

Substance: **Magnesium Zirconium Oxide**
CAS: -
EC: 939-960-9
Registration deadline : 2013
Dossier type : Full dossier (dopant)
Lead registrant : Treibacher Schleifmittel GmbH (Imerys)

Communication performed for Magnesium Zirconium Oxide

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2013-03-13 Update registration dossier ZrO2

Dear SIEF member,

As a Lead registrant, on 20 November 2012, SEPR received an ECHA final decision (CCH-D-0000002628-68-03/F) on the compliance check of the registration dossier submitted for zirconium dioxide (CAS 1314-23-4 EC 215-227-2). The compliance check was performed as part of the procedure for evaluation of the testing proposal for developmental toxicity, which was included in the dossier submitted in 2010.

This SIEF communication has been prepared by the MOZO Consortium after several rounds of questions-and-answers with ECHA to clarify the implications of the decision. The aim of this communication is to inform you of the content and implications of the decision as well as of the actions that (may) need to be taken from your side.

Content of the final decision

The final decision indicates as follows:

“ECHA observes that the composition reported in the dossier covers, besides the pure zirconium dioxide, also zirconium dioxide present together with other oxide constituents reported as impurities. Several of these other oxide constituents, in particular yttrium oxide, magnesium oxide, calcium oxide and cerium dioxide, are well established dopants for zirconium dioxide. ECHA points out that such chemicals cannot be considered as impurities in the context of Article 3(1) of REACH: they are not unintended constituents derived from the manufacturing process but contribute to the composition of doped zirconium dioxide following deliberate addition at some stage in the chemical processing for the manufacturing of doped substances.”

After repeated written communication with ECHA (the last letter from ECHA was received on 8 February 2013), no definition of what is considered ‘a dopant’ in this decision was obtained. Apart from the issue of defining “dopants”, it is indeed the case that certain substances (such as those mentioned above) can be added intentionally to ZrO₂ during the production process to stabilise a certain crystallographic structure (which is not stable at room temperature otherwise) or to slightly adjust certain physicochemical properties of the zirconia. Please note that the specific substances mentioned in the decision of ECHA can also be present as ‘real’ impurities, derived from raw materials, and hence not intentionally added to the production process.

Hence, the decision imposes the update of the registration dossier to bring the substance composition part of the ZrO₂ dossier in line with ECHA’s indications, and ensure that no intentionally added substance is present – this was confirmed by ECHA lastly on 8 February 2013. The adjustment of the lead registrant dossier was due on 20 February 2013 (i.e. 3 months after receiving the final decision) - the dossier has been adjusted accordingly. At the same time, the Substance Identification Profile was adjusted accordingly by the Mixed Oxides and Zirconium Oxides Consortium (MOZO). The adjusted SIP is attached to this message for your information.

Finally, the Lead Registrant (SEPR) informed ECHA on 20 February 2013 that actions are being taken to inform the co-registrants and other SIEF members of the implications of the final decision.

As a result of these developments, each SIEF member having already registered ZrO₂ has to make the necessary adjustments in its company specific part of the registration dossier.

Implications of the decision, including implications towards zirconia that are not covered by the dossier

It may be the case that your company decided/is considering (as current/future co-registrant) to cover certain zirconia by the ZrO₂ dossier that contain intentionally added substances that can qualify as “dopants”. As indicated above, this may be against ECHA’s opinion.

The attached SIP has been adjusted accordingly to avoid any misunderstandings. The MOZO Consortium (represented by SEPR as lead registrant for ZrO₂) sent several questions to ECHA to clarify the way forward for these zirconia and to clarify what substances should be considered as a ‘dopant’, as no official definition is available at this point in time.

During the communication with ECHA, ECHA kept referring to the fact that under the previous legislation (Dangerous Substances Directive notification duty and EINECS reporting rules), there also was an obligation to notify a ‘doped’ substance as a separate substance from the ‘un-doped’ version. Although no official definition of a ‘dopant’ exists under REACH, ECHA mentions that the same reasoning is followed under REACH. The logical result of these considerations is that separate registration dossiers will have to be prepared for differently ‘doped’ zirconia.

The registration approach ECHA suggested is the following:

- The ‘doped’ zirconia, i.e., ZrO₂+dopant, is considered as a single ‘main constituent’.

- If this 'main constituent' is present at a concentration of $\geq 80\%$ w/w, the mono-constituent approach can be followed, the remainder of the composition being made up by 'real' impurities, i.e. components not intentionally added but merely derived from the raw materials and production process.

The MOZO consortium has also discussed further considerations that may be taken into account, such as whether the intentionally added substance is incorporated in the crystal lattice or not.

The MOZO Consortium is currently revising its internal list of zirconia forms with intentionally added substances that, in its members' opinion, cannot be covered by the current ZrO₂ dossier as updated on Feb 20th in view of ECHA's decision, and will soon inform you as to which zirconia forms will be covered by the Consortium in the future.

Should you have intentionally added substance(s) in your ZrO₂ substance(s), please review your specific situation in the light of the decision of ECHA mentioned in §1 of this communication.

We have also indicated in the beginning of §2 potential implications of this ECHA decision. However, we cannot account for every specific situation and you should seek independent advice if needed as to how to approach your specific situation.

Finally, since some zirconia forming crystal matrices with intentionally added substances may not yet have an EC number, and hence could not have been pre-registered, it may be the case that one or more of your zirconia are not covered by phase-in status anymore. Similarly, for zirconia with an EC number, it may be the case that the due registration date has been passed already or – in case no pre-registration was made – it is too late for late pre-registration.

For such cases, ECHA recommended to contact the involved national competent enforcement authorities to explain the situation and agree on a timing to put everything back in compliance.

It is recommended that each company individually contacts its national CA. To align this communication, the MOZO Consortium is currently preparing a standard letter that can be used for communication with the national CAs and will be shared with you in a following SIEF communication.

SIEF and LoA implications

There may be occasions where a co-registrant already bought a LoA whereas, after re-evaluation of status based on this communication, no LoA or a LoA for a lower tonnage band would have been needed. Should your company be in this case, please contact Arcadis, manager of the MOZO Consortium to try to find an acceptable solution.

After all involved companies have gone through the review stipulated above, it may become clear whether or not the ZrO₂ SIEF should be split or not. The MOZO Consortium is currently checking the procedure and possibilities for this, should it appear necessary.

Update of the ZrO₂ dossier and technical approach for new dossiers

The technical approach for building dossiers around the 'doped'-forms of zirconia (read across, data needs, etc.) will be further discussed in April, however, it is clear that the recently updated ZrO₂ dossier will form the basis for most new dossiers. The current ZrO₂ dossier will need to be updated too, because some of the tests used in the dossier were conducted with ZrO₂ containing small amounts of intentionally added Y₂O₃. Since both substances are of extremely low solubility and toxicity, and no specific genotoxic effects are known, the outcome of the hazard evaluation as well as the classification mentioned in the ZrO₂ dossier will remain unaffected.

Another update that can be expected soon is related to the testing proposal for developmental toxicity. Also on 20th of November 2012, ECHA sent a draft decision to SEPR, indicating that the study needs to be performed. SEPR, supported by the MOZO Consortium, submitted comments to this draft decision asking ECHA to await the results of the testing for the 2013 substances covered by the MOZO Consortium, so that read across possibilities could be evaluated before the final decision is taken whether to perform a new test for ZrO₂. No final decision or reaction of ECHA has been received yet on this.

The implications on the price of LoAs will be communicated later on when more information is available on the costs involved.

Sincerely,
ARCADIS on behalf of the Mixed Oxides & Zirconia Oxides Consortium
MOZOcreach@arcadis-us.com

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We cannot accept responsibility for losses occasioned by any persons acting or refraining from acting as a result of material contained in this communication.

2014-01-16 Registration update, merging and SIP

16 January 2014

MAGNESIUM ZIRCONIUM OXIDE | EC 939-960-9

REACTION MASS OF MAGNESIUM OXIDE AND ZIRCONIUM DIOXIDE | EC 910-019-4

MAGNESIUM ZIRCONIUM TRIOXIDE | CAS 12032-31-4 | EC 234-768-5

Dear SIEF participant,

You have received this email because you REACH Pre-Registered with ECHA for magnesium zirconium oxide and/or reaction mass of magnesium oxide and zirconium dioxide and/or magnesium zirconium trioxide.

This communication is in the first place a communication to the SIEF participants of magnesium zirconium oxide. However, because pre-registrants for the reaction mass of magnesium oxide and zirconium dioxide and magnesium zirconium trioxide may agree that they manufacture, intend to manufacture, or import a substance that is sufficiently similar to magnesium zirconium oxide to allow read-across and/or to merge into one SIEF, we invite all SIEF participants for the reaction mass of magnesium oxide and zirconium dioxide and magnesium zirconium trioxide to take part in this survey too.

Due to an ECHA decision on the registration dossier of zirconium dioxide the Mixed Oxides & Zirconia Oxides Consortium has taken the decision to register several 'doped/stabilised' forms of zirconia. Although ECHA did not define the word 'dopant', they suggested – referring to the initial guidance such as the Manual of Decisions under the Dangerous Substances Directive – that the mono-constituent approach needs to be followed when the 'intentionally added substance(s)' is/are incorporated in the crystal lattice, together with ZrO₂ (see the SIP for further details).

One of these substances for which this approach can be followed is magnesium zirconium oxide (EC 939-960-9). This substance has already been registered by **Imerys Fused Minerals (formerly known as Treibacher Schleifmittel GmbH)** in the 100-1000 t/y tonnage band as a full substance and this company (which is a member of the MOZO Consortium) is willing to take the Lead Registrant role.

In this email you will find further information on:

- **MIXED OXIDES & ZIRCONIA OXIDES CONSORTIUM**
- **ARCADIS**
- **MERGER WITH OTHER SUBSTANCES**
- **SIP (SUBSTANCE IDENTIFICATION PROFILE)**
- **LEAD REGISTRANT**
- **NEXT STEPS FOR YOU**

MIXED OXIDES & ZIRCONIA OXIDES CONSORTIUM

First of all, we wish to inform you about the existence and activities of the Mixed Oxides & Zirconia Oxides Consortium related to REACH as well as to understand the level of activity at which you wish to be engaged in the SIEF process as pre-registrant of magnesium zirconium oxide or reaction mass of magnesium oxide and zirconium dioxide or magnesium zirconium trioxide. We would like to introduce the potential Lead Registrant for magnesium zirconium oxide and request your vote.

The Mixed Oxides & Zirconia Oxides Consortium brings together manufacturers and importers of a number of zirconium compounds. At this point in time the companies involved in this consortium are:

- SEPR: SOCIETE EUROPEENNE DES PRODUITS REFRACTAIRES (Part of SAINT-GOBAIN)
- RHODIA Operations (Member of the Solvay group)

- DAIICHI KIGENSO KAGAKU KOGYO CO., LTD
- TREIBACHER INDUSTRIE AG
- IMERYS FUSED MINERALS
- TOSOH CORPORATION
- MEL Chemicals (Division of Magnesium Elektron Limited)
- CEZUS SA: COMPAGNIE EUROPEENNE DU ZIRCONIUM (Part of AREVA group)
- FOSKOR Zirconia (Pty) Limited

The Mixed Oxides & Zirconia Oxides Consortium has been asked by its members and its Management Committee to initiate contacts between all the potentially relevant Pre-SIEF for this substance.

ARCADIS

ARCADIS will provide technical and administrative assistance on behalf of the Mixed Oxides & Zirconia Oxides Consortium. All communication can be sent to the following address of the consortium secretariat: MOZOCreach@arcadisbelgium.be

For more information on ARCADIS please go to: www.reach-consulting.be

MERGER WITH OTHER SUBSTANCES

It is foreseen to merge the SIEF for magnesium zirconium oxide with that for:

1. Reaction mass of magnesium oxide and zirconium dioxide, if the substances pre-registered under the latter SIEF are also rather mono-constituent substances in which magnesium oxide and zirconium dioxide are incorporated in one single crystal lattice.
2. Magnesium zirconium trioxide, if the substances pre-registered under the latter SIEF can be sufficiently described by the information in the SIP for magnesium zirconium oxide.

Because pre-registrants for the reaction mass of magnesium oxide and zirconium dioxide and magnesium zirconium trioxide may agree that they manufacture, intend to manufacture, or import a substance that is sufficiently similar to magnesium zirconium oxide to allow read-across and/or to merge into one SIEF, we invite all SIEF participants for the reaction mass of magnesium oxide and zirconium dioxide and magnesium zirconium trioxide to take part in this survey too.

To indicate your position on the merging of above substance(s), we invite you to **complete the section MERGING of the survey.**

SIP (SUBSTANCE IDENTIFICATION PROFILE)

The substance identification profile for magnesium zirconium oxide (EC 939-960-9) as used for the registration can be found in attached document (SIP MgZrO, version v.1, 16/01/2014). The possible substances for merging are also taken into account in the Substance Identification Profile. You can indicate in the survey your position on the Substance Identification Profile.

LEAD REGISTRANT

Imerys Fused Minerals is a member of the Oxides & Zirconia Oxides Consortium and is volunteering as lead registrant for magnesium zirconium oxide. Its candidacy is supported by all Consortium members.

The Mixed Oxides & Zirconia Oxides Consortium has been actively involved in the preparation of the registration dossier and thus will be involved in the SIEF activities to support **Imerys Fused Minerals**.

To indicate your position on the candidacy of **Imerys Fused Minerals** as Lead Registrant for magnesium zirconium oxide, we invite you to **complete the section 'LEAD REGISTRANT' of the survey.**

NEXT STEPS FOR YOU

We need your participation on the following issues in order to proceed as soon as possible with the SIEF communication. Below is a link to a survey for you to complete to inform us of:

1. Your position vs **Imerys Fused Minerals** as Lead Registrant for magnesium zirconium oxide;
2. Possession of data, which could be relevant for REACH registration.
3. Agreement on the merging with other substances.
4. Agreement on Substance Identification Profile.
5. Registration intentions

Please click [here](#) to respond to the survey for magnesium zirconium oxide latest **29 January 2014**.

If we do not hear back from you by this date, we will assume that you do not intend to file a registration dossier and that you are neither interested in participating in the consortium nor in the legitimate possession of data which is mandatory to share. In this case we assume that your status is "dormant". In this case, no further communication will be sent apart from communications sent to the entire SIEF like those related to mandatory data sharing, information on filing of the registration dossier, and proposed harmonised classification & labelling.

NOTE: In order to efficiently communicate amongst SIEF participants we kindly ask you to include the CAS-numbers and the chemical name of the substances you are concerned with in the "Subject" line of any email.

Please send all correspondence to the email address of the Consortium Secretariat at mozocreach@arcadisbelgium.be

Best regards,

ARCADIS Belgium on behalf of the Mixed Oxides & Zirconium Oxides consortium.

MOZOCreach@arcadisbelgium.be

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August 1, 2016

MAGNESIUM ZIRCONIUM OXIDE | EC 939-960-9

REACTION MASS OF MAGNESIUM OXIDE AND ZIRCONIUM DIOXIDE | EC 910-019-4

MAGNESIUM ZIRCONIUM TRIOXIDE | CAS 12032-31-4 | EC 234-768-5

Dear SIEF participant,

You have received this email because you REACH Pre-Registered with ECHA for magnesium zirconium oxide and/or reaction mass of magnesium oxide and zirconium dioxide and/or magnesium zirconium trioxide.

This communication is addressed to the SIEF participants of the merged SIEF's of Magnesium Zirconium Oxide, Magnesium Zirconium Trioxide, and RM of Magnesium Oxide and Zirconium Oxide. We invite all SIEF participants to take part in this survey on the registration intentions.

In 2013, due to an ECHA decision on the registration dossier of zirconium dioxide (CAS 1314-23-4 | EC 215-227-2), the MOZO Consortium has taken the decision to register the 'doped/stabilized' Yttrium Zirconium Oxide. Although ECHA did not define the word 'dopant', they suggested – referring to the initial guidance such as the Manual of Decisions under the Dangerous Substances Directive – that the mono-constituent approach needs to be followed when the 'intentionally added substance(s)' is/are incorporated in the crystal lattice, together with ZrO₂.

One of these substances for which this approach can be followed is Magnesium Zirconium Oxide (EC 939-960-9). This substance has already been registered by the Lead Registrant Imerys Fused Minerals (formerly known as Treibacher Schleifmittel GmbH) in the 100-1000 t/y tonnage band as a full dossier. An update of the registration dossier is foreseen to be submitted within the next 3 months. The registration dossier also takes into account the coverage of Magnesium Zirconium Trioxide and RM of Magnesium Oxide and Zirconium Oxide.

In 2016, an update of the SIP (substance identification profile) was performed in the light of the update of the registration dossier. This SIP has not yet been approved by the SIEF members. Therefore, the SIEF survey also serves for the approval of the updated SIP.

The Lead Registrant, in collaboration with the MOZO Consortium, is implementing the new regulation on data sharing (Regulation (EU) 2016/9). In this respect, the price of the Letter of Access will be calculated to take into account the potential number of co-registrants per tonnage band. We therefore request you to confirm your registration intention as well as your tonnage band.

Below is a link to a survey for you to complete to inform us of your registration intention and tonnage band, and your position on the updated SIP. One survey per legal entity will need to be completed.

Please click here to respond to the survey for Magnesium Zirconium Oxide before September 12, 2016.

In this SIEF communication, you will find further information on:

- **MIXED OXIDES & ZIRCONIA OXIDES CONSORTIUM**
- **ARCADIS**
- **REASONS FOR JOINING THE CONSORTIUM VS LETTER OF ACCESS**
- **SIP (SUBSTANCE IDENTIFICATION PROFILE)**
- **DOPED/STABILIZED FORMS OF ZIRCONIA**
- **CLASSIFICATION**

- **LEAD REGISTRANT**
- **NEXT STEPS FOR YOU**

MIXED OXIDES & ZIRCONIA OXIDES CONSORTIUM

The MOZO Consortium brings together manufacturers and importers of a number of zirconium compounds. At this point in time, the companies involved in this consortium are:

- SEPR: SOCIETE EUROPEENNE DES PRODUITS REFRACTAIRES (Part of SAINT-GOBAIN)
- RHODIA Operations (Member of the Solvay group)
- DAIICHI KIGENSO KAGAKU KOGYO CO., LTD
- TREIBACHER INDUSTRIE AG
- IMERYS FUSED MINERALS Villach GmbH
- TOSOH CORPORATION
- MEL Chemicals (Division of Magnesium Elektron Limited)
- AREVA NP (Part of AREVA group)
- FOSKOR Zirconia (Pty) Limited

For more information on the MOZO Consortium please go to: www.mozoreach.eu

ARCADIS

Arcadis will provide technical and administrative assistance on behalf of the MOZO Consortium. All communication can be sent to the following address of the consortium secretariat: MOZOCreach@arcadis.com.

For more information on Arcadis please go to: www.arcadis.com

THE MOZO CONSORTIUM AND LETTER OF ACCESS

For specific questions, or any inquiry regarding letters of access, please contact the secretariat of the Consortium: MOZOCreach@arcadis.com

SIP (SUBSTANCE IDENTIFICATION PROFILE)

The SIP has been updated and will need to be approved by the SIEF members. You can find the updated SIP for Magnesium Zirconium Oxide in the attached document (SIP ZrO₂MgO v3). Once approved, the updated SIP will be made available on www.mozoreach.eu. The SIP takes into account the coverage of Magnesium Zirconium Trioxide and RM of Magnesium Oxide and Zirconium Oxide within the Magnesium Zirconium Oxide registration dossier. The SIP takes into account a maximum concentration of MgO of 10% w/w.

The registration dossier and the related SIP are not fit for any material that meets the definition of a nanomaterial as defined in the European Commission Recommendation dated 18 October 2011.

You can indicate in the survey your position on the updated Substance Identification Profile.

DOPED/STABILIZED FORMS OF ZIRCONIA

As stated above, the registration dossier only covers forms of Magnesium Zirconium Oxide in which the Magnesium Oxide is an intentionally added substance. The concentration of Magnesium Oxide, incorporated into a single crystal lattice of ZrO₂, is covered up to 10% w/w by the registration dossier. XRD and other analytical means can be used to confirm the identity of the substance as being Magnesium Zirconium Oxide, incorporated in one single crystal lattice with ZrO₂.

The registration approach ECHA suggested is the following:

- The 'doped' zirconia, i.e., ZrO₂+dopant, is considered as a single 'main constituent'.
- If this 'main constituent' is present at a concentration of $\geq 80\%$ w/w, the mono-constituent approach can be followed, the remainder of the composition being made up by 'real' impurities, i.e. components not intentionally added but merely derived from the raw materials and production process.

For more information on the doped/stabilized forms of zirconia, please go to www.mozoreach.eu or contact the Consortium Secretariat at MOZOCReach@arcadis.com.

CLASSIFICATION

Magnesium Zirconium Oxide, as well as all other covered substances, are non-classified. Both components of Magnesium Zirconium Oxide, Zirconium Oxide and Magnesium Oxide, are non-classified substances. The registration dossier addresses only the pure substance (solid) without any hazardous impurities.

LEAD REGISTRANT

Imerys Fused Minerals (formerly known as Treibacher Schleifmittel GmbH) is a member of the MOZO Consortium and has acted as lead registrant for Magnesium Zirconium Oxide. Its candidacy was supported by all Consortium members as well as the members of the merged SIEF for Magnesium Zirconium Oxide, Magnesium Zirconium Trioxide, and RM of Magnesium Oxide and Zirconium Oxide.

The MOZO Consortium has been actively involved in the preparation of the registration dossier and thus is involved in the SIEF activities to support Imerys Fused Minerals.

NEXT STEPS FOR YOU

We need your participation on the following issues in order to proceed as soon as possible with the SIEF merging process and the Letter of Access calculation. Below is a link to a survey for you to complete to inform us of:

1. Agreement on the updated SIP (substance identification profile)
2. Registration Intentions

As mentioned before, we request you to complete the **SIEF survey before September 12, 2016**.

If we do not hear back from you by this date, we will assume that you are neither interested in registering the substance nor that you are interested in participating in the consortium. In this case we assume that your status is “dormant”, and no further communication will be sent apart from communications sent to the entire SIEF like those related to mandatory data sharing, information on filing of the registration dossier, and proposed harmonized classification & labeling.

NOTE: In order to efficiently communicate amongst SIEF participants, we kindly ask you to include the CAS-numbers and the chemical name of the substances you are concerned with in the “Subject” line of any e-mail.

Please send all correspondence to the e-mail address of the Consortium Secretariat at: MOZOCreach@arcadis.com

Best regards,

Arcadis Belgium on behalf of the members of the Mixed Oxides & Zirconium Oxides Consortium.

MOZOCreach@arcadis.com

<http://mozoreach.eu/>

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