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DECISION ON SUBSTANCE EVALUATION PURSUANT TO ARTICLE 46(1) OF REGULATION (EC) NO 1907/2006

For S-(tricyclo[5.2.1.0 2,6]deca-3-en-8(or 9)-yl) O-(isopropyl or isobutyl or 2-ethylhexyl) O-(isopropyl or isobutyl or 2-ethylhexyl) phosphorodithioate, CAS No 255881-94-8 (EC No 401-850-9)

Addressees: Registrant(s)[1] of S-(tricyclo[5.2.1.0 2,6]deca-3-en-8(or 9)-yl) O-(isopropyl or isobutyl or 2-ethylhexyl) O-(isopropyl or isobutyl or 2-ethylhexyl) phosphorodithioate

This decision is addressed to the Registrant(s) of the above substance with active registrations pursuant to Article 6 of the REACH Regulation on the date on which the draft for the decision was first sent for comments. If Registrant(s) ceased manufacture upon receipt of the draft decision pursuant to Article 50(3) of the REACH Regulation, they did not become addressee(s) of the decision. A list of all the relevant registration numbers of the Registrant(s) that are addressees of the present decision is provided as an Annex to this decision.

Based on an evaluation by the Belgian Federal Public Service Health, Food Chain Safety and Environment, Risk Management Service as the Competent Authority of Belgium (evaluating MSCA), the European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 52 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

This decision is based on the registration dossier(s) on 6 May 2015, i.e. the day on which the draft decision was notified to the Registrant(s) pursuant to Article 50(1) of the REACH Regulation.

This decision does not imply that the information provided by the Registrant(s) in the registration(s) is in compliance with the REACH requirements. The decision neither prevents ECHA from initiating compliance checks on the dossier(s) of the Registrant(s) at a later stage, nor does it prevent a subsequent decision under the current substance evaluation or a new substance evaluation process once the present substance evaluation has been completed.

I. Procedure

Pursuant to Article 45(4) of the REACH Regulation the Competent Authority of Belgium has initiated substance evaluation for S-(tricyclo[5.2.1.0^{2,6}]deca-3-en-8(or 9)-yl) O-(isopropyl or isobutyl or 2-ethylhexyl) O-(isopropyl or isobutyl or 2-ethylhexyl) phosphorodithioate, CAS No 255881-94-8 (EC No 401-850-9) based on registration(s) submitted by the Registrant(s) and other relevant and available information and prepared the present decision in

[1] The term Registrant(s) is used throughout the decision, irrespective of the number of registrants addressed by the decision.

accordance with Article 46(1) of the REACH Regulation.

On the basis of an opinion of the ECHA Member State Committee and due to initial grounds for concern relating to suspected PBT/vPvB, wide dispersive use and exposure of the environment, S-(tricyclo[5.2.1.$0^{2,6}$]deca-3-en-8(or 9)-yl) O-(isopropyl or isobutyl or 2-ethylhexyl) O-(isopropyl or isobutyl or 2-ethylhexyl) phosphorodithioate was included in the Community rolling action plan (CoRAP) for substance evaluation to be evaluated in 2014. The updated CoRAP was published on the ECHA website on 26 March 2014. The Competent Authority of Belgium was appointed to carry out the evaluation.

The evaluating MSCA considered that further information was required to clarify the concerns related to suspected PBT/vPvB. Therefore, it prepared a draft decision pursuant to Article 46(1) of the REACH Regulation to request further information. It submitted the draft decision to ECHA on 19 March 2015.

On 6 May 2015 ECHA sent the draft decision to the Registrant(s) and invited them pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision.

Registrant(s) commenting phase

By 12 June 2015 ECHA received comments from the Registrant(s) of which it informed the evaluating MSCA without delay.

The evaluating MSCA considered the comments received from the Registrant(s).

The information contained therein is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

Commenting by other MSCAs and ECHA

In accordance with Article 52(1) of the REACH Regulation, on 9 June 2016 the evaluating MSCA notified the Competent Authorities of the other Member States and ECHA of its draft decision and invited them pursuant to Articles 52(2) and 51(2) of the REACH Regulation to submit proposals to amend the draft decision within 30 days of the receipt of the notification.

Subsequently, Competent Authorities of the Member States submitted proposals for amendment to the draft decision.

On 15 July 2016 ECHA notified the Registrant(s) of the proposals for amendment to the draft decision and invited them pursuant to Articles 52(2) and 51(5) of the REACH Regulation to provide comments on those proposals for amendment within 30 days of the receipt of the notification.

The evaluating MSCA reviewed the proposals for amendment received and amended the draft decision.

Referral to Member State Committee

On 25 July 2016 ECHA referred the draft decision to the Member State Committee.

By 15 August 2016 the Registrant(s)' provided comments on the proposed amendments. The Member State Committee took these comments into account. The Registrant(s) also provided comments on the draft decision not related to the proposals for amendments.

These comments were not taken into account by the Member State Committee as they were considered to be outside of the scope of Article 51(5).

A unanimous agreement of the Member State Committee on the draft decision was reached on 29 August 2016 in a written procedure launched on 18 August 2016.

ECHA took the decision pursuant to Article 52(2) and 51(6) of the REACH Regulation.

II. Information required

Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall submit the following information using the indicated test methods (in accordance with Article 13(3) and (4) of the REACH Regulation) and the constituent S-(tricyclo[5.2.1.$0^{2,6}$]deca-3-en-8(or 9)-yl) O-isopropyl O'-isopropyl phosphorodithioate of the registered substance subject to the present decision:

1. **Water Solubility Test: EU A.6/OECD 105 using the column elution method.**

Depending on the outcome of the water solubility test, either option 2.1 or 2.2 shall be performed.

2.1. **Aerobic Mineralisation in Surface Water - Simulation Biodegradation Test: EU C.25 / OECD 309 at 12 °C** in fresh water using radiolabelling and without the addition of coarse particles. This test shall be performed if monitoring is analytically feasible under the following conditions: the test item concentration in the water simulation test is lower or equal to the water solubility of the test item **and** the limit of quantification is equal to or less than 10 % of the applied concentration in the water simulation test (cf. paragraph 15 of OECD Guideline 309);

or,

2.2. **Aerobic and Anaerobic Transformation in Soil Test: EU C.23/OECD 307 at 12 °C** using radiolabelling. This test shall be performed if both conditions for conducting the simulation biodegradation test in 2.1. cannot be fulfilled simultaneously.

Deadline for submitting the required information

Pursuant to Article 46(2) of the REACH Regulation, the Registrant(s) shall submit to ECHA by **26 March 2019** an update of the registration(s) containing the information required by this decision[2], including robust study summaries and, where relevant, an update of the Chemical Safety Report.

III. Statement of reasons

S-(tricyclo[5.2.1.$0^{2,6}$]deca-3-en-8(or 9)-yl) O-(isopropyl or isobutyl or 2-ethylhexyl) O-(isopropyl or isobutyl or 2-ethylhexyl) phosphorodithioate, CAS No 255881-94-8 (EC No 401-850-9) (hereinafter called 'the registered substance" or "the substance") is a substance of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB) consisting of six homologous groups of trialkyldithiophosphates. It was screened to be a potential PBT/vPvB substance. If the registered substance is eventually confirmed to meet the criteria for PBT/vPvB, the evaluating Member State Competent Authority will assess the need for appropriately revised Risk Management Measures under the REACH

[2] The deadline set by the decision already takes into account the time that registrants may require to agree on who is to perform any required tests and the time that ECHA would require to designate a registrant to carry out the test(s) in the absence of the aforementioned agreement by the registrants (Article 53(1) of the REACH Regulation).

Regulation or any other relevant legislation. For a PBT/vPvB substance, this would typically be inclusion in the candidate list as a Substance of Very High Concern (SVHC) and authorisation under Title VII of the REACH Regulation.

As stated in Chapter R.11 (PBT Assessment) of ECHA's *Guidance on information requirements and chemical safety assessment* (November 2014), the PBT/vPvB assessment must consider persistence, bioaccumulation and toxicity against each respective criterion of Annex XIII of the REACH Regulation in order to conclude on the properties of a substance and its relevant constituents, impurities, additives and transformation/degradation products.

In order to enhance the readability of this decision the various constituents are denoted as follows:

S-(tricyclo[5.2.1.$0^{2,6}$]deca-3-en-8(or 9)-yl) O-isopropyl O'-isopropyl phosphorodithioate = **ip-ip-constituents**.
S-(tricyclo[5.2.1.$0^{2,6}$]deca-3-en-8(or 9)-yl) O-isopropyl O'-isobutyl phosphorodithioate = **ip-ib-constituents**.
S-(tricyclo[5.2.1.$0^{2,6}$]deca-3-en-8(or 9)-yl) O-isopropyl O'-2-ethylhexyl) phosphorodithioate = **ip-eh-constituents**.
S-(tricyclo[5.2.1.$0^{2,6}$]deca-3-en-8(or 9)-yl) O-isobutyl O'-isobutyl phosphorodithioate = **ib-ib-constituents**.
S-(tricyclo[5.2.1.$0^{2,6}$]deca-3-en-8(or 9)-yl) O-isobutyl O'-2-ethylhexyl phosphorodithioate = **ib-eh-constituents**.
S-(tricyclo[5.2.1.$0^{2,6}$]deca-3-en-8(or 9)-yl) O-(2-ethylhexyl) O'-(2-ethylhexyl) phosphorodithioate = **eh-eh-constituents**.

1. **Water Solubility Test.**

The registration dossiers contain a water solubility test on the registered UVCB-substance. The Registrant(s) conclude from this test that the water solubility of the substance is 1.4 mg/L. In contrast, the QSAR model WatSol v1.01 in EpiSuite v4.1 predicts water solubility values for the various constituents that are 82 to 2,800,000 times lower. In order to determine whether the persistence (P) criterion of Annex XIII of the REACH Regulation is fulfilled, further biodegradation simulation testing on the most soluble constituent is considered necessary (see request 2). A water solubility test with this constituent will provide essential information to decide whether a biodegradation simulation test in water is analytically feasible or not.

Given that the solubility is dependent on the temperature, it is recommended to perform this water solubility test at the same temperature as the simulation study, i.e. 12 °C.

Conclusion
Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to carry out the following study **using the constituent S-(tricyclo[5.2.1.$0^{2,6}$]deca-3-en-8(or 9)-yl) O-isopropyl O'-isopropyl phosphorodithioate** (=**ip-ip-constituents**) of the registered substance subject to this decision: water solubility test: EU A.6 / OECD 105 using the column elution method.

2. **Simulation testing**

Conditional testing approach

If, based on the outcome of the above requested water solubility test, the Registrant(s) determine that it is analytically feasible to perform a simulation test in water, option 2.1 (aerobic mineralization in surface water study) shall be performed. The following conditions

need to be fulfilled: the test item concentration in the water simulation test is lower or equal to the water solubility of the test item **and** the limit of quantification is equal to or less than 10 % of the applied concentration in the water simulation test. (cf. paragraph 15 of OECD Guideline 309). If both conditions cannot be fulfilled simultaneously, the Registrant(s) shall perform a simulation test in soil, i.e. option 2.2.

Need for further testing

With regards to the available information on persistence, experimental results are only available for the registered substance and not for the individual constituents or for potential degradation product(s). In the registration dossier(s), both experimental data on biodegradation and non-test data in the form of a read-across and a QSAR argumentation relating to primary degradation are available. Two ready biodegradation tests without application of enhancement techniques were performed using the registered substance. In both tests, biodegradation levels were very low (< 4% after 28 days). In 2011, an enhanced biodegradation study according to OECD 301D was performed in which silicone oil and polyethylene glycol were added to enhance bioavailability. In this test, a maximum degradation level of 46 % was found after 35 days and a level of 34 % at the end of the test after 63 days. In addition, the reliability of the test is questionable since the negative control showed up to 30 % biodegradation. These biodegradation tests were not monitored analytically.

Since the pass level was not reached in any of the biodegradation tests described above, it can be concluded that the parent substance is not readily biodegradable.

In their registration dossier(s) the Registrant(s) refer to an inherent biodegradation study on a specific trialkyldithiophosphate (malathion) in which a very high level of biodegradation is demonstrated. In contrast to this study, the results of a series of ready biodegradation studies with esters of dithiophosphates show biodegradation levels lower than 10 %. In contrast to the Registrant(s)' claim these observations do not allow a definitive conclusion to be made on the identity and the half-life of the degradation product(s).

Following an evaluation of the available information, ECHA considers that the registered substance is not readily biodegradable and does not degrade abiotically. Furthermore, the available information is not sufficient to enable an unequivocal conclusion regarding the identity and half-lives of the potential degradation product(s). There is a possible risk that the substance meets the (very) persistence (vP) criterion of Annex XIII of the REACH Regulation and further data is needed to clarify this concern.

The available information also shows that some constituents of the registered substance have a high potential for aquatic bioaccumulation, and no terrestrial bioaccumulation data is available. For the potential degradation product(s), the Registrant(s) performed a QSAR prediction to demonstrate that these compounds do not show a high aquatic bioaccumulation potential. The identity of the relevant degradation product(s) remains uncertain, however, many of the potential degradation products identified in the Registrant's QSAR prediction have high predicted log K_{ow} and log K_{oa} values and could lead to bioaccumulation in air-breathing organisms. Consequently, further data may be needed to clarify this concern.

A long-term test on daphnia demonstrates that the substance fulfils the toxicity (T) criterion of Annex XIII of the REACH Regulation for freshwater organisms but this is insufficient to allow an assessment of the ecotoxicological effects of the individual constituents or potential degradation product(s). Consequently, there is a possible risk that the individual constituents or potential degradation product(s) meet the toxicity (T) criterion and further data may be needed to clarify this concern.

As stated within Chapter R.11 of the abovementioned Guidance, when deciding on the persistence, bioaccumulation or toxicity information required to reach an unequivocal conclusion, vertebrate animal testing must be avoided whenever possible. Therefore, when further information for several properties is required, the assessment should normally clarify the potential for persistence first. When it is clear that the P criterion is fulfilled, a stepwise approach is followed to clarify whether the B criterion is fulfilled, eventually followed by toxicity testing to clarify the T properties. Furthermore, experience with other substances has shown that if the parent compound is transformed under environmentally relevant conditions, it is appropriate to first focus on persistence and to examine carefully which transformation products are potentially persistent.

Therefore, the information requested within the present decision is focussed upon the need to clarify the biodegradation of the registered substance and its constituents, and to identify any potential degradation product(s) of relevance to the PBT assessment. The requested information will enable a clear understanding of the environmental fate of the registered substance. This will allow a subsequent consideration of any further information required to clarify the B and T properties of the registered substance, its constituents and/or its transformation products. This approach focuses the evaluation on those constituents and/or degradation products of relevance to the PBT assessment, potentially minimising any subsequent costs, time and experimental studies that may be required to clarify the PBT/vPvB concern.

Based on the available information, ECHA concludes that there is no clear view on the biodegradation pattern of the constituents of the registered substance. There are indications that the constituents may undergo primary degradation but that subsequent degradation steps occur very slowly. As a first step, the uncertainty with regard to the identity and the half-lives of the potential degradation products must be clarified by performing a test that simulates the fate of the registered substance under environmental conditions.

As stated within chapter R.11 of the abovementioned guidance, simulation tests address the fate and behaviour of a substance as it may be expected in the environment including information about primary degradation, route of degradation (degradation products), and degradation half-lives.

As laid down in Annex IX, Section 9.2.1. of the REACH Regulation, simulation testing is a standard REACH information requirement for substances manufactured or imported in quantities of 100 tonnes or more per annum. The substance subject to the present decision is currently registered at tonnages below this threshold, while further information for the PBT/vPvB assessment needs to be generated regardless of the tonnage band for the substance. A request for a simulation test under substance evaluation is the most appropriate and proportionate approach to obtain the information necessary to clarify the potential persistence of the registered substance.

Determination of the most appropriate compartment

The determination of the most relevant environmental compartment depends on the use pattern of the substance and on its intrinsic properties. As can be seen from the Mackay level III model calculations in EpiSuite, the aquatic, sediment and soil compartments are all considered as relevant.

Below are listed the predicted relative mass distribution (%) according to the Mackay level III (steady state) model of EpiSuite v. 4.1 for the ip-ip and eh-eh constituents covering the highest and lowest water soluble constituents of the registered substance according to the two mentioned default environmental emission patterns; one with equal emission to air, soil

and surface water, and another one assuming only emission to surface water.

Emission	Equal to air, soil and water		Only to water	
Constituent	**ip-ip**	**eh-eh**	**ip-ip**	**eh-eh**
Air	0.0319	0.06	0.03	3.58e-005
Water	9.32	23.6	32.6	90.2
Soil	71.5	73.8	0.07	0.000913
Sediment	19.2	2.55	67.3	9.76

Provided below are the STP (sewage treatment plant) model (EpiSuite v. 4.1) results for the ip-ip and eh-eh constituents where environmental emission takes place via emission to the sewer and STP. This can easily be done by modelling the fate in a suitable STP model where the fractions at steady state is presented: volatilisation to air, adsorption to STP-sludge, STP-degradation and the emission fraction to surface water. Typically such modes employ the fugacity concept. The fraction adsorbed to STP sludge is normally assumed to be disposed of on soil and hence this fraction is normally assumed exposing the soil environment.

Removal In Wastewater Treatment:	IP-IP	EH-EH
Total removal:	92.56 %	94.04 %
Total biodegradation:	0.77 %	0.78 %
Total sludge adsorption (potentially deposed of on soil):	91.65 %	93.26 %
Total to Air:	0.15 %	0.00 %
Not removed in the STP, i.e. released to surface water	7.44 %	5.96 %

It appears from these modelling results that both the ip-ip constituent and the eh-eh constituent are predicted to be distributed to surface water to a significant extent (e.g. for the ip-ip constituent: 9.3-32.6 % depending of release pattern in the Mackay III model; 7.4 % according to the STP model). It is also clear from these modelling results that also soil or sediments may be significantly exposed, the former mostly depending on the extent of deposition of STP sludge on soil. Therefore, in principle, simulation tests in all three compartments could be requested. However, ECHA considers that this would not be proportionate and that one test will be sufficient to inform on the Persistence of the substance.

The main objective of this simulation test is to determine whether biodegradation of the registered substance leads to degradation products that are persistent and if so, to determine their chemical identity and degradation half-lives. In view of the complex organic composition of soil and sediment, it is deemed appropriate to perform this test in surface water. Furthermore, it is recognised that the complex UVCB character of the registered substance can hamper the correct execution of the test as chemical analysis could become impractical.

Moreover, Non-Extractable Residues (NER) formation in a soil simulation test can complicate a reliable determination of the half-life of the parent compound or degradation products. Therefore, preference is given to a simulation test in water, if considered analytically feasible. If not feasible, a soil test is considered most appropriate.

Determination of the constituent to be tested

All constituents of the registered substance contain a dithiophosphate moiety as functional

group but the length of two alkyl ester chains differs. Therefore, it is plausible to expect that all constituents react chemically in a relatively similar way and will show a similar biodegradation pattern. Consequently, it is reasonable to assume that the degradation pattern of one constituent will be indicative for the other constituents, and can be used to develop a reliable analysis of the biodegradation of the registered substance as a whole. Therefore, ECHA considers that the most appropriate approach is to perform the surface water simulation test with the most soluble constituent of the registered substance (i.e. S-(tricyclo[5.2.1.$0^{2,6}$]deca-3-en-8(or 9)-yl) O-isopropyl O'-isopropyl phosphorodithioate (= ip-ip)).

A proposal for amendment (PfA) was received suggesting to add a clearer justification to explain why the most soluble constituent is preferred for testing as a conservative approach compared to the other constituents. The Registrant(s) interpreted this PfA as stating that performing the test on only one constituent will not provide useful information to which they agree.

The evaluating MSCA considers that the obtained biodegradation results with the ip-ip constituents can be used to evaluate the biodegradation pattern of the other constituents. The QSAR estimations obtained with Biowin v4.10 (submodel 3: ultimate biodegradation model) for the various constituents provide the following degradation rates: ip-ip= 2.59; ip-ib = 2.56; ip-eh = 2.73; ib-eh : 2.7; eh-eh = 2.87. Also the other submodels in Biowin predict quite similar degradation rates for the various homologues so it seems that read-across between the homologues may be applied.

Moreover, using the ip-ip constituent seems the most conservative approach since this constituent is probably less subject to biodegradation than the larger constituents. All constituents contain the same dithiophosphate functionality and the same sulfur substituted tricyclic moiety. The potential recalcitrant character of these compounds is mainly caused by the tricyclic moiety and not by the linear alkyl chains of varying length that are also present in these compounds. Linear (unbranched) alkyl chains tend to biodegrade more rapidly and therefore the constituent with the shortest alkyl chains (i.e. ip-ip constituent) can be assessed as being a conservative representative.

Comments from the Registrant(s) on the original draft decision

In their comments on the draft decision, the Registrant(s) state that the registered substance and its constituents are not PBT or vPvB, on the basis that all constituents undergo rapid primary degradation and the predicted degradation products are not bioaccumulative. As part of their justification, the Registrant(s) use QSAR modelling (Catalogic 301 C model) to demonstrate that primary degradation corresponding to parent compound disappearance occurs rapidly, leaving behind stable metabolites which do not biodegrade easily. The Registrant(s) conclude that the main process was identified by the model as 'thiophosphate oxidative desulfuration'.

Furthermore, the Registrant(s) state that should further testing be deemed necessary, an OECD 309 study is not environmentally relevant to the registered substance, since fugacity modelling demonstrates that soil is always the most affected compartment. As an alternative to the OECD 309 study, the Registrant(s) propose an enhanced biodegradability study on the registered substance with specific chemical analysis of the constituents and degradation products. The Registrant(s) consider that a study performed on the registered substance is more conclusive than one performed on a single constituent, since the constituents are similar both structurally and with respect to their environmental properties.

The biodegradation of the registered substance was predicted by the Registrant(s) using the model 301C v.08.11 of CATALOGIC. However, ECHA notes that the constituents contain 16

to 24 % of fragments not recognised by this QSAR model, and therefore are not fully in the applicability domain of the QSAR model because they are out of the structural domain. In addition, for the metabolites predicted by the QSAR model, it is uncertain whether only oxidative desulfuration will occur and at what rate. It is plausible that the main metabolite(s) predicted by the Registrant(s) are hydrolytically unstable and lead to other metabolites, or, that the substance may undergo other degradation pathways than the transformations integrated in the QSAR model. Therefore, ECHA concludes that the predictions by the QSAR model of the primary half-life and of the stable metabolites are not sufficiently reliable for the purpose of the PBT/vPvB assessment.

ECHA notes that the fugacity modelling indicates that the constituents of the registered substance are also distributed to sediment and water, and that 7.6 - 23.6 % of the non-degraded constituents are predicted within the water compartment. Therefore, ECHA considers that the water is an environmentally relevant compartment. Furthermore, experience has shown that from an analytical perspective, simulation tests in water are likely to be easier to conduct compared to simulation tests in soil.

ECHA considers that although an enhanced ready biodegradability study could be used to identify the degradation products, it does not allow a determination of the half-lives of the stable degradation products, which are necessary to definitively conclude whether the (v)P criterion is met or not.

Consequently, ECHA considers that an OECD 309 test using the constituent S-(tricyclo[5.2.1.$0^{2,6}$]deca-3-en-8(or 9)-yl) O-(isopropyl) O'-(isopropyl) phosphorodithioate (=ip-ip) is both relevant and the most suitable approach to assess the persistence of the parent compound and its potential degradation products.

Moreover, chapter R.11 of the abovementioned Guidance states that since the 32nd meeting of the Member State Committee, new simulation degradation studies shall be performed around neutral pH values and at 12 °C, which is understood as the average temperature of surface waters in the EU. OECD Guideline 309 states that "*incubation should take place at a controlled temperature*". Therefore, in order to simulate as much as possible the real environmental conditions in the EU, but avoiding to perform the test at multiple temperatures, it is deemed appropriate to conduct this surface water simulation test at 12 °C.

It is recognized that the character of the competent degrader can play a substantial role in the determination of the degradation rate and possibly also in the stable degradation products that are formed. As the temperature influence differs from case to case it is an appropriate approach not to apply temperature corrections afterwards, but to perform the test in circumstances as realistic as possible, i.e. at 12 °C.

2.1 Simulation testing on ultimate degradation in surface water

Specificities of the test:

The water simulation test shall be conducted in fresh water as it is plausible to assume that releases will be mainly to soil and fresh water and not to marine waters. The test shall be performed without the addition of coarse particles (i.e. a pelagic test type) because adsorption to solid carbon will reduce the bioavailability of the test item and thus diminish the reliability of the test.

As full mineralization is expected to occur very slowly, the main focus of the simulation study in water shall be on the determination of the half-life of the test item and the detection of stable transformation product(s) that meet the P criterion for the fresh water

environment (i.e. $T_{1/2}$ > 40 days). If transformation products are formed that meet the P criterion, their identity shall be determined by a substance specific analysis. If necessary to achieve a reliable determination of the chemical identity of stable transformation products an adapted execution of the study with higher test item concentrations shall be considered as described in the last sentence of paragraph 1 of the OECD 309 Guideline.

A crucial aspect in the appropriate execution of the simulation study is to prevent the test item and its degradation products escaping from the test system. As mentioned in paragraph 29 of the Guideline and in order to prevent test item loss the use of a closed test system is preferred and minimization of the head space can be considered. Moreover, the Registrant(s) as a response to a PfA agreed that the volatility of the substance should be taken into account. In addition, the test item shall be radiolabelled with ^{14}C and the radiolabel shall be incorporated in the tricyclic moiety of the test item to be able to establish a reliable mass balance.

In principle, the duration of the test shall be 90 days as mineralization is expected to occur very slowly. As suggested in paragraph 21 and further detailed in annex 3 of the OECD 309 Guideline, the test shall be started in the usual batch mode and during the test one may switch to a semi-continuous test procedure if there are indications that the viability of the microbial community is substantially reduced. Moreover, the test may be terminated if mineralization, measured as the amount of $^{14}CO_2$ formation, has reached a level of 20 %. It is recommended that in order to reliably examine the biodegradation pattern of the test item withdrawal of samples for chemical analysis is performed at day 0, 1, 3, 5 and 7 during the first week and afterwards every week till the end of the study.

2.2 Aerobic and anaerobic degradation test in soil

Specificities of the test:

If the simulation test is executed in soil, the main focus shall again be on the determination of the half-life of the test item and on the detection of stable transformation product(s) that meet the P criterion for the soil compartment (i.e. $T_{1/2}$ > 120 days). The test item shall be radiolabelled with ^{14}C and the radiolabel shall be incorporated in the tricyclic moiety of the test item to be able to establish a reliable mass balance. If transformation products that meet the P criterion are formed, their identity shall be determined by a substance specific analysis.

If the available analytical technique is not sufficient to achieve a reliable determination of the chemical identity of stable transformation product(s), incubation of separate soil samples with higher test item concentrations shall be considered as described in the last sentence of paragraph 41 of the OECD 307 Guideline. Also the recommendations given in paragraph 14 of the OECD 307 Guideline concerning the appropriate choice of test item level shall be considered.

As mineralization of the test item is expected to occur very slowly, the duration of the test shall be 120 days. However, the test may be terminated earlier if mineralization, measured as the amount of $^{14}CO_2$ formation, has reached a level of 20 %. It is recommended that in order to reliably examine the biodegradation pattern of the test item withdrawal of samples for chemical analysis is performed at day 0, 1, 3, 5 and 7 during the first week and afterwards samples shall be taken after 14, 28, 42, 56, 70, 84, 98 and 120 days.

The Registrant(s) shall pay special attention to select the most appropriate solvent for extraction purposes for this specific class of compounds, i.e. trialkyl di- and monothiophosphates in order to avoid that poor recovery of test substance is wrongly

interpreted as formation of bound residues.

Conclusion

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to carry out one of the following studies, using the constituent S-(tricyclo[5.2.1.$0^{2,6}$]deca-3-en-8(or 9)-yl) O-(isopropyl) O'-(isopropyl) phosphorodithioate of the registered substance subject to this decision, depending on the outcome of the water solubility test:

Aerobic Mineralisation in Surface Water - Simulation Biodegradation Test: EU C.25 / OECD 309 without addition of suspended solids, at 12 °C;

or

Aerobic and Anaerobic Transformation in Soil Test: EU C.23 / OECD 307, at 12 °C.

IV. Adequate identification of the composition of the tested material

In relation to the required experimental Water Solubility test and the Aerobic Mineralisation in Surface Water study or Aerobic and Anaerobic Transformation in Soil study, the sample of the substance to be used shall have a composition that matches with an identification as a mono-constituent substance. It is the responsibility of all the Registrant(s) to agree on the tested material to be subjected to the test subject to this decision and to document the necessary information on composition of the test material. The substance identity information of the registered substance and of the sample tested must enable the evaluating MSCA and ECHA to confirm the relevance of the testing for the substance subject to substance evaluation. Finally, the test must be shared by the Registrant(s).

V. Deadline

In the original draft decision the time indicated to provide the requested information was 21 months from the date of adoption of the decision. This period of time took into account the fact that the draft decision only requested a simulation study. Considering the new request for a water solubility test, ECHA considers that a reasonable time period for providing the currently required information in the form of an updated registration is 27 months from the date of the adoption of the decision.

VI. Avoidance of unnecessary testing by data- and cost-sharing

In relation to the experimental study the legal text foresees the sharing of information and costs between Registrant(s) (Article 53 of the REACH Regulation). Registrant(s) are therefore required to make every effort to reach an agreement regarding each experimental study for every endpoint as to who is to carry out the study on behalf of the other Registrant(s) and to inform ECHA accordingly within 90 days from the date of this decision under Article 53(1) of the REACH Regulation. This information should be submitted to ECHA using the following form stating the decision number above at: https://comments.echa.europa.eu/comments_cms/SEDraftDecisionComments.aspx

Further advice can be found at: http://echa.europa.eu/regulations/reach/registration/data-sharing.

If ECHA is not informed of such agreement within 90 days, it will designate one of the Registrants to perform the study on behalf of all of them.

VII. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Articles 52(2) and 51(8) of the REACH Regulation. Such an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on the ECHA's internet page at http://www.echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

Authorised[3] by Leena Ylä-Mononen, Director of Evaluation

Annex: List of registration numbers for the addressees of this decision. This annex is confidential and not included in the public version of this decision.

[3] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.