Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name):	Potassium titanium oxide (K2Ti6O13).
Chemical Group:	Mono-constituent inorganic
EC Number:	432-240-0
CAS Number:	12056-51-8
Submitted by:	France
Published:	26/03/2014

Note

This document has been prepared by the evaluating Member State given in the CoRAP update.

Contents

1 IDENTITY OF THE SUBSTANCE

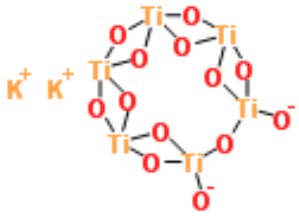
1.1 Other identifiers of the substance

Table 1: Substance identity

EC name:	-
IUPAC name:	Potassium titanium oxide (K2Ti6O13)
Index number in Annex VI of the CLP Regulation	022-004-00-1
Molecular formula:	K2 Ti6 O13
Molecular weight or molecular weight range:	Ca. 573.5
Synonyms/Trade names:	TISMO-N; TXAX

Type of substance ☒ Mono-constituent ☐ Multi-constituent ☐ UVCB

Structural formula:



1.2 Similar substances/grouping possibilities

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2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

Carc. 2; H351: Suspected of causing cancer. Danger; GHS08

2.2 Self classification

- In the registrations (Three individual registrants A, B and C)

A. Carc. 2; H351: Suspected of causing cancer.

STOT SE 3; H335: May cause respiratory irritation.
Affected organs: Upper respiratory tract (nose)

Warning; GHS07, GHS08

B. Carc. 2; H351: Suspected of causing cancer by inhalation.

Acute Tox. 4; H333: May be harmful if inhaled.
In the labelling part H332 (Harmful if inhaled.) is given.

Warning; GHS07, GHS08

C. Carc. 2; H351: Suspected of causing cancer.

Danger; GHS08

- In addition are the following C&L notifications registered in C&L Inventory:

No other hazard classes are notified to CLI.

2.3 Proposal for Harmonised Classification in Annex VI of the CLP

None.

3 INFORMATION ON AGGREGATED TONNAGE AND USES

☐ 1 – 10 tpa	☒ 10 – 100 tpa	☐ 100 – 1000 tpa
☐ 1000 – 10,000 tpa	☐ 10,000 – 100,000 tpa	☐ 100,000 – 1,000,000 tpa
☐ 1,000,000 – 10,000,000 tpa	☐ 10,000,000 – 100,000,000 tpa	☐ > 100,000,000 tpa
☐ <1 . . . . . >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		☐ Confidential

☒ Industrial use	☐ Professional use	☐ Consumer use	☐ Closed System

E.g. Wear-resistant material in disc-pads, brake-linings and clutch.

PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises
PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)

PC 0: Other: Friction material manufacture

4 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

4.1 Legal basis for the proposal

☒ Article 44(2) (refined prioritisation criteria for substance evaluation)

☐ Article 45(5) (Member State priority)

4.2 Selection criteria met (why the substance qualifies for being in CoRAP)

☒ Fulfils criteria as CMR/ Suspected CMR

☐ Fulfils criteria as Sensitiser/ Suspected sensitiser

☐ Fulfils criteria as potential endocrine disrupter

☐ Fulfils criteria as PBT/vPvB / Suspected PBT/vPvB

☐ Fulfils criteria high (aggregated) tonnage (*tpa > 1000*)

☐ Fulfils exposure criteria

☐ Fulfils MS's (national) priorities

4.3 Initial Grounds for concern to be clarified under Substance Evaluation

Hazard based concerns		
CMR ☒C ☐M ☐R	Suspected CMR[1] ☐C ☐M ☐R	☐ Potential endocrine disruptor
☐ Sensitiser	☐ Suspected Sensitiser[1]	
☐ PBT/vPvB	☐ Suspected PBT/vPvB[1]	☐ Other (please specify below)
Exposure / risk based concerns		
☐ Wide dispersive use	☐ Consumer use	☐ Exposure of sensitive populations
☐ Exposure of environment	☒ Exposure of workers	☐ Cumulative exposure
☐ High RCR	☐ High (aggregated) tonnage	☐ Other (please specify below)

The substance was notified at VIIA under NONS so there was limited toxicological data available.

At the time, the evaluating MSCA felt that Carc Cat 3 was appropriate because of the physical properties of the fibers and the possibility that they could split longitudinally to form long thin fibers of concern, although the company did argue that the fibers would also split across the length to produce shorter fibers.
There was evidence in the 90-day study that the substance could produce respirable fibers which could accumulate in the lungs, however there were indications that these would be removed by macrophages and there was no obvious mature collagen deposition (fibrosis).

In the absence of any other data, the classification was agreed at the NONS C&L group (18th meeting) although later another MS suggested they had data to support Carc cat 2 and they would forward it for discussion at a future meeting. However, this was never received and there were no further meetings of the C&L group.

It appears that the dossier has been upgraded to REACH Annex IX so there may be new studies that could clarify the concern on the carcinogenicity of the substance.

Moreover, although these fibers are not silicate, additional studies specific to MMMF fibers might be needed to evaluate the bio-persistency and carcinogenicity of the substance.

The evaluation of the substance should allow clarifying this concern.

[1] CMR/Sensitiser: known carcinogenic and/or mutagenic and/or reprotoxic properties/known sensitising properties (according to CLP harmonized or registrant self-classification or CLP Inventory)
Suspected CMR/Suspected sensitiser: suspected carcinogenic and/or mutagenic and/or reprotoxic properties/suspected sensitising properties (not classified according to CLP harmonized or registrant self-classification)
Suspected PBT: Potentially Persistent, Bioaccumulative and Toxic

4.4 Other completed/ongoing regulatory processes that may affect suitability for substance evaluation

☐ Compliance check, Final decision	☒ Dangerous substances Directive 67/548/EEC
☐ Testing proposal	☐ Existing Substances Regulation 793/93/EEC
☐ Annex VI (CLP)	☐ Plant Protection Products Regulation 91/414/EEC
☐ Annex XV (SVHC)	☐ Biocidal Products Directive 98/8/EEC
☐ Annex XIV (Authorisation)	☐ Other (provide further details below)
☐ Annex XVII (Restriction)	
The substance was evaluated by UK as a new substance (ELINCS).	

4.5 Information that is important for the substance evaluation and that maybe be requested to clarify the suspected risk

☒ Information on toxicological properties	☒ Information on physico-chemical properties
☐ Information on fate and behaviour	☒ Information on exposure
☐ Information on ecotoxicological properties	☐ Information on uses
☐ Information on ED potential	☐ Other (provide further details below)
Although these fibers are not silicate, additional studies specific to MMMF fibers might be needed to evaluate the bio-persistency and carcinogenicity of the substance.	

4.6 Potential follow-up and link to risk management

☒ Harmonised C&L	☐ Restriction	☐ Authorisation	☐ Other (provide further details)