Risk Management Option Analysis Conclusion Document

Substance Name: Cobalt titanite green spinel

EC Number: 269-047-4

CAS Number: 68186-85-6

Authority: The Netherlands

Date: December 2015

Version 2.1
October 2015

DISCLAIMER

The author does not accept any liability with regard to the use that may be made of the information contained in this document. Usage of the information remains under the sole responsibility of the user. Statements made or information contained in the document are without prejudice to any further regulatory work that ECHA or the Member States may initiate at a later stage. Risk Management Option Analyses and their conclusions are compiled on the basis of available information and may change in light of newly available information or further assessment.

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

Testing proposal: ECHA has taken a decision on the testing proposal for Cobalt bis(2-ethylhexanoate) in November 2013. The registrant has carried out an sub-chronic toxicity (90-day) study in rats, oral route, and a prenatal development study in rats or rabbits, oral route, with the analogue substances cobalt dichloride and cobalt tetraoxide. The deadline for an updated dossier is November 2015.

Classification and Labelling: On November 15th 2013, the Netherlands notified the intention to submit a CLH dossier for cobalt and cobalt compounds. During the last 1½ year, the Netherlands had several good discussions with industry representatives and additional information was collected. The Netherlands intents to submit a draft version of the CLH dossiers on August 1st, 2015; which will be shared with stakeholders. Final submission is foreseen at November 1st, 2015. The CLH dossiers will consider the CMR endpoints.

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.

For cobalt titanite green spinel, an RMOA is conducted to discusses among others the desirability to put this substance on the Candidate list as a consequence of its impurities.

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

3. NO ACTION NEEDED AT THIS TIME

The present concern relates to worker and consumer exposure to the pigment Cobalt titanite green spinel in the presence of an impurity. The impurity content is the cause of concern for Carc. Cat1. Consequently, Cobalt titanite green spinel might meet the SVHC Roadmap 2020 criteria for those cases where the impurity is > 0.1%. The registration dossier indicates that Cobalt titanite green spinel has wide dispersive uses including consumer use and worker exposure.

4. Table: SVHC Roadmap 2020 criteria

	Yes
a) Art 57 criteria fulfilled?	X, when impurity is >0.1%
b) Registrations in accordance with Article 10?	X
c) Registrations include uses within scope of authorisation?	X
d) Known uses not already regulated by specific EU	X

legislation that provides a pressure for substitution?	

However, as indicated by the registrant upon personal communication, consumer uses might have been indicated in the registration dossier for the wrong reasons and may not reflect the real life uses of the pigment.

Furthermore, upon personal communication, the registrant indicates a recent change in the production process of Cobalt titanite green spinel that will result in impurity concentrations below the specific concentration limit for classification and labelling. The registrant indicates that this “pure P.G.50” will soon be registered as a new substance in the tonnage band 10 – 100 t/a. Based on the available information, it remains uncertain how much Cobalt titanite green spinel will remain on the market containing impurities > 0.1%. As this change in process is initiated from the positive market push to work with non-carcinogeneous materials, there might be a chance that the remaining “non-pure” pigment will be relatively small and may disappear altogether by voluntary action. However, based on the current data, a scenario may also be that impure P.G.50 will remain at the EU market at production volumes of 10 – 100 t/a.

According to the registrant, it is possible to avoid the impurity by a change of the process parameters of the P.G. 50 production to suppress the formation of the unwanted impurity. The “pure P.G. 50” will not have to be classified as Carcinogenic substance category 1, neither does it have to be classified for any other health hazard, at present. Consequently, according to the information available to date, pure P.G. 50 does not meet the SVHC Roadmap criteria for a possible substance of very high concern. As a consequence hereof, any discussion on the appropriateness for authorization will no longer stand. Also, restriction is no discussion as there is no information available that the pure P.G. 50 exhibit a risk.

Authorization may still be considered though for the remaining P.G. 50 for which the production process will not be optimized and which, for that reason will continue to contain significant amounts the impurity. Because the total volume of this “impure P.G. 50” that will remain on the market is uncertain, no conclusion can be drawn yet on the appropriateness of authorization at this moment in time. Once the remaining uses and production volume of the impure P.G. 50 become clear, also restriction should be reconsidered as a possible risk management option. At present, there is no clear indication that the impure P.G. 50 induces a risk at EU level though. If this would have been the case, a restriction could target the content of the impurity, limiting this to acceptable levels.

Ongoing developments

The discussion above depends to a large extend on the information supplied to the NL-CA by the registrant via written communications and is not yet reflected in the registration dossier. This particularly relates to the type of uses and the impurity content. It should be clear that the registration dossier should be updated to appropriately reflect this (new) information.

Furthermore, the 90-days study, ongoing in the context of the testing proposal, may shed further light on the possible toxicity of the Cobalt complex. Depending on the outcome of the study, expected November 2015, the conclusions drawn in this RMOA should be revisited. This also applies to any new insights evolving from the Dutch CLH proposal for classification of Cobalt compounds. If any new insights resulting from that initiative should suggest different toxicity or interpretation of health concerns for Cobalt titanite green spinel, the conclusions of the RMOA should be revisited too.

Based on the available information and ongoing developments it is concluded that no further risk management measures are needed at present to address

the concern for possible health effects of Cobalt titanite green spinel (P.G.50; pure and impure).

However, it is also concluded that this conclusion should be revisited upon the next update of the registration dossier, the publication of results from the 90-days study and the results of the Dutch initiative to classify Cobalt compounds as a group of substances.