Justification Document for the Selection of a CoRAP Substance

- Update -

Substance Name (public name):	Potassium titanium oxide (K2Ti6O13)
EC Number:	432-240-0
CAS Number:	12056-51-8
Authority:	France
Date:	26/03/2014 21/03/2017 (Updated version)

Cover Note

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

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1 IDENTITY OF THE SUBSTANCE

1.1 Other identifiers of the substance

Table: Other Substance identifiers

EC name (public):	-
IUPAC name (public):	• Potassium Titanium Oxide • Potassium titanium oxide (K2Ti6O13) • TOFIX
Index number in Annex VI of the CLP Regulation:	022-004-00-1 (annex I)
Molecular formula:	K2 Ti6 O13
Molecular weight or molecular weight range:	573.6
Synonyms:	Trade names • TOFIX-LL • TOFIX-S • TOFIX-SNR • TOFIX-SS

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

Structural formula:

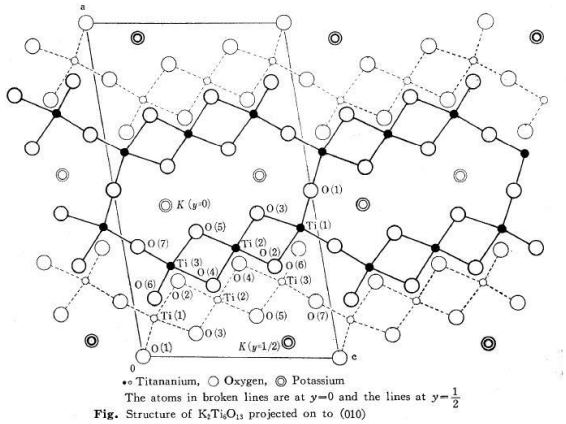

Fig. Structure of $K_2Ti_6O_{13}$ projected on to (010)

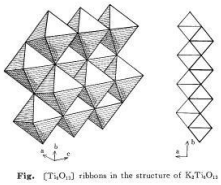
Fig. $[Ti_6O_{13}]$ ribbons in the structure of $K_2Ti_6O_{13}$

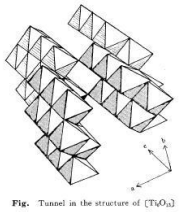
Fig. Tunnel in the structure of $[Ti_6O_{13}]$

1.2 Similar substances/grouping possibilities

Other titanium dioxide with fibre morphologies:

Titanium dioxide with fibre-like morphologies (e.g wire, belt, tube, fibre…) have been identified in the literature. Thus, similarities between potassium titanium dioxide and other titanium dioxide or titanate with fibre-like morphologies can be foreseen. Depending on our understanding of the existing materials, their properties and the data available, a read-across on their carcinogenic properties can be envisaged. For example, Hamilton (2009) concluded that "*long TiO_2 nanobelts interact with lung macrophages in a manner very similar to asbestos or silica. […]. These observations suggest that any modification of a nanomaterial, resulting in a wire, fibre, belt or tube, be tested for pathogenic potential.*" If additional substances of concern are identified in the course of the evaluation, they would be addressed either in the following CoRAP or according to Art. 45(5). We are however inviting all the operators who believe that their substance meets the characteristics indicated above, to contact the evaluating Member State for further clarification.

2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table: Completed or ongoing processes

RMOA	☐ Risk Management Option Analysis (RMOA)	
REACH Processes	Evaluation	☐ Compliance check, Final decision
		☐ Testing proposal
		☒ CoRAP and Substance Evaluation
	Authorisation	☐ Candidate List
		☐ Annex XIV
	Restric -tion	☐ Annex XVII[1]
Harmonised C&L	☒ Annex VI (CLP) (see section 3.1)	

[1] Please specify the relevant entry.

Processes under other EU legislation	☐ Plant Protection Products Regulation Regulation (EC) No 1107/2009
	☐ Biocidal Product Regulation Regulation (EU) 528/2012 and amendments
Previous legislation	☒ Dangerous substances Directive Directive 67/548/EEC (NONS)
	☐ Existing Substances Regulation Regulation 793/93/EEC (RAR/RRS)
(UNEP) Stockholm convention (POPs Protocol)	☐ Assessment
	☐ In relevant Annex
Other processes / EU legislation	☐ Other (provide further details below)
Further details	

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

Table: Harmonised classification

Index No	International Chemical Identification	EC No	CAS No	Classification		Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)		
022-004-00-1	potassium titanium oxide (K2Ti6O13)	432-240-0	12056-51-8	Carc. 2	H351		

3.1.2 Self classification

- In the registration (three individual registrants):

Acute Tox 4 – H332 (one submitter)

STOT SE 3 – H335 (one submitter)

- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:

No other classes are notified.

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

Potassium titanium dioxide has a current harmonized classification as Carc. 2.

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES[2]

4.1 Tonnage and registration status

Table: Tonnage and registration status

From ECHA dissemination site		
☒ Full registration(s) (Art. 10)	☐ Intermediate registration(s) (Art. 17 and/or 18)	
Tonnage band (as per dissemination site)		
☐ 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
☒ 100+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		☐ Confidential
3 registration dossiers are available.		

[2] *The dissemination site was accessed 3 January 2017.*

4.2 Overview of uses

K2Ti6O13 is used to manufacture automotive brakes parts:

- PC 0: Other: Friction material manufacture; wear-resistant material in disc-pads, brake-linings and clutch; automotive components
- SU 17: General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment; SU 0: Other: manufacture of automotive brakes; garages
- AC 01: Other (non intended to be released): automotive brakes; wear resistant articles used in maintenance, repair and service of cars

Uses for K2Ti6O13 showing potential worker exposure occur during formulation, manufacture of automotive brakes parts (industrial use), professional use of article in in automotive industry, professional use of articles in garages and articles service life (driving of automotive vehicles and maintenance of automotive breaks). In particular, the following processes are expected:

- 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)
- PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities
- PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities
- PROC 10: Roller application or brushing
- PROC 14: Production of preparations or articles by tabletting, compression, extrusion, palletisation
- PROC 21: Low energy manipulation of substances bound in materials and/or articles
- PROC 24: High (mechanical) energy work-up of substances bound in materials and/or articles
- PROC 26: Handling of solid inorganic substances at ambient temperature

Consumers may also be exposed during articles servie life (driving of automotive vehicles and maintenance of automotive breaks).

Table: Uses

Part 1:

☐ Manufacture	☒ Formulation	☒ Industrial use	☒ Professional use	☒ Consumer use	☒ Article service life	☐ Closed system

5. JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

5.1. Legal basis for the proposal

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

☐ Article 45(5) (Member State priority)

5.2. 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

5.3. 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[3]	
☐ 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)

There was evidence from the registration dossier that potassium titanium dioxide could produce respirable fibres. Fibres are known to induce lung cancers but also malignant mesotheliomas after translocation to the pleura in humans. For example, these results have conducted to an harmonized classification as Carc. 1A for asbestos (index number 650-013-00-6). Potassium titanium dioxide have a current harmonized classification as Carc. 2. Considering the possible production of respirable fibres and depending on their characteristics, it should be clarified if a more severe classification is required for potassium titanium dioxide.

The evaluation of the substance should allow to determine if additional studies is needed to evaluate the biopersistency and carcinogenicity of the substance. These data are essential to conclude if an update of the classification from Carc. 2 to Carc. 1B or 1A would be needed. This would have a significant impact on the current risk management

of potassium titanium dioxide. Indeed, substances classified as Carc. 1A or 1B are subject to very stringent control of uses. Therefore, depending on the results of the evaluation of the hazards, it must be reviewed if safe use is guaranteed for these specific morphologies that can have similar carcinogenic properties as asbestos. All these reflexions may be extended to other titanium dioxide with similar morphologies. At this time, titanium dioxide does not have a harmonized classification for carcinogenicity. However, a classification proposal as Carc. 1B was proposed by France and would be discussed at the RAC level in 2017. Depending on the results of the evaluation, an update of the classification of these specific forms may be required.

5.4. Preliminary indication of information that may need to be requested to clarify the concern

☒ 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 ED potential	☐ Other (provide further details below)
Adequate characterization (diameter, shape, length, width, ratio length/width etc) and information to evaluate the biopersistency and carcinogenicity of the substance might be needed. As there is potential for worker exposure and as consumers may also be exposed to fibres during articles service life, exposure of workers and consumers may also be evaluated.	

5.5. Potential follow-up and link to risk management

☒ Harmonised C&L	☒ Restriction	☐ Authorisation	☐ Other (provide further details)
Fibres like asbestos are known human carcinogens. Depending on the outcome of the substance evaluation, an update of the current classification as carcinogen (from Carc. 2 to 1B or 1A) can be envisaged for potassium titanium dioxide (which may be extended to other titanium dioxide with fibre-like morphologies) or some of its forms. In the meantime, this classification could be extended to other substances (different CAS numbers) with similar properties/forms. Moreover, restriction of uses could be envisaged if a risk is demontrated.			

[3] 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