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Helsinki, 15 June 2020

Addressees
Registrants of 1,3-dihydro-4(or 5)-methyl-2H-benzimidazole-2-thione, zinc salt listed in the last Appendix of this decision (registrant(s)[1])

Decision/annotation number
[For the final decision] Please refer to the REACH-IT message which delivered this communication (in format SEV-D-XXXXXXXXXX-XX-XX/F)

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: 1,3-dihydro-4(or 5)-methyl-2H-benzimidazole-2-thione, zinc salt
EC number: 262-872-0
CAS number: 61617-00-3

DECISION ON SUBSTANCE EVALUATION

In accordance with Article 46(1) of Regulation (EC) No 1907/2006 (REACH), you must submit the following information:

Environment

Request 1

Amphibian Metamorphosis Assay (AMA); test method: OECD test guideline 231 with 1,3-dihydro-4(or 5)-methyl-2H-benzimidazole-2-thione (MMBI; CAS number 53988-10-6; EC number 258-904-8)

Deadline to submit the requested information

Appendix 1: Section [4] provides further details of how the deadline was derived.

You must provide an update of the registration dossier(s) containing the requested information, including robust study summaries and, where relevant, an update of the chemical safety report by the deadline (s) indicated below.

In addition to the robust study summaries, you must submit the full study report for the AMA test (Request 1) by the same deadline, by attaching it to the relevant endpoint study record in IUCLID.

Request 1: The information required must be generated and provided by **15**

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

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September 2021. The deadline takes into account the time that you, the Registrant(s), may need to agree which of the registrant(s) will perform the required tests.

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

Who performs the testing?

The test listed above under Request 1 is also required in the separate substance evaluation decision for EC 258-904-8, 1,3-dihydro-4(or 5)-methyl-2H-benzimidazole-2-thione (MMBI). Therefore, the addressees of this decision are required to coordinate with the addressees of the decision on EC 258-904-8 who are listed in the notification letter to this decision.

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

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 a suspensive effect and is subject to a fee. Further details are described under: http://echa.europa.eu/regulations/appeals.

Authorised[2] by Director of Hazard Assessment

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

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Appendix 1: Reasons

Based on the evaluation of all relevant information submitted on 1,3-dihydro-4(or 5)-methyl-2H-benzimidazole-2-thione, zinc salt (ZnMMBI) and other relevant available information, ECHA concludes that further information is required to enable the evaluating Member State competent authority (MSCA) to complete the evaluation of whether the Substance constitutes a risk to the environment.

The evaluating MSCA will subsequently review the information submitted by you and evaluate if further information should be requested in another decision to clarify the concern, according to Article 46(3) of REACH.

1 The potential risk – environment

The identification of a potential risk is based on a combination of exposure and hazard information.

It is noted that ZnMMBI has a full registration under REACH. The evaluating MSCA has reviewed the information available in these registration dossiers and in the open literature for the purpose of this substance evaluation. Additionally, the evaluating MSCA has consulted you regarding exposure clarifications, which were also considered in this substance evaluation.

According to information in the registration dossier the Substance is used as process regulator for polymerisation processes in production of resins, rubbers, polymers, tyres and plastic goods. Significant exposure of the environment cannot be excluded.

Based on information from the published literature as detailed below, there is a concern that the Substance may be an endocrine disruptor (ED) for environment according to the World Health Organisation/International Programme on Chemical Safety working definition (WHO/IPCS, 2002).

Based on this exposure and hazard information, there is a potential risk for the environment. As the available information is not sufficient to conclude on potential ED properties, further information is needed, as explained below.

2 The possible risk management measures – environment

If the obtained data from Request 1 (AMA, OECD TG 231), together with all information available, is sufficient to confirm the suspected ED properties as defined in World Health Organisation/International Programme on Chemical Safety working definition (WHO/IPCS, 2002), the evaluating MSCA will assess the need for further regulatory risk management in the form of identification as a substance of very high concern (SVHC) under Article 57 of REACH and subsequent authorisation or restriction of the Substance.

This would lead to stricter risk management measures than those currently in place.

3 Explanation of the testing strategy – environment

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REQUEST 1 (AMA, OECD TG 231): The concern identified

Available *in vitro* and *in vivo* data for the two related substances MMBI, ZnMMBI and structurally similar compounds like 2-mercaptobenzimidazole (MBI, CAS 583-39-1) indicate that MMBI and ZnMMBI might affect the thyroid hormone system.

Regarding interaction of MMBI with the thyroid hormone system an *in vitro* assay of OECD Conceptual Framework (CF) level 2 (OECD, 2018) is available:

- Sakemi et al. (2002) – Klimisch reliability 2 - studied the inhibition of lactoperoxicase (LPX), as a well-known proxy for the enzyme thyroid peroxidase (TPO), by thioureylenes and their desulfurated compounds using MBI, MMBI mix (CAS 53988-10-6; 1:1 mix of 4-methyl and 5-methyl isomers), as well as 5-MMBI (CAS 27231-36-3), 4-MMBI (CAS 27231-33-0) and 5-MeBI (CAS 614-97-1), respectively.

  Method: Excess hydrogen peroxide was added to a mixture of LPX, test chemicals, and guaiacol in 0.1 M phosphate buffer (pH 7.0). The initial concentrations of hydrogen peroxide, LPX and guaiacol were 0.2 mM, 60 nM and 33 mM, respectively. Test chemicals were dissolved in ethanol and added to the reaction mixtures (1% v/v). The rate of guaiacol oxidation was followed on a recording spectrophotometer (Shimadzu UV-1600PC) at 470 nm using a cuvette with a 1.0-cm light path with a total volume of 3.0 ml reaction mixture at room temperature. The enzyme activity at 30 s after initiation was compared with that of the control reaction mixture containing 1% ethanol. The inhibitory potency (IC_{50}) was calculated from the plots of percentage enzyme inhibition rate versus inhibitor concentrations using the linear part of the concentration ranges near 50% inhibition.

  Results: The IC_{50} against lactoperoxidase activity of MBI (a known thyroid toxicant), MMBI (mixture of methyl isomers of MBI), MMBI (1:1 w/w mixture of 4-MMBI and 5-MMBI), 4-MMBI, and 5-MMBI were 20.6 µM, 43.7 µM, 42.1 µM, 45.6 µM and 31.6 µM, respectively.

In summary, the available *in vitro* data for MMBI (1:1 w/w mixture of 4-MMBI and 5-MMBI as well as a technical mixture of methyl isomers of MBI), 4-MMBI and 5-MMBI show their anti-thyroidal activity by their potential to inhibit TPO, a key enzyme to regulate thyroid hormone homeostasis. The TPO inhibitory effects of MMBIs observed are in the same order of magnitude as those described for the known and structurally similar thyroid toxicant MBI. On the molecular level the methylation pattern of the different MMBIs at the MBI core structure seems to have no or only a weak (5-MMBI seems to be a bit more potent than the other MMBIs measured) modulating effect on the interaction with the TPO enzyme. Given this mode of action data for MMBIs, the raised concern needs to be further clarified on the *in vivo* level with regard to environmental species.

In vivo studies with 1:1 mix of 4-MMBI and 5-MMBI (Klimisch reliability score indicated herein as per the registration dossiers):

- Saitoh et al. (1999) – Klimisch reliability 2

  Method: The test was conducted according to (Lorke, 1983). Two tests (first and second stage) were conducted. In the first stage test 3 rats per group were administered by gavage 10, 100 and 1000 mg/kg bw. In the second stage test 2 rats per group were administered by gavage 120, 180, 270, 405 and 608 mg/kg bw.

  Results: In both tests clinical toxicity signs and mortality were monitored. At concentrations ≥100 mg/kg bw signs of neurotoxicity and at concentrations ≥400 mg/kg bw fatty enlargements of the liver were observed. The LD_{50} value was determined to be 330 mg/kg bw for both male and female Wistar rats.

- Saitoh et al. (1999) – Klimisch reliability 2

  Method: Male and female rats were treated with MMBIs (2-mercaptomethylbenzimidazoles (a 1:1 mixture of 4-methyl and 5-methyl isomers, MMBIs) by gavage at doses 0 (corn oil), 4, 20 and 100 mg/kg for 28 consecutive days followed by a 2-week recovery period for the control and highest dose groups. Body weight and food consumption, clinical signs, organ weights, clinical biochemistry and hematological parameters including clotting times and micronuclei induction in bone marrow erythropoeitic cells were recorded and a histopathological examination was conducted.

  Results: Male rats administered 100 mg/kg bw/d exhibited a 1.8 fold increase in thyroid weight associated with histopathological changes (hypertrophy, hyperplasia, decreased colloid) but not altered serum thyroid hormone levels (T_3, T_4). Hypercholesterolemia was observed in both sexes. Relative organ weights of lung, liver, kidney, and serum cholesterol and phospholipid significantly increased in male but not in female rats treated with MMBIs at doses of 20 and 100 mg/kg bw/d. At 100 mg/kg bw the relative weight of liver (moderate hepatocyte swelling) and kidney increased in females. Changes in clinical biochemistry were observed. After recovery (14 days), male rats showed increased spleen and decreased testis weight. The organ weights in females were normal. There were no histological findings after recovery.

- Sakemi et al. (2002) – Klimisch reliability 2

  Method: MBI and the MMBIs (4-MMBI and 5-MMBI), and a 1:1 mixture of these 4- and 5-methylated isomers (MMBI mix) suspended in corn oil were repeatedly administered (at 0.3–0.6 mmol/ kg = ca. 49.2-98.4 mg/kg bw) to male Wistar rats by gavage once daily for 2 weeks. After the first and last administrations, blood and urine samples were collected and the levels of unchanged compounds and their desulfurated metabolites were determined by HPLC. Body weight and thyroid hormones (T_3, T_4), and thyroid-stimulating hormone (TSH) in the serum were determined. A histopathologic examination on selected organs was performed.

Results: Repeated oral application (ROA) of 0.3 mmol/kg MBI for 8 days and 15 days resulted in 4.0- and 7.0-fold increase in relative thyroid weight, respectively. Relative liver weight also increased by 27.4% and 31.6%, respectively. However, no significant increases of thyroid and liver weights were observed after ROA of 0.3 mmol or 0.6 mmol/kg MMBI mix. On the other hand, relative thyroid weights increased 1.7- and 2.7-fold for 4-MMBI and 5-MMBI, respectively, after treatment with 0.6 mmol/kg for 14 days. Significant increases in liver weight were also seen after ROA with 4-MMBI and 5-MMBI. Regardless of the follicular epithelium being slightly cuboidal to columnar in rats exposed for 14 days to 4-MMBI (0.6 mmol/kg), moderate diffuse hyperplasia of the follicular cells, which were lined with the morphological features caused by MBI, was apparent in rats exposed for 14 days to 5-MMBI (0.6 mmol/kg). Repeated treatment with MBI resulted in remarkable decrease of serum T_3/T_4 and increase of TSH levels. However, no changes of these hormone levels were found following treatment with the MMBI mix. The authors suggested that the marked decrease of thyroid toxicity by methyl substitution of MBI is caused mainly by a decrease in systemic exposure to the compounds and partly by a decrease in inhibition of thyroid hormone synthesis. On the other hand, repeated treatment with 4-MMBI, but not with 5-MMBI, showed a slight decrease (14%) of serum T_4 and increased level (36%) of TSH. Increased levels of serum total cholesterol, known to be a clinically diagnostic marker for hypothyreosis, were observed.

In vivo data on the endocrine properties of ZnMMBI; an OECD TG 422 guideline study is available:

- [redacted] (2006) - Klimisch reliability 1

  Method: The test was conducted under Good Laboratory Practice (GLP) conditions according to OECD test guideline 422. 10 male and 10 female Sprague-Dawley Crl:CD (SD) IGS BR strain rats were used per treatment (1000 – 2750 – 7500 ppm) and control. Rats were orally exposed 14 days prior to pairing with ZnMMBI. The test lasted 47 days. The concentrations were analytically confirmed (HPLC).

  Results: Multiple systemic toxicity effects were observed. An increased thyroid weight (hypertrophy) with a LOAEL of 40 to 45 mg/kg, as well as increased plasma cholesterol were observed. Mortality, decreased body weight, and clinical findings occurred especially in mid-dose females. Effects on fertility in all dose groups including decreased mean corpora lutea and total implantation counts, and increased gestation length were observed.

In summary, the *in vitro* test results with MMBI and MBI raise concern that ZnMMBI might provoke anti-thyroidal activity via inhibition of TPO. *In vivo* data with ZnMMBI obtained with test method OECD TG 422 reveal an increased thyroid weight as well as increased plasma cholesterol, positive parental endocrine organ endpoints and – with decreased mean corpora lutea and total implantations counts as well as an increased gestation length – effects on reproductive/developmental endpoints.

Taking together and applying OECD Guidance Document No. 150 (OECD, 2018),

available *in vitro* and *in vivo* data provide evidence of possible endocrine mediated adverse effects of the Substance on endocrine/reproductive/developmental endpoints via an anti-thyroidal mechanism.

REQUEST 1 (AMA, OECD TG 231): Why new information is needed

Based on the information described above, the evaluating MSCA has identified a concern for possible endocrine disrupting properties of ZnMMBI in vertebrate wildlife species.

For MMBIs (4-MMBI, 5-MMBI and a 1:1 w/w mixture of both isomers) the available *in vitro* data point to an anti-thyroidal mode of action. The available *in vivo* data from rat studies with MMBI as well as ZnMMBI show effects on apical endpoints (thyroid weight, thyroid hyperthrophy, decreased colloids in males, hypercholesterolemia as well as changes in T_3/T_4 and TSH blood levels) that support the concern of an anti-thyroidal activity of MMBIs.

However, the available data from mammalian studies do not allow for a conclusion on the population relevance of the observed adverse effects in the environment. Hence, in order to clarify whether ZnMMBI is an endocrine disrupting substance with respect to the environment, an Amphibian Metamorphosis Assay (AMA, OECD TG 231) is requested.

As there is evidence for an anti-thyroidal mode of action of the Substance, a histopathological analysis of the thyroid is of great significance to be able to properly interpret the assay results. Therefore, thyroid histopathology must be performed for the AMA requested in this decision.

The results of the AMA, together with all information available, may be sufficient to conclude on whether ZnMMBI meets the WHO definition for endocrine disruptors in the environment and whether the Substance could be identified as SVHC based on REACH Article 57 (f).

However, if after reviewing the information submitted, no clear conclusion can be drawn, a level 4 or 5 study as described in OECD Guidance Document No. 150 (OECD, 2018) may need to be requested in the potential follow up decision making process. In light of the already available data pointing to an anti-thyroidal mode of action via TPO inhibition, further testing may especially be necessary when the result of the AMA is negative or inconclusive, e.g. showing effects on thyroid histopathology but not on apical endpoints.

When assessing the need for further higher tier testing to be requested in a potential follow up decision making process, ECHA will consider the results of the AMA, and all other available data, including the newly generated Extended One Generation Reproductive Toxicity Study (EOGRTS, OECD TG 443) with the Substance.

REQUEST 1 (AMA, OECD TG 231): Considerations on the test method

An AMA (OECD TG 231) test addresses the thyroidal mode of action. The histopathological analysis of the thyroid is necessary to distinguish non-specific systemic from HTP-axis mediated toxicity.

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The AMA test shall include 5 instead of 3 test concentrations in order to reduce the possibility of false negative results and to derive a robust concentration-response relationship to calculate precise NOEC/LOEC or ECx to be used for further risk management processes. Additionally, a full concentration-response relationship helps to distinguish the expected specific anti-thyroidal effects from systemic toxic effects. The highest concentration should give a clear systemic (i.e. non endocrine-specific) toxicity.

You must submit the full study report for Request 1. Considering the complexity of the case as described above, a complete rationale of test design and interpretation of results and access to all information available in the full study report (implemented method, raw data collected, interpretations and calculations, consideration of uncertainties, argumentation, etc.) are needed. This will allow the evaluating MSCA to fully assess all the provided information, including the statistical analysis, and to efficiently clarify the concern for ED properties of the Substance.

The AMA is requested using the related substance MMBI. Since ZnMMBI is the zinc salt of MMBI, the endocrine active moiety is considered to be similar to MMBI. Additionally, it is considered that in aqueous test media ZnMMBI is mostly dissociated into MMBI.

REQUEST 1 (AMA, OECD TG 231): Alternative approaches and proportionality of the request

The initial draft decision sent to you for commenting requested a Larval Amphibian Growth and Development Assay (LAGDA, OECD TG 241). In your comments you have voiced your preference for an AMA for the following reasons: First, you pointed out that the endpoint addressed in the AMA (OECD TG 231) and LAGDA (OECD TG 241) can in this specific case be considered comparable regarding adverse effects solely mediated via the Hypothalamus-pituitary-thyroid (HPT) axis. Second, you also noted that as regards LAGDA there is insufficient experience of testing laboratories and concerns regarding false positive results based on limited historical data. Based on these considerations you propose to perform the AMA to address the concern raised.

ECHA disagrees with your general considerations against LAGDA. However, ECHA considers that an AMA as a level 3 test according to the OECD CF, in combination with thyroid histopathology may be expected in this specific case to be sufficient to conclude on the thyroidal mode of action and resulting adverse effects of the Substance (unless the results point out the need for further testing as already discussed above).

ECHA notes that the LAGDA is a fully validated OECD method, which can be used for regulatory purposes and is not vulnerable to producing unusually high numbers of false positive results. Thus, your arguments against the LAGDA test per se are not scientifically based and therefore not shared by ECHA.

4 Consideration of your comments on the original draft decision and the proposals for amendment

In your comments on the choice of AMA/LAGDA and the steps to follow you conclude that according to the "Guidance for the identification of endocrine disruptors in the

context of Regulations (EU) No 528/2012 and (EC) No 1107/2009 (ECHA and EFSA, 2018), negative results if obtained in the Amphibian Metamorphosis Assay (OECD, 2009) would be sufficient to support that 'T-mediated adversity is unlikely because no T-related endocrine activity has been observed'."

ECHA does not agree to this conclusion in this specific case and further testing, as pointed out above under section "REQUEST 1 (AMA, OECD TG 231): Why new information is needed", might be necessary in case of a negative or inconclusive result of the requested AMA study.

5 Consideration of the time needed to perform the requested studies

The deadline for provision of the requested data takes into account the time that you may need to agree on which of the registrant(s) will perform the required tests(3 months is allocated for this) and include the time required for developing an analytical method, conduct of the study according to the test guideline OECD 231, preparation of the study report and reporting in IUCLID.

For Request 1, ECHA considers that 12 months is a sufficient time for conducting and reporting of the study. In your comments you requested a deadline extension for performing the LAGDA. ECHA notes that in order to be able to give due consideration to a request for extending a deadline, you should have provided documentary evidence from the selected test laboratory indicating the scheduling timelines for the study in question. Nevertheless, as the LAGDA is no longer requested, your comment became non-relevant.

Therefore, ECHA considers that the following deadline is sufficient for fulfilling the information requirement:

Test requested	**Deadline**
Request 1 [AMA, OECD TG 231]	12 + 3 = 15 months

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5 References

Lorke D. (1983): A new approach to practical acute toxicity testing. Arch Toxicol 54 (4), 275-287. http://www.ncbi.nlm.nih.gov/pubmed/6667118

OECD (2018): Revised Guidance Document 150 on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption. DOI: doi:https://doi.org/10.1787/9789264304741-en

Saitoh M., Umemura T., Kawasaki Y., Momma J., Matsushima Y., Sakemi K., Isama K., Kitajima S., Ogawa Y., Hasegawa R., Suzuki T., Hayashi M., Inoue T., Ohno Y., Sofuni T., Kurokawa Y., and Tsuda M. (1999): Toxicity Study of a Rubber Antioxidant, Mixture of 2-Mercaptomethylbenzimidazoles, by Repeated Oral Administration to Rats. Food and Chemical Toxicology 37 (7), 777-787. DOI: https://doi.org/10.1016/S0278-6915(99)00058-7

Sakemi K., Ito R., Umemura T., Ohno Y., and Tsuda M. (2002): Comparative toxicokinetic/toxicodynamic study of rubber antioxidants, 2-mercaptobenzimidazole and its methyl substituted derivatives, by repeated oral administration in rats. Arch Toxicol 76 (12), 682-691. DOI: 10.1007/s00204-002-0392-0

[redacted] (2006): Dietary Combined Repeat Dose Toxicity Study with Reproduction/Developmental Screening Test in the Rat. [redacted]

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6 Abbreviations

5-MeBI	5-methylbenzimidazole
4-MMBI	2-mercapto-4-methylbenzimidazole
5-MMBI	2-mercapto-5-methylbenzimidazole
AMA	Amphibian metamorphosis assay
CF	OECD Conceptual Framework for Testing and Assessment of Endocrine Disrupters
CoRAP	Community rolling action plan
EC_{50}	Half maximal effect concentration
ED	Endocrine disruptor
HPT	Hypothalamus-pituitary-thyroid
IC_{50}	Half maximal inhibitory concentration
LAGDA	Larval amphibian growth and development assay
LPX	Lactoperoxidase
LOEC	Lowest observed effect concentration
MBI	2-mercaptobenzimidazole
MBP	Myelin basic protein
MMBI	1,3-dihydro-4(or 5)-methyl-2H-benzimidazole-2-thione
MSCA	Member State Competent Authority
OECD	Organisation for Economic Co-operation and Development
SVHC	Substances of Very High Concern
T	Testosterone
T_3	Triiodothyronine
T_4	Thyroxin
TG	Test guideline
TH	Thyroid hormone
TPO	Thyroid Peroxidase
TR	Thyroid receptor
TTR	Transtyretin
ZnMMBI	1,3-dihydro-4(or 5)-methyl-2H-benzimidazole-2-thione, zinc salt (2:1)

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Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the day until which the evaluating MSCA granted an extension for submitting dossier updates which it would take into consideration i.e. after 01 June 2018.

On the basis of an opinion of the ECHA Member State Committee and due to initial grounds for concern relating to potential endocrine disruptor and exposure of environment, 1,3-dihydro-4(or 5)-methyl-2H-benzimidazole-2-thione, zinc salt CAS No 61617-00-3 (EC No 262-872-0) was included in the Community rolling action plan (CoRAP) for substance evaluation to be evaluated in 2018. The updated CoRAP was published on the ECHA website on 20 March 2018. The competent authority of Germany (hereafter called the evaluating MSCA) was appointed to carry out the evaluation.

In accordance with Article 45(4) of the REACH Regulation, the evaluating MSCA carried out the evaluation of the above substance based on the information in your registration(s) and other relevant and available information.

The evaluating MSCA considered that further information was required to clarify the concern for potential endocrine disruptor. Therefore, it prepared a draft decision under Article 46(1) of the REACH Regulation to request further information. It subsequently submitted the draft decision to ECHA on 20 March 2019.

The decision making followed the procedure of Articles 50 and 52 of the REACH Regulation as described below.

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

Registrant(s)' commenting phase

ECHA received comments from you and forwarded them to the evaluating MSCA without delay.

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

Subsequently, the evaluating MSCA received proposal(s) for amendment to the draft decision and modified the draft decision. They are reflected in the reasons (Appendix 1).

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

ECHA invited you to comment on the proposed amendment(s).

Your comments on the proposals for amendment were taken into account by the Member State Committee.

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MSC agreement seeking stage

The Member State Committee reached a unanimous agreement on the draft decision in its MSC-69 meeting and ECHA took the decision according to Article 51(6) of the REACH Regulation.

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Appendix 3: Further information, observations and technical guidance

1. This decision does not imply that the information provided by you in the registration(s) is in compliance with the REACH requirements. The decision neither prevents ECHA from initiating compliance checks on your dossier(s) at a later stage, nor does it prevent a subsequent decision under the current substance evaluation or a new substance evaluation process once the present substance evaluation has been completed.

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

3. In relation to the required experimental study/ies, the sample of the substance to be used ('test material') has to have a composition that is within the specifications of the substance composition that are given by all registrant(s). It is the responsibility of all the registrant(s) to agree on the tested material to be subjected to the test(s) subject to this decision and to document the necessary information on the composition of the test material. The substance identity information of the Substance and of the sample tested must enable the evaluating MSCA and ECHA to confirm the relevance of the testing for the substance subject to substance evaluation.

4. In relation to the experimental stud(y/ies) the legal text foresees the sharing of information and costs between registrant(s) (Article 53 of the REACH Regulation). You are therefore required to make every effort to reach an agreement regarding each experimental study for every endpoint as to who will carry out the study on behalf of the other registrant(s) and to inform ECHA accordingly within 90 days from the date of this decision under Article 53(1) of the REACH Regulation. This information should be submitted to ECHA using the following form stating the decision number above at:
https://comments.echa.europa.eu/comments_cms/SEDraftDecisionComments.aspx?CaseNumber=SEV-262-872-0-1

   Further advice can be found at
http://echa.europa.eu/regulations/reach/registration/data-sharing. If ECHA is not informed of such agreement within 90 days, it will designate one of the registrants to perform the stud(y/ies) on behalf of all of them.