~~Confidential~~

Helsinki, 06 September 2022

Addressees
Registrant(s) of JS 111497-86-0 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
15 September 2020

Registered substance subject to this decision ("the Substance")
Substance name: 2-Propenoic acid, (1-methyl-1,2-ethanediyl) bis[oxy(methyl-2,1-ethanediyl)] ester, reaction products with diethylamine
EC number: 601-101-8

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

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***12 December 2024***.

Requested information must be generated using the Substance unless otherwise specified.

Information required from all the Registrants subject to Annex VII of REACH

1. Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.; test method: EU C.2./OECD TG 202)

2. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method: EU C.3./OECD TG 201)

Information required from all the Registrants subject to Annex VIII of REACH

3. Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.; test method: EU C.1./OECD TG 203)

Information required from all the Registrants subject to Annex IX of REACH

4. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: EU C.20./OECD TG 211)

5. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: EU C.47./OECD TG 210)

The reasons for the decision(s) are explained in Appendix 1.

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you in accordance with Articles 10(a) and 12(1) of REACH. The addressees of the decision and their corresponding information requirements based on registered tonnage band are listed

in Appendix 3.

You are only required to share the costs of information that you must submit to fulfil your information requirements.

How to comply with your information requirements

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

You must follow the general requirements for testing and reporting new tests under REACH, see Appendix 4.

Appeal

This decision, when adopted under Article 51 of REACH, may be appealed to the Board of Appeal of ECHA within three months of its notification to you. Please refer to http://echa.europa.eu/regulations/appeals for further information.

Failure to comply

If you do not comply with the information required by this decision by the deadline indicated above, ECHA will notify the enforcement authorities of your Member State.

Authorised[1] under the authority of Mike Rasenberg, Director of Hazard Assessment

Appendix 1: Reasons for the decision
Appendix 2: Procedure
Appendix 3: Addressees of the decision and their individual information requirements
Appendix 4: Conducting and reporting new tests under REACH

[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 1: Reasons for the decision

Contents

Reasons related to the information under Annex VII of REACH

1. Short-term toxicity testing on aquatic invertebrates

1 Short-term toxicity testing on aquatic invertebrates is an information requirement under Annex VII to REACH (Section 9.1.1.).

1.1. Information provided

2 You have provided a study on Daphnia sp. Acute Immobilisation (1999) with the Substance.

1.2. Assessment of the information provided

3 We have assessed this information and identified the following issue:

1.2.1. The provided study does not meet the information requirement

4 To fulfil the information requirement, a study must comply with OECD TG 202 and the requirements of OECD GD 23 if the substance is difficult to test (Article 13(3) of REACH). Therefore, the following specifications must be met:

5 Characterisation of exposure

a) analytical monitoring must be conducted. A reliable analytical method for the quantification of the test material in the test solutions with reported specificity, recovery efficiency, precision, limits of determination (i.e. detection and quantification) and working range must be available;
b) the effect values can only be based on nominal or measured initial concentration if the concentration of the test material has been satisfactorily maintained within 20 % of the nominal or measured initial concentration throughout the test (see also Guidance on IRs and CSA, Section R.7.8.4.1).

6 The Substance is difficult to test since it is a UVCB substance and it is hydrolytically unstable (half-life of 11 h at pH 7, 24.1°C).

7 Your registration dossier provides an OECD TG 202 study showing the following:

8 Characterisation of exposure

a) no analytical monitoring of exposure concentrations was conducted;
b) the reported effect values are based on nominal concentrations of the Substance.

9 Based on the above,

- the Substance is difficult to test and there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, the Substance is not stable in test solutions since hydrolysable and nominal concentrations may not be representative of actual exposure concentrations. In the absence of analytical monitoring of exposure concentrations, you have not demonstrated that exposure concentrations were maintained within ±20% of the nominal concentrations. The results based on nominal values are therefore considered unreliable.

10 Therefore, the requirements of OECD TG 202 are not met.

11 On this basis, the information requirement is not fulfilled.

1.3. Study design and test specifications

12 The Substance is difficult to test since it is an UVCB substance, hydrolytically unstable (half-life of 11 h at pH 7, 24.1°C) and adsorptive (surface activity of 32.4 mN/m). OECD TG 202 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented. Considering that the Substance is rapidly hydrolysable, it is important to take into account the relative toxicities of the parent test chemical and hydrolysis products to determine the appropriate test design and test media preparation methods for the Substance. Due to the properties of Substance, it may be difficult to achieve and maintain the desired exposure concentrations of the Substance or its hydrolysis products. Therefore, you must monitor the test concentration(s) of the Substance, or its hydrolysis products, throughout the exposure duration and report the results. If it is not possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the effect concentration based on measured values as described in OECD TG 202. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solution.

13 For multi-constituents/UVCBs, the analytical method must be adequate to monitor qualitative and quantitative changes in exposure to the dissolved fraction of the test material during the test (e.g. by comparing mass spectral full-scan GC or HPLC chromatogram peak areas or by using targeted measures of key constituents or groups of constituents).

14 If you decide to use the Water Accommodated Fraction (WAF) approach, in addition to the above, you must:

- use loading rates that are sufficiently low to be in the solubility range of most constituents (or that are consistent with the PEC value). This condition is mandatory to provide relevant information for the hazard and risk assessment (Guidance on IRs and CSA, Appendix R.7.8.1-1, Table R.7.8-3);
- provide a full description of the method used to prepare the WAF (including, among others, loading rates, details on the mixing procedure, method to separate any remaining non-dissolved test material including a justification for the separation technique);prepare WAFs separately for each dose level (i.e. loading rate) and in a consistent manner.

15 In the comments on the draft decision, you agree that the study provided does not meet the current standards of an OECD TG 202 study. Instead of performing a new OECD TG 202 study as requested, you propose to perform the long-term toxicity to aquatic invertebrates study (OECD TG 211) requested in Appendix 1, Section 4.

16 REACH Annex VII section 9.1.1 column 2 specifies that the short-term toxicity study does not need to be conducted if a long-term aquatic toxicity study on invertebrates is available. At present no long-term toxicity study on aquatic invertebrates is provided in the IUCLID dossier, therefore no conclusion on the compliance can currently be made. You remain responsible for complying with this decision by the set deadline.

2. Growth inhibition study aquatic plants

17 Growth inhibition study on aquatic plants is an information requirement under Annex VII to REACH (Section 9.1.2.).

2.1. Information provided

18 You have provided a study on Algal Growth Inhibition (1999) with the Substance.

2.2. Assessment of the information provided

19 We have assessed this information and identified the following issue:

2.2.1. The provided study does not meet the information requirement

20 To fulfil the information requirement, a study must comply with OECD TG 201 and the requirements of OECD GD 23 if the substance is difficult to test (Article 13(3) of REACH). Therefore, the following specifications must be met:

21 Characterisation of exposure

a) analytical monitoring must be conducted. Alternatively, a justification why the analytical monitoring of exposure concentrations is not technically feasible must be provided;
b) the results can be based on nominal or measured initial concentration only if the concentration of the test material has been maintained within ±20 % of the nominal or measured initial concentration throughout the test (see also Guidance on IRs and CSA, Section R.7.8.4.1);

22 Reporting of the methodology and results

c) the results of algal biomass determined in each flask at least daily during the test period are reported in a tabular form;

23 Validity criteria

d) the following criteria must be met:

- exponential growth in the control cultures is observed over the entire duration of the test;
- at least 16-fold increase in biomass is observed in the control cultures by the end of the test;
- the mean coefficient of variation for section-by-section specific growth rates (days 0-1, 1-2 and 2-3, for 72-hour tests) in the control cultures is ≤ 35%;
- the coefficient of variation of average specific growth rates during the whole test period in replicate control cultures is ≤ 7% in tests with *Desmodesmus subspicatus*.

24 The Substance is difficult to test since it is a UVCB substance and it is hydrolytically unstable (half-life of 11 h at pH 7, 24.1°C).

25 Your registration dossier provides an OECD TG 201 study showing the following:

26 Characterisation of exposure

a) no analytical monitoring of exposure was conducted and no justification has been provided;
b) you have expressed the effect values based on nominal concentrations;

27 Reporting of the methodology and results

c) tabulated data on the algal biomass determined daily for each treatment group and

control are not reported;

28 Validity criteria

d) you have not provided data on the control cultures allowing independent assessment of the validity criteria.

29 Based on the above,

- the Substance is difficult to test and there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, the Substance is not stable in test solutions since hydrolysable and nominal concentrations may not be representative of actual exposure concentrations. In the absence of analytical monitoring of exposure concentrations, you have not demonstrated that exposure concentrations were maintained within ±20% of the nominal concentrations. The results based on nominal values are therefore considered unreliable.
- the reporting of the study is not sufficient to conduct an independent assessment of its reliability. More specifically, in the absence of tabulated data on the algae biomass in the controls, it is not possible to determine if the validity criteria were met.

30 Therefore, the requirements of OECD TG 201 are not met.

31 On this basis, the information requirement is not fulfilled.

2.3. Study design and test specifications

32 OECD TG 201 specifies that, for difficult to test substances, OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design and test specifications' under Request 1.

33 In your comments on the draft decision you agree to perform the requested study to fulfil this information requirement.

Reasons related to the information under Annex VIII of REACH

3. Short-term toxicity testing on fish

34 Short-term toxicity testing on fish is an information requirement under Annex VIII to REACH (Section 9.1.3.).

3.1. Information provided

35 You have provided a study on Fish, Acute Toxicity (1999) with the Substance.

3.2. Assessment of the information provided

36 We have assessed this information and identified the following issue:

3.2.1. The provided study does not meet the information requirement

37 To fulfil the information requirement, a study must comply with OECD TG 203 and the requirements of OECD GD 23 if the substance is difficult to test (Article 13(3) of REACH). Therefore, the following specifications must be met:

38 Technical specifications impacting the sensitivity/reliability of the test

a) the test is conducted on juveniles of similar age (or size);

39 Characterisation of exposure

b) analytical monitoring must be conducted. A reliable analytical method for the quantification of the test material in the test solutions with reported specificity, recovery efficiency, precision, limits of determination (i.e. detection and quantification) and working range must be available;
c) the results can be based on nominal or measured initial concentration only if the concentration of the test material has been maintained within ±20 % of the nominal or measured initial concentration throughout the test (see also Guidance on IRs and CSA, Section R.7.8.4.1).

40 The Substance is difficult to test since it is a UVCB substance and it is hydrolytically unstable (half-life of 11 h at pH 7, 24.1°C).

41 Your registration dossier provides an OECD TG 203 study showing the following:

42 Technical specifications impacting the sensitivity/reliability of the test

a) the mean size of fish was 3.4 cm at test start, which does not correspond to juveniles for *Danio rerio* (i.e. 1-2 cm, Appendix 2 of OECD TG 203);

43 Characterisation of exposure

b) no analytical monitoring of exposure was conducted;
c) you have expressed the effect values based on nominal concentrations.

44 Based on the above,

- there are critical methodological deficiencies resulting in the rejection of the study results. More, specifically the provided study conducted with non-juvenile fish cannot be considered to have equivalent sensitivity and reliability to OECD TG 201, which requires juveniles to be tested.

- Furthemore, the Substance is difficult to test and there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, the Substance is not stable in test solutions since hydrolysable and nominal concentrations may not be representative of actual exposure concentrations. In the absence of analytical monitoring of exposure concentrations, you have not demonstrated that exposure concentrations were maintained within ±20% of the nominal concentrations. The results based on nominal values are therefore considered unreliable.

45 Therefore, the requirements of OECD TG 203 are not met.

46 On this basis, the information requirement is not fulfilled.

3.3. Study design and test specifications

47 OECD TG 203 specifies that, for difficult to test substances, OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design and test specifications' under Request 1.

48 In the comments to the draft decision, you agree that the study provided does not meet the current standards of an OECD TG 203 study. Instead of performing a new OECD TG 203 study as requested, you propose to perform the long-term toxicity to fish study (OECD TG 210) requested in Appendix 1, Section 5.

49 REACH Annex VIII section 9.1.3. column 2 specifies that the short-term toxicity study does not need to be conducted if a long-term aquatic toxicity study on fish is available. At present no long-term toxicity study on fish is provided in the IUCLID dossier, therefore no conclusion on the compliance can currently be made. You remain responsible for complying with this decision by the set deadline.

Reasons related to the information under Annex IX of REACH

4. Long-term toxicity testing on aquatic invertebrates

50 Long-term toxicity testing on aquatic invertebrates is an information requirement under Annex IX to REACH (Section 9.1.5.).

4.1. Information provided

51 You have adapted this information requirement by using Column 2 of Annex IX, Section 9.1. To support the adaptation, you have provided the following justification:

(i) *"Amine synergist hydrolyses rapidly and its degradation products have been shown to biodegrade extensively. Long-term exposure to aquatic organisms is not expected. Moreover, all the RCR's are below 1 and all the supported uses are therefore safe.*

In accordance with column 2 of REACH Annex IX, the study shall be proposed if the chemical safety assessment according to Annex I indicates the need to investigate further the effects on aquatic organisms. As the exposure assessment does not indicate the need to investigate further the effects on aquatic organisms (as all the RCR's to all the compartments are below 1 and all the supported uses are therefore assessed to be safe) no further long-term testing is proposed for aquatic compartments."

4.2. Assessment of the information provided

52 We have assessed this information and identified the following issue:

4.2.1. Annex IX, Section 9.1., Column 2 is not a valid basis to omit the study

53 Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to aquatic invertebrates under Column 1. It must be understood as a trigger for providing further information on aquatic invertebrates if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).

54 Your adaptation is therefore rejected.

55 On this basis, the information requirement is not fulfilled.

4.3. Study design and test specifications

56 OECD TG 211 specifies that, for difficult to test substances, OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design and test specifications' under Request 1.

57 In your comments on the draft decision you agree to perform the requested study to fulfil this information requirements.

5. Long-term toxicity testing on fish

58 Long-term toxicity testing on fish is an information requirement under Annex IX to REACH (Section 9.1.6.).

5.1. Information provided

59 You have adapted this information requirement by using Column 2 of Annex IX, Section 9.1. To support the adaptation, you have provided the following justification:

(i) *"Amine synergist hydrolyses rapidly and its degradation products have been shown to biodegrade extensively. Long-term exposure to aquatic organisms is not expected. Moreover, all the RCR's are below 1 and all the supported uses are therefore safe.*

In accordance with column 2 of REACH Annex IX, the study shall be proposed if the chemical safety assessment according to Annex I indicates the need to investigate further the effects on aquatic organisms. As the exposure assessment does not indicate the need to investigate further the effects on aquatic organisms (as all the RCR's to all the compartments are below 1 and all the supported uses are therefore assessed to be safe) no further long-term testing is proposed for aquatic compartments."

5.2. Assessment of the information provided

60 We have assessed this information and identified the following issue:

5.2.1. Annex IX, Section 9.1., Column 2 is not a valid basis to omit the study

61 Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to fish under Column 1. It must be understood as a trigger for providing further information on long-term toxicity to fish if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).

62 Your adaptation is therefore rejected.

63 On this basis, the information requirement is not fulfilled.

5.3. Study design and test specifications

64 To fulfil the information requirement for the Substance, the Fish, Early-life Stage Toxicity Test (test method OECD TG 210) is the most appropriate (Guidance on IRs and CSA, Section R.7.8.2.).

65 OECD TG 210 specifies that, for difficult to test substances, OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design and test specifications' under Request 1.

66 In your comments on the draft decision you agree to perform the requested study to fulfil this information requirements.

References

The following documents may have been cited in the decision.

Guidance on information requirements and chemical safety assessment (Guidance on IRs & CSA)

Chapter R.4 Evaluation of available information; ECHA (2011).
Chapter R.6 QSARs, read-across and grouping; ECHA (2008).
Appendix to Chapter R.6 for nanoforms; ECHA (2019).
Chapter R.7a Endpoint specific guidance, Sections R.7.1 – R.7.7; ECHA (2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Chapter R.7b Endpoint specific guidance, Sections R.7.8 – R.7.9; ECHA (2017).
Appendix to Chapter R.7b for nanomaterials; ECHA (2017).
Chapter R.7c Endpoint specific guidance, Sections R.7.10 – R.7.13; (ECHA 2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Appendix R.7.13-2 Environmental risk assessment for metals and metal compounds; ECHA (2008).
Chapter R.11 PBT/vPvB assessment; ECHA (2017).
Chapter R.16 Environmental exposure assessment; ECHA (2016).

Guidance on data-sharing; ECHA (2017).

All Guidance on REACH is available online: https://echa.europa.eu/guidance-documents/guidance-on-reach

Read-across assessment framework (RAAF)

RAAF, 2017 Read-across assessment framework (RAAF), ECHA (2017)
RAAF UVCB, 2017 Read-across assessment framework (RAAF) – considerations on multi- constituent substances and UVCBs), ECHA (2017).

The RAAF and related documents are available online:
https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

***OECD Guidance documents* (OECD GDs)**

OECD GD 23 Guidance document on aquatic toxicity testing of difficult substances and mixtures; No. 23 in the OECD series on testing and assessment, OECD (2019).
OECD GD 29 Guidance document on transformation/dissolution of metals and metal compounds in aqueous media; No. 29 in the OECD series on testing and assessment, OECD (2002).
OECD GD 150 Revised guidance document 150 on standardised test guidelines for evaluating chemicals for endocrine disruption; No. 150 in the OECD series on testing and assessment, OECD (2018).
OECD GD 151 Guidance document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test; No. 151 in the OECD series on testing and assessment, OECD (2013).

Appendix 2: Procedure

This decision does not prevent ECHA from initiating further compliance checks at a later stage on the registrations present.

ECHA followed the procedure detailed in Articles 50 and 51 of REACH.

The compliance check was initiated on 04 October 2021.

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

ECHA took into account your comments and amended the deadline.

In the comments on the draft decision, you requested an extension of the deadline from 12 to 24 months from the date of adoption of the decision.

You justified the request by additional time required to complete the testing due to anticipated delays in laboratory capacity to conduct the studies and the time required to define appropriate test design and analytical method.

Based on the documentary evidence provided, ECHA has agreed with your request for a deadline extension and has extended the deadline to 24 months.

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 3: Addressees of this decision and their corresponding information requirements

In accordance with Articles 10(a) and 12(1) of REACH, the information requirements for individual registrations are defined as follows:

- the information specified in Annex VII to REACH, for registration at 1-10 tonnes per year (tpa), or as a transported isolated intermediate in quantity above 1000 tpa;
- the information specified in Annexes VII and VIII to REACH, for registration at 10-100 tpa;
- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa;
- the information specified in Annexes VII to X to REACH, for registration at more than 1000 tpa.

Registrant Name	Registration number	Highest REACH Annex applicable to you
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.

Appendix 4: Conducting and reporting new tests for REACH purposes

1. Requirements when conducting and reporting new tests for REACH purposes

1.1. Test methods, GLP requirements and reporting

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

(2) 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.

(3) 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 on How to report robust study summaries[2].

(4) Under the introductory part of Annexes VII/VIII/IX/X to REACH, where a test method offers flexibility in the study design, for example in relation to the choice of dose levels or concentrations, the chosen study design must ensure that the data generated are adequate for hazard identification and risk assessment.

1.2. Test material

Before generating new data, you must agree within the joint submission on the chemical composition of the material to be tested (Test Material) which must be relevant for all the registrants of the Substance.

Selection of the Test material(s)

The Test Material used to generate the new data must be selected taking into account the following:

a) the variation in compositions reported by all members of the joint submission,
b) the boundary composition(s) of the Substance,
c) 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.

Information on the Test Material needed in the updated dossier

a) You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
b) The reported composition must include the careful identification and description of the characteristics of the Tests Materials in accordance with OECD GLP

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

(ENV/MC/CHEM(98)16) and EU Test Methods Regulation (EU) 440/2008 (Note, Annex), namely all the constituents must be identified as far as possible as well as their concentration. Also any constituents that have harmonised classification and labelling according to the CLP Regulation must be identified and quantified using the appropriate analytical methods.

With that detailed information, ECHA can confirm whether the Test Material is relevant for the Substance and whether it is suitable for use by all members of the joint submission.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers (https://echa.europa.eu/manuals).

2. General recommendations for conducting and reporting new tests

2.1. Environmental testing for substances containing multiple constituents

Your Substance contains multiple constituents and, as indicated in Guidance on IRs & CSA, Section R.11.4.2.2, you are advised to consider the following approaches for persistency, bioaccumulation and aquatic toxicity testing:

- the "known constituents approach" (by assessing specific constituents), or
- the "fraction/block approach, (performed on the basis of fractions/blocks of constituents), or
- the "whole substance approach", or
- various combinations of the approaches described above

Selection of the appropriate approach must take into account the possibility to characterise the Substance (i.e. knowledge of its constituents and/or fractions and any differences in their properties) and the possibility to isolate or synthesize its relevant constituents and/or fractions.

References to Guidance on REACH and other supporting documents can be found in Appendix 1.