Risk Management Option Analysis Conclusion Document

Substance Name: Tricobalt tetraoxide

EC Number: 215-157-2

CAS Number: 1308-06-1

Authority: NL-CA

Date: May 2017

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Foreword

The purpose of Risk Management Option analysis (RMOA) is to help authorities decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern.

RMOA is a voluntary step, i.e., it is not part of the processes as defined in the legislation. For authorities, documenting the RMOA allows the sharing of information and promoting early discussion, which helps lead to a common understanding on the action pursued. A Member State or ECHA (at the request of the Commission) can carry out this case-by-case analysis in order to conclude whether a substance is a 'relevant substance of very high concern (SVHC)' in the sense of the SVHC Roadmap to 2020[1].

An RMOA can conclude that regulatory risk management at EU level is required for a substance (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. Any subsequent regulatory processes under the REACH Regulation include consultation of interested parties and appropriate decision making involving Member State Competent Authorities and the European Commission as defined in REACH.

This Conclusion document provides the outcome of the RMOA carried out by the author authority. In this conclusion document, the authority considers how the available information collected on the substance can be used to conclude whether regulatory risk management activities are required for a substance and which is the most appropriate instrument to address a concern. With this Conclusion document the Commission, the competent authorities of the other Member States and stakeholders are informed of the considerations of the author authority. In case the author authority proposes in this conclusion document further regulatory risk management measures, this shall not be considered initiating those other measures or processes. Since this document only reflects the views of the author authority, it does not preclude Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate.

[1] For more information on the SVHC Roadmap: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Tricobalt tetraoxide is not listed in Annex VI of the CLP. Classification of reported impurities are listed in Annex VI of the CLP

Nickel oxide (028-003-00-2): Carc. 1A; STOT RE 1; Skin Sens. 1; Aquatic Chronic 4
Zinc oxide (030-013-00-7): Aquatic Acute 1; Aquatic Chronic 1
Cobalt oxide (027-002-00-4): Acute Tox*4; Skin Sens 1; Aquatic Acute 1; Aquatic Chronic 1; M=10

The classification of tricobalt tetraoxide is contingent on the composition of the impurity or impurities. The registration dossier provides a list of 12 profiles which are listed in the table below. Impurity(s) considered relevant for classification of the substance are indicated in bold type. The self-classification of Resp. Sens. 1B is due to tricobalt tetraoxide.

Concentration range of tricobalt tetraoxide	**Classification per profile (substance and impurity)**
Profile 1: Tricobalt tetraoxide >= 95.3 — <= 100.0 % Pure substance	Resp. Sens. 1B Aquatic Chronic 3
Profile 2 Tricobalt tetraoxide >= 95.3 — <= 100.0 %	Resp. Sens. 1B Carc. 1A Aquatic Chronic 3
Profile 3 Tricobalt tetraoxide >= 95.3 — <= 100.0 %	Resp. Sens. 1B Skin Sens. 1 STOT Rep. Exp. 2 Carc. 1A Aquatic Chronic 3
Profile 4 Tricobalt tetraoxide >= 95.3 — <= 100.0 %	Resp. Sens. 1B Aquatic Chronic 2
Profile 5 Tricobalt tetraoxide >= 95.3 — <= 100.0 %	Resp. Sens. 1B Carc. 1A Aquatic Chronic 2
Profile 6 Tricobalt tetraoxide >= 95.3 — <= 100.0 %	Resp. Sens. 1B Skin Sens. 1 Aquatic Chronic 2
Profile 7 Tricobalt tetraoxide >= 95.3 — <= 100.0 %	Resp. Sens. 1B Carc. 1A Skin Sens. 1 Aquatic Chronic 2
Profile 8 Tricobalt tetraoxide >= 95.3 — <= 100.0 %	Resp. Sens. 1B Skin Sens. 1 Aquatic Chronic 2
Profile 9 Tricobalt tetraoxide >= 95.3 — <= 100.0 %	Resp. Sens. 1B Carc. 1A Skin Sens. 1 Aquatic Chronic 2
Profile 10 Tricobalt tetraoxide >= 95.3 — <= 100.0 %	Resp. Sens. 1B Skin Sens. 1 Aquatic Acute 1 (M=10) Aquatic Chronic 1 (M-10)
Profile 11 Tricobalt tetraoxide >= 95.3 — <= 100.0 %	Resp. Sens. 1B Skin Sens. 1 Carc 1A Aquatic Acute 1 (M=10) Aquatic Chronic 1 (M-10)
Profile 12* Tricobalt tetraoxide >= 70.0 — <= 90.0%	

* By personal communication, the Registrant indicated that profile 12 is no longer relevant to the registration dossier. The Cobalt REACH Consortium will recommend its members to remove this particular profile from the REACH registration dossier with the next.

2. CONCLUSION OF RMOA

This conclusion is based on the REACH and CLP data as well as other available relevant information taking into account the SVHC Roadmap to 2020, where appropriate.

Conclusions	**Tick box**
Need for follow-up regulatory action at EU level:	
Harmonised classification and labelling	
Identification as SVHC (authorisation)	X
Restriction under REACH	
Other EU-wide regulatory measures	
Need for action other than EU regulatory action	
No action needed at this time	

3. NEED FOR FOLLOW-UP REGULATORY ACTION AT EU LEVEL

3.1 Identification as a substance of very high concern, SVHC (first step towards authorisation)

There are no comprehensive EU risk assessments or known risk reduction strategies for cobalt compounds.

Need for (further) risk management

SVHC Roadmap 2020 criteria

There is no harmonised classification for the substance. Tricobalt tetraoxide may meet the Art 57 criteria for equivalent level of concern (57f) and for carcinogenicity (57a) depending on the specific profile and the different impurities therein (see self-classification section 3.1.2)

	Yes	**No**
a) Article 57 criteria fulfilled?	X (see comment above, regarding impurity) Carc. 1A for profiles 2, 3, 5, 7, 9, 11 Possibly through ELoC based on Resp Sens 1B (once harmonized)	
b) Registrations in accordance with Article 10?	X	
c) Registrations include uses within scope of authorisation?	X	
d) Known uses already regulated by specific EU legislation that provides a pressure for substitution?		X

Tricobalt tetraoxide could be considered similar to other cobalt substances where the Co^{++} species is considered to be responsible for toxicity effects. This applies without

restriction to all cobalt compounds capable of releasing cobalt ions. Cobalt substances already in the candidate list are: cobalt acetate, cobalt dichloride, cobalt nitrate, cobalt sulphate and cobalt carbonate. The reason for inclusion is: Art. 57a and 57c (Carcinogenic and toxic for reproduction, respectively). Having said this, the cobalt substances in the candidate list are considered soluble or show high bioavailability where tricobalt tetraoxide represents a poorly soluble cobalt substance. Recent test data suggest that tricobalt tetraoxide is no carcinogenic or reproductive toxicant.

Concern for tricobalt tetraoxide relates to its respiratory sensitizing properties and the carcinogenic properties of those profiles containing the impurity NiO. Concerns for workers relate to exposure to the substance or to formulations (mixtures) or articles in which the substance is used. Concerns for consumers relate to the use of articles in which the substance is used.

Technical and economical feasibility of possible alternatives to the lower grade tricobalt tetraoxide profiles 2, 3, 5, 7, 9 and 11

According to the Registrant, industry is already using the more pure grades containing impurities below their SCL/GCL wherever possible (i.e. profiles 1, 4, 6, 8 and 10).

Lower grade profiles are still in use for (the production of) pigments and the decolourization of glass. The Registrant indicates that it is technically feasible to purify the tricobalt tetraoxide used for pigments and decolourising glass such that any remaining impurity is below the SCL. Hence, from a technical perspective, a purer grade of tricobalt tetraoxide could be used as an alternative.

Nevertheless, the Registrant indicates that impurities like the NiO function in pigments to fine tune the specific colour of the end-product. The nature and/or concentration of the impurity determines the variation in colour of the pigment. Though substitution of lower grade tricobalt tetraoxide by more pure tricobalt tetraoxide is technically feasible, this will affect the end-product. From a market perspective and from the viewpoint of the pigment sector this is not always desirable.

According to the Registrant, substitution of lower grade tricobalt tetraoxide by more pure tricobalt tetraoxide will also have significant economic consequences on the pigment sector, since purification involves extra processing steps (leading to higher costs). Few alternative substances exist for the use of tricobalt tetraoxide in pigments, and, based on the information of the Registrant, these will be more expensive and produce lower output yields. The eMSCA has no information on the identity of these possible few alternatives. The eMSCA also has no more specific information on the order of magnitude of the economic impact of substituting low grade tricobalt tetraoxide by higher grade tricobalt tetraoxide.

Furthermore, the Registrant indicates that low-grade tricobalt tetraoxide is added to mixtures containing components (other substances) that by themselves already five rise to a more severe mixture classification than would result from the presence of the low-grade tricobalt tetraoxide profile. Replacing the “impure” tricobalt tetraoxide profile by a higher purity one would consequently not result in less severe classification for most mixtures. The Registrant did not provide any further information on the composition of these mixtures, nor on the specific use of these mixtures and consequent exposure of workers and consumers.

Is there some evidence that socio-economic benefits of continued use are low?

As indicated previously, tricobalt tetraoxide is produced, imported and exported at relatively high tonnage levels and may be used in Europe by a little over 800 users that notified the substance under CLP. When risk management measures will target tricobalt

tetraoxide on the basis of a concern for respiratory sensitization, possible all uses will be affected somehow. This is expected to be less when risk management measures will only address those profiles that contain impurities above their GCL for classification as carc. 1A. Information from the Registrant suggests that a small part of all users use the profiles 2, 3, 5, 7, 9 and 11 that should be self-classified as carc. 1A because of the presence of NiO as an impurity. These users may at this moment gain from the economic benefits of marketing or applying low purity profiles. In case of implementation of a risk management measure targeting the presence of NiO these users would be somehow affected. However, there may be possible alternatives available, at higher costs and with possible consequences for the possible coloration of end-uses. The volume of low purity profiles is less than 10% of the total volume of tricobalt tetraoxide produced and imported in the EU per year. As no information is available on the costs involved in substituting low-grade tricobalt tetraoxide for technical and economically feasible alternatives, it is at this moment difficult to estimate the potential socio-economic loss (or costs) of these profiles in case of implementation of a risk management measure.

On the other hand, current use of low-grade profiles might cause health effects in workers that are deemed serious (giving rise to carcinogenicity or respiratory effects). Health effects will result in health care costs, potential loss in working time and intangible costs for patients (disease burden). The number of notifiers of tricobalt tetraoxide is substantial (over 800). According to the Registrant though, only a limited amount of workers might be exposed to those profiles self-classified as carc. 1A.

With regard to risk management measures targeting the NiO containing profiles, the Registrant indicates that industry has already substituted low purity profiles for high purity profiles for all uses except in pigments and the decolouration of glass, and that low purity profiles are used in formulations including other substances that dominate the hazard characteristics of the formulation. Risk management measures leading to the substitution of low purity profiles by high purity profiles are therefore suggested by the registrant not to contribute to a reduction of the health hazards for the workers involved. From the information available it is not possible to verify this statement. The eMSCA is of the opinion that even if the statement is true, a reduction of health hazards may still be expected for workers handling the substance.

To conclude, it is at the moment difficult to estimate economic benefits of the use of low purity profiles of tricobalt tetraoxide or to estimate the potential health effects of the use of these profiles. A more elaborated socio-economic analysis would be required to be able to say more on the balance of costs and benefits of continued use or the implementation of a risk management measure that could be used as underpinning of a policy decision on this substance. However, such a more elaborated SEA is beyond the scope of this RMOA.

Identification and assessment of risk management options

Classification Labelling and Packaging Regulation, Annex VI (classification and labelling)

Tricobalt tetraoxide is not listed in Annex VI. The Netherlands are currently assessing the need for further harmonized classification of cobalt compounds of which Tricobalt tetraoxide is one. Tricobalt tetraoxide should be self-classified in the presence of impurities above the SCL/GCL. Consequently, profiles with an NiO content >0.1% have to be (self)classified as carcinogenic cat.1A (see also section 3.1.2).

The available data furthermore do suggest that Tricobalt tetraoxide could be harmonized under CLP as a Resp. Sens 1B classification. The registrant provided four reliable studies (Klimisch score 2) describing exposure related observations in humans for cobalt and

cobalt compounds and information from occupational exposure studies in cobalt facilities. Tricobalt tetraoxide was considered to be a respiratory sensitizer based human epidemiological data showing cases of occupational asthma following prolonged exposure toward cobalt salts, -oxides and hydroxides. The preparation of an Annex VI dossier for Resp. Sens. 1B may therefore be an appropriate risk management option for tricobalt tetraoxide. The endpoint of Respiratory Sensitization is presently not included in the assessment of cobalt compounds by the Netherlands where the primary focus is on CMR. It may, however, be taken up as an endpoint of interest in the near future.

Harmonized classification on this endpoint will ensure that the hazards presented by the substance are clearly communicated to workers and instigates the implementation of proper risk management measures at the workplace. It is therefore concluded that CLH for Resp. Sens. is an appropriate risk management option for this substance.

Voluntary measures at the workplace:

Risk management measures to control the risk of exposure such as respiratory protective equipment (RPE) and general good occupational hygiene practices are reported in the CSR. Industry is already obliged to strictly control the production process. Industry has assessed a number of exposure scenarios for:

(1) manufacture of tricobalt tetraoxide,
(2) manufacture of tricobalt tetraoxide in the catalyst industry,
(3) industrial use of tricobalt tetraoxide as catalyst,
(4) industrial use of tricobalt tetraoxide in the manufacture of inorganic pigments & frits, glass, ceramic ware, varistors and magnets (calcination/sintering processes) (intermediate use),
(5) manufacture and industrial use of plastics and/or PET using tricobalt tetraoxide,
(6) manufacture, formulation and industrial use of coatings and inks using tricobalt tetraoxide as drier, pigment and/or pre-formulations of paints,
(7) industrial use of tricobalt tetraoxide in the manufacture of chemicals and in other wet-chemical processes as intermediate,
(8) professional uses of coatings and inks containing tricobalt tetraoxide,
(9) professional uses of plastics and/or PET containing tricobalt tetraoxide and
(10) service life of articles containing tricobalt tetraoxide encapsulated in the internal part of the product.

Based on the risk characterization ratios (RCR < 1), the CSR indicates no risk for the workers.
Out of a voluntary initiative, industry has already substituted low purity profiles for high purity profiles in uses other than pigments and decolouration of glass. On the basis of the CSR, it is not possible for the eMSCA to verify this statement. Based on the information provided by industry, the eMSCA concludes that there is no economic incentive nor a direct market incentive to substitute the low purity profiles for high purity profiles (or for alternative substances) in the remaining uses. Industry also states there is no incentive for substitution driven by a wish to further reduce the concern for human health. The eMSCA however, has no further information to substantiate this statement. On the basis of the information available for this RMOA it is concluded unlikely that voluntary initiatives will lead to a further substitution of low-grade tricobalt tetraoxide.

Worker legislation (setting an OEL):

OELs are a well-established tool for setting safe levels of exposure or implementing adequate control to provide worker protection. A harmonized EU OEL for cobalt is under review by the SCOEL (Scientific Committee for OELs) (EC, Employment, Social Affairs and Equal Opportunities document online, May 2013). Information on the status of this review could not be located. Setting an OEL offers the opportunity to reduce and keep

exposure of tricobalt tetraoxide to a minimum.

Current occupational exposure limits on cobalt or cobalt compounds range from 0.05 mg/m^3 - 0.1 mg/m^3. The current UK workplace exposure limit for cobalt and cobalt compounds is 0.1 mg/m^3 (HSE, 2007) and the American Conference of Governmental Industrial Hygienists (ACGIH) threshold limit value (TLV) is 0.02 mg/m^3 (CAREX Canada, 2010). UK workplace exposure limits are normally set at limits that are believed to be achievable through good occupational hygiene practice (Etna, 2008). Additional occupational exposure limits include the Occupational Safety and Health Administration (OSHA) permissible exposure limit (PEL) for cobalt metal, dust, and fume (as Co) of 0.1 mg/m^3 and the National Institute for Occupational Safety and Health (NIOSH) has established a recommended exposure limit (REL) for cobalt metal, dust, and fume of 0.05 mg/m^3.
The highest exposure concentration for workers reported in the CSR is 0.033 mg/L. This value is lower than the current occupational limit value ranges mentioned above.
For working with low purity profiles, the risk management measures in the workplace should be driven by the most stringent conditions. In the current case, where the concern involves profiles of tricobalt tetraoxide containing NiO a SCOEL recommendation for nickel oxide is available. In this specific case, using the recommended SCOEL to address the exposure of concern to nickel oxide should already be in place at the work floor. The French MSCA concluded in their RMOA on Ni-compounds that SCOEL should be asked to derive a BOELV and proposed 0.01 mg/m^3 as a possible appropriate limit value.

REACH Annex XIV (authorisation) and Candidate List

Based on the present data (in the absence of a harmonized classification for tricobalt tetraoxide), the substance tricobalt tetraoxide does meet the criteria of article 57 of REACH only in the presence of impurities in concentrations above the SCL/GCL, e.g. NiO (Carc. Cat.1A, article 57a). Consequently, preparing an Annex XV dossier for tricobalt tetraoxide profiles containing >0.1% NiO for the Candidate List with the eventual purpose of Authorisation is a possible risk management option to regulate the current concern for workers using these profiles. Placing tricobalt tetraoxide in the candidate list would create an incentive for industry to reduce using the substance containing impurities above the SGL/GCL. From a technical perspective, substitution of more hazardous by less hazardous profiles may be possible for most, if not all uses. It is therefore expected that once this substance is included in Annex XIV, there will be a good chance that substitution will occur.

It is furthermore expected that through Candidate Listing, already in an early phase of the regulatory process more information will be obtained about the uses of the different profiles.

It is anticipated that the volume of tricobalt tetraoxide affected by this risk management option will be at most 10% of the total volume manufactured, imported and used. Consequently, 10% of the total volume may be affected by Authorisation. When the use of low purity profiles is in formulations in which more pure profiles will not impact the overall hazard characteristic of the formulation though, as is claimed by the Registrant, the impact of this measure on human health may be small but is still expected to impact the health of those workers that are handling the substance.

Proposing tricobalt tetraoxide as an SVHC based on its respiratory sensitizing properties may become an option once the substance passed the process leading to its harmonized classification for that endpoint.

REACH Annex XVII (restriction)

Based on the current data, greatest concern is for workers involved in the use of tricobalt tetraoxide profiles in the pigment and decolourising glass sector. Developing a restriction of the use of low-grade tricobalt tetraoxide for these particular uses has the possibility to target only those uses that are currently of concern. Based on the information from the CSR though, there is no data suggesting an urgent risk for society. Nor is there, to the knowledge of the eMSCA, any other information suggesting a risk for society due to exposure to tricobalt tetraoxide or due to the exposure of low purity profiles of tricobalt tetraoxide including NiO. Consequently, based on the currently available information, restricting the use or application of tricobalt tetraoxide via a ban on the substance or a targeted restriction of use or application in certain uses of the substance does not seem proportional.

Conclusions on the most appropriate (combination of) risk management options

The assessment suggests that tricobalt tetraoxide including the NiO impurity >0.1% meets the criteria of art 57a and thereby could be proposed for SVHC identification. Consequently, the preparation of an SVHC Annex XV dossier for tricobalt tetraoxide is a possible risk management option that would most likely result in the further purification of profiles currently containing NiO > 0.1%.

However, as discussed above, the impact on human health is uncertain.

The above concern is based on the carcinogenic property of the impurity, nickel oxide. The CSR reports different profiles for tricobalt tetraoxide based on 4 different impurities. It is not clear how, and with what volumes the different profiles are used in the manufacturing, formulation, processes and uses of tricobalt tetraoxide. This information would be helpful in determining if in reality the need to control risk should be targeted on the impurity(s). Monitoring could be considered to determine if concentrations of nickel oxide in tricobalt tetraoxide in the work place pose a risk for workers. Substance evaluation or an Article 36 information request could also be considered to obtain further insight in the uses per profile.

Harmonized classification to Resp. Sens. Category 1B is another risk management option for tricobalt tetraoxide. Harmonized classification on this endpoint will impact the production and use of all tricobalt tetraoxide and will ensure that the hazards presented by the substance are clearly communicated to workers and instigate the implementation of proper risk management measures at the workplace. Harmonizing the classification of tricobalt tetraoxide as respiratory sensitizer will furthermore open the possibility to regulate this substance via authorisation. However, if harmonizing the classification of tricobalt tetraoxide is considered, a grouping approach for similar cobalt-compounds should be further elaborated on.

Based on the current data, harmonizing the classification of tricobalt tetraoxide as Resp Sens 1B is considered an appropriate risk management option, possibly as part of a group of cobalt compounds. The current information furthermore suggests that Authorisation of tricobalt tetraoxide containing ≥ 0.1% NiO impurity may be an appropriate risk management option to create an incentive for substitution of the remaining fraction of Tricobalt tetraoxide uses for which there is currently no market incentive available. Substance evaluation or an Article 36 information request could be considered to obtain further insight in the uses that would be impacted by such an Authorisation. However, it is expected that the further insight in the exact uses per profile will not significantly impact the wish for substitution and moreover, the time involved with obtaining this information is judged disproportional.

To summarize, it is concluded that SVHC identification of tricobalt tetraoxide based on the presence of NiO, followed by Authorisation, is the most appropriate RMO for this substance. In parallel, is concluded that harmonized classification for respiratory sensitization should be initiated for the group of cobalt compounds.

Follow-up action	**Date for intention**	**Actor**
Annex XV dossier for SVHC identification (Authorisation)	2017	NL-CA