EUROPEAN CHEMICALS AGENCY

Helsinki, 3 February 2020

Addressees
Registrants of JS_EC number 923-900-3 listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject of this decision
5 April 2018

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Esterification products of fatty acids, C16 and C16-18 (even numbered, unsaturated) alkyl and adipic acid with pentaerythritol
EC number: 923-900-3
CAS number: -

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

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (REACH), ECHA requests that you submit the information listed below by the deadline of ***10 August 2022***.

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

1. Robust study summary for "Alga, Growth Inhibition Test with [redacted]" (Annex VII, Section 9.1.2. in conjunction with Annex I, Section 3.1.5.)

   OR

   Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method EU C.3./OECD TG 201, in conjunction with the OECD Guidance 23) with the Substance

B. 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. Robust study summary for "Daphnia magna, Reproduction Test with [redacted]" (Annex IX, Section 9.1.5. in conjunction with Annex I, Section 3.1.5.)

   OR

   Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method EU C.20./OECD TG 211, in conjunction with the OECD Guidance 23) with the Substance

3. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method OECD TG 210, in conjunction with the OECD Guidance 23) 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 registered tonnage of the Substance at the time of evaluation. You have to comply with the requirements of Annexes VII, VIII and IX of REACH, if you have registered a substance at 100-1000 tpa;

The Appendix on general considerations addresses common arguments that are applicable throughout the present decision 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 testing material used to perform the required studies shall be selected and reported in accordance with the specifications prescribed in Appendix F: Observations and technical guidance.

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.

Approved[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 ECHA and OECD Guidance documents referred to in this decision are listed in Appendix F of this decision.

Aquatic toxicity testing

For the substances which are difficult to test, procedures described in the OECD Guidance 23 on aquatic toxicity testing of difficult substances and mixtures must be followed, in addition to the procedures described in the relevant aquatic toxicity testing test guidelines. The OECD Guidance 23 relates to the practical aspects of carrying out valid tests and presenting the results with difficult to test chemicals.

According to Tables 1 and 2 of the OECD Guidance 23, water solubility of less than 100 mg/L at 25°C indicates difficulties in achieving/maintaining required exposure concentrations and analysing exposure concentration.

You have reported a water solubility of < 3 mg/L for the Substance.

Therefore the Substance is considered "difficult to test" being poorly or sparingly water-soluble and aquatic toxicity studies must follow the specifications/requirements of the applicable OECD Guidance Document 23.

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Appendix A: Reasons for the requests to comply with Annex VII of REACH

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 1 to 10 tonnes or more per year must contain, as a minimum, the information specified in Annex VII to the REACH Regulation.

1. **Robust study summary for "Alga, Growth Inhibition Test with [redacted]" (Annex VII, Section 9.1.2. in conjunction with Annex I, Section 3.1.5.)**

   OR

   Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.);

Growth inhibition study aquatic plants is a standard information requirement in Annex VII to the REACH Regulation.

You have provided a robust study summary for the key study conducted according to OECD TG 201 (GLP compliant).

We have assessed this information and identified the following issues:

A robust study summary must be provided for all key data used in the hazard assessment (Articles 3(28) and 10(a)(vii) and Annex I, Section 3.1.5 of REACH). It must provide a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study.

The OECD TG 201 in conjuction with OECD Guidance 23 requires that for poorly/sparingly water-soluble substances you must:
- provide results of a preliminary solubility experiment as it forms the basis of the test solution preparation procedures adopted for the toxicity tests;
- document the procedures required to achieve the maximum dissolved concentration that can be achieved in the specific test solution under test conditions, including mixing/contact time;
- justify the separation technique especially if filtration is used, as it can cause losses due to adsorption onto the filter matrix;
- apply the methods required to achieve the maximum dissolved concentrations in your aquatic toxicity test.

As noted in the Appendix on general considerations the Substance is poorly/sparingly water-soluble substance.

In the study summary you provided you state that the test solutions were prepared by addition of the test substance to dilution water, followed by stirring for 24 h and removal of undissolved particles by filtration using a Sartorius stedim SARTOBRAN 150 sterile Capsule of 0.45 + 0.2 µm pore size.

You have not provided information on the preliminary solubility experiment or any other documentation which would justify the methods to prepare the test solutions.

Therefore, it is not possible to make an independent assessment of the study and its reliability with regards to preparation of the test solutions, the use of filter as a separation method and stirring time of 24-h.

In the comments to the draft decision, you provided explanations as a justification of the test solution preparation methods.

We have assessed this information and identified the following issues:

The OECD TG 201 in conjuction with OECD Guidance 23 requires that for poorly/sparingly water-soluble substances you must:

- use a sufficiently sensitive analytical method for the analysis of the test chemical in the conducted toxicity study and in the preliminary stability study to investigate the appropriate design of the applied methods. For example, sum parameter methods (e.g. total organic carbon) will not demonstrate the stability of individual UVCB components during the test and are limited by relatively poor sensitivity (approximately 1 mg/L);
- provide a statement from an analytical chemist if the dissolved fraction cannot be analytically measured (e.g. when solubility is below a quantifiable level), in order to confirm that the analytical methods used were state of the art, and to justify why lower detection limits were not feasible (any preliminary analytical efforts should also be described);

You consider that the available water solubility study according to OECD TG 105 can be used as a preliminary stability study because the test solution preparation was the same as in the aquatic toxicity studies and one is unlikely to observe significantly different solubility values for the test item within test media in comparison to demineralized water. A water solubility value of <3 mg/L in the water solubility study was derived using TOC method where the LOQ was 3 mg/L. Based on this result, you consider the Substance poorly soluble and therefore assume that the maximum saturation of the test substance is reached even without detecting the substance in the test solution.

You also consider in the comments that the stirring time would not make a difference to maximum dissolved concentration based on structure and logKow of the constituents. You have not provided any evidence how the chemical structure or LogKow can be used to predict the required stirring times. You also did not provide logKow values for each constituents separately to indicate poor solubility of all constituents.

Similarly you consider that the separation method would not affect the achieved dissolved concentrations since the maximum concentration of the test item is lower than the used test item concentration in this test. You did not further explain why the maximum initial loading is relevant to consider the potential losses by the filter separation technique.

The use of the water solubility experiment according to OECD TG 105 cannot be considered as a preliminary solubility experiment and to deliver the requested information for the following reasons.

The chemical analysis performed by TOC in the OECD TG 105/solubility experiment was limited by poor sensitivity and did not allow to detect the test substance in the test solution. Therefore this method may not be suitable to investigate how to achieve the maximum dissolved concentrations in a preliminary experiment. You did not provide a statement from an analytical chemist confirming that preliminary analytical efforts were taken and no lower detection limits could have been feasible.

ECHA however acknowledges that the Substance may be difficult to dissolve in water. This information, or any other information related to maximising the dissolved test

concentrations, can however be obtained when e.g. performing the requested Long-term toxicity study on fish (see request B.3) and its preliminary solubility experiment with appropriate analytical methods.

The information provided in the comments does not allow to make an independent assessment of the study and its reliability with regards to preparation of the test solutions.

Based on the above, the provided information does not fulfil the information requirement. To allow an independent assessment of the submitted study, you need to provide a complete robust study summary with the above missing elements for the study. Alternatively, if methods required to achieve the maximum dissolved concentrations were not applied in the toxicity test provided in your dossier, you need to submit the following study for the Substance: Freshwater Alga and Cyanobacteria, Growth Inhibition Test (EU C.3/OECD TG 201 in conjunction with the OECD Guidance 23).

Appendix B: Reasons for the requests to comply with Annex IX of REACH

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes or more per year must contain, as a minimum, the information specified in Annexes VII-IX to the REACH Regulation.

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 to REACH.

You have provided an adaptation in your dossier, claiming that *"A subacute oral toxicity study (28 days, OECD TG 407) with the test substance revealed no substance-related findings at clinical observations and no effect on survival".* While you have not provided a specific legal reference for your adaptation, ECHA has evaluated the provided information according to Annex IX, Section 8.6.2, Column 2.

As provided in Annex IX, Section 8.6.2, Column 2, you may adapt the information requirement provided you fulfil the following cumulative criteria: the Substance is unreactive, insoluble and not inhalable and there is no evidence of absorption and no evidence of toxicity in a 28-day 'limit test', particularly if it is coupled with limited human exposure.

You have provided in your dossier a 28-day repeated dose toxicity study which provides evidence of absorption. Evidence of toxicity has also been obtained in this 28-day repeated dose toxicity study from the observation of effects on the liver, the thyroid gland and the mesenterial lymph nodes. As noted in the dossier: *"a single effect in the mesenterial lymph nodes (foamy macrophage aggregates of minimal to moderate degree in the high dose animals and to a minimal in a single female of the mid dose group)"* was reported and used as a basis for identification of a NOAEL.

Furthermore, you have not provided any evidence of a limited human exposure. In the absence of exposure scenarios characterising the extend of the exposure it is not possible to confirm that there is only limited human exposure/quantify the exposure.

The conditions of the adaptation are not fulfilled and your adaptation is therefore rejected.

Based on the above, the provided information does not fulfil the information requirement.

Information on the design of the study to be performed (route/species)

As the substance is a liquid of very low vapour pressure (2.2 10^{-8} Pa at 25°C) and no uses with spray application are reported that could potentially lead to aerosols of inhalable size, oral route is the most appropriate route of administration as indicated in ECHA Guidance R.7a, Section R.7.5.4.3. Therefore, the sub-chronic toxicity study must be performed according to the OECD TG 408, in rats and with oral administration of the Substance. .

In your comments to the Draft Decision you agreed to perform the requested study.

2. **Robust study summary for "Daphnia magna, Reproduction Test with [redacted]" (Annex IX, Section 9.1.5. in conjunction with Annex I, Section 3.1.5.)**

   OR

Long-term toxicity testing on invertebrates (Annex IX, Section 9.1.5.)

Long-term toxicity testing on aquatic invertebrates is a standard information requirement in Annex IX to the REACH Regulation.

You have provided a robust study summary for the key study conducted according to OECD TG 211 (GLP compliant).

We have assessed this information and identified the following issues:

A robust study summary must be provided for all key data used in the hazard assessment (Articles 3(28) and 10(a)(vii) and Annex I, Section 3.1.5 of REACH). It must provide a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study.

The OECD TG 211 in conjuction with OECD Guidance 23 requires that for poorly/sparingly water-soluble substances you must:

- provide results of a preliminary solubility experiment as it forms the basis of the test solution preparation procedures adopted for the toxicity tests;
- document the procedures required to achive the maximum dissolved concentration that can be achieved in the specific test solution under test conditions, including mixing/contact time;
- justify the separation technique especially if filtration is used, as it can cause losses due to adsorption onto the filter matrix;
- apply the methods required to achieve the maximum dissolved concentrations in your aquatic toxicity test.

As noted in the Appendix on general considerations the Substance is poorly/sparingly water-soluble substance.

In the study summary you provided you state that the test solutions were prepared by addition of the test substance to dilution water, followed by stirring for 24 h and removal of undissolved particles by filtration using a a Sartorius stedim SARTOBRAN 150 sterile Capsule of 0.45 + 0.2 µm pore size.

You have not provided information on the preliminary solubility experiment or any other documentation which would justify the methods to prepare the test solutions.

Therefore, it is not possible to make an independent assessment of the study and its reliability with regards to preparation of the test solutions, the use of filter as a separation method and stirring time of 24-h.

In the comments to the draft decision, you provided explanations as a justification of the test solution preparation methods.

We have assessed this information and identified the following issues:

The OECD TG 201 in conjuction with OECD Guidance 23 requires that for poorly/sparingly water-soluble substances you must:

- use a sufficiently sensitive analytical method for the analysis of the test chemical in the conducted toxicity study and in the preliminary stability study to investigate the appropriate design of the applied methods. For example, sum parameter methods

(e.g. total organic carbon) will not demonstrate the stability of individual UVCB components during the test and are limited by relatively poor sensitivity (approximately 1 mg/L);
- provide a statement from an analytical chemist if the dissolved fraction cannot be analytically measured (e.g. when solubility is below a quantifiable level), in order to confirm that the analytical methods used were state of the art, and to justify why lower detection limits were not feasible (any preliminary analytical efforts should also be described);

You consider that the available water solubility study according to OECD TG 105 can be used as a preliminary stability study because the test solution preparation was the same as in the aquatic toxicity studies and one is unlikely to observe significantly different solubility values for the test item within test media in comparison to demineralized water. A water solubility value of <3mg/L in the water solubility study was derived using TOC method where the LOQ was 3mg/L. Based on this result, you consider the Substance poorly soluble and therefore assume that the maximum saturation of the test substance is reached even without detecting the substance in the test solution.

You also consider in the comments that the stirring time would not make a difference to maximum dissolved concentration based on structure and logKow of the constituents. You have not provided any evidence how the chemical structure or LogKow can be used to predict the required stirring times. You also did not provide logKow values for each constituents separately to indicate poor solubility of all constituents.

Similarly you consider that the separation method would not affect the achieved dissolved concentrations since the maximum concentration of the test item is lower than the used test item concentration in this test. You did not further explain why the maximum initial loading is relevant to consider the potential losses by the filter separation technique.

The use of the water solubility experiment according to OECD TG 105 cannot be considered as a preliminary solubility experiment and to deliver the requested information for the following reasons.

The chemical analysis performed by TOC in the OECD TG 105/solubility experiment was limited by poor sensitivity and did not allow to detect the test substance in the test solution. Therefore this method may not be suitable to investigate how to achieve the maximum dissolved concentrations in a preliminary experiment. You did not provide a statement from an analytical chemist confirming that preliminary analytical efforts were taken and no lower detection limits could have been feasible.

ECHA however acknowledges that the Substance may be difficult to dissolve in water. This information, or any other information related to maximising the dissolved test concentrations, can however be obtained when e.g. performing the requested Long-term toxicity study on fish (see request B.3) and its preliminary solubility experiment with appropriate analytical methods.

The information provided in the comments does not allow to make an independent assessment of the study and its reliability with regards to preparation of the test solutions.

Based on the above, the provided information does not fulfil the information requirement.

To allow an independent assessment of the submitted study, you need to provide a complete robust study summary with the above missing elements for the study.

Alternatively, if methods required to achieve the maximum dissolved concentrations were not applied in the toxicity test provided in your dossier, you need to submit the following study for the Substance: *Daphnia magna* reproduction test (EU C.20./OECD TG 211 in conjunction with the OECD Guidance 23).

3. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.)

Long-term toxicity testing on fish is a standard information requirement in Annex IX to the REACH Regulation.

You have adapted this information requirement by using Column 2 of Annex IX Section 9.1, claiming that the chemical safety assessment does not indicate the need to investigate further the effects on fish. You further argue that there are no *"further indications that the substance may be hazardous to the environment. This is supported by the result of a chronic test with Daphnia magna"*.

To adapt the information requirement for long-term toxicity testing on fish based on Annex IX, Section 9.1, Column 2, the Chemical Safety Assessment (CSA) needs to assess and document that risks arising from the Substance are controlled (Annex I, Section 0.1).

In particular, you need to take into account environmental hazard assessment including classification and labelling and identification of PNEC, as described in Annex I.

For the purpose of hazard assessment, the available toxicity information should at least cover species of three trophic levels: algae/aquatic plants, invertebrates (Daphnia preferred), and fish. Regarding long-term toxicity testing, there are no further requirements for fish testing if there is compelling evidence to suggest that the fish is likely to be at least a factor of about 10 less sensitive than invertebrates or algae. In case the relative sensitivity of fish cannot be predicted, further testing is needed.[2]

For hydrophobic/poorly water soluble substances, short-term toxicity studies cannot constitute the compelling evidence to indicate a lack of effects in the long-term studies nor to predict relative species sensitivity. Hydrophobic/poorly soluble substances require longer time to be significantly taken up by the test organisms and in consequence the steady state conditions are likely not to be reached within the duration of a short-term toxicity test. For this reason, short-term tests may not give a true measure of toxicity for this type of substances.

The Substance is an organic UVCB for which you reported a calculated logP value of higher than 20. You have not reported the octanol/water partition coefficient separately for the constituents, but based on the reported partition coefficient value the constituents can be considered hydrophobic with a certain (unknown) range.

You have provided short-term toxicity studies on fish, *Daphnia* and algae, and a long-term toxicity study on *Daphnia*.

You have not justified, nor provided supporting evidence, why you can reliably predict the (lack of) effects in long-term fish study based on the results from chronic toxicity study on *Daphnia*.

[2] ECHA Guidance R.7b, Section R.7.8.5.3

Therefore there is no compelling evidence to predict the relative sensitivity of fish, and long-term testing on fish is needed for the CSA to document that risks to the aquatic environment are controlled.

Based on the above, the information you provided does not fulfil the information requirement.

In your comments to the Draft Decision you agreed to perform the requested study.

Appendix C: Procedural history

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 the REACH Regulation.

The compliance check was initiated on 29 June 2018.

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

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

ECHA took into account your comments and did not amend the request(s).

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 D: Observations and technical guidance

1. The information requirement under Section 8.7.3. of Annex IX to REACH (Extended one-generation reproductive toxicity study) is not addressed in this decision.

2. This compliance check decision does not prevent ECHA from initiating further 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 the Member States.

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 shall 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[3]'.

4. Test material

   Selection of the test material(s) for UVCB substances

   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*".

   In order to meet this requirement, all the constituents of the test material used for each

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

test shall be identified as far as possible. For each constituent the concentration value in the test material shall be reported in the Test material section of the endpoint study record.

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.

Technical instructions are available in the manual "How to prepare registration and PPORD dossiers" on the ECHA website[4].

5. List of references of the ECHA Guidance documents[5] and OECD Guidance documents

Evaluation of available information
Guidance on information requirements and chemical safety assessment, Chapter R.4 (version 1.1., December 2011), referred to as ECHA Guidance R.4 in this decision.

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)[6]

Physical-chemical properties
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.

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.

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

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.

Guidance on aquatic toxicity testing of difficult to test chemicals
OECD Guidance Document 23 (ENV/JM/MONO(2000)6/REV1), referred to as OECD Guidance 23 in this decision

Appendix E: 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 fufilled
[redacted]	[redacted]	[redacted]