	-	-	-	-
R4 / stream	0.066	-	0.066	-	-	-	-

*[Only scenarios where the trigger is not met at FOCUSsw step 1-2 should be included in step 3.]

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product **(Name)**
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**[If the Trigger value has been adjusted during the risk assessment, it should always be clear on what basis the risk assessment has been performed, i.e. what the AF value is and for which organism and endpoint it refers.]
values in **bold** exceed the relevant RAC, indicating an unacceptable risk

$FOCUS_{sw}$ step 1 – PEC/RAC comparisons for RPA 406341 – Winter Cereals (BBCH 00) at 12.5 g ai/ha

Scenario	**PEC global max (µg L)**	**fish acute**	**Aquatic invertebrates**	**Algae**
		Oncrhynchus mykiss	*Daphnia magna*	*Pseudokirchneriella subcapitata*
		LC_{50}	EC_{50}	EC_{50}
		378 µg/L	51780 µg/L	55.7 µg/L
RAC		**3.78 µg/L**	**517.8 µg/L**	**5.57 µg/L**
Asessment factor**		100	100	10
FOCUS Step 1	0.74	0.74	0.74	0.74

*[Only scenarios where the trigger is not met at FOCUSsw step 1-2 should be included in step 3.]
**[If the Trigger value has been adjusted during the risk assessment, it should always be clear on what basis the risk assessment has been performed, i.e. what the AF value is and for which organism and endpoint it refers.]
values in **bold** exceed the relevant RAC, indicating an unacceptable risk

$FOCUS_{sw}$ step 1 – PEC/RAC comparisons for RPA 406341 – Spring Cereals (BBCH 00) at 12.5 g ai/ha

Scenario	**PEC global max (µg L)**	**fish acute**	**Aquatic invertebrates**	**Algae**
		Oncrhynchus mykiss	*Daphnia magna*	*Pseudokirchneriella subcapitata*
		LC_{50}	EC_{50}	EC_{50}
		378 µg/L	51780 µg/L	55.7 µg/L
RAC		**3.78 µg/L**	**517.8 µg/L**	**5.57 µg/L**

Asessment factor**		100	100	*Pseudokirchneriella subcapitata*
FOCUS Step 1	0.74	0.74	0.74	0.74

*[Only scenarios where the trigger is not met at FOCUSsw step 1-2 should be included in step 3.]
**[If the Trigger value has been adjusted during the risk assessment, it should always be clear on what basis the risk assessment has been performed, i.e. what the AF value is and for which organism and endpoint it refers.]
values in **bold** exceed the relevant RAC, indicating an unacceptable risk

FOCUS$_{sw}$ step 1 – PEC/RAC comparisons for RPA 404766 – Winter Cereals (BBCH 00) at 12.5 g ai/ha

Scenario	**PEC global max (µg L)**	**fish acute**	**Aquatic invertebrates**	**Algae**
		Oncrhynchus mykiss	*Daphnia magna*	*Pseudokirchneriella subcapitata*
		LC_{50}	EC_{50}	EC_{50}
		378 µg/L	100000 µg/L	55.7 µg/L
RAC		**3.78µg/L**	**1000 µg/L**	**5.57 µg/L**
Asessment factor**		100	100	10
FOCUS Step 1	0.55	0.55	0.55	0.55

*[Only scenarios where the trigger is not met at FOCUSsw step 1-2 should be included in step 3.]
**[If the Trigger value has been adjusted during the risk assessment, it should always be clear on what basis the risk assessment has been performed, i.e. what the AF value is and for which organism and endpoint it refers.]
values in **bold** exceed the relevant RAC, indicating an unacceptable risk

FOCUS$_{sw}$ step 1 – PEC/RAC comparisons for RPA 404766 – Spring Cereals (BBCH 00) at 12.5 g ai/ha

Scenario	**PEC global max (µg L)**	**fish acute**	**Aquatic invertebrates**	**Algae**
		Oncrhynchus	*Daphnia*	*Pseudokirchneriella*

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		mykiss	*magna*	*subcapitata*
		LC_{50}	EC_{50}	EC_{50}
		378 µg/L	100000 µg/L	55.7 µg/L
RAC		**3.78 µg/L**	**1000 µg/L**	**5.57 µg/L**
Asessment factor**		100	100	10
FOCUS Step 1	0.55	0.55	0.55	0.55

*[Only scenarios where the trigger is not met at FOCUSsw step 1-2 should be included in step 3.]
**[If the Trigger value has been adjusted during the risk assessment, it should always be clear on what basis the risk assessment has been performed, i.e. what the AF value is and for which organism and endpoint it refers.]
values in **bold** exceed the relevant RAC, indicating an unacceptable risk

$FOCUS_{sw}$ step 1 – PEC/RAC comparisons for RPA 406203 – Winter Cereals (BBCH 00) at 12.5 g ai/ha

Scenario	PEC global max (µg L)	fish acute	Aquatic invertebrates	Algae
		Oncrhynchus mykiss	*Daphnia magna*	*Pseudokirchneriella subcapitata*
		LC_{50}	EC_{50}	EC_{50}
		360 µg/L	3400 µg/L	64830 µg/L
RAC		**3.6 µg/L**	**34 µg/L**	**6483 µg/L**
Asessment factor**		100	100	10
FOCUS Step 1	1.99	1.99	1.99	1.99

*[Only scenarios where the trigger is not met at FOCUSsw step 1-2 should be included in step 3.]
**[If the Trigger value has been adjusted during the risk assessment, it should always be clear on what basis the risk assessment has been performed, i.e. what the AF value is and for which organism and endpoint it refers.]
values in **bold** exceed the relevant RAC, indicating an unacceptable risk

$FOCUS_{sw}$ step 1 – PEC/RAC comparisons for RPA 406203 – Spring Cereals (BBCH 00) at 12.5 g ai/ha

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Scenario	**PEC global max (µg L)**	**fish acute**	**Aquatic invertebrates**	**Algae**
		Oncrhynchus mykiss	*Daphnia magna*	*Pseudokirchneriella subcapitata*
		LC_{50}	EC_{50}	EC_{50}
		360 µg/L	3400 µg/L	64830 µg/L
RAC		**3.6 µg/L**	**34 µg/L**	**6483 µg/L**
Asessment factor**		100	100	10
FOCUS Step 1	1.99	1.99	1.99	1.99

*[Only scenarios where the trigger is not met at FOCUSsw step 1-2 should be included in step 3.]

**[If the Trigger value has been adjusted during the risk assessment, it should always be clear on what basis the risk assessment has been performed, i.e. what the AF value is and for which organism and endpoint it refers.]

values in **bold** exceed the relevant RAC, indicating an unacceptable risk

$FOCUS_{sw}$ step 1 – PEC/RAC comparisons for Met 6 – Winter Cereals (BBCH 00) at 12.5 g ai/ha

Scenario	**PEC global max (µg L)**	**fish acute**	**Aquatic invertebrates**	**Algae**
		Oncrhynchus mykiss	*Daphnia magna*	*Pseudokirchneriella subcapitata*
		LC_{50}	EC_{50}	EC_{50}
		377 µg/L	823 µg/L	55.5 µg/L
RAC		**3.77 µg/L**	**8.23 µg/L**	**5.55 µg/L**
Asessment factor**		100	100	10
FOCUS Step 1	0.41	0.41	0.41	0.41

*[Only scenarios where the trigger is not met at FOCUSsw step 1-2 should be included in step 3.]

**[If the Trigger value has been adjusted during the risk assessment, it should always be clear on what basis the risk assessment has been performed, i.e. what the AF value is and for which organism and endpoint it refers.]

values in **bold** exceed the relevant RAC, indicating an unacceptable risk

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product **(Name)**
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FOCUS$_{sw}$ step 1 – PEC/RAC comparisons for Met 6 – Spring Cereals (BBCH 00) at 12.5 g ai/ha

Scenario	**PEC global max (µg L)**	**fish acute**	**Aquatic invertebrates**	**Algae**
		Oncrhynchus mykiss	*Daphnia magna*	*Pseudokirchneriella subcapitata*
		LC_{50}	EC_{50}	EC_{50}
		377 µg/L	823 µg/L	55.5 µg/L
RAC		**3.77 µg/L**	**8.23 µg/L**	**5.55 µg/L**
Asessment factor**		100	100	10
FOCUS Step 1	0.41	0.41	0.41	0.41

*[Only scenarios where the trigger is not met at FOCUSsw step 1-2 should be included in step 3.]

**[If the Trigger value has been adjusted during the risk assessment, it should always be clear on what basis the risk assessment has been performed, i.e. what the AF value is and for which organism and endpoint it refers.]

values in **bold** exceed the relevant RAC, indicating an unacceptable risk

FOCUS$_{sw}$ step 1 – PEC/RAC comparisons for Met 7 – Winter Cereals (BBCH 00) at 12.5 g ai/ha

Scenario	**PEC global max (µg L)**	**fish acute**	**Aquatic invertebrates**	**Algae**
		Oncrhynchus mykiss	*Daphnia magna*	*Pseudokirchneriella subcapitata*
		LC_{50}	EC_{50}	EC_{50}
		357 µg/L	778 µg/L	52.5 µg/L
RAC		**3.57 µg/L**	**7.78 µg/L**	**5.25 µg/L**
Asessment factor**		100	100	10
FOCUS Step 1	0.19	0.19	0.19	0.19

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Rapporteur Member State	Month and year	Active substance and Plant Protection Product **(Name)**
AT	**July 2018**	**Triticonazole**

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*[Only scenarios where the trigger is not met at FOCUSsw step 1-2 should be included in step 3.]
**[If the Trigger value has been adjusted during the risk assessment, it should always be clear on what basis the risk assessment has been performed, i.e. what the AF value is and for which organism and endpoint it refers.]
values in **bold** exceed the relevant RAC, indicating an unacceptable risk

FOCUS$_{sw}$ step 1-2 – PEC/RAC comparisons for Met 7 – Spring Cereals (BBCH 00) at 12.5 g ai/ha

Scenario	**PEC global max (µg L)**	**fish acute**	**Aquatic invertebrates**	**Algae**
		Oncrhynchus mykiss	*Daphnia magna*	*Pseudokirchneriella subcapitata*
		LC_{50}	EC_{50}	EC_{50}
		357 µg/L	778 µg/L	52.5 µg/L
RAC		**3.57 µg/L**	**7.78 µg/L**	**5.25 µg/L**
Asessment factor**		100	100	10
FOCUS Step 1	0.19	0.19	0.19	0.19

*[Only scenarios where the trigger is not met at FOCUSsw step 1-2 should be included in step 3.]
**[If the Trigger value has been adjusted during the risk assessment, it should always be clear on what basis the risk assessment has been performed, i.e. what the AF value is and for which organism and endpoint it refers.]
values in **bold** exceed the relevant RAC, indicating an unacceptable risk

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (**Name**)
AT	**July 2018**	**Triticonazole**

Section 5 Ecotoxicology

Effects on bees (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.1 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.1)*

* This section does reflect the new EFSA Guidance Document on bees which has not yet been noted by the Standing Committee on Plants, Animals, Food and Feed.

Species	Test substance	Time scale/type of endpoint	End point	toxicity
Apis mellifera	a.s.	Acute	Oral toxicity (LD_{50})	**> 155.5** µg ai/bee
Apis mellifera	a.s.	Acute	Oral toxicity (LD_{50})	> 96.26 µg ai/bee
Apis mellifera	Preparation Premis 25 FS	Acute	Oral toxicity (LD_{50})	3287.54 µg prep./bee (**76.74** µg ai/bee)
Apis mellifera	a.s.	Acute	Contact toxicity (LD_{50})	**> 100** µg ai/bee
Apis mellifera	a.s.	Acute	Contact toxicity (LD_{50})	> 100 µg ai/bee
Apis mellifera	Preparation Premis 25 FS	Acute	Contact toxicity (LD_{50})	>856.8 µg prep./bee (**> 20** µg ai/bee)
Apis mellifera	Preparation Premis 25 FS	Chronic	10 d LDD_{50} 10 d NOED 10 d LC_{50} 10 d NOEC	**12.9** µg/bee/day 8.0 µg ai/bee/day 674.2 mg ai/kg food 312.5 mg ai/kg food
		Sub-lethal effects (behavioural and reproductive)	NOEC hypopharyngeal glands	No data
Apis mellifera	Preparation Premis 25 FS	Bee brood development*	LD_{50} larvae NOED larvae LC_{50} larvae NOEC larvae	**85.6** µg ai/larva 28.8 µg ai/larva/developmental period 2.526 g ai/kg food 0.731 g ai/kg food
Apis mellifera	a.s.	Sub-lethal effects (behavioural and reproductive)	NOEC hypopharyngeal glands	No data

* Note: study duration was 8 d and did not include pupae emergence

Potential for accumulative toxicity: No data
Semi-field test (Cage and tunnel test): Not required
Field tests: Not required

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Risk assessment for – Cereals at BBCH00 at 12.5 g ai/ha [single application]

Species	Test substance	Risk quotient	HQ/ETR	Trigger
Apis mellifera	a.s.	HQ contact	< 0.01	14
Apis mellifera	a.s.	ETRacute adult oral	< 0.001	0.2
Apis mellifera	Preparation Premis 25 FS	HQ contact	< 0.06	14
Apis mellifera	Preparation Premis 25 FS	ETRacute adult oral	0.001	0.2
Apis mellifera	Preparation Premis 25 FS	ETRchronic adult oral	0.002	0.03
Apis mellifera	Preparation Premis 25 FS	ETRlarvae	0.00	0.2
Apis mellifera	Preparation Premis 25 FS	ETRdrinking water sw acute	0.00	0.2
Apis mellifera	Preparation Premis 25 FS	ETRdrinking water sw chronic	0.00	0.03
Apis mellifera	Preparation Premis 25 FS	ETRdrinking water sw larvae	0.00	0.2
Apis mellifera	Preparation Premis 25 FS	ETRdrinking water puddle acute	0.00	0.2
Apis mellifera	Preparation Premis 25 FS	ETRdrinking water puddle chronic	0.00	0.03
Apis mellifera	Preparation Premis 25 FS	ETRdrinking water puddle larvae	0.00	0.2
Apis mellifera	Preparation Premis 25 FS	ETRdrinking water guttation acute	0.00	0.2
Apis mellifera	Preparation Premis 25 FS	ETRdrinking water guttation chronic	0.00	0.03
Apis mellifera	Preparation Premis 25 FS	ETRdrinking water guttation larvae	0.00	0.2

Risk assessment for – Cereals at BBCH00 at 0.0032 mg ai/seed* [single application]

Species	Test substance	Risk quotient	HQ/ETR	Trigger
Apis mellifera	a.s.	ETRacute adult oral	< 0.001	0.2

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Apis mellifera	Preparation Premis 25 FS	ETRacute adult oral	0.001	0.2
Apis mellifera	Preparation Premis 25 FS	ETRchronic adult oral	0.0001	0.03
Apis mellifera	Preparation Premis 25 FS	ETRlarvae	0.00	0.2

*Overall minimum and maximum thousand grain weight values of all intended cereals: 21-64 g

Risk assessment for – Cereals at BBCH00 at 0.00105 mg ai/seed* [single application]

Species	Test substance	Risk quotient	HQ/ETR	Trigger
Apis mellifera	Preparation Premis 25 FS (0.00105 mg ai/seed)	ETRacute adult oral	< 0.001	0.2
Apis mellifera	Preparation Premis 25 FS	ETRacute adult oral	0.001	0.2
Apis mellifera	Preparation Premis 25 FS	ETRchronic adult oral	0.0001	0.03
Apis mellifera	Preparation Premis 25 FS	ETRlarvae	0.00	0.2

*Overall minimum and maximum thousand grain weight values of all intended cereals: 21-64 g

Effects on other arthropod species (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.2)

Laboratory tests with standard sensitive species

Species	Test Substance	End point	Toxicity
No relevant studies available			

First tier risk assessment for – Cereals at 12.5 g ai/ha [single application]

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[1]	Trigger
Not applicable					

Extended laboratory tests, aged residue tests

Species	Life stage	Test substance, substrate	Time scale	Dose (g/ha)[1,2]	End point	% effect[3]	ER_{50}
Poecilus cupreus	larvae	BAS 595 01 F, exposure to treated wheat seeds in soil		7.5 g ai/ha	Mortality, reproduction	-5.6, 0.4	> 7.5 g ai/ha

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Species	Life stage	Test substance, substrate	Time scale	Dose (g/ha)[1,2]	End point	% effect[3]	ER_{50}
Poecilus cupreus	larvae	BAS 595 01 F exposure to treated wheat seeds in soil		11.65 g ai/ha	Mortality, reproduction	-5.6, 1.3	> 11.65 g ai/ha
Aleochara bilineata	adult	BAS 595 01 F exposure to treated wheat seeds in soil		9.6 g ai/ha	reproduction	-6.5	> 9.6 g ai/ha

[1] indicate whether initial or aged residues
[2] for preparations indicate whether dose is expressed in units of a.s. or preparation
[3] positive percentages relate to adverse effects

Risk assessment for – cereals at 12.5 g a.s./ha [single applications] based on extended lab tests

Standard risk assessment is not applicable for seed treatments.

Non-target arthropods may be exposed to formulated triticonazole by contact with treated seeds in soil. The concentrations tested do not cover the intended application rate of 12.5 g ai/ha. However, the LR_{50} and ER_{50} values estimated by the studies are > values. Observed effects are all less than 10% or even positive.

Semi-field tests
Not required
Field studies
Not required
Additional specific test
Not required

Effects on non-target soil meso- and macro fauna; effects on soil nitrogen transformation (Regulation (EU) N° 283/2013, Annex Part A, points 8.4, 8.5, and Regulation (EU) N° 284/2013 Annex Part A, points 10.4, 10.5)

Test organism	Test substance	Application method of test a.s./ OM[1]	Time scale	End point	Toxicity
Earthworms					
Eisenia fetida	a.s.	Incorporation/OM 10%	Chronic, 56 d	Reproduction	$NOEC_{corr}$ = **125** mg ai/kg d.w.soil
Eisenia fetida	Preparation Premis 25 FS	Incorporation/OM 5%	Chronic, 56 d	Reproduction	5.7 mg prep./kg soil dw (0.1328 mg ai/kg soil dw)
Eisenia fetida	Metabolite RPA 404766	Incorporation/OM 10%	Chronic, 56 d	Mortality, Growth, Reproduction	NOEC = 250 mg/kg d.w.soil

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Test organism	Test substance	Application method of test a.s./ OM[1]	Time scale	End point	Toxicity
Eisenia fetida	Metabolite RPA 407922	Incorporation/OM 10%	Chronic, 56 d	Reproduction	NOEC = 125 mg/kg d.w.soil
Eisenia fetida	Metabolite RPA 406341	Incorporation/OM 5%	Chronic, 56 d	Reproduction	$NOEC_{corr}$ = 5 mg/kg d.w.soil
Other soil macroorganisms					
Folsomia candida	a.s.	Incorporation/OM 5%	Chronic, 28 d	Mortality	$NOEC_{corr}$ = 62.5 mg ai/kg d.w.soil
Folsomia candida	Preparation Premis 25 FS	Incorporation/OM 10%	Chronic, 28 d	Mortality, Growth, Reproduction	500 mg prep./kg soil dw (12.2 mg ai/kg soil dw)
Folsomia candida	Metabolite RPA 404766	Incorporation/OM 5%	Chronic, 28 d	Mortality, Growth, Reproduction	NOEC = 500 mg/kg d.w.soil
Folsomia candida	Metabolite RPA 407922	Incorporation/OM 5%	Chronic, 28 d	Mortality, Growth, Reproduction	NOEC = 250 mg/kg d.w.soil
Folsomia candida	Metabolite RPA 406341	Incorporation/OM 5%	Chronic, 28 d	Mortality, Growth, Reproduction	$NOEC_{corr}$ = 25 mg/kg d.w.soil
Hypoaspis aculeifer	a.s.	Incorporation/OM 5%	Chronic, 14 d	Reproduction	$NOEC_{corr}$ = 250 mg ai/kg d.w.soil
Hypoaspis aculeifer	Preparation Premis 25 FS	Incorporation/OM 5%	Chronic, 14 d	Mortality, Growth, Reproduction	14 d NOEC = 500 mg prep./kg soil dw (11.7 mg ai/kg soil dw)
Hypoaspis aculeifer	Metabolite RPA 406341	Incorporation/OM 5%	Chronic, 14 d	Mortality, Growth, Reproduction	$NOEC_{corr}$ = 5 mg/kg d.w.soil

[1]To indicate whether the test substance was oversprayed/to indicate the organic content of the test soil (e.g. 5 % or 10 %).

Higher tier testing (e.g. modelling or field studies): not required

Nitrogen transformation	Preparation Premis 25 FS	28 d	+10% effect at day 28 at 7.13 mg prep./kg d.w. soil (0.167 mg ai/kg d.w.soil)
Nitrogen transformation	Metabolite RPA 404766	42 d	24.8% effect at day 42 at 1 mg/kg d.w.soil
Nitrogen transformation	Metabolite RPA 407922	28 d	+3.5% effect at day 28 at 1 mg/kg d.w.soil
Nitrogen transformation	Metabolite RPA 406341	28 d	12.33% effect at day 28 at 10 mg/kg d.w.soil

+…increase of nitrogen transformation

Toxicity/exposure ratios for soil organisms

Cereals at 12.5 g ai/ha [single application]

Test organism	Test substance	Time scale	Soil PEC[1] [mg/kg soil dw]	TER	Trigger
Earthworms					
Eisenia fetida	a.s.	Chronic	0.0189	6614	5
	Preparation Premis 25 FS	Chronic	0.0189	7.03	5
	Metabolite RPA 404766	Chronic	0.0027	> 10000	5
	Metabolite RPA 406341	Chronic	0.0037	1351	5
	Metabolite MET 6[2]	Chronic	0.0022	> 10000	5
	Metabolite MET 7[3]	Chronic	0.0010	> 10000	5
Other soil macroorganisms					
Folsomia candida	a.s.	Chronic	0.0189	3307	5
	Preparation Premis 25 FS	Chronic	0.0189	646	5
	Metabolite RPA 404766	Chronic	0.0027	> 10000	5
	Metabolite RPA 406341	Chronic	0.0037	6757	5
	Metabolite MET 6[2]	Chronic	0.0022	> 10000	5
	Metabolite MET 7[3]	Chronic	0.0010	> 10000	5
Hypoaspis aculeifer	a.s.	Chronic	0.0189	> 10000	5
	Preparation Premis 25 FS	Chronic	0.0189	619	5
	Metabolite RPA 404766	Chronic	0.0027	9630	5
	Metabolite RPA 406341	Chronic	0.0037	1351	5
	Metabolite MET 6[2]	Chronic	0.0022	> 10000	5
	Metabolite MET 7[3]	Chronic	0.0010	> 10000	5

[1] $PEC_{accumulation}$

[2] No toxicity study available - calculated by considering the molecular weight of the metabolite of 333 g/mol and assuming 10-times more toxicity than the parent

[3] No toxicity study available - calculated by considering the molecular weight of the metabolite of 315 g/mol and assuming 10-times more toxicity than the parent

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Effects on terrestrial non target higher plants (Regulation (EU) N° 283/2013, Annex Part A, point 8.6 and Regulation (EU) N° 284/2013 Annex Part A, point 10.6)

According to the data requirements for active substances (Commission Regulation (EU) 283/2013) and/or plant protection products (Commission Regulation (EU) 284/2013) no testing on non-target terrestrial plants is necessary for seed treatments.

Effects on biological methods for sewage treatment (Regulation (EU) N° 283/2013, Annex Part A, point 8.8)

Test type/organism	end point
Activated sludge	3 h EC_{50} > 100 mg ai/L
Pseudomonas sp	Not required

Monitoring data (Regulation (EU) N° 283/2013, Annex Part A, point 8.9 and Regulation (EU) N° 284/2013, Annex Part A, point 10.8)

Available monitoring data concerning adverse effect of the a.s.
No data available
Available monitoring data concerning effect of the PPP.
No data available

Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2) Ecotoxicologically relevant compounds[1]

Compartment	
soil	Parent triticonazole
water	Parent triticonazole
sediment	Parent triticonazole
groundwater	Parent triticonazole

[1] metabolites are considered relevant when, based on the risk assessment, they pose a risk comparable or higher than the parent

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Section 5 Ecotoxicology

Classification and labelling with regard to ecotoxicological data (Regulation (EU) N° 283/2013, Annex Part A, Section 10)

Substance	Triticonazole
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended][7]:	H400/H410
Peer review proposal[8] for harmonised classification according to Regulation (EC) No 1272/2008:	H400/H410 Acute category 1: E_rC_{50} 0.46 mg ai./L *(Skeletonema costatum)* , i.e. < 1 mg/L Chronic category 1: Not readily biodegradable, not rapidly degradable (DT_{50} water/sediment > 16 days), no data on metabolites NOEC = 0.0114 mg ai/L (*Oncorhynchus mykiss)*, i.e. < 0.1 mg a.s./L for not rapidly degradable substances M-factor: Acute: 1 Chronic: 1

[7] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

[8] It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

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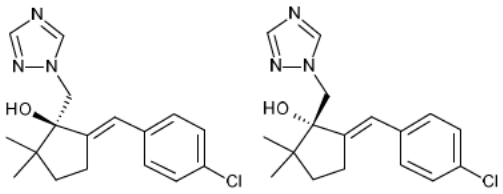
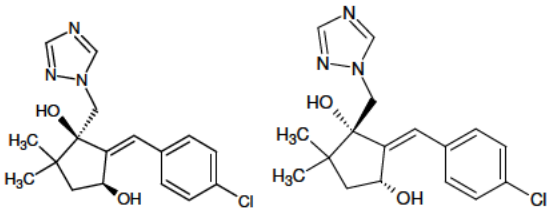
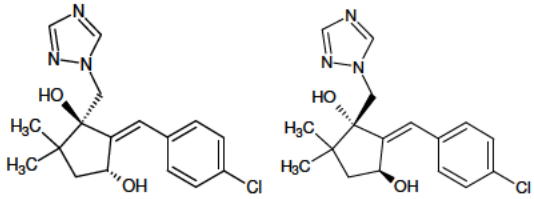
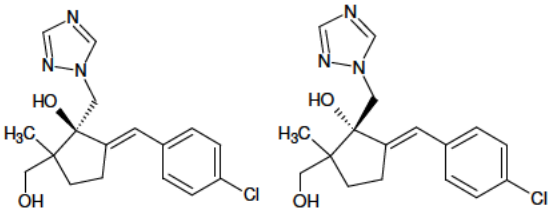
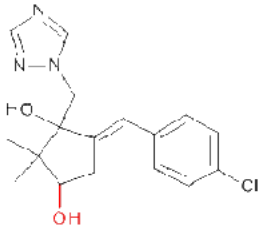
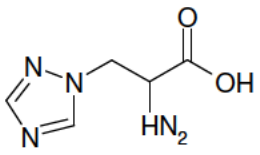
Appendix

Used compounds code(s)

Code/Trivial name*	IUPAC name/SMILES notation	Structural formula
Triticonazole (a.i.) Further codes: BAS 595 F, RPA 400727, M595F000	(1RS, 5E)-5-(4-chlorobenzylidene)-2,2-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl) cyclopentanol	
RPA 404766 **(Cis-diol)** Further codes: Beta-hydroxy-triticonazole, **M595F001**, **R2**, AE 0591653, Reg. Nr. 5079285)	(1RS,2E,3RS)-2-(4-chlorobenzylidene)-5,5-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl)-1,3-cyclopentanediol	
RPA 406341 **(Trans-diol)** Further codes: Alpha-hydroxy-triticonazole, **M595F002**, AE 0540093, Reg. Nr. 5059144	(1RS,2E,3SR)-2-(4-chlorobenzylidene)-5,5-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl)-1,3-cyclopentanediol	
RPA 404886 Further codes: **M595F005, R4**, Reg. Nr. 5079247	(1RS,5E)-5-(4-chlorobenzylidene)-2-(hydroxymethyl)-2-methyl-1-(1H-1,2,4-triazol-1-ylmethyl) cyclopentanol	
RPA 406780 Further codes: **M595F007**, **R5**, Reg. Nr. 5079286	(1SR,3RS,5E)-5-(4-chlorobenzylidene)-2,2-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentane-1,3-diol	 (four isomers)
Triazole alanine Further codes: **R9**, Reg. Nr. 270412	2-amino-3-(1H-1,2,4-triazol-1-yl)propionic acid	

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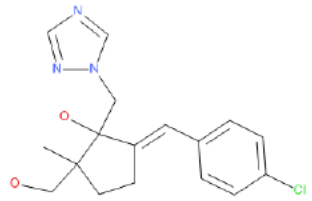
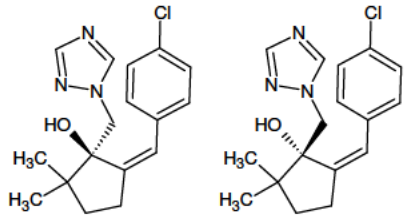
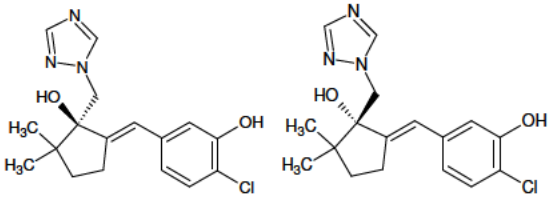
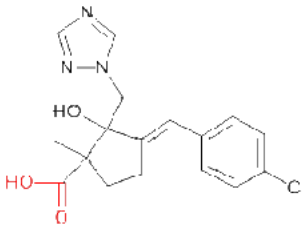
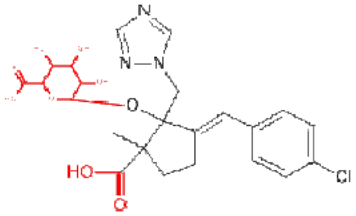
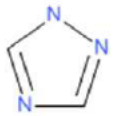
RPA 405826	(5E)-5-(4-chlorobenzylidene)-2-hydroxymethyl-2-methyl-1-(1H-1,2,4-triazol-1-ylmethyl)-cyclopentanol	
RPA 406203 **Z-isomer** Further codes: **M595F014**, photo-metabolite, Reg. No. 5079359	(1RS, 5Z)-5-(4-chlorobenzylidene)-2,2-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl) cyclopentanol	
RPA 407922 Further codes: **M595F013**, **R1**, Reg. Nr. 5079288	2-chloro-5-{(E)-[(2RS)-2-hydroxy-3,3-dimethyl-2-(1H-1,2,4-triazol-1-ylmethyl)cyclopentylidene]methyl}phenol	
RPA 406972 Further codes: **M595F0006**, Reg. Nr. 5079450		
M595F010		
1,2,4-triazole Further codes: **M595F009**, AE C500859, Reg. Nr. 87084	1,2,4-(1H)-triazole	

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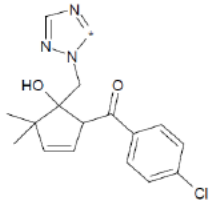
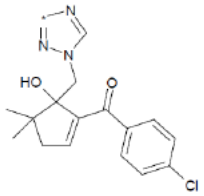
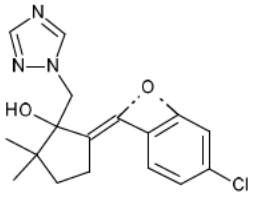
M595F004 (structure tentative)		 Or isomer 
M595F015 (structure tentative)		
Metabolite fraction 'Met 6 (MWT 333)'		Unidentified
Metabolite fraction 'Met 7 (MWT 315)'		Unidentified

* The compound code / trivial name in bold is the name used in the list of endpoints.