Helsinki, 1 September 2020

Addressees
Registrants of JS_2280-49-1 listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject of this decision
07/11/2017

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: N-phenyl-N-[(trichloromethyl)thio]benzenesulphonamide
EC number: 218-915-0
CAS number: 2280-49-1

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 deadlines provided.

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

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

2. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method EU C.25./OECD TG 309) "suspended sediment test" at a temperature of 12 °C with the Substance;

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

Conditions to comply with the requests

Each addressee of this decision is bound by the requests for information corresponding to the REACH Annexes applicable to their own registered tonnage of the Substance at the time of evaluation of the jointly submitted dossier.

To identify your legal obligations, please refer to the following:

- 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;

Registrants are only required to share the costs of information that they are must submit to fulfil the information requirements for their registration.

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

You must submit the information requested in point A.1 above in an updated registration dossier by ***6 June 2022***, and the information requested in points A.2 – A.3 above by ***6 June 2023***.

You must also update the chemical safety report, where relevant, including any changes to classification and labelling based on the newly generated information. The timeline has been set to allow for sequential testing where relevant.

Appeal

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

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

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

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

In accordance with Articles 10(a) and 12(1) of REACH, 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 REACH.

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

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

You have provided a study and an adaptation for this endpoint in your dossier:

i. An oral sub-acute toxicity study OECD 407 with registered substance; with rats, gavage, reliability 1, according to GLP, [redacted] 2013; and
ii. An adaptation, which refers to local irritation caused by the registered substance.

We have assessed this information and identified the following issue(s):

A. Sub-acute study

To be considered compliant and enable concluding whether the Substance has dangerous properties and supports the determination of the No-Observed Adverse Effect Level (NOAEL), a study has to meet the requirements of OECD TG 408.

The repeated dose oral toxicity study (OECD TG 407) you provided does not have the required exposure duration of 90 days as required in OECD TG 408, because you indicated an exposure duration of 28 days, and it was conducted with less than 10 animals per sex per test dose group. The statistical power of the information provided is not sufficient because it does not fulfil the criterion of 20 animals (10 males + 10 females) for each test group set in OECD TG 408.

The study was not performed according to the criteria of the OECD TG 408[2], and you did not justify why the deviation from the OECD TG 408, such as duration of exposure, can be considered acceptable.

B. Adaptation

You have proposed to adapt the information and claimed that a study is scientifically not necessary. You have justified the proposal for adaptation with a reference to local irritation of the registered substance.

According to the introductory paragraph 4 of Annex IX of the REACH Regulation "in vivo testing with corrosive substances at concentration/dose levels causing corrosivity shall be avoided". However, non-corrosive concentration(s) can be tested. Therefore, introductory paragraph 4 is not a legal basis for adapting standard information requirements.

The general principle of adjusting the concentration of the test substance to avoid corrosion and irritation is set out in the relevant test guidelines (OECD 413 and OECD 408).

In your comments to the draft decision, you proposed to adapt the information in accordance with Annex XI, 1.1. You further justified the proposal for adaptation with a reference to local irritation caused by the Substance.

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

The relevant provision, which is Annex XI, 1.1.2, applies to studies that are "not carried out according to GLP or the test methods referred to in Article 13(3)".

However, the sub-acute study that you refer to in your adaptation is compliant with GLP and performed according to the OECD test guideline 407.

Your argument based on local irritation has been addressed above (in the original draft decision). You did not provide such new information in your comments that would change our evaluation of your adaptation.

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

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

ECHA has evaluated the most appropriate route of administration for the study. Based on the information provided in the technical dossier and/or in the chemical safety report, ECHA considers that the oral route - which is the preferred one as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 65.0, December July 20176) Chapter R.7a, Section R.7.5.4.3 - is the most appropriate route of administration. More specifically, even though the information indicates that human exposure to the registered substance by the inhalation route is likely, potential inhalation-specific effects are already addressed by performing a qualitative assessment for inhalation, local effects. Hence, the test shall be performed by the oral route using the test method OECD TG 408.

2. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.)

Simulation testing on ultimate degradation in surface water is a standard information requirement at Annex IX to REACH. Under column 2 of Annex IX, Section 9.2., you must propose further degradation testing if there is a need to investigate further the degradation of the Substance and its degradation products.

You have sought to adapt this information requirement by stating that "*studies on ready and inherent biodegradation showed that the substance is not biodegradable at all*" and that "*an additional study is not expected to provide new data which is relevant for the assessment".*

Annex XIII of REACH makes the distinction between 'screening information' and 'assessment information'. Section 2.1. of this Annex specifies that "*no additional information needs to be generated for the assessment of PBT/vPvB properties if there is no indication of P or B properties following the result from the screening test or other information*".

Therefore, as long as screening information indicates that the substance could potentially be persistent (P) and bioaccumulative (B), then further information, i.e. 'assessment information', needs to be generated. For the P/vP assessment, results from simulation testing can constitute such assessment information (Section 3.2.1. of Annex XIII of REACH).

Screening information demonstrating potential PBT or vPvB properties include the following (Annex XIII of REACH and ECHA Guidance R.11, Sections R.11.4):

- the substance is not readily biodegradable and thus potentially persistent; and
- the substance has high potential for bioaccumulation (log Kow > 4.5).

In addition, if degradation in an inherent biodegradability test equivalent to the OECD 302 series is ≤20%, then it may provide sufficient information to confirm that the P-criterion is

fulfilled without the need for further simulation testing (ECHA Guidance R.11, section R.11.4.1.1.3)

For the PBT/vPvB assessment, in Chapter 8 of your Chemical Safety Report (CSR), you concluded that your Substance should be considered persistent and very persistent (P/vP). However, as an overall conclusion you have also claimed that your substance is not a PBT/vPvB substance, in particular because you considered that the B and vB criteria were not fulfilled.

No mineralisation was observed after 28 days in a ready biodegradability study performed according to EU method C4-D (equivalent to OECD test guideline 301F). Besides, 41% mineralisation was observed after 28 days in an inherent biodegradability study performed according to OECD test guideline 302C. Both test results constitute screening information (Section 3.1.1. of Annex XIII of REACH) which shows that the Substance could *potentially* be P/vP. However, it is not possible to conclude that it is *definitively* P/vP.

As for your B/vB assessment, ECHA disagrees with your conclusion for the following reasons:

- The experimental log Kow value reported in your dossier is 4.7. A log Kow higher than 4.5 constitutes screening information which shows that the substance could potentially be bioaccumulative or very bioaccumulative (Section 3.1.2. of Annex XIII of REACH and Chapter R.11 of the ECHA Guidance on information requirements and chemical safety assessment (version 3.0, June 2017)).
- For assessing the bioaccumulation potential of the Substance, you have provided a QSAR prediction from the BCFBAF model (in EPI-Suite). However, QSAR predictions are not mentioned as possible assessment information for the B/vB assessment (Section 3.2.2. of Annex XIII of REACH). Therefore, this QSAR prediction cannot supersede the screening information represented by the log Kow of 4.7.
- Most of the structural fragments contained in the Substance are not present or are under-represented in the training set of the BCFBAF model. In particular, there is no occurrence of the fragment defined by SMILES code N(c)(S)S in the training set of the model and the fragment defined by SMILES code C(Cl)(Cl)(Cl)S is present only once. Therefore, this QSAR prediction does not meet the requirements of Annex XI, Section 1.3 of REACH and it is not reliable for assessing the bioaccumulation potential of the Substance.

Therefore, the Substance is potentially B/vB.

As explained above, available screening information is not sufficient to conclude on the PBT/vPvB properties of the Substance. Therefore, your adaptation is rejected.

Study design

OECD test guideline 309 is an appropriate method for studying degradation in surface water. Annex XIII of REACH indicates that information used for PBT/vPvB assessment shall be obtained under relevant conditions. Therefore, simulation tests should be performed 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 test guideline 309.

You have claimed that once the Substance is dissolved it is expected to hydrolyse very rapidly. However, you have also indicated that the Substance is poorly soluble in water and you were not able to calculate a hydrolysis rate. The claim that hydrolysis is rapid cannot alone lead to the conclusion that the Substance is not persistent. Information on hydrolysis always need to be considered in connection with other properties of the Substance, such as partitioning and

ionogenic properties, both of which may significantly influence the extent and strength of sorption of the Substance to solids and therefore could cause attenuation of the hydrolysis rate. Therefore, when performing the OECD TG 309 test, you must use the "suspended sediment test" (i.e. with surface water amended with suspended solids/sediment of 0.01 to 1 g/L dry weight) as it will better address the influence of the suspended solids to the hydrolysis rate.

Non-extractable residues (NER) needs to 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. Identification of degradation products (Annex IX, 9.2.3.)

Identification of the degradation products is a standard information requirement at Annex IX of REACH.

Annex XIII of REACH requires that "*the identification* [of PBT and vPvB substances] *shall also take account of the PBT/vPvB-properties of relevant constituents of a substance and relevant transformation and/or degradation products*". Your assessment must consider each relevant degradation/transformation product in concentrations as low as technically quantifiable. Alternatively, you must provide a justification for why you consider these not relevant for the PBT/vPvB assessment.

In your dossier, you have mentioned the formation of a possible hydrolysis product, Benzenesulfonanilide (CAS: 1678-25-7). You have provided no information on potential biotic degradation products.

No mineralisation was observed after 28 days in a ready biodegradability study performed according to EU method C4-D (equivalent to OECD test guideline 301F), and 41% mineralisation was observed after 28 days in an inherent biodegradability study performed according to OECD test guideline 302C.

Any mineralisation measured in screening biodegradability tests would denote ultimate biodegradation. However, the lack of observed mineralisation in a ready or in an inherent biodegradability test does not necessarily imply that the Substance itself is intrinsically persistent because primary degradation could take place. Any primary degradation would imply the formation of degradation products.

You have measured Benzenesulfonanilide (CAS: 1678-25-7) in a preliminary hydrolysis test[3]. It was also measured in the long-term toxicity test on *Daphnia*[4]. You have assumed that Benzenesulfonanilide is the main hydrolysis product. However, this finding is inconclusive with regard to the information requirement for the following reasons:

- You have not identified other potential hydrolysis products.
- You have indicated that the Substance is poorly soluble in water, but you have also claimed that once it is dissolved it is expected to hydrolyse very rapidly. However, you were not able to calculate a hydrolysis half-life. Benzenesulfonanilide is also an impurity of the Substance (up to [redacted] of the Substance). The amounts of

[3] [redacted] 2012. [redacted]

[4] [redacted] 2017 [redacted]

Benzenesulfonanilide measured in the preliminary hydrolysis study or in the long-term toxicity test on *Daphnia* are low: up to c.a. [redacted] of the nominal Substance concentration after 4 days of stirring in the aqueous medium, but [redacted] or less (i.e. in the range of the initial impurity concentration) when the stirring time is just 1 day. Therefore, the actual formation of Benzenesulfonamide from hydrolysis does not seem to be very rapid in practice.

- The available result for the inherent biodegradability test indicates that some biodegradation could occur. Therefore some biotic degradation products could be formed. However, you have not identified any potential biotic degradation products.

Therefore, the information provided does not fulfil the information requirement.

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 degradation products may be investigated. You may obtain this information from the degradation study also requested in this decision or by some other measure. If the any other method than the requested simulation test (see Appendix A.2 above) is used for identification of the degradation products, you must provide a scientifically valid justification for the chosen method.

Appendix B: 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 14 January 2019.

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

ECHA took into account your comments and did not amend the request(s) and/or the deadline. ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

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

Appendix C: Observations and technical guidance

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

2. 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.

3. 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'[5].

4. Test material

   Selection of the test material(s)

   The registrants of the Substance are responsible for agreeing on the composition of the test material to be selected for carrying out the tests required by the present decision. The test material selected must be relevant for all the registrants of the Substance, i.e. it takes into account the variation in compositions reported by all members of the joint submission. The composition of the test material(s) must fall within the boundary composition(s) of the Substance.

   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.

   Technical reporting of the test material

   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"[6].

[5] https://echa.europa.eu/practical-guides
[6] https://echa.europa.eu/manuals

5. List of references of the ECHA Guidance and other guidance/ reference documents[7]

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)[8]

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.

OECD Guidance documents[9]
Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD23.
Guidance Document supporting the OECD TG 443 on the extended one-generation reproductive toxicity test – No 151, referred to as OECD GD151.

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

Appendix D: List of the registrants to which the decision is addressed 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) Data requirements to be fufilled
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Note: 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.