EUROPEAN CHEMICALS AGENCY

Helsinki, 21 December 2020

**Addressees**
Registrant(s) of JS_EC#403-830-5 as listed in the last Appendix of this decision

**Date of submission of the dossier subject to this decision**
01/04/2019

**Registered substance subject to this decision ("the Substance")**
Substance name: 6'-(dibutylamino)-3'-methyl-2'-(phenylamino)spiro[isobenzofuran-1(3H),9-(9H)-xanthen]-3-one
EC number: 403-830-5
CAS number: 89331-94-2

**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 ***3 January 2024***.

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

1. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: OECD TG 210) with the Substance

2. Soil simulation testing (Annex IX, Section 9.2.1.3.; test method: EU C.23./OECD TG 307) at a temperature of 12 °C with the Substance

3. Sediment simulation testing (Annex IX, Section 9.2.1.4.; test method: EU C.24./OECD TG 308) at a temperature of 12 °C with the Substance

4. Identification of degradation products (Annex IX, 9.2.3.; test method: using an appropriate test method) with the Substance

Reasons for the request(s) are explained in the following appendix entitled "Reasons to request information required under Annexes IX of REACH".

### Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you, and in accordance with Articles 10(a) and 12(1) of REACH:

- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa;

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 testing and reporting requirements provided under the Appendix entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes". In addition, you should follow the general recommendations provided under the Appendix entitled "General recommendations when conducting and reporting new tests for REACH purposes". For references used in this decision, please consult the Appendix entitled "List of references".

## 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 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 A: Reasons to request information required under Annex IX of REACH

### 1. Long-term toxicity testing on fish

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

You have provided results from two studies performed according to OECD test guideline 204 (Fish, Prolonged Toxicity Test: 14-Day Study): a key study with species *Oncorhynchus mykiss* and a supporting study with species *Oryzias latipes*. Both studies were prolonged to 21 days.

Tests on substances must be conducted in accordance with the relevant OECD test guidelines or another recognised international test method (Article 13(3) of REACH).

The results you have provided were obtained from studies performed according to OECD test guideline 204.

However, this test guideline is no longer applicable. It was indeed deleted in 2014 following a decision from the OECD Council.

The following test methods can fulfil the standard information requirement of Annex IX, Section 9.1.6. for long-term toxicity testing on fish: fish early-life stage (FELS) toxicity test (Annex IX, Section 9.1.6.1.), fish short-term toxicity test on embryo and sac-fry stages (Annex IX, Section 9.1.6.2.) and fish juvenile growth test (Annex IX, Section 9.1.6.3.).

However, OECD test guideline 204 is not part of the test methods recommended to fulfil the standard information requirement.

Under Annex, Section XI 1.1.2. existing data from studies not carried out according to the test methods referred to in Article 13(3) could be considered equivalent to data generated by those test methods if the following cumulative conditions are met:

1. Adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test methods referred to in Article 13(3);
2. Exposure duration comparable to or longer than the corresponding test methods referred to in Article 13(3);
3. Adequate and reliable documentation of the study is provided; and
4. Adequacy for the purpose of classification and labelling and/or risk assessment.

The duration of the two studies you have provided is 21 days. This is shorter than the exposure period expected for a long-term toxicity study on fish. Furthermore, those studies do not provide an adequate coverage of some key parameters such as observations on the stage of embryonic development, hatching and survival, abnormal appearance/behaviour, weight and length. OECD test guideline 204 was in fact a prolonged acute study with fish mortality as the major endpoint examined.

In your comments to the draft decision you acknowledge that studies performed in accordance with OECD test guideline 204 are not recommended to fulfil the standard information requirements of Annex IX, Section 9.1.6 for long-term toxicity testing on fish. However, you provided a new adaptation indicating that the available data on aquatic or terrestrial animals as well as on mammals suggests that the substance has a low toxicity and you assume that the result from a proper long term toxicity study on fish will not lead to a substantial different classification and labelling of the Substance.

However, you have provided no scientific justification that could support your assumption.

In your comments to the draft decision, you also claim that further testing on fish would not be compatible with animal welfare.

We have assessed this information and identified the following issue:

You have not provided any legal basis for your adaptation and it is unclear whether it relates to any legal basis available; animal welfare as such does not constitute a valid justification to omit the standard information requirements of Annex IX or an adaptation to these information requirements.

Therefore, the studies you have provided cannot be regarded as proper long-term toxicity studies and they do not fulfil the information requirement.

The fish early-life stage (FELS) toxicity test (Annex IX, section 9.1.6.1.) is more appropriate than the fish, short-term toxicity test on embryo and sac-fry stages (Annex IX, section 9.1.6.2.), or than the fish, juvenile growth test (Annex IX, section 9.1.6.3.), as it covers several life stages of the fish from the newly fertilised egg, through hatch to early stages of growth. Moreover, the FELS toxicity test is preferable for examining the potential toxic effects of substances which are expected to cause effects under a longer-term exposure, or which require a longer period of time to reach steady state (in particular poorly soluble/hydrophobic substances).

Therefore, you must submit the following information: Fish, early-life stage (FELS) toxicity test (test method: OECD test guideline 210) with the Substance.

## 2. Soil simulation testing

Soil simulation testing is a standard information requirement at Annex IX of REACH for substances with a high potential for adsorption to soil. The partition coefficient, log Kow, of the Substance was determined to be above 4.66 at 20°C. The adsorption coefficient was measured in three different types of soil with results ranging from 126 to 2053. Therefore the Substance has a high potential for adsorption to soil.

You have sought to adapt this information requirement based on Annex IX, Section 9.2.1.3, Column 2. You justified the adaptation by stating that direct and indirect exposure of soil was unlikely.

Annex IX, Section 9.2.1.3, Column 2 mentions that simulation testing on soil does not need to be conducted if direct or indirect exposure of soil is unlikely.

However, you have not demonstrated the absence of exposure of soil. The Substance is not handled under strictly controlled conditions throughout its life cycle. It is mainly used in [redacted]. This is a wide dispersive use, which can hardly be controlled. The quantitative exposure assessment reported in your Chemical Safety Report (CSR) shows that exposure of soil cannot be ruled out.

In your comments to the draft decision, you acknowledge that the adaptation does not fulfil the information requirement. You explain that the information may not be needed for the PBT/vPvB assessment if an ongoing bioaccumulation study shows that the Substance does not fulfil the B and vB criteria. You propose to postpone the assessment of the persistence of the Substance until the results of the bioaccumulation study are available. See ECHA's response to your deadline extension request in Appendix C, below.

Therefore, your adaptation does not fulfil the information requirement. Accordingly, you must perform soil simulation testing (OECD test guideline 307).

Under Annex XIII, the information must be based on data obtained under conditions relevant for the PBT/vPvB assessment. Therefore you must perform the test at the temperature of 12°C, the average environmental temperature for the EU (ECHA Guidance R.16, Table R.16-8). Performing the test at this temperature is in line with the applicable test conditions of the OECD TG 307.

Non-extractable residues (NER) must be quantified in all simulation studies. The reporting of results must include a scientific justification of the used extraction procedures and solvents. By default, total NER is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NER may be differentiated and quantified as irreversibly bound or as degraded to biogenic NER. Such fractions could be regarded as removed when calculating the degradation half-life(s) (ECHA Guidance Chapter R.11).

### 3. Sediment simulation testing

Sediment simulation testing is a standard information requirement at Annex IX of REACH for substances with a high potential for adsorption to sediment. The Substance has a high partition coefficient (log Kow above 4.66 at 20°C) and high adsorption coefficient (measured log Koc values ranging from 126 to 2053). Therefore it has a high potential for adsorption to sediment.

You have sought to adapt this information requirement by claiming that the Substance is highly insoluble in water and that the test is not technically feasible.

However, Annex IX, Section 9.2.1.4., Column 2 contains no provision allowing to omit the information requirement based on low on or no water solubility of the Substance.

Contrary to your claim, the low water solubility of the Substance does not prevent sediment simulation testing. For example, OECD test guideline 308 explicitly indicates that it is applicable to poorly water-soluble substances.

In your comments to the draft decision, you acknowledge that the adaptation does not fulfil the information requirement. You explain that the information may not be needed for the PBT/vPvB assessment if an ongoing bioaccumulation study shows that the Substance does not fulfil the B and vB criteria. You propose to postpone the assessment of the persistence of the Substance until the results of the bioaccumulation study are available. See ECHA's response to your deadline extension request in Appendix C, below.

Therefore, your adaptation does not fulfil the information requirement. Accordingly, you must perform sediment simulation testing.

OECD test guideline 308 is an appropriate method for studying the degradation in sediment. The requested simulation test must be performed under relevant conditions (12°C) and non-extractable residues (NER) must be quantified, for the reasons explained above in Appendix A, section 2.

### 4. Identification of degradation products

You have not provided any information on the identification of degradation products, nor an adaptation in accordance with column 2 of Annex IX, Sections 9.2 or 9.2.3. or with the general rules of Annex XI for this standard information requirement.

Identity and relevance of degradation products must be included in the risk assessment and PBT/vPvB assessment.

Identification of degradation products does not need to be conducted if the Substance is readily biodegradable (Annex IX, Section 9.2.3, column 2).

You have concluded that the Substance is not readily biodegradable.

In your comments to the draft decision, you explain that the information may not be needed for the PBT/vPvB assessment if an ongoing bioaccumulation study shows that the Substance does not fulfil the B and vB criteria. You propose to postpone the assessment of the persistence of the Substance until the results of the bioaccumulation study are available.

However, your comments do not address the need to take account of the potential PBT/vPvB properties of the relevant degradation products. Under Annex XIII, the PBT/vPvB assessment must take account of the potential PBT/vPvB properties not only of the Substance but also of its relevant degradation products. Therefore, information on the identity and relevance of degradation products must be provided.

Therefore, the information requirement is not fulfilled.

Regarding appropriate and suitable test method, the methods will have to be substance-specific. Identity, stability, behaviour, and molar quantity of the degradation/transformation products relative to the Substance must be evaluated and reported, when analytically possible. In addition, degradation half-life, log Kow and potential toxicity of the transformation/degradation may be investigated. You may obtain this information from the two degradation studies also requested in Appendix A, sections 2 and 3 above. You must provide a scientifically valid justification for the chosen method.

## Appendix B: Requirements to fulfil when conducting and reporting new tests for REACH purposes

### A. 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].

### B. 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.

1. Selection of the Test material(s)

   The Test Material used to generate the new data must be selected taking into account the following:
   - the variation in compositions reported by all members of the joint submission,
   - the boundary composition(s) of the Substance,
   - 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.

2. Information on the Test Material needed in the updated dossier
   - 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.
   - The reported composition must include all constituents of each Test Material and their concentration values and other parameters relevant for the property to be tested.

This information is needed to assess 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[3].

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

## Appendix C: 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 27 September 2019.

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

ECHA took into account your comments and amended the deadline.

The timeline indicated in the draft decision to provide the information requested was 24 months from the date of adoption of the decision. In your comments on the draft decision, you requested an extension of the timeline to 36 months. You justified your request stating that the deadline should allow sequential testing for the information (OECD TG 210, OECD TG 307 and OECD TG 308) needed for the PBT assessment and should allow the update of your dossier. ECHA notes that whilst the deadline for providing the requested information, has been set to allow sequential testing and to take into account a request of a bioaccumulation study in a separate decision, the aspect of the PBT assessment revision is considered justified. Therefore, ECHA has extended the deadline of the decision to 36 months.

At this stage of the decision making process, additional registrants are not listed in Appendix E, below.

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: List of references - ECHA Guidance[4] and other supporting 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 where relevant.

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 where relevant.

Read-across assessment framework (RAAF, March 2017)[5]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[5]

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.

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.

Data sharing
Guidance on data-sharing (version 3.1, January 2017), referred to as ECHA Guidance on data sharing in this decision.

OECD Guidance documents[6]
Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

[4] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[5] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[6] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

Guidance document on transformation/dissolution of metals and metal compounds in aqueous media – No 29, referred to as OECD GD 29.

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

Guidance Document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test – No 151, referred to as OECD GD 151.

## Appendix E: Addressees of this decision and the corresponding information requirements applicable to them

You must provide the information requested in this decision for all REACH Annexes applicable to you.

| Registrant Name | Registration number | Highest REACH Annex applicable to you |
|---|---|---|
| [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.