Annex 15 Report
Proposal for identification of a substance of very high concern (SVHC)

Bumetrizole (UV-326)

EC Number: 223-445-4

CAS Number: 3896-11-5

July 2026

Contents

1. Proposal

Substance name: Bumetrizole (UV-326)

EC number: 223-445-4

CAS number: 3896-11-5

Bumetrizole (2-tert-butyl-6-(5-chloro-2H-benzotriazol-2-yl)-4 methylphenol), which is also known as UV-326, has been identified as a substance of very high concern (SVHC) in accordance with the requirements set out in Annex 15 of EU REACH (ECHA, 2023a). This is based on the substance fulfilling the very persistent and very bioaccumulative (vPvB) criteria under Annex 13 of EU REACH.

This technical report provides an independent scientific assessment by the Agency[1] on whether UV-326 should be identified as an SVHC under UK REACH. It considers only studies presented in the equivalent document produced by the European Chemicals Agency (ECHA) i.e., the EU Member State Committee (MSC) support document (ECHA, 2023b). Relevant observations on studies made in the EU MSC support document have been summarised and Agency comments have been added where appropriate. Unpublished study reports were generally not available and have not been examined, unless stated otherwise. A literature search was not performed because the existing information is considered to be sufficient for decision making.

It is proposed to identify UV-326 as vPvB according to Article 57(e) of UK REACH.

Summary of how the substance meets the criteria set out in Article 57 of UK REACH

A weight-of-evidence determination according to the provisions of Annex 13 of UK REACH has been used to identify UV-326 as vPvB.

Persistence

UV-326 screens as potentially P/vP based on the results of the ready biodegradability studies where < 20% degradation was observed. The freshwater sediment degradation DT_{50} value for UV-326 was > 100 days at 20°C in a non-standard aerobic river water/sediment simulation study which generally followed Organisation for Economic Cooperation and Development (OECD) Test Guideline (TG) 308. This is extrapolated to > 212 days at 12°C, which exceeds the very persistent (vP) criterion of Annex 13 of UK REACH for freshwater sediment (half-life > 180 days). The conclusion is supported by:

[1]The Health and Safety Executive (HSE) acting in its capacity as the Agency for UK REACH, and with support from the Environment Agency in accordance with Article 2B of UK REACH.

- Read-across from the freshwater pond whole system DT_{50} value (278 days at 12°C; OECD TG 308) for M1 (a transformation product of UV-384). M1 is structurally very similar to UV-326 so is expected to have similar fate and behaviour properties.
- Sediment core data that indicate the presence of UV-326 over several decades under the environmental conditions prevalent in these sediments.
- Monitoring evidence that UV-326 degrades slowly in agricultural soil following its application via sewage sludge (estimated DT_{50} values from 81 to 155 days).

The Agency concludes from the weight of evidence available that UV-326 fulfils the P and vP criteria of Annex 13 of UK REACH.

Bioaccumulation

UV-326 screens as potentially B/vB as experimental log K_{OW} values ranged from ≥ 6.5 to 7.38. The lipid normalised BCF values for UV-326 determined from a study conducted to OECD TG 305 ranged from 6355 to 14255 L/kg depending how the value was determined (BCF_{SS} or BCF_k, test solutions uncentrifuged or centrifuged). All values were greater than the criteria for identification as vB (BCF > 5,000).

The Agency concludes that UV-326 fulfils the B and vB criteria of Annex 13 of UK REACH.

Conclusion

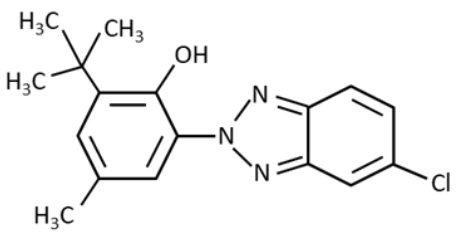
Based on the information available, the Agency concludes that UV-326 fulfils the vPvB criteria of Annex 13 of UK REACH and can therefore be identified as an SVHC in accordance with Article 57(e) of UK REACH.

2. Justification

2.1 Identity of the substance and physical and chemical properties

2.1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	223-445-4
EC name:	Bumetrizole
SMILES[a]:	Oc(c(cc(c1)C)C(C)(C)C)c1n(nc(c2cc(c3)Cl)c3)n2
CAS number:	3896-11-5
IUPAC[b] name:	2-*tert*-butyl-6-(5-chloro-2H-benzotriazol-2-yl)-4-methylphenol
Index number in GB Mandatory Classification and Labelling (MCL) List[c]:	No mandatory classification
Molecular formula:	$C_{17}H_{18}ClN_3O$
Molecular weight range:	315.8 g/mol
Synonyms:	2-(2'-hydroxy-3'-t-butyl-5'-methylphenyl)-5- chlorobenzotriazole 2-(2'-hydroxy-3-*tert*-butyl-5-methylphenyl)-5-chloro-2H-benzotriazole 2-(5-chloro-2-benzotriazolyl)-6-*tert*-butyl-p-cresol 2-(5-chloro-2H-benzotriazol-2-yl)-6-(1,1- dimethylethyl)-4-methylphenol 2-*tert*-butyl-6-(5-chloro-2H-benzotriazol-2-yl)-p-cresol UV-326
Structural formula:	

[a] SMILES: Simplified Molecular Input Line Entry System
[b] IUPAC: International Union of Pure and Applied Chemistry
[c] GB MCL list in accordance with the retained Regulation (EC) No 1272/2008 as amended for Great Britain

2.1.2 Composition of the substance

Substance type: mono-constituent

Table 2: Constituents other than impurities/additives

Constituents	Typical concentration
UV-326	≤ 100%

Impurities and/or additives are not relevant for SVHC identification of the substance.

2.1.3 Identity and composition of transformation products relevant for the SVHC assessment

No transformation products were considered in the EU MSC support document.

The Agency does not consider it necessary to consider transformation products due to the findings for the parent compound.

2.1.4 Identity and composition of structurally related substances (used in grouping or read-across approach)

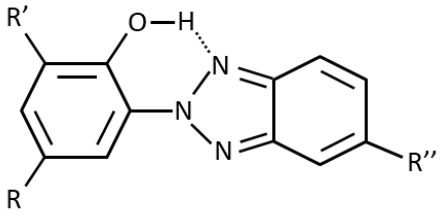
UV-326 is part of a group of substances that have a 2-(2-hydroxyphenyl)-2H-benzotriazole moiety as a common structural feature (

Figure 1). These substances are collectively called phenolic benzotriazoles, or UV-benzotriazoles.

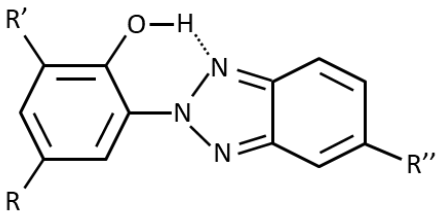


Figure 1: General structure of phenolic benzotriazoles

The 2-(2-hydroxyphenyl)-2H-benzotriazole moiety is associated with high stability and lipophilicity leading to low water solubility and a high adsorption potential. Alkyl substituents are generally considered to increase lipophilicity and reduce water solubility,

with larger substituents leading to higher lipophilicity. Substituents in the ortho position to the hydroxy group also provide steric stabilisation to the intramolecular hydrogen bond, and an absence of substituents at the phenyl moiety might enable enzymatic attacks at those sites.

UV-326 is similar in structure to UV-320, UV-327, UV-328, and UV-350 (Figure 2) which have already been identified as SVHCs due to their vPvB properties in either 2014 or 2015 when the United Kingdom was a member state of the EU. UV-326 is most similar structurally to UV-327.

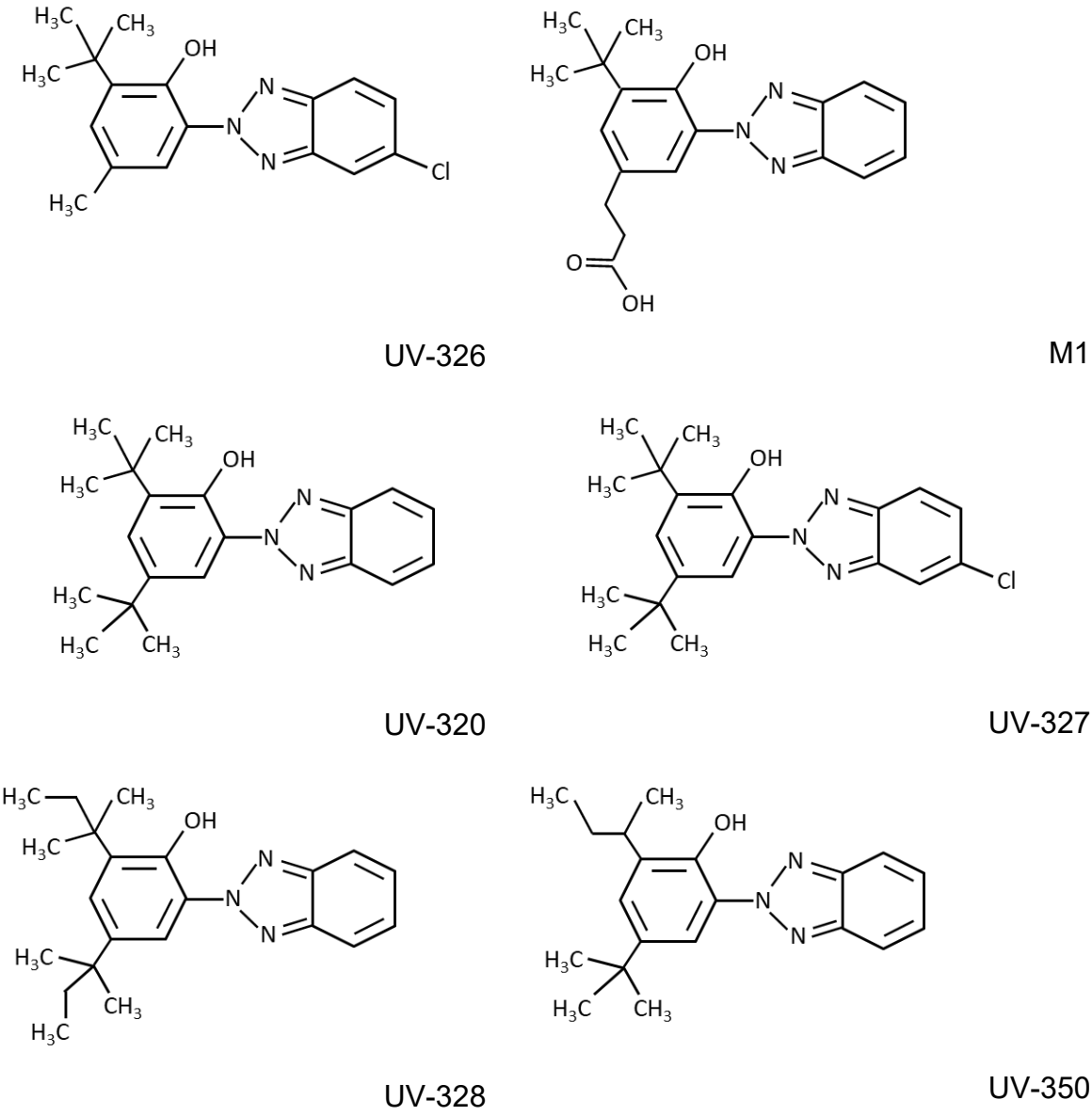
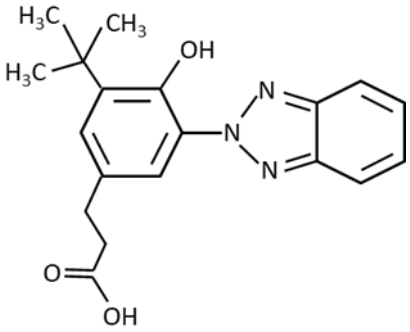


Figure 2: Structures of phenolic benzotriazoles relevant to this assessment

The persistence assessments of UV-320, UV-327, UV-328, and UV-350 all rely to some extent on read-across from a metabolite of UV-384 named M1 (EC no. 630-348-4). The

physicochemical properties of M1 are summarised in Appendix A (Table A 1). M1 has two functional groups that could ionise: the hydroxyl group and the carboxyl group. The hydroxyl group is stabilised in a similar way to UV-326 so dissociation is unlikely. The carboxyl group is noted to dissociate in the environmentally relevant pH range of pH 4–9 and, with a pK_a of 4.25, will mainly be present in its ionised (carboxylate) form.

Table 3: Identity of structurally related substance M1

EC number:	630-348-4
EC name:	3-[3-(2H-benzotriazol-2-yl)-5-*tert*-butyl-4-hydroxyphenyl]propanoic acid
SMILES:	CC(C)(C)c1cc(CCC(O)=O)cc(n2nc3ccccc3n2)c1O
CAS number:	84268-36-0
IUPAC name:	3-[3-(2H-benzotriazol-2-yl)-5-*tert*-butyl-4-hydroxyphenyl]propanoic acid
Index number in GB MCL List:	No mandatory classification
Molecular formula:	$C_{19}H_{21}N_3O_3$
Molecular weight range:	339.39 g/mol
Synonyms:	3-(2H-benzotriazol-2-yl)-5-(1,1-dimethylethyl)-4-hydroxybenzenepropanoic acid M1
Structural formula:	

2.1.5 Physicochemical properties

Physicochemical property information for UV-326 from the EU registration dossier[2] are summarised in Table 4. The data are considered to be reliable or reliable with restrictions

[2] ECHA Chemicals database; ECHA CHEM https://chem.echa.europa.eu/

by the EU registrants, but the Agency has not been able to independently verify the reliability of this information.

Table 4: Overview of physicochemical properties of UV-326 from the EU registration dossier

Property	Value
Physical state at 20°C and 101.3 kPa	Solid, slightly yellow powder
Melting/freezing point (°C)	137–141
Boiling point (°C)	> 225
Vapour pressure (Pa at 20°C)	7.5×10^{-7}
Density (kg/m^3 at 20°C)	1,320
Water solubility (µg/L at 20°C)	4 (pH 6.3)
n-Octanol–water partition coefficient (log K_{OW})	5.4 to 7.38
Acid dissociation constant (pK_a)	10 to 10.2 (estimated values)

The pK_a values indicate that UV-326 will not be ionised at environmentally relevant pH values.

2.2 Mandatory classification and labelling

UV-326 is not listed on the GB mandatory classification and labelling (MCL) list nor on Annex 6 of Regulation (EC) No 1272/2008.

2.3 Environmental fate properties

2.3.1 Degradation

2.3.1.1 Abiotic degradation

The information on abiotic degradation presented in the EU MSC support document is summarised in Table 5.

Table 5: Summary of abiotic degradation data

Abiotic degradation process	Information presented	Results / conclusions
Hydrolysis	No experimental data Outside the applicability domain of estimation models	UV-326 does not contain functional groups susceptible to hydrolysis
Oxidation	No data	-
Phototransformation	No data	-

2.3.1.2 Biodegradation

2.3.1.2.1 Biodegradation in aqueous media

2.3.1.2.1.1 Screening tests

Three ready biodegradability screening tests for UV-326 are presented in the EU MSC support document. All were reported as reliable or reliable with restrictions (Klimisch score 1 or 2) by the registrant in the EU REACH registration dossier. Results are summarised in Table 6 and all three indicate that UV-326 is not readily biodegradable.

Table 6: Summary of screening test results for UV-326 presented in the EU MSC support document

Author / year	Study type	Results
Unpublished report (2007)	OECD TG 301B Klimisch score 2	Observed CO_2 evolution after 28 days was between 10 and 20% (test concentration 16 mg/L).
Unpublished report (1996)	OECD TG 301C Klimisch score 1	0% degradation was observed after 28 days by BOD measurement (100 mg/L test concentration).
Unpublished report (1988)	OECD TG 301B Klimisch score 2	10% and 2% CO_2 evolution were determined after 28 days (test concentrations of 10 and 20 mg/L respectively).

2.3.1.2.1.2 Biodegradation studies (simulation tests)

Three water/sediment simulation studies are included in the EU MSC support document (Table 7), which considered all three to be reliable with restrictions (Klimisch score 2).

Table 7: Summary of biodegradation data presented in the EU MSC support document

Author / year	Study type	Results
Wick *et al.* (2016a); Wick *et al.* (2016b)	Aerobic river water/sediment study (generally followed OECD TG 308) Klimisch score 2	No significant decrease of UV-326 concentration in the water/sediment system after 100 days. DT_{50} significantly greater than 100 days at 20°C (significantly greater than 212 days at 12°C).
Liu *et al.* (2013)	Examination of the dissipation of a mixture of UV filters in an aquifer system, not to GLP Klimisch core 2	Dissipation DT_{50}: 52.4 days (aerobic system) at 20°C
ECHA (2014)	Water/sediment study for UV-384; river and pond system (OECD TG 308) Klimisch score 2	DT_{50} values for the metabolite M1: River (aerobic): 3 days (water), 32 days (sediment) Pond (aerobic): 4 days (water), 248 days (sediment)

- Wick *et al.* (2016a); Wick *et al.* (2016b)

This aerobic river water/sediment study generally followed OECD TG 308 (OECD, 2002) with some deviations noted in the EU MSC support document:

- Only one sediment was used.
- The sampling site for the sediment was where previous contamination with organic chemicals was expected and therefore there was a possibility of pre-adaptation of micro-organisms.
- No volatiles were collected.

The EU MSC support document concluded that the deviations did not have a significant impact on the outcome of the test because the sediment chosen was appropriate, no degradation was observed, and recoveries were sufficient without volatile detection.

The Agency has examined the original literature reports and agrees with these conclusions, although also notes that the weight of the results would be strengthened if more than one sediment had been used in the study. UV-326 was rapidly adsorbed to the sediment and therefore the degradation DT_{50} value reported in Table 7 can be considered as a DT_{50} for sediment.

- Liu *et al.* (2013)

This study examined the dissipation of a mixture of ultraviolet (UV) filters in an aquifer system, including phenolic benzotriazoles but also substances more susceptible to degradation such as benzophenone-3. The authors of the study assumed that interaction effects were negligible although the EU MSC support document notes that co-metabolism could potentially occur. The EU MSC support document states that the study is reliable with restrictions but lists the following deviations from OECD TG 308:

- Only one sediment was tested a (coarse texture, low total organic carbon of 0.4%).
- The sediment was taken from 5 m below the ground surface.
- The sampled groundwater from a well nearby had a very low oxygen level (0.4 mg/L).
- The test system was small (5 g sediment and 5 mL of water), and the sediment water ratio deviated from the guideline recommendation.
- Detection of transformation products was not attempted.

The EU MSC support document observes that the fitting of the loss of UV-326 with Single First Order (SFO) kinetics to obtain a dissipation DT_{50} value was visually poor and attempted fitting with biphasic models. Fitting was visually better, but it concludes that 'no modelled DT_{50} is preferred'. The EU MSC support document states that several deviations from OECD TG 308 may have impacted study results and lists several factors that may have contributed towards the observed dissipation of UV-326.

The Agency used CAKE (Computer Aided Kinetic Evaluation) v3.7 to repeat the fitting of the data with SFO and Double First Order in Parallel (DFOP) kinetics and the results are presented in Appendix B in Table B 1 and Figure B 1. Fitting with DFOP kinetics was visually slightly improved compared to SFO kinetics, the chi^2 value was also slightly improved, but neither k_1 nor k_2 were statistically acceptable therefore biphasic kinetic fitting is not justified. The statistical fitting for SFO was acceptable according to the forum for the co-ordination of pesticide fate models and their use (FOCUS) kinetic guidance (FOCUS, 2014), and visual fitting was also acceptable. The SFO DT_{50} value reported by the authors from this study of 52.4 days at 20°C is equivalent to 111 days at 12°C using the Arrhenius equation and an activation energy of 65.4 KJ/mol.

The Agency notes that the DT_{50} from this study is a dissipation value and agrees that it should be treated with some caution given the deviations from the test guideline and the questionable relevance of the aquifer sediment.

- ECHA (2014)

The EU MSC support document only provides a short summary of this water/sediment study conducted to OECD TG 308 on EC no. 407-000-3 (UV-384) under aerobic

conditions because it is described in detail elsewhere (ECHA, 2014). The study investigated degradation of UV-384 in both a river and a pond system (aerobic conditions) and a pond system (anaerobic conditions) at a temperature of 20°C. The metabolite formed (M1) is structurally similar to UV-326 and dissipation half-lives were determined as part of the assessment of UV-328.

The EU MSC support document states that M1's susceptibility to degradation is similar or higher than that of UV-326 and concludes that UV-326 is expected to have comparable degradation behaviour to M1.

The Agency agrees that there is no clear reason from the structures of M1 and UV-326 to conclude that the rate of degradation of UV-326 would differ significantly from M1.

The Agency notes that the kinetic assessment for the formation and dissipation of M1 in this study is presented in the SVHC support document for UV-328 (ECHA, 2014). It is based on modelling the loss of parent (whole system) to M1 (water), M1 (sediment) or non-extractable residues (NER) with potential movement between M1 (water) and M1 (sediment). This approach to modelling parent and metabolite is inevitably complex and although good visual fits were obtained, some of the parameters are not statistically acceptable. It does not follow FOCUS kinetic guidance (FOCUS, 2014), which underlines the complexities involved for this level of modelling.

It is possible to model losses for parent and M1 to give whole system DT_{50} values. Given that M1 dissipates relatively quickly from the water phase, the whole system values could be used as a surrogate for degradation in the sediment. FOCUS kinetics guidance indicates that for deriving trigger endpoints for metabolites, the best fit kinetics for the parent should be used. Biphasic kinetics was found to give a better fit than SFO (see Table B 2 and Figure B 2) therefore DFOP kinetics were fitted to the parent. SFO kinetic fitting was used for the metabolite and combined fitting of parent and metabolite was acceptable (see Table B 3 and Figure B 3). The resulting whole system DT_{50} values for M1 at the study temperature of 20°C and adjusted to 12°C using the Arrhenius equation (E_a = 65.4 KJ/mol) are presented in Table 8.

Table 8: Whole system DT_{50} values for M1 in the river and pond aerobic systems from kinetic fitting by the Agency

System	DT_{50} (days)	
	20°C	12°C
River	48.9	104
Pond	131	278

2.3.1.2.1.3 Sediment core data

The EU MSC support document contains data for sediment cores from nine published studies, all given Klimisch score 2. A brief summary of the studies that included analysis of

UV-326 is presented in Table 9. The remaining studies only included analysis of structurally related substances. The EU MSC support document concludes that these studies provide indirect evidence that UV-326 can persist in sediments for several decades.

The Agency notes that the EU MSC support document does not report the redox conditions of the sediments and that the lack of degradation may be specifically related to the environmental conditions present. The Agency notes that anaerobic conditions are likely to be prevalent in the sediments and that REACH guidance recommends not to judge whether a substance has an environmental half-life exceeding the P and/or vP thresholds using only anaerobic simulation data. This is because generally it is expected that an anaerobic half-life would be greater than an aerobic half-life where the main route of degradation is aerobic. Therefore, this sediment core data is only used as supporting evidence.

Table 9: Sediment core data for UV-326 presented in the EU MSC support document

Author / year	Study type	Results
Peng *et al.* (2017)	Analysis of sediment cores from the Pearl river estuary, which is influenced by diffuse sources of pollution.	UV-326 found in sediments dating back several decades (1965 to 2004).
Cantwell *et al.* (2015)	Analysis of sediment cores from Salem Sound, an urban estuary influenced by benzotriazole production sites nearby	UV-326 found in sediments dating back several decades.
Cantwell *et al.* (2015)	Analysis of a sediment core from Narragansett Bay. Benzotriazole production nearby ceased in 1985.	UV-326 was detected in the core from 1961 and peaked in 1991
Reddy *et al.* (2000)	Analysis of a sediment core from Narragansett Bay and Pawtuxet River	UV-326 was present in both cores, reported in the Pawtuxet River core up to a depth of 20 cm, corresponding to 1979 to 1982

2.3.1.2.2 Biodegradation in soil

Two soil dissipation studies both considered reliable with restrictions are reported in the EU MSC support document and summarised in Table 10. The EU MSC support document notes some shortcomings with these two studies including:

- Initial concentrations in the dewatered sludge and after initial amendment were not reported.

- Limits of detection and quantification were quite high compared to some of the concentrations found in some applications.
- There was no information on NER values.
- There was a rise in concentrations in the winter and this data was not considered, reducing the data points for kinetic assessment.
- There was no inclusion of a substance with a known DT_{50} value as a reference.

The EU MSC support document states that the results can be regarded as a best case for disappearance as only the warmer period of the year is considered, micro-organism adaptation may have occurred as the biosolids were applied from 4 years before sampling, only dissipation was monitored, and NER was not considered.

Table 10: Summary of soil biodegradation data presented in the EU MSC support document

Author / year	Study type	Results
Lai *et al.* (2014a)	Dewatered sludge from a wastewater treatment plant in Beijing was applied to agricultural land in Shandong, China from 2007 to 2010. There was either a single treatment (T1) in 2007 or repeated treatments each year (T2) Klimisch score 2	DT_{50} values: 105 and 155 days for T1 and T2 respectively (fitting of data from March to October 2011)
Lai *et al.* (2014b)	Dewatered sludge from a wastewater treatment plant in Beijing was applied to agricultural land in Shandong, China from 2006 to 2010. Klimisch score 2	DT_{50} values 81 to 135 days (7 treatments)

- Lai *et al.* (2014a)

The Agency has examined the original literature report of this study. The concentration of UV-326 in the study was reported monthly for one year from October 2010. The data was quite variable, which is not unexpected for a biosolid amended soil. The data for the winter months to February 2011 showed an unexpected increase in concentrations, for which there was no clear explanation. DT_{50} values from the original study and reported in the EU MSC support document used the data from March to October 2011 in a 'dynamic fitting' process. The Agency repeated fitting for the mean data (triplicate data was not reported numerically) and obtained similar DT_{50} values for treatments T1 and T2 (105 and 155

days, respectively) to those reported in the study; the fitting was acceptable statistically and visually in both cases. A summary of the fittings is presented in the Appendix B in Table B 4 and Figure B 4. It is also possible to say that UV-326 was still present in the soil 5 years after the single treatment but as the initial concentration was not reported no further inference can be made. The Agency concludes that some caution needs to be applied to this study because of the unexplained increasing concentrations in the winter months and the lack of data on the concentration of UV-326 in the biosolids.

- Lai *et al.* (2014b)

The Agency has examined the original literature report of this study. The concentration data for UV-326 was reported monthly for one year from October 2010. The data was quite variable, which is not unexpected for a biosolid amended soil. Again, the data for the winter months to February 2011 showed an unexpected increase in concentrations, which the authors speculated could be due to release on breakdown of the biosolid. Only data from March 2011 was considered in the kinetic assessment. The Agency also notes that for several of the treatments the mean concentration values for April and July 2011 were close to or greater than the preceding month (Appendix B, Figure B 5); it is not clear if this could also be due to biosolid breakdown. The DT_{50} values for the 7 treatments were again obtained by the authors using a 'dynamic fitting' process. The Agency repeated fitting the mean data (triplicate data was not reported numerically) from March to October 2011 using SFO kinetics and this gave dissipation DT_{50} values similar to those reported in the study (Appendix B, Table B 5). The Agency concludes that some caution needs to be applied to these DT_{50} values because of the increasing concentrations in the winter months.

The single treatments (NT2-NT4) were applied in October 2010 while the equivalent multiple treatments (OT2-OT4) were applied for 5 consecutive years from October 2006. Although the data was quite variable, comparison of concentrations shows that the mean concentration was 1.5 to 2.2 times greater for the multiple applications (Table 11). This provides some evidence that degradation was slow enough to allow accumulation to occur, but this inference would depend on the concentration of UV-326 in the biosolid being consistent over the 5 years. Concentrations in the biosolids were not reported in the study and so this inference cannot be made with any confidence.

Table 11: Mean relative concentration (OT/NT) for treatments 2, 3, and 4

Treatments	Biosolid application (tonnes / ha)	Mean relative concentration (OT/NT) in the soil (Oct 2010 to Oct 2011)
OT2 / NT2	10	1.5
OT3 / NT3	20	1.7
OT4 / NT4	40	2.2

2.3.1.3 Summary and discussion of degradation

UV-326 screens as potentially P/vP based on the results of the ready biodegradability studies.

There was no degradation observed in a single river water/sediment system (Wick *et al*., 2016a; Wick *et al*., 2016b). The estimated degradation DT_{50} for sediment is > 212 days.

The whole system degradation half-lives of the structurally related substance M1 in two water/sediment systems were 104 and 278 days (at 12°C). UV-326 is similar in structure to M1, differing only in the para-substitution (methyl compared to carboxymethyl) and a chlorine substitution in the benzotriazole moiety. It is noted that this read-across to M1 has been used for the similar phenolic benzotriazoles UV-320, UV-327, UV-328 and UV-350 which have already been identified as SVHCs due to their vPvB properties in either 2014 or 2015 when the UK was a member state of the European Union.

There is contradictory evidence of degradation in an aquifer sediment/water system (Liu *et al*., 2013), but the Agency agrees with the approach of the EU MSC support document that less weight should be given to this study given the deviations from the test guideline and the aquifer sediment used.

The soil studies (Lai *et al*., 2014a, 2014b) provide supporting evidence that UV-326 degrades slowly in the environment. Limited weight can be given to these studies because of the uncertainty in the data.

The sediment core data also provides supporting evidence that UV-326 degrades slowly under the environmental conditions prevalent in these sediments.

Overall, the evidence indicates that UV-326 is likely to degrade slowly in aqueous and terrestrial environments.

2.3.2 Bioaccumulation

2.3.2.1 Bioaccumulation in aquatic organisms (pelagic & sediment organisms)

2.3.2.1.1 Screening data

Three log K_{OW} values are reported for UV-326 in the EU MSC support document, summarised in Table 12. All values exceed the Annex 13 bioaccumulative (B) and very bioaccumulative (vB) trigger (log K_{OW} > 4.5) and therefore UV-326 screens as potentially B/vB.

Table 12: Log K_{OW} values reported for UV-326 presented in the EU MSC support document

Source of log K_{OW} value	Log K_{OW}	Comment
COSMOtherm	6.7	Predicted value
Unpublished report (2012)	≥ 6.5	OECD TG 117 study; reliability score of 2 given by the registrant
Do *et al.* (2022)	7.38	Experimental value from a combination of a dynamic permeation method and a third-phase partitioning method

2.3.2.1.2 Aquatic bioaccumulation data

One aquatic bioaccumulation study is presented in the EU MSC support document (Table 13).

Table 13: Summary of aquatic bioaccumulation data presented in the EU MSC support document

Author / year	Study type	Results
Unpublished report (2020)	OECD TG 305 study using Juvenile rainbow trout (*Oncorhynchus mykiss*) Klimisch score 1	Based on un centrifuged test solutions: BCF_{SS}: 6355 L/kg $BCF_{kinetic}$: 7093 L/kg Based on centrifuged test solutions: BCF_{SS}: 12743 L/kg $BCF_{kinetic}$: 14225 L/kg All values after lipid normalisation

- Unpublished report (2020)

The EU MSC support document states that all validity criteria for this study were achieved and does not report any deviations from the guideline. It gives the study a Klimisch score 1 (reliable without restrictions).

Based on the information in the study summary and presented in the EU registration dossier, the Agency considers this assessment appropriate.

The Agency notes that another study (unpublished report, 1998) is presented in the EU registration dossier (ECHA, 2020). This is a flow through fish bioconcentration study using the test species Common Carp (*Cyprinus carpio*) conducted according to OECD TG 305 that was not reported in the EU MSC support document. The water solubility of UV-326 is reported to be 4 µg/L and even the lowest nominal concentration used in this study is above this concentration. The study therefore fails the validity test for test substance concentration. There is not enough information presented to consider whether the other validity criteria were met. The Agency, based on the information available, concludes that the study is not reliable and no further consideration is given to it in this assessment.

2.3.2.2 Summary and discussion of bioaccumulation

UV-326 screens as potentially B/vB based on log K_{OW} values which were all greater than 4.5.

The lipid normalised BCF values for UV-326 determined from a study conducted to OECD TG 305 (Klimisch score 1) ranged from 6355 to 14255 L/kg depending on how the value was determined (BCF_{SS} or BCF_k, test solutions uncentrifuged or centrifuged).

The Agency concludes that this evidence indicates that UV-326 has highly bioaccumulative properties.

2.4 Conclusions on the SVHC properties

2.4.1 PBT and vPvB assessment

2.4.1.1 Persistence

UV-326 screens as potentially P/vP based on the results of the ready biodegradability studies where < 20% degradation was observed. The freshwater sediment degradation DT_{50} value of UV-326 was > 100 days at 20°C in a non-standard aerobic river water/sediment simulation study (which generally followed OECD TG 308). This is extrapolated to > 212 days at 12°C, which exceeds both the P and vP criteria of Annex 13 of UK REACH (half-life > 180 days). There are several lines of evidence that support this conclusion:

- Read-across from the freshwater pond whole system DT_{50} value (278 days at 12°C; OECD TG 308) for M1 (a transformation product of UV-384). M1 is structurally very similar to UV-326 and is expected to have similar fate and behaviour properties.
- Sediment core data that indicate the presence of UV-326 over several decades under the environmental conditions prevalent in these sediments.
- Monitoring evidence that UV-326 degrades slowly in agricultural soil following its application via sewage sludge (estimated DT_{50} values from 81 to 155 days).

The Agency concludes from the weight of evidence available that UV-326 fulfils the P and vP criteria of Annex 13 of UK REACH.

2.4.1.2 Bioaccumulation

UV-326 screens as potentially B/vB as experimental log K_{OW} values ranged from ≥ 6.5 to 7.38. The lipid normalised BCF values for UV-326 determined from a study conducted to OECD TG 305 ranged from 6355 to 14255 L/kg depending how the value was determined (BCF_{SS} or BCF_k, test solutions uncentrifuged or centrifuged). All values were greater than the criteria for identification as vB (BCF > 5,000).

The Agency concludes that UV-326 fulfils the B and vB criteria of Annex 13 of UK REACH.

2.4.1.3 Overall conclusions on the PBT and vPvB properties

Based on the information available, the Agency concludes that UV-326 fulfils the vPvB criteria of Annex 13 of UK REACH and can therefore be identified as an SVHC in accordance with Article 57(e) of UK REACH.

3. Information on use, exposure and alternatives

3.1 UK and EU REACH registration status and tonnage

Under UK REACH, the substance is registered with an aggregated tonnage of 10 - 100 tonnes per annum (tpa).

In addition, a total of 125 Downstream User Import Notifications (DUINs[3]) have been submitted.

Under EU REACH, the substance is registered with an aggregated tonnage of 1000 – 10,000 tpa (17 active registrants)[4].

3.2 General description of uses and exposure

Bumetrizole is a UV-stabiliser with applications in industrial, professional and consumer settings. It is added to materials to prevent photodegradation and improve product durability, particularly in products intended for long-term outdoor use. It is commonly used in production of plastics, rubber, resins, coatings, adhesives and sealants (ECHA, 2026).

Formulations containing bumetrizole are reportedly used in a broad range of applications and the substance is incorporated into finished articles. As noted in ECHA (2026), such applications include electrical/electronic equipment, automotive parts, construction materials and some general consumer products e.g., those requiring weather resistant properties. It is reportedly used in plastic food contact material and may also be present in other consumer products or formulations, potentially including cosmetics, fragrances, personal care and washing or cleaning products[4].

Potential routes of environmental exposure may arise during formulation and repacking activities (e.g., during transferring, mixing, sampling and packaging operations associated with preparation of masterbatches, compounds and additive mixtures) and from subsequent industrial formulation and processing stages, such as compounding and conversion of masterbatches to produce polymers and incorporation into plastics or other materials (see above). Environmental release can also occur during the service life of the resulting formulations and products in industrial, professional and consumer applications.

[3] GB-based companies who imported substances from EU-based suppliers before UK REACH became law on 1 January 2021 had no EU REACH registration obligations as they were classed as Downstream Users (DUs). As they are now importers from outside of GB, they may have registration obligations under UK REACH. However, a transitional measure allows former DUs to suspend the registration until one of three deadlines (depending on tonnage and hazard). Where the identity of these imported substances was known, they could be included in a Downstream User Import Notification (DUIN) submitted to the Agency.

[4] ECHA Chemicals database; ECHA CHEM https://chem.echa.europa.eu/

This includes the use of long-life articles and materials, although release during normal use is expected to be low (ECHA, 2023a).

3.3 Alternatives

No available data.

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Glossary

Agency, the	HSE
B	Bioaccumulative
BCF	Bioconcentration factor
CAKE	Computer Assisted Kinetic Evaluation
CAS	Chemical Abstracts Service
DFOP	Double first-order in parallel
DT_{50}	Time taken for 50% decline in mass or concentration. If the decline is described by first order kinetics then this is also called the half-life
DU	Downstream User
DUIN	Downstream User Import Notification
ECHA	European Chemicals Agency
EC	European Community
EU	European Union
FOCUS	Forum for the co-ordination of pesticide fate models and their use
IUPAC	International Union of Pure and Applied Chemistry
K_{ow}	n-Octanol–water partition coefficient
MCL	Mandatory classification and labelling
MSC	Member State Committee
NER	Non-extractable residues
OECD	Organisation for Economic Cooperation and Development
P	Persistent
pK_a	Acid dissociation constant (logarithmic form)
POP	Persistent organic pollutant
REACH	Registration, evaluation, authorisation and restriction of chemicals
SFO	Single first order
SMILES	Simplified Molecular Input Line Entry System
SVHC	Substance of very high concern
TG	Test guideline
UK	United Kingdom
UV	Ultraviolet

vB	Very bioaccumulative
vP	Very persistent
vPvB	Very persistent and very bioaccumulative

Appendix A

Physicochemical properties for M1 presented in the EU MSC support document are summarised in Table A 1.

Table A 1: Overview of physicochemical properties of the structurally related M1

Property	Value
Physical state at 20 °C and 101.3 kPa	Solid, slightly yellow powder
Melting/freezing point (°C)	195
Boiling point (°C)	No observed boiling up to 400 °C
Vapour pressure (Pa at 20°C)	2.933×10^{-10}
Density (kg/m^3 at 20°C)	785
Water solubility (µg/L at 20°C)	<1 (pH 7.1)
n-Octanol–water partition coefficient (log K_{OW})	≥ 2.75 (at 25 °C, pH 6.9) 3.32
Dissociation constant (pK_a)	4.25 (25 °C; lowest value)

Appendix B

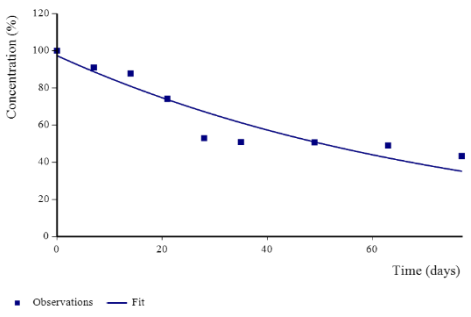
Kinetic modelling from simulation and field studies

Table B 1: Summary of the kinetic fitting of whole system data (Liu *et al.*, 2013)

Component	Kinetic model	Parameters	Prob > t	Chi^2	Visual fitting	DT_{50} (days)
UV-326	DFOP	M_0: 104 k_1: 0.03555 k_2: 3.26E-11 g: 0.6301	- 0.2881 0.5 -	7.53	Acceptable	19.5 (fast) > 10 000 (slow)
	SFO	M_0: 97.34 k: 0.01322	- 0.002076	8.79	Acceptable	52.4

Figure B 1: Visual fitting of whole system data (Liu *et al.*, 2013)

SFO kinetic fitting



DFOP kinetic fitting

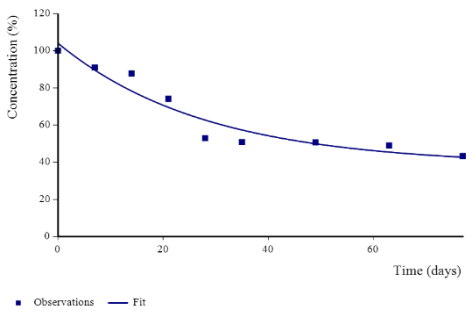
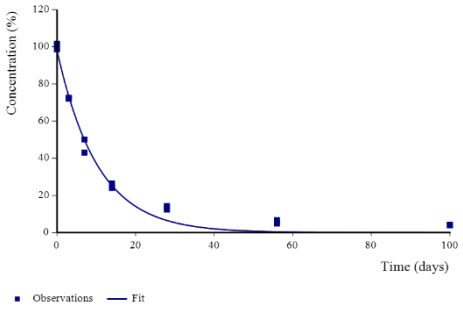


Table B 2: Kinetic fitting for UV-384 (whole system; sediment/water study) (ECHA, 2014)

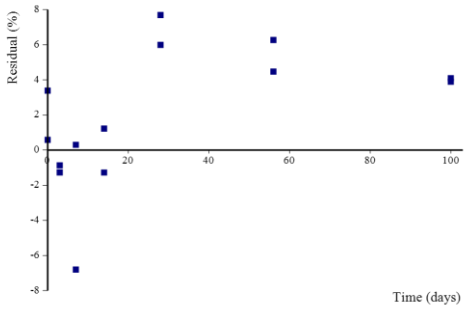
Component	Kinetic model	Parameters	Prob > t	Chi^2	Visual fitting
River system					
UV-384	SFO	M_0: 98.12 k: 0.09688	- 3.58E-09	8.15	Acceptable
	DFOP	M_0: 100.4 k_1: 0.1362 k_2: 0.01573 g: 0.8366	- 2.19E-07 0.01374 -	1.76	Excellent
Pond system					
UV-384	SFO	M_0: 93.35 k: 0.09563	- 1.25E-06	13.3	Acceptable
	DFOP	M_0: 100.0 k_1: 0.4238 k_2: 0.04794 g: 0.4262	- 0.02074 6.55E-04 -	5.02	Excellent

Figure B 2: Visual fitting for UV-384 (whole system; sediment/water study) (ECHA, 2014)

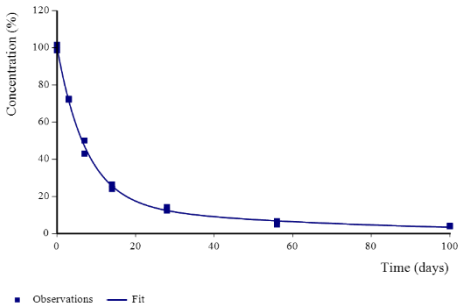
River system (SFO kinetic fitting)



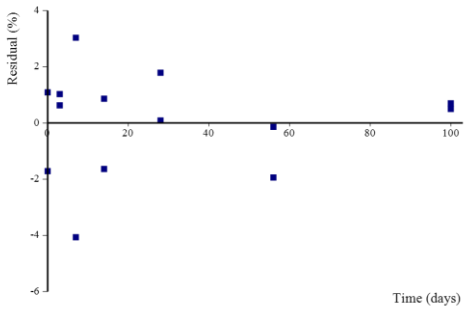
River system (SFO kinetic fitting; residuals)



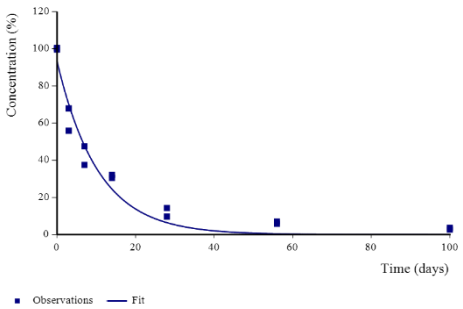
River system (DFOP kinetic fitting)



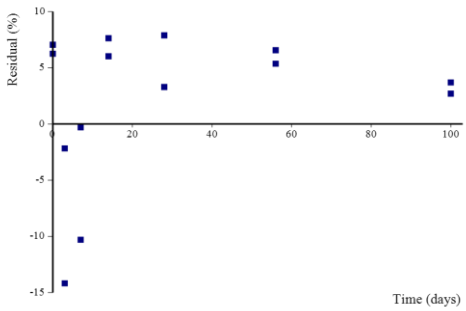
River system (DFOP kinetic fitting; residuals)



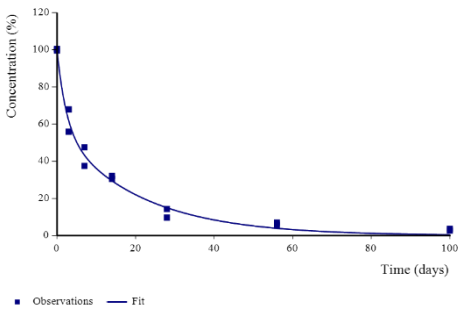
Pond system (SFO kinetic fitting)



Pond system (SFO kinetic fitting; residuals)



Pond system (DFOP kinetic fitting)



Pond system (DFOP kinetic fitting; residuals)

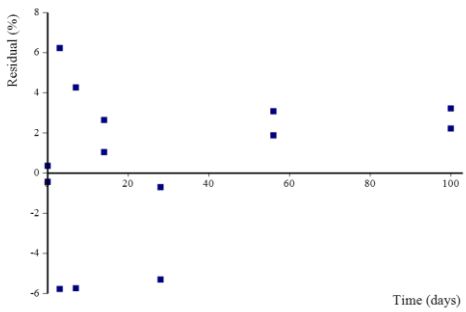
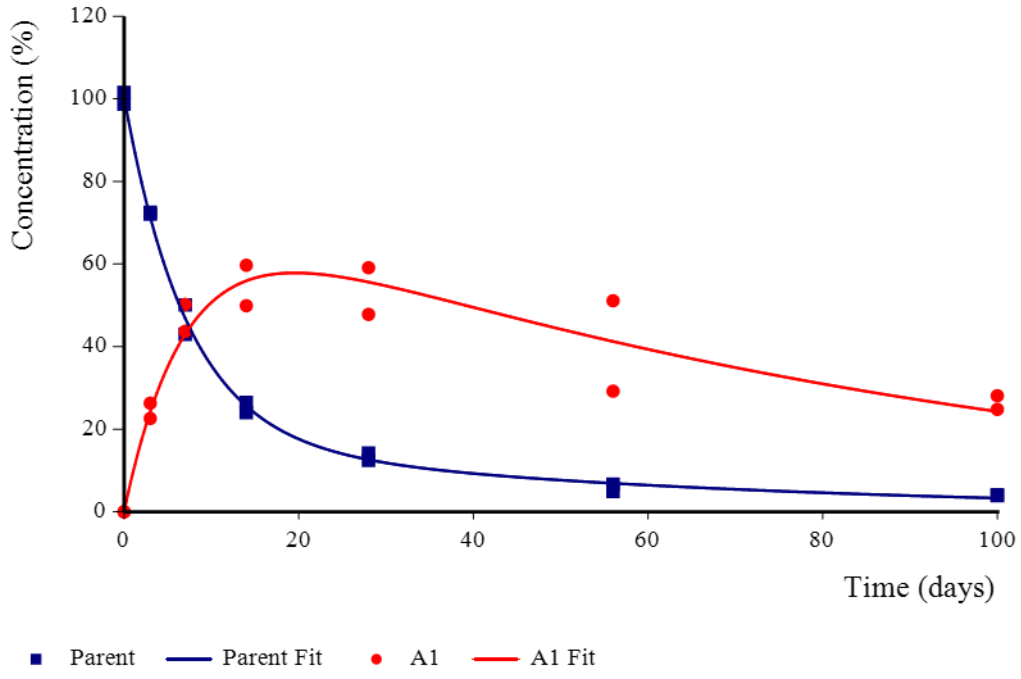


Table B 3: Whole system kinetic fitting for UV-384 and metabolite M1 (ECHA, 2014)

Component	Kinetic model	Parameters	Prob > t	Chi^2	Visual fitting
River system (aerobic)					
Parent	DFOP	M_0: 100.6 k_1: 0.1392 k_2: 0.0166 g: 0.827	- 1.14E-10 5.89E-03 -	1.79	Excellent
M1	SFO	k: 0.01417 f: 0.8471	2.04E-06 -	4.16	Good
Pond system (aerobic)					
Parent	DFOP	M_0: 100.9 k_1: 0.393 k_2: 0.04093 g: 0.4886	- 0.003576 1.99E-04 -	5.56	Good
M1	SFO	k: 0.005144 f: 0.7423	0.0156 -	13.8	Acceptable

Figure B 3: Whole system kinetic fitting for UV-384 and metabolite M1 (visual fitting) (ECHA, 2014)

River system (Parent DFOP, M1 SFO kinetic fitting)



Pond system (Parent DFOP, M1 SFO kinetic fitting)

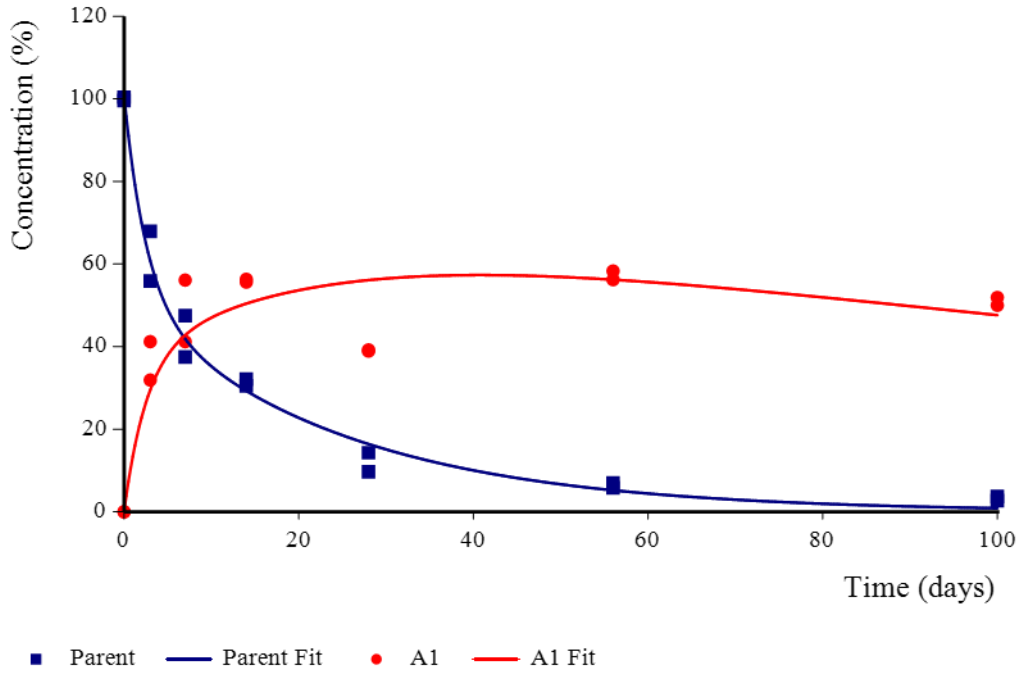


Table B 4: Kinetic fitting for treatment T1 and T2 (Lai *et al.*, 2014a)

Treatment	Kinetic model	Parameters	Prob > t	Chi^2	Visual fitting	DT_{50} (days)
Treatment T1	SFO	M_0: 2.671 k: 0.006588	0 7.17E-04	14	Acceptable	105
Treatment T2	SFO	M_0: 9.155 k: 0.004456	- 9.18E-04	10.8	Acceptable	155

Figure B 4: Visual fitting for treatment T1 and T2 (Lai *et al.*, 2014a)

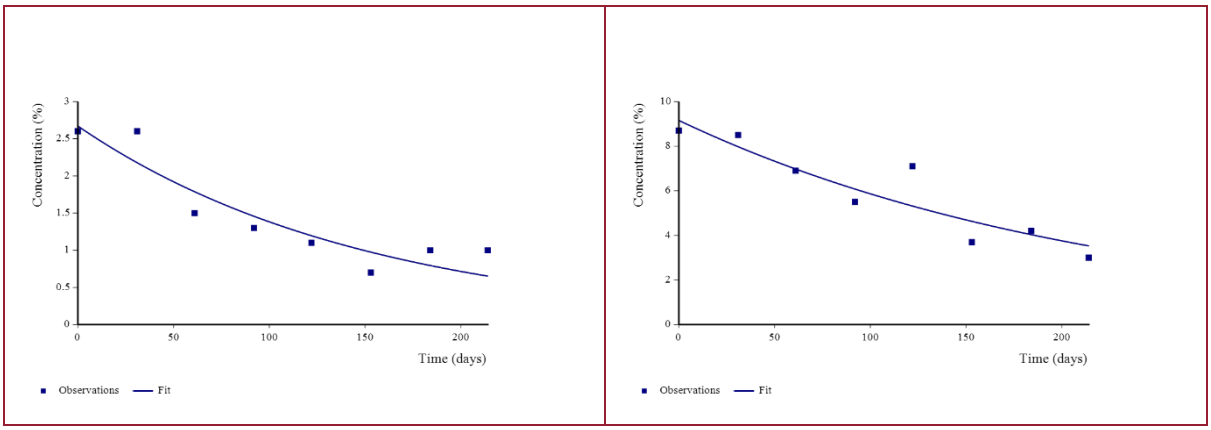
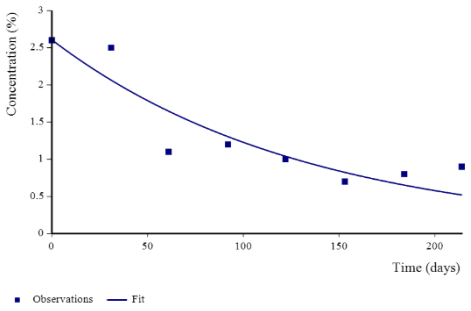


Table B 5: Kinetic fitting for treatment OT1-OT4 and NT2-NT4 (Lai *et al.*, 2014b)

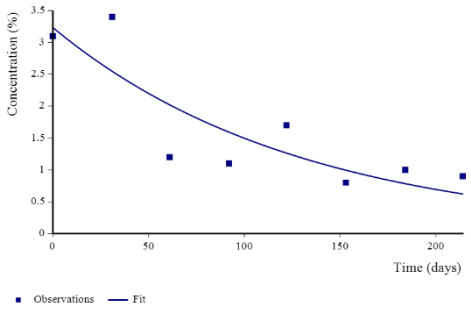
Component	Kinetic model	Parameters	Prob > t	Chi^2	Visual fitting	DT_{50} (days)
Treatment OT2						
OT1	SFO	M_0: 2.606 k: 0.00753	-0.001281	17.3	Acceptable	92
OT2	SFO	M_0: 3.233 k: 0.007704	-0.005741	24.2	Poor	90
OT3	SFO	M_0: 3.657 k: 0.004522	-0.02215	22.7	Poor	153
OT4	SFO	M_0: 6.028 k: 0.005773	-0.01722	25.8	Poor	120
Treatment NT2						
NT2	SFO	M_0: 2.39 k: 0.008266	-0.000828	16.9	Acceptable	84
NT3	SFO	M_0: 2.509 k: 0.005582	-0.000800	12.7	Acceptable	124
NT4	SFO	M_0: 3.097 k: 0.004921	-0.001544	13	Acceptable	141

Figure B 5: Visual fitting for treatments OT1-OT4 and NT2-4 (Lai *et al.*, 2014b)

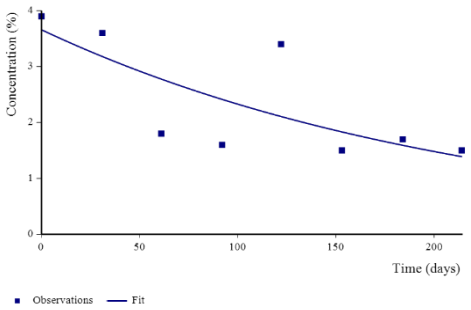
OT1 (all data)



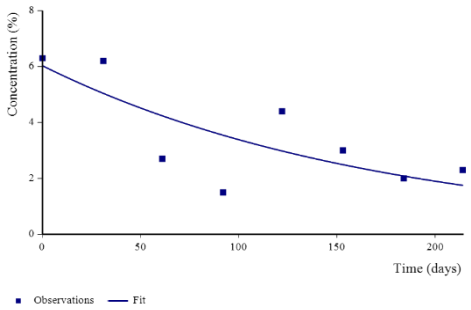
OT2 (all data)



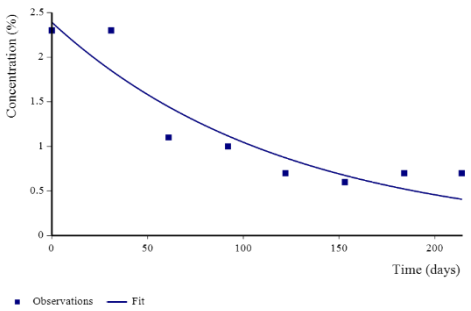
OT3



OT4



NT2



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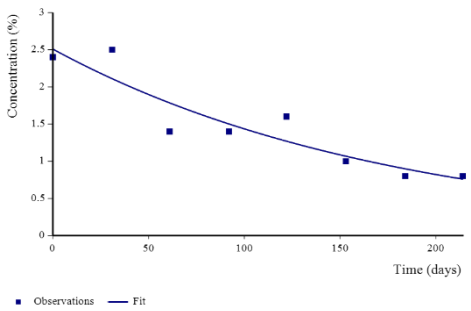
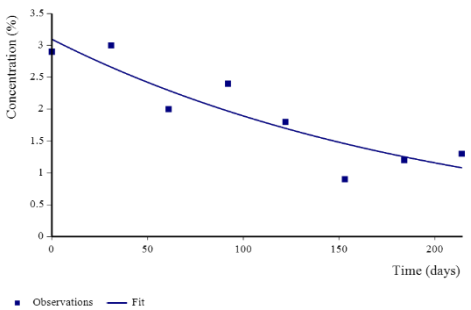


NT4



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