Helsinki, 19 May 2020

Addressees
Registrant of CAS 101748-77-7 JS listed in the last Appendix of this decision

Date of submission for the dossier subject of a decision
5 April 2019

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Zinc, O,O-mixed (iso-Bu), (iso-Pr), (pentyl) phosphorodithioate
EC number: 820-225-5
CAS number: 101747-77-7

Decision number: [Please refer to the REACH-IT message which delivered this communication (in format TPE-D-XXXXXXXXXX-XX-XX/F)]

DECISION ON A TESTING PROPOSAL

Based on Article 40 of Regulation (EC) No 1907/2006 (REACH), ECHA requests that you submit the information listed below by the deadline of ***26 November 2021***.

A. Requirements applicable to all the Registrants subject to Annex IX of REACH

1. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method OECD TG 408) in rats with the Substance;

2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method OECD TG 414) in a first species (rat or rabbit), oral route; with the Substance.

Conditions to comply with the requests

You are bound by the requests for information corresponding to the REACH Annexes applicable to your own registered tonnage of the Substance at the time of evaluation. Therefore you have to comply with the requirements of:

- Annexes VII to IX of REACH, if you have registered a substance at 100-1000 tpa;

The Appendix on general considerations addresses issues relevant for several requests while the other Appendices state the reasons for the requests for information to fulfil the requirements set out in the respective Annexes of REACH.

The Appendix entitled Observations and technical guidance addresses the generic approach for the selection and reporting of the test material used to perform the required studies and provides generic recommendations and references to ECHA guidance and other reference documents.

You must submit the information requested in this decision by the deadline indicated above in an updated registration dossier and also update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, has to be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under: http://echa.europa.eu/regulations/appeals.

Authorised[1] under the authority of Christel Schilliger-Musset, Director of Hazard Assessment

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

Appendix on general considerations

The decision of ECHA is based on the examination of the testing proposals submitted by you, for substance Zinc, O,O-mixed (iso-Bu), (iso-Pr), (pentyl) phosphorodithioate (EC: 820-225-5; CAS: 101747-77-7), hereafter referred to as "the Substance".

In relation to the testing proposals subject to the present decision, you propose to fulfil the standard information requirements for:

- Repeated-dose oral toxicity study (Annex IX, Section 8.6.2)
- Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)

using an analogue substance phosphorodithioic acid, mixed O,O-bis(iso-Bu and pentyl) esters, zinc salts (EC: 270-608-0; CAS: 68457-79-4), hereafter referred to as "source substance". You propose to use the results obtained to adapt the standard information requirements for your Substance by using a grouping and read-across approach according to Annex XI, Section 1.5. of the REACH Regulation.

ECHA has considered first the scientific and regulatory validity of your proposed grouping and read-across approach in general, before addressing the individual endpoints in the following appendices(s).

(i) Assessment of the Grouping of substances and read-across approach, in light of the requirements of Annex XI, Section 1.5.

A. Legal Background on ECHA's assessment of the grouping of substances and read-across hypothesis

The evaluation by ECHA of testing proposals submitted by registrants aims at ensuring that generation of information is tailored to real information needs. To this end, it is necessary to consider whether testing programmes proposed by you are appropriate to fulfil the relevant information requirements and to guarantee the identification of health and environmental hazards of substances. In that respect, the REACH Regulation aims at promoting wherever possible the use of alternative means, where equivalent results to the prescribed test are provided on health and environmental hazards.

Article 13(1) of the REACH Regulation provides that information on intrinsic properties of substances may be generated whenever possible by means other than vertebrate animal tests, including information from structurally related substances (grouping of substances and read-across), "*provided that the conditions set out in Annex XI are met*".

The first Recital and the first Article of the REACH Regulation establish the "*promotion of alternative methods for assessment of hazards of substances*" as an objective pursued by the Regulation. In accordance with that objective, ECHA considers whether a prediction of the relevant properties of the Substance subject to the present decision by using the results of the proposed tests is plausible based on the information currently available.

B. Scope of the grouping

Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be

predicted from data for reference substance(s) within the group. Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance R.6 and the ECHA RAAF document.

B.1. Description of the grouping

In your registration dossier you have provided the following documents as separate attachments in IUCLID Section 13:

- [redacted] (hereafter "justification document"). The document contains an overview of read-across category approach, data matrices with the physicochemical properties (Table 2), and the (eco)toxicological properties (Table 3) of the category members.
- [redacted] (hereafter "toxicokinetic statement"). The document provides an overview of the toxicokinetics and toxicological profile of the Substance, based on information from analogue substances.

In your read-across justification document you have proposed a category approach that includes the following substances:

- Zinc, O,O-mixed (iso-Bu), (iso-Pr), (pentyl) phosphorodithioate (CAS: 101747-77-7; EC: 820-225-5) – your Substance;
- Phosphorodithioic acid, mixed O,O-bis(iso-Bu and pentyl) esters, zinc salts (CAS 68457-79-4; EC 270-608-0) – the source substance proposed to be tested;
- Phosphorodithioic acid, mixed O,O-bis(1,3 -dimethylbutyl and iso-propyl) esters, zinc salts (CAS 84605 - 29 -8; EC 283-392-8) – source substance;
- Zinc bis[O,O-bis(2-ethylhexyl)] bis(dithiophosphate) (CAS 4259-15-8; EC 224-235-5) – source substance.

You have provided the following reasoning for the grouping:

- You consider that there is "*high*" structural similarity between your Substance and the source substances because they "*share the common organometallic core structure consisting of a central zinc metal complexing four alkyldithiophosphate esters (ligands) - $Zn[(S2P(OR)_2]_2$*" and "*thus give rise to an (identical) common compound Phosphorodithioic acid moiety that can be released by the breakage of ester bonds and dissociation from the Zinc complex*".

- You state that the source substances are members of the "Zinc Dialkyldithiophosphate Category" (ZDDP) created by the HPV Chemical Challenge Program (2005). The category members are "*alkyl (C3-C12) or alkaryl (C12 alkylphenol) substituted phosphorodithioic acid structures complexed with zinc*". Therefore, the Substance "*can be added to this category as well, because its alkyl rests are in the range of the chain lengths defined for this category*".

- You state that the Substance and the source substances "*are of high purity containing 10-15 wt-% highly refined lubricating base oil*".

As support of your grouping you claim that the Substance and the source substances have similar physicochemical properties (physical states, densities, melting points, similar

decomposition temperatures and the same order of magnitude of vapour pressures and partition coefficients).

B.2. Assessment of the grouping

Annex XI, Section 1.5 requires that whenever grouping and read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must provide a category definition describing the structures that the members of the category must have in order to be included in the category, a hypothesis on why the category was formed, a clear description of the applicability domain of the category, a description of the identity of the category members and a justification supporting the category hypothesis.

In your Justification document you have only provided a cross-reference to "*an existing ZDDP category*" created in a different regulatory context.

ECHA notes the following deficiencies with regard to the grouping:

B.2.1. Characterisation of the group members

Annex XI, Section 1.5 of the REACH Regulation provides that "*substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of chemical similarity may be considered as group.*"

According to the ECHA Guidance, "*in identifying a category, it is important that all potential category members are described as comprehensively as possible*", because the purity profile and composition can influence the overall toxicity/properties of the potential category members.[2] Therefore, qualitative and quantitative information on the compositions of the category members should be provided to confirm the category membership.

Furthermore, the provided information for categories consisting of UVCB (Unknown or Variable composition, Complex reaction products or of Biological materials) substances needs to include qualitative compositional information of the individual constituents of the category members, as well as quantitative characterisation in the form of information on the concentration of the individual constituents of these substances, to the extent that this is measurable.[3]

However, you have described the source substances by their EC and CAS numbers and provided high level information on the structures of common and non-common constituents between the source substances and the Substance. You state that the substances "*containing [redacted] % highly refined lubricating base oil*".
You have not provided a detailed comparison of the composition of the source substances with the Substance. In particular, you have not reported the qualitative and quantitative differences in the composition of your Substance and the source substance. Details on the minimum and maximum concentrations for each constituent for the different UVCB substances is necessary to characterise the variability in the composition of the individual substances. This information is required for a meaningful comparison of the compositions of the substances in order to confirm their compositional similarities.

Further, ECHA notes that based on the reported composition of your Substance, no base oil of any kind is present. You have not provided any information on the identity of the base oils present in the composition of the source substances.

[2] ECHA Guidance R.6, Section R.6.2.4.1
[3] ECHA Guidance R.6, Section R.6.2.5.5

In the absence of this information, the category membership cannot be confirmed.

B.2.2. Applicability domain of the category

According to the ECHA Guidance, a category (grouping) hypothesis should address *"the set of inclusion and/or exclusion rules that identify the ranges of values within which reliable estimations can be made for category members for the given endpoint".* Particularly, *"the applicability domain of a (sub)category would identify the structural requirements and ranges of physico-chemical, environmental fate, toxicological or ecotoxicological properties within which reliable estimations can be made for the (sub)category members"*.[4] Therefore, to reliably predict properties within a category the applicability domain should be described including the borders of the category, for which chemicals the category does not hold and a justification for the inclusion and/or exclusion rules.

You have provided the following description of the ZDDP category members: *"alkyl (C3-C12) or alkaryl (C12 alkylphenol) substituted phosphorodithioic acid structures complexed with zinc".*

This description does not provide sufficient information on the applicability domain. It does not introduce unambiguous inclusion/exclusion criteria which would identify the structural requirements and ranges of physico-chemical, environmental fate, toxicological or (eco)toxicological properties within which reliable estimations can be made for the (sub)category members.

Conclusion on the category

In the absence of the necessary documentation of the category and information on the above described issues, we cannot verify whether the grouping you refer to complies with the requirements of Annex XI, Section 1.5 of the REACH Regulation and that the Substance belongs to this category.

C. Predictions for properties

C.1. Prediction for toxicological properties

You have provided documentation as described under B.1. above.

In your read-across justification document you have provided the following reasoning for the prediction of toxicological properties:
"As a result of high structural similarity, the chemical reactivity and thus environmental fate and (eco)toxicity of the target and the source substances can be expected to be very similar".

You report that the substances give rise to a common compound phosphorodithionic acid through the breakage of ester bonds and dissociation from the zinc complex of the parent compound. You consider that the exposure to the following non-common compounds: the parent compounds and the alkyl alcohols would not influence the prediction of the toxicological properties because *"they are considered to have the same biological targets and to cause the same type of effects through a common underlying mechanism due to the same functional groups"*. In addition, you assume that *"the same mode of toxicological action is expected for the target and the source substances".*

[4] ECHA Guidance, Section R.6.2.1.2

ECHA understands that you predict the properties of the Substance using a read-across hypothesis which is based on the formation of a common (bio)transformation product.
The properties of your Substance are predicted to be quantitatively equal to those of the source substance.

You provided the following information:

Hydrolysis

In your toxicokinetic statement document you report that preliminary studies (OECD TG 111) with the test source substance EC: 270-608-0 and the source substance EC: 283-392-8 determined them to be "*hydrolytically stable*".

Results of toxicity studies

You have provided a data matrix showing the (eco)toxicological data for the source substances including acute toxicity, skin/eye irritation, skin sensitization and genotoxicity.

You provided information on repeated dose toxicity as follows:

(i) Screening for reproduction/developmental toxicity study in rats, oral-gavage, (OECD TG 422, GLP compliant; 2010), performed with the test source substance (EC: 270-608-0). The derived NOEL for local effects is 40 mg/kg bw/day (based on effects on the non-glandular stomach) and the NOAEL for systemic effects is 160 mg/kg bw/day (the HDT);
(ii) Short-term (28-day) repeated dose toxicity study in rats, oral-gavage, (equivalent to OECD TG 407, GLP compliant, [redacted] 1994) with the source substance EC: 224-235-5. The derived NOAEL for local effects is 10 mg/kg bw/day (gastric irritation) and the NOAEL for systemic effects is 125 mg/kg bw/day (clinical signs, body weight changes at 250 and 500 mg/kg bw/day);
(iii) Screening for reproduction/developmental toxicity study in rats, oral-gavage, (OECD TG 421, GLP compliant; 1995) with the source substance EC: 224-235-5). The study reports decreased fertility indices (200 mg/kg bw/day) and increased number of dead pups during the post-natal period (100 and 200 mg/kg/day). The derived NOAEL for parental and neonatal toxicity is 30 mg/kg bw/day.

You did not provide any toxicological data with the Substance.

C.2. Assessment of the prediction

Supporting information

Annex XI, Section 1.5 of the REACH Regulation states that "*physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s)*". For this purpose "*it is important to provide supporting information to strengthen the rationale for the read-across*"[5]. The set of supporting information should allow to verify the crucial aspects of the read-across hypothesis and establish that the properties of the Substance can be predicted from the data on other category members.

ECHA considers that there is insufficient data to support your hypothesis, as follows:

[5] ECHA Guidance, Section R.6.2.2.1.f

Missing information on the formation of common compound

As indicated above, your read-across hypothesis is based on the (bio)transformation of the category members to a common compound(s). In this context, information characterising the rate and extent of the hydrolysis of the category members is necessary to confirm the formation of the proposed common hydrolysis product and to assess the impact of the exposure to the parent compounds.

You claim that the category members EC 270-608-0 and EC 283-302-8 are hydrolytically stable under the conditions of OECD TG 111.

ECHA notes that you have not provided any experimental data to justify your claim and neither any that would allow to compare the rate of dissociation of the substances in the gastrointestinal tract (GIT) and the formation of the phosphorodithionic acid.

In the absence of this information, you have not provided supporting evidence establishing that the proposed common product is formed as assumed in your read-across hypothesis. Therefore, you have not provided sufficient supporting information to strengthen the rationale for the read-across.

Missing information on the impact of non-common compounds

As indicated above, your read-across hypothesis is based on the (bio)transformation of the Substance and of the source substance(s) to a common compound(s). In this context, exposure to the Substance and of the source substance(s) may also lead to exposure to other compounds than the common compound of interest. The impact of exposure to these non-common compounds on the prediction of properties of the target needs to be assessed to ensure that a reliable prediction can be made.

You state that the exposure to the following non-common compounds: parent molecules and the counter alkyl alcohols, "*would not influence the prediction of the toxicological properties [...]*" because "*they are considered to have the same biological targets and to cause the same type of effects through a common underlying mechanism due to the same functional groups*".

However, you have not provided information characterising the exposure to those compounds resulting from exposure to the Substance and of the source substance(s).

In addition, you have not provided any data to substantiate your claim that the non-common compounds have "*the same biological targets*" and therefore have "*the same type of effects*".

In the absence of such information, you have not established that a reliable prediction of the property under consideration of the Substance can be derived on the basis of your read-across hypothesis. Therefore you have not provided sufficient supporting information to strengthen the rationale for the read-across.

Missing relevant supporting information for the same mode of toxicological action

According to the ECHA Guidance[5] "*it is important to provide supporting information to strengthen the rationale for the read-across approach. Thus, in addition to the property/endpoint being read-across, it is also useful to show that additional properties, relevant to the endpoint, are also (qualitatively or quantitatively) similar between the source and target chemicals*".

In order to support your claim that *"the same mode of toxicological action is expected for the target and the source substances"* you refer to information obtained from toxicological studies conducted with the source substances EC 270-608-0 and EC 283-302-8. Based on the data from the repeated dose toxicity studies (i-iii) with those substances, you claim that the local GIT irritation is the primary effect, therefore *"also for the target substance gastric irritation is expected to be the main effect"*.

ECHA notes that you have not provided any experimental data with the Substance which would allow to compare the properties of the substances. Therefore, your claim is not substantiated with sufficient data to support your prediction of same mode of action.

D. Conclusion on the grouping and read-across approach

Based on the above considerations we conclude that you have not provided adequate and reliable information to demonstrate that the proposed read-across approach is plausible for the endpoints in consideration. Therefore we conclude that the criteria of Annex XI, Section 1.5, are not met, and consequently the testing proposed on the source substance is not appropriate to fulfil the information requirements of the substance subject to the present decision.

Appendix A: Reasons for the requirements applicable to all the Registrants subject to Annex IX of REACH

1. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.)

A sub-chronic toxicity study (90 day) is a standard information requirement in Annex IX, Section 8.6.2. to REACH.

You have submitted a testing proposal for a sub-chronic toxicity study (90 day) in rats by the oral route according to OECD TG 408 with the analogue substance phosphorodithioic acid, mixed O,O-bis(iso-Bu and pentyl) esters, zinc salts (EC no 270-608-0).

ECHA notes that you provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement(s) for which testing is proposed. ECHA has taken these considerations into account.

ECHA has evaluated your proposal to perform the test with the analogue substance. As explained in the Appendix on general considerations, your adaptation according to Annex XI, Section 1.5 is rejected. Therefore testing on the Substance is needed.

You proposed testing in rats. According to the test method OECD TG 408 the rat is the preferred species. ECHA considers this species as being appropriate and testing with the Substance should be performed with the rat.

You proposed testing by the oral route. Based on the information provided in the technical dossier and/or in the chemical safety report, ECHA considers that the oral route - which is the preferred one[6] is the most appropriate route of administration with the registered substance. More specifically, even though the information indicates that human exposure to the registered substance by the inhalation route is likely (PROC 7), the exposure concentrations reported in the chemical safety report for the inhalation route is low (maximum [redacted] mg/m^3). Hence, the test shall be performed by the oral route using the test method EU B.26./OECD TG 408.

Under Article 40(3)(c) of the REACH Regulation, you are requested to carry out the study with the Substance, while pursuant to Article 40(3)(d) your originally proposed test with the source substance: phosphorodithioic acid, mixed O,O-bis(iso-Bu and pentyl) esters, zinc salts (EC no 270-608-0) is rejected.

2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.) in a first species

A pre-natal developmental toxicity (PNDT) study (OECD TG 414) in one species is a standard information requirement in Annex IX, Section 8.7.2. to REACH.

You have submitted a testing proposal for a PNDT study according to OECD TG 414 with the analogue substance: phosphorodithioic acid, mixed O,O-bis(iso-Bu and pentyl) esters, zinc salts (EC no 270-608-0) in the rat by the oral route.

You provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement(s) for which testing is proposed. ECHA has taken these considerations into account.

[6] ECHA Guidance R.7a, Section R.7.5.4.3

ECHA has evaluated your proposal to perform the test with the analogue substance. As explained in the Appendix on general considerations, your adaptation according to Annex XI, Section 1.5 is rejected. Therefore testing on the Substance is needed.

You proposed testing with the rat as a first species and by the oral route. ECHA agrees with your proposal. You may select between the rat or the rabbit because both are preferred species under the OECD TG 414. The oral route is the most appropriate route of administration to investigate reproductive toxicity[7].

Under Article 40(3)(c) of the REACH Regulation, you are requested to carry out the study with the Substance, while pursuant to Article 40(3)(d) your originally proposed test with the source substance: phosphorodithioic acid, mixed O,O-bis(iso-Bu and pentyl) esters, zinc salts (EC no 270-608-0) is rejected.

[7] ECHA Guidance R.7a, Section R.7.6.2.3.2.

Appendix B: Procedural history

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 12 October 2018.

ECHA held a third party consultation for the testing proposals from 26 April 2019 until 10 June 2019. ECHA did not receive information from third parties.

For the purpose of the decision-making, this decision does not take into account any updates of registration dossiers after the date on which you were notified the draft decision according to Article 50(1) of REACH.

The decision making followed the procedure of Articles 50 and 51 of REACH, as described below:

ECHA notified you of the draft decision and invited you to provide comments within 30 days of the notification.

ECHA did not receive any comments within the 30-day notification period.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no amendments were proposed, ECHA adopted the decision under Article 51(3) of REACH.

Appendix C: Observations and technical guidance

1. The information requirement under Section 8.7.3. of Annex IX to REACH (Extended one-generation reproductive toxicity study, EOGRTS) is not addressed in this decision, because the information from the Sub-chronic toxicity study (90-day), requested in the present this decision, is relevant for the design of the EOGRTS.

2. This testing proposal examination decision does not prevent ECHA from initiating compliance checks at a later stage on the registrations present.

3. Failure to comply with the requests in this decision, or to otherwise fulfil the information requirements with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State(s).

4. Test guidelines, GLP requirements and reporting

   Under Article 13(3) of REACH, all new data generated as a result of this decision needs to be conducted according to the test methods laid down in a European Commission Regulation or according to international test methods recognised by the Commission or ECHA as being appropriate.

   Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses must be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.

   Under Article 10 (a) (vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide: 'How to report robust study summaries'[8].

5. Test material

   You reported within the joint submission the registered substance as Phosphorodithioic acid, mixed-O,O-bis(iso-Bu and iso-Pr and pentyl) esters, zinc salts (list number: 820-225-5). The substance is registered as Unknown or Variable Composition, Complex reaction products and Biological materials (UVCB Substance). It is a zinc dithiodialkylphosphate (ZDDP) consisting of neutral and basic zinc salts as constituents, which are UVCB substances themselves.

   The main constituents and their concentration ranges in the boundary composition are:
   - 40 – 90 % neutral iso-butyl/iso-propyl/pentyl ZDDP consisting of two core structures of iso-butyl/iso-propyl/pentyl dithiophosphoric acids forming a zinc salt.
   - 10 - 50 % basic iso-butyl/iso-propyl/pentyl ZDDP consisting of six core structures of iso-butyl/iso-propyl/pentyl dithiophosphoric acids forming zinc salts and coordinated via four zinc atoms to one oxygen;
   - 0 - 20% of "Various organothiophosphate species and unreacted starting material (alcohols)" including up to 1% of the three alcohols used as starting materials
   - Based on the reported composition, no base oil of any kind is present

[8] https://echa.europa.eu/practical-guides

Due to the wide concentration ranges of the reported constituents/group of constituents in the boundary composition record, possible compositions of the Substance may be e.g.:

- 50 % neutral iso-butyl/iso-propyl/pentyl ZDDP and 50 % basic iso-butyl/iso-propyl/pentyl ZDDP or
- 90 % neutral iso-butyl/iso-propyl/pentyl ZDDP and 10 % basic iso-butyl/iso-propyl/pentyl ZDDP or
- 40 % neutral iso-butyl/iso-propyl/pentyl ZDDP and 40 % basic iso-butyl/iso-propyl/pentyl ZDDP and 20% "Various organothiophosphate species" or
- any composition between these concentration values.

ECHA therefore considers it likely that the different possible constituent ratios result in different hazard properties, if tested in toxicity studies. To avoid underestimation of the hazard caused by the inappropriate selection of the test material, the test material should represent a worst case in terms of expected absorption and expected toxicity. ECHA therefore provides considerations on the selection of the test material and how it should be reported below.

While selecting the test material you must take into account the impact of each constituent/ impurity on the test results for the endpoint to be assessed. For example, if a constituent/impurity of the Substance is known to have an impact on (eco)toxicity, the selected test material must contain that constituent/impurity. Any constituents that have harmonised classification and labelling according to the CLP Regulation (Regulation (EC) No 1272/2008) must be identified and quantified using the appropriate analytical methods.

The OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, Number 11 [ENV/MC/CHEM(98)16] requires a careful identification of the test material and description of its characteristics. In addition, the Test Methods Regulation (EU) 440/2008, as amended by Regulation (EU) 2016/266, requires that "*if the test method is used for the testing of a* [...] *UVCB* [...] *sufficient information on its composition should be made available, as far as possible, e.g. by the chemical identity of its constituents, their quantitative occurrence, and relevant properties of the constituents*".

Detailed information on the composition of the test material using appropriate analytical techniques is required. The reporting for each tested material must include the concentration value of the monomeric neutral iso-butyl/iso-propyl/pentyl ZDDP, the concentration value of the dimeric iso-butyl/iso-propyl/pentyl ZDDP, the concentration value of the basic iso-butyl/iso-propyl/pentyl ZDDP, and the concentrations, identities and compositions of any other relevant constituent present in the sample.

Technical Reporting of the test material for UVCB substances

The composition of the selected test material must be reported in the respective endpoint study record, under the Test material section. The composition must include all constituents of the test material and their concentration values. Without such detailed reporting, ECHA may not be able to confirm that the test material is relevant for the Substance and to all the registrants of the Substance.

6. List of references of the ECHA Guidance and other guidance/ reference documents[9]

QSARs, read-across and grouping
Guidance on information requirements and chemical safety assessment, Chapter R.6 (version 1.0, May 2008), referred to as ECHA Guidance R.6 in this decision.

ECHA Read-across assessment framework (RAAF, March 2017)[10]

Toxicology
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

Environmental toxicology and fate
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017), referred to as ECHA Guidance R.7b in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

PBT assessment
Guidance on information requirements and chemical safety assessment, Chapter R.11 (version 3.0, June 2017), referred to as ECHA Guidance R.11 in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.16 (version 3.0, February 2016), referred to as ECHA Guidance R.16 in this decision.

OECD Guidance documents
Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

Guidance Document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption – No 150, referred to as OECD GD 150.

[9] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[10] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

Appendix D: List of the registrants to which the decision is addressed and the corresponding information requirements applicable to them

Registrant Name	Registration number	(Highest) Data requirements to be fulfilled
[redacted]	[redacted]	[redacted]

Note: where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas the decision is sent to the actual registrant.