EUROPEAN CHEMICALS AGENCY

Helsinki, 16 June 2017

Substance name: reaction mass of O,O'-diisopropyl (pentathio)dithioformate and O,O'-diisopropyl (trithio)dithioformate and O,O'-diisopropyl (tetrathio)dithioformate (ROBAC AS/100)
EC number: 403-030-6
CAS number: 137398-54-0
Date of Latest submission(s) considered: 14 June 2016
Decision/annotation number: Please refer to the REACH-IT message which delivered this communication (in format SEV-D-XXXXXXXXXX-XX-XX/F
Addressees: Registrant(s)[1] of a reaction mass of O,O'-diisopropyl (pentathio)dithioformate and O,O'-diisopropyl (trithio)dithioformate and O,O'-diisopropyl (tetrathio)dithioformate (Registrant(s))

DECISION ON SUBSTANCE EVALUATION

1. Requested information

Based on Article 46(1) of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), you are requested to submit the following information on the registered substance:

Either:

Sediment simulation testing; test method: Aerobic and anaerobic transformation in aquatic sediment systems, EU TM C.24. / OECD TG 308 using the registered substance. The simulation test should be performed at a temperature of 12°C with the test item added directly to the sediment and include analytical measurement of the registered substance and degradants/impurities including 0,0-di(1-methylethyl)dithio-bisthioformate (DIXD), CAS: 105-65-7.

Or:

Simulation testing on ultimate degradation in surface water; test method: Aerobic mineralisation in surface water – simulation biodegradation test, EU C.25./OECD TG 309 using the registered substance. The simulation test should be performed at a temperature of 12°C and include analytical measurement of the registered substance and degradants/impurities including DIXD. The study should follow the "pelagic test" option with a concentration of suspended solids in the surface water approximately 15 mg dw/L (natural surface water containing between 10 and 20 mg SPM dw/L is considered acceptable).

You shall consult the REACH Guidance on Information Requirements and Chemical Safety Assessment Chapter R.11: PBT/vPvB assessment, November 2014, Section R.11.4.1.1 in order to decide on the most appropriate test method based

[1] The terms Registrant(s), dossier(s) or registration(s) are used throughout the decision, irrespective of the number of Registrants addressed by the decision.

on the water solubility of the registered substance.

For the study conducted, when reporting the non-extractable residues (NER), you should explain and scientifically justify the extraction procedure and solvent used for obtaining a quantitative measure of NER.

You shall provide an update of the registration dossier(s) containing the requested information, including robust study summary, study report and, where relevant, an update of the Chemical Safety Report by **2 January 2019**.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2. Further information, observations and technical guidance as appropriate are provided in Appendix 3. Appendix 4 contains a list of registration numbers for the addressees of this decision. This Appendix is confidential and not included in the public version of this decision.

2. Who performs the testing

Based on Article 53 of the REACH Regulation, you are requested to inform ECHA who will carry out the study/ies on behalf of all Registrant(s) within 90 days. Instructions on how to do this are provided in Appendix 3.

3. Appeal

You can appeal this decision to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, shall 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[2] by Leena Ylä-Mononen, Director of Evaluation

[2] 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 1: Reasons

Based on the evaluation of all relevant information submitted on a reaction mass of O,O'-diisopropyl (pentathio)dithioformate and O,O'-diisopropyl (trithio)dithioformate and O,O'-diisopropyl (tetrathio)dithioformate (ROBAC AS/100), and other relevant available information, ECHA concludes that further information is required in order to enable the evaluating Member State Competent Authority (MSCA) to complete the PBT evaluation of the substance. The evaluating MSCA will subsequently review the information submitted by you and evaluate if further information should be requested in order to clarify the concern for PBT /vPvB properties.

The registered substance was evaluated under Directive 67/548/EEC (the Notification of New Substances (NONS) Regulations in the UK). This included a PBT assessment. It was noted that the substance hydrolyses primarily to 0,0-di(1-methylethyl)dithio-bisthioformate (DIXD) which in turn was considered stable. On this basis, the registered substance (as DIXD) was considered to screen as persistent / very persistent (P/vP).

The registered substance screened as bioaccumulative / very bioaccumulative (B/vB) on the basis of the measured log K_{ow} >5.9 for the parent substance and a measured log K_{ow} of 5.72 for the degradation product DIXD. There is insufficient information on either the registered substance or DIXD to come to a definitive conclusion on T at present. On this basis, the registered substance was considered potentially PBT and/or vPvB.

At the time NONS transitioned to REACH, an enhanced ready biodegradation study using the degradant DIXD was required (requested on 30 May 2008 with a deadline of 31 March 2009) to characterise persistence. Considering the available hydrolysis information, this request was for a 56-day enhanced ready biodegradation study using the degradant DIXD with measurement of mineralisation and DIXD concentrations.

This request was adapted by you and on 11 February 2015, you submitted an extended ready biodegradation study using the registered substance in a silicone preparation to limit hydrolysis. You concluded that the registered substance did not meet the readily biodegradable criteria. The evaluating Member State has reviewed the study and consider it does not allow a conclusion to be reached for whether the registered substance or DIXD screens as P/vP. This is discussed further in the section below.

In conclusion, ECHA has reviewed the available hazard and fate information in the registration dossier. Based on available data, in the view of ECHA, the registered substance continues to screen as potentially PBT and vPvB.

The information requested (fate testing) in this decision constitutes the first tier in a testing strategy to clarify the concerns for PBT assessment. Hence, the evaluating MSCA will review the information submitted by you as an outcome of tier 1 of the testing strategy, and evaluate if further information (e.g. bioaccumulation and ecotoxicity) should be requested in a future decision in order to clarify the PBT concern.

Persistence testing following either OECD TG 308 or OECD TG 309

The Concern(s) Identified

There is concern that the registered substance and/or its degradant DIXD (CAS: 105-65-7) may be persistent in the environment and may fulfil the criteria for PBT/vPvB according to REACH Annex XIII.

Why new information is needed

In your PBT assessment you consider that the registered substance is not persistent on the basis that it hydrolyses to DIXD.

REACH Annex XIII states that PBT assessment shall also take account of the PBT/vPvB-properties of relevant constituents of a substance and relevant transformation and/or degradation products.

In a GLP hydrolysis study (considered valid under NONS) the registered substance was observed to be more hydrolytically unstable at higher pH. The following hydrolysis half lives, converted to 12°C, were generated: 508.3 hours at pH 4; 458.9 hours at pH 7; and 8.75 hours at pH 9. The principle degradant was DIXD with sulphur as an additional hydrolysis product. Concentrations of DIXD increased during test with a decrease in parent registered substance indicating that the rate of hydrolysis of DIXD is slower than its rate of formation. This study indicates that under these laboratory conditions the registered substance undergoes fairly rapid hydrolysis.

In a GLP Ready Biodegradation study (considered valid under NONS) the registered substance was considered not readily biodegradable based on 10 to 15% mineralisation by day 28.

During summer 2014 you corresponded with the Competent Authority of the United Kingdom (UKCA) by email requesting informal advice about the outstanding proposed fate study. As you started to manufacture the registered substance in amounts exceeding 100 tonnes/year, the UKCA suggested that you consider a test strategy to reflect REACH Annex IX information requirements and PBT, vP/vB properties instead of the previously requested study. You responded proposing an extended ready biodegradation study using the registered substance with sample preparation to minimise hydrolysis and analytical monitoring of the registered substance and degradant DIXD. At this point the UKCA noted that the study may be difficult to interpret and that further fate testing may be required. To this, you acknowledged further environmental testing may be needed regarding persistence.

In February 2015 you submitted a GLP extended 60-day ready biodegradation study using the registered substance. The test item was dispersed in silicone oil at a concentration an order of magnitude above the quoted water solubility for the reaction mass[3]. The silicone oil was added to slow premature hydrolysis of the parent substance (and therefore formation of DIXD) to allow potential biodegradation of the parent to occur.

[3] Registrant reported water solubility for the registered substance:
0.752 mg/l at 20°C (GLP, EU Guideline A.6 and accepted under NONS with Registrant reliability score 1)
1.3 mg/l at 20-23°C (non-GLP, OECD TG 105 in-house test method with Registrant reliability score 1).

On the basis of inorganic carbon (IC) analysis, 15% biodegradation was observed at day 28 and 26% biodegradation by day 61. The level of mineralisation at day 28 is in line with the results of the original ready biodegradation study. As IC analysis reflects mineralisation of both the registered substance parent and degradant DIXD, it is unclear what proportion of the degradation represents direct biodegradation of registered substance parent and hydrolysis and subsequent biodegradation of DIXD.

Using HPLC analysis, on day 0, 1 and 5 the registered substance parent was 100% of nominal with DIXD below the limit of quantification. The next analytical point was study termination at day 61 when concentrations of the registered substance equated to 65-67% of nominal. At day 61, the concentration of DIXD was 7.44 to 7.83 mg/L demonstrating that some hydrolysis had occurred. However, as there was no analysis between day 5 and day 61, the hydrolysis rate cannot be determined. The study report considered that 11-13% biodegradation had occurred (based on addition of measured parent substance and degradant as a percentage of the initial nominal parent concentrations).

No other metabolites were investigated or quantified although small peaks were observed in the example chromatogram on day 61 which were not present in the control or day 0 sample.

The use of silicone oil was anticipated by you to inhibit the rate of hydrolysis. The extent of inhibition achieved is unclear. In addition, it is not known whether the presence of undissolved test substance caused lower biodegradation.

Overall, the study does not indicate significant biodegradation of the registered substance. In addition, it is not possible to judge whether the degradant DIXD is rapidly degradable or not.

In addition to the February 2015 fate study, a non-GLP inherent biodegradability study is available in the registration dossier using the registered substance and following a 28-day Chinese guideline modified MITI (II) method using a mixture of Chinese domestic and industrial inoculum. Based on biological oxygen demand (BOD), degradation was 6.26 to 6.39%. Based on analysis of the registered substance, 7.54 to 11.5% biodegradation was observed.

The data mentioned above (including the extended ready biodegradation study submitted in February 2015) are not considered to provide sufficient data to conclude whether the registered substance and/or DIXD are P/vP.

On the basis of the available degradation data, ECHA considers that the registered substance and its hydrolysis degradant DIXD still screen as potentially P/vP. Therefore, further experimental work is required to allow a conclusion to be reached about whether the registered substance and/or DIXD meet the P/vP criteria according to REACH Annex XIII.

Considerations on the test method and testing strategy

You are offered the choice of either OECD TG 308 or OECD TG 309. You shall justify your choice of simulation test method considering available physico-chemical information and anticipated partitioning. Specific advice for this is available in the REACH Guidance on Information Requirements and Chemical Safety Assessment Chapter R.11: PBT/vPvB assessment.

ECHA has reviewed the available physico-chemical information. At present, using the SIMPLETREAT model (in EUSES v2.03) with the GLP water solubility of 0.752 mg/l at 20 °C, vapour pressure of 2.2 x 10^{-5} Pa at 25 °C, log K_{ow} >5.9 and log Koc >5.6, and EUSES calculated Henry's Law Constant of 9.16 x 10^{-3} Pa m^3/mol, the substance is anticipated to partition to sludge / sediment in aquatic systems with less than 9.5% to the water phase and >90.5% to sludge. It is noted that there is uncertainty around the water solubility which is measured using the reaction mass as a whole. This may not be representative of all components as some components may be more soluble than others. While this suggests that performing an OECD TG 308 study would be most appropriate, ECHA considers that, if technically feasible, the OECD TG 309 method is generally preferred as it avoids interpretation problems arising from bound residues.

The simulation testing should include analytical measurement of the registered substance, DIXD and any further relevant transformation products to calculate half lives.

Alternative approaches and Proportionality of the request

Although degradation model predictions have not currently been considered by you, ECHA has reviewed the BIOWIN QSAR model to consider degradation predictions for the registered substance. There are no chemicals or fragments containing xanthogens or sulphides in the model, and so there are no sulphur-containing substances structurally similar to the registered substance. The BIOWIN predictions are either calculated from the biodegradability of the remaining fragments (for example methyl groups) and a factor for the molecular weight, or from molecular weight alone. ECHA considers this results in significant uncertainty as a large proportion of the molecule is excluded from the prediction. Overall, while the molecular weight of the registered substance is within the molecular weight domain of the model, ECHA considers that this alone is insufficient to be confident of the predictions.

Therefore, the chemical is not assessed by ECHA to be within the domain of the BIOWIN models, and this is not an alternative to the testing specified in section 1 in this case.

ECHA has considered requesting a repeat enhanced biodegradation test without silicone using either the registered substance or the degradant DIXD. Given the low levels of degradation/mineralisation observed in available studies and the difficulties in interpreting such studies without near complete mineralisation, a simulation study is required to provide valid aquatic environment half-life information. This is because ECHA considers that further enhanced testing will not provide an unequivocal conclusion regarding Persistence. The present data suggests that the parent registered substance screening as P/vP cannot be excluded (contrary to the original assessment). In addition the level of DIXD degradation does not suggest mineralisation >60% in 60 days would be reasonably expected.

As the hydrolysis rate of the registered substance in natural water with dissolved organic carbon is unclear, ECHA considers it is appropriate to conduct the simulation study with the registered substance with measurement of the degradant. The study outputs including DT_{50} values will allow clear comparison with Annex XIII Persistence criteria.

Depending on available physico-chemical information, anticipated partitioning and analytical feasibility, either the OECD TG 308 or 309 method is the most suitable simulation test to address the specific concern for persistence. If the fate data, once obtained, confirm that the registered substance meets the P/vP criteria, a further testing strategy considering solubility, bioaccumulation and ecotoxicity may be requested. If the registered substance or degradation product meets the PBT or vPvB criteria, you will need to review your exposure scenarios to minimise environmental emissions, and regulatory authorities may consider further risk management measures such as identification as a Substance of Very High Concern in accordance with REACH Article 57.

Following evaluation of the requested fate study and updated PBT assessment (including assessment of available bioaccumulation and ecotoxicity data), a further testing strategy may be requested to refine the PBT assessment. In particular a fish bioaccumulation test may be required. At that time the choice of test substance and method will be clearer from the persistence testing.

Consideration of Registrants' comments

In your comments you stated you would carry out persistence testing following OECD TG 308 with radiolabelled test item as Robac AS100. ECHA highlights that the choice of radio-label and position should allow identification of metabolites in the degradation pathway.

In November 2016, after the formal commenting period had ended, you asked the UKCA for a teleconference on the basis that you had further considerations for assessing the persistence endpoint. You proposed to conduct a further enhanced biodegradation study using degradant DIXD to address the persistence concerns of the registered substance.

You said that you considered the impact of the silicone sample preparation in the 2015 enhanced biodegradation study was unclear. Given that it is unclear if the degradant DIXD degrades you suggested exploring levels of DIXD degradation in an enhanced biodegradation study.

As described under *Alternative approaches and Proportionality of the request*, ECHA has considered this option, but the level of mineralisation in the two recent biodegradation tests (enhanced study:~26% mineralisation of the registered substance over 60 days with up to 11.5% degradation of the registered substance by day 28; non-GLP inherent study with up to 11.5% biodegradation by day 28) does not indicate repeating an enhanced test with the degradant DIXD would provide conclusive information to assess persistence for the registered substance. Therefore the request for the simulation study is retained in the Decision.

Consideration of Other Member States comments

Three proposals for amendments (PfAs) were submitted proposing suspended solid test conditions for the OECD TG 309 test method and requirement for the Registrant to justify the extraction method for NER measurement. ECHA agrees and the decision was updated using text agreed for previous similar cases at the Member State Committee. As the same issue for NER arises for the OECD TG 308 test, the justification for the extraction method and solvent used is required which ever simulation test is done.

A further PfA included a suggestion that the test item should be added directly to the sediment in the OECD TG 308 study. ECHA agrees this is appropriate to limit hydrolysis, simplify degradation kinetics and allow sufficient time / measurement to determine DT50 values. The decision was therefore updated accordingly.

In your comments on the PfAs you asked which sediment degradation test is required. ECHA confirms that you are required to provide the study using aerobic sediment. ECHA confirms that the test using exclusively anaerobic sediment is not required.

Conclusion

Therefore, based on the substance evaluation and pursuant to Article 46(1) of the REACH Regulation, ECHA concludes that you are required to carry out one of the following studies using the registered substance subject to this decision:

Either:

Sediment simulation testing; test method: Aerobic and anaerobic transformation in aquatic sediment systems, EU C.24. / OECD TG 308 using the registered substance. The simulation test should be performed at a temperature of 12°C with the test item added directly to the sediment and include analytical measurement of the registered substance and degradants/impurities including DIXD (CAS: 105-65-7).

Or:

Simulation testing on ultimate degradation in surface water; test method: Aerobic mineralisation in surface water – simulation biodegradation test, EU C.25./OECD TG 309 using the registered substance. The simulation test should be performed at a temperature of 12°C and include analytical measurement of the registered substance and degradants/impurities including DIXD (CAS: 105-65-7). The study should follow the "pelagic test" option with a concentration of suspended solids in the surface water approximately 15 mg dw/L (natural surface water containing between 10 and 20 mg SPM dw/L is considered acceptable).

For the study conducted, when reporting the non-extractable residues (NER) you should explain and scientifically justify the extraction procedure and solvent used obtaining a quantitative measure of NER.

Deadline to submit the requested Information

In the draft decision communicated to you the time indicated to provide the requested information was 33 months, or 24 months (if the fish bioaccumulation study was not required), from the date of adoption of the decision. In your comments on the draft decision of 2 May 2016, you requested an extension of the timeline to 20 months for persistence testing and an additional 23 moths for the bioaccumulation testing. You sought to justify this request by including a breakdown of the timeline to include initial read across considerations, manufacture of radiolabel, time for carrying out the study (including delays at the test house) and producing the report and finally producing the RSS and dossier update.

You also proposed to include an initial step to explore and evaluate QSARs but did not suggest a time for this.

ECHA points out that the timescales were set according to the standard deadlines used for all decisions and that they take into account the steps described in your comments. Additionally, any investigation of QSARs and read across can be initiated immediately without waiting for the final decision so this should not impact the final deadline.

However, in the draft decision communicated to you, the time indicated to provide the requested information took into account the fact that the draft decision also requested a Water solubility (OECD TG 105) and a Bioaccumulation in fish (OECD TG 305) study. As these studies are not addressed in the present decision, ECHA considers that a reasonable time period for providing the required information in the form of an updated registration is 18 months from the date of the adoption of the decision. The decision was therefore modified accordingly. This is similar to your proposed timeframe of 20 months for P testing, which included 2 months for the assessment of read across.

Appendix 2: Procedural history

You notified a reaction mass of O,O'-diisopropyl (pentathio)dithioformate and O,O'-diisopropyl (trithio)dithioformate and O,O'-diisopropyl (tetrathio)dithioformate (ROBAC AS/100) pursuant to the national legislation implementing Directive 67/548/EEC relating to the classification, packaging and labelling of dangerous substances (as amended) by submitting a notification to the Competent Authority of the United Kingdom (UKCA) in accordance with Article 7 of Directive 67/548/EEC. The notification number allocated was 89-06-0139. Article 24(1) of the REACH Regulation provides that the notification is regarded as a registration and ECHA has assigned a registration number.

Under Directive 67/548/EEC the UKCA started the evaluation targeted on the PBT properties of the substance based on the dossier and the SNIF files available from the notification and issued a decision to you on 30 May 2008.

According to Article 135, requests to the notifier to provide further information on a substance in accordance with Article 16(1) of Directive 67/548/EEC shall be considered to be decisions adopted in accordance with Article 52 of the REACH Regulation, which relates to Substance Evaluation. Such substances are regarded as being included in the Community rolling action plan (CoRAP) in accordance with Article 44(2) of the REACH Regulation.

In the course of this follow up transitional evaluation, on 7 March 2013 you provided an updated dossier containing a CSR and updated PBT assessment but not the Enhanced Ready Degradation test as requested in the decision from 30 May 2008. This information was evaluated by the UKCA but it was concluded that it did not remove the requirement for data to update the PBT assessment and as such you were found to be non-compliant with the decision of 30 May 2008. Following intervention by the UK National Enforcement Authority you indicated you were carrying out further work to address the UKCA concerns.

On 11 February 2015, you submitted an enhanced biodegradation study using the registered substance with the addition of silicone oil to minimise hydrolysis.

Pursuant to Article 45(4) of the REACH Regulation the UKCA carried out the evaluation of the above substance based on the information in the registration dossier and other relevant and available information.

The UKCA considered that further information was required to clarify the PBT, vPvB concerns. 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 11 February 2016.

ECHA notified you of the draft decision and invited you to provide comments.

Registrant(s)' commenting phase

You contacted ECHA on 11 May 2016 indicating that the registered substance had been mislabelled as a mixture in the draft decision and that it should be considered a reaction mass. Subsequently, ECHA confirmed the registered substance is considered a reaction mass. You also requested an extension to the commenting period. While an extension to the standard commenting period was not feasible, the UKCA agreed to accept a dossier update.

ECHA received comments from you on 6 June 2016 and forwarded them to the UKCA without delay.

The UKCA took into account the comments from you, which were sent within the commenting period, and they are reflected in the Reasons (Appendix 1).

In addition, on 14 June 2016 you submitted an update of the registration dossier. The UKCA took the information in the updated registration dossier into account and the water solubility requirement (OECD TG 105) was removed from the decision.

Additionally the request for a Bioaccumulation study (OECD TG 305) has been removed in this first decision, the UKCA focussing the request on Persistence first.

In November 2016, on your request, a teleconference was held with the UKCA. You wanted to discuss further considerations for assessing the persistence endpoint. Whilst this was after the formal commenting period the comments have been considered above.

Proposals for amendment by other MSCAs and ECHA and referral to Member State Committee

The UKCA notified the draft decision to the Competent Authorities of the other Member States and ECHA for proposal(s) for amendment.

Subsequently, the UKCA received proposals for amendment to the draft decision and modified the draft decision. They are reflected in the Reasons (Appendix 1).

ECHA referred the draft decision, together with your comments, to the Member State Committee.

ECHA invited you to comment on the proposed amendments. Any comments on the proposal(s) for amendment were taken into account by the Member State Committee and are reflected in the Reasons (Appendix 1). The Member State Committee did not take into account any comments on the draft decision as they were not related to the proposal(s) for amendment made and are therefore considered outside the scope of Article 52(2) and Article 51(5).

MSC agreement seeking stage

The Member State Committee (MSC) reached a unanimous agreement on the draft decision during its MSC-53 meeting and ECHA took the decision according to Article 52(2) and 51(6) of the REACH Regulation.

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Appendix 3: Further information, observations and technical guidance

1. This decision does not imply that the information provided by you in the registration(s) is in compliance with the REACH requirements. The decision neither prevents ECHA from initiating compliance checks on your dossier(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.

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

3. In relation to the required experimental study/ies, the sample of the substance to be used shall have a composition that is within the specifications of the substance composition that are given by all Registrant(s). It is the responsibility of all the Registrant(s) to agree on the tested material to be subjected to the test(s) 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 (UKCA) and ECHA to confirm the relevance of the testing for the substance subject to substance evaluation.

4. In relation to the experimental stud(y/ies) the legal text foresees the sharing of information and costs between Registrant(s) (Article 53 of the REACH Regulation). You 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 stud(y/ies) on behalf of all of them.