Justification Document for the Selection of a CoRAP Substance

– Update –

Substance Name (public name):	Titanium dioxide
EC Number:	236-675-5
CAS Number:	13463-67-7
Authority:	FRANCE
Date:	20/03/2013 22/03/2016 1. Update 20/03/2018 2. Update

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):	titanium dioxide
IUPAC name (public):	• diooxotitanium • dioxo titanium • Dioxotitanium • Oxid titaničitý • TiO2-R • Titandioxid (in the form of Rutile Sand) 13463-67-7 • titania in 1-methoxy-2-propanol • Titanium Dioxide • titanium dioxide white • Titanium Dioxide, Anatase, Rutile • Titanium oxide • Titanium(IV) Oxide • Titanium(IV)oxide • Titannium dioxide • Titaum dioxide
Index number in Annex VI of the CLP Regulation:	-
Molecular formula:	O2Ti
Molecular weight or molecular weight range:	79.8658
Synonyms:	• AEROPERL • AEROXIDE TiO2 • ANATASA • ANATASA 98% MIN • ANATASA 98.5% MIN • ANATASA A-X • ANATASA BAJA EN NEOBIO • ANATASA E • ANATASA ENAMEL GRADE • ANATASA FIBRA • ANATASA GRADO ESMALTES • ANATASA GRADO FRITA • ANATASA I • ANATASA PAPEL • ANATASA R • Anatase • Anatase Titanium Dioxide • biel tytanowa • Cosmetica® Super White 9000SReflexTM Rutile Fine R-901DAutomotiveTM Dazzling White A-901S • Crimea TiOx • Crimea TiOx-220 • Crimea TiOx-230

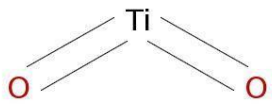
	• Crimea TiOx-270 • Crimea TiOx-271 • Crimea TiOx-280 • Cristal • CSB • CSP • DHA-100 • DHA-130 • DIOXIDO DE TITANIO • DIOXIDO DE TITANIO ANATASA • DIOXIDO DE TITANIO DJ240 • DIOXIDO DE TITANIO DJ2400 • DIOXIDO DE TITANIO ORIGEN CHINA • DIOXIDO DE TITANIO ORIGEN REPUBLICA CHECA • DIOXIDO DE TITANIO ORIGEN RUSIA • DIOXIDO DE TITANIO ORIGEN UKRANIA • DIOXIDO DE TITANIO R-203 • DIOXIDO DE TITANIO R-221 • DIOXIDO DE TITANIO R-222 • DIOXIDO DE TITANIO R-223 • DIOXIDO DE TITANIO R-606 • DIOXIDO DE TITANIO R216 • DIOXIDO DE TITANIO R248 • DIOXIDO DE TITANIO R258 • DIOXIDO DE TITANIO R298 • DIOXIDO DE TITANIO R500 • DIOXIDO DE TITANIO R501 • DIOXIDO DE TITANIO R601 • DIOXIDO DE TITANIO R621 • DIOXIDO DE TITANIO RUTILO • DIOXIDO DE TITANIO RUTILO R996 • Dwutlenek tytanu • FerroTint White F31 • HOMBIKAT • HOMBITAN • HOMBITEC • KA-100 • KR-1000 • KR-2000 • KRONOS Titanium dioxide • KRONOS TITANIUM DIOXIDE KA-10 • KRONOS TITANIUM DIOXIDE KR-310 • Kronox • MT(Micro Titanium Dioxide) • No specific trade name • RFC • Rutile • Rutile Titanium Dioxide • SACHTLEBEN • SSP • STR • SUMTITAN • SUMTITAN R-202 • SUMTITAN R-203 • SUMTITAN R-204 • SUMTITAN R-206

	• T-Lite • Tego • Ti-Pure® • Ti-Pure™ • TIO2 • Tiona • Tiona(r) • Tipure • Titandioxid KA 100 (Anatase) • Titandioxid R-Z (Rutile) • TITANIO BIOSSIDO ANATASIO • TITANIO BIOSSIDO ANATASIO BASSO NEOBIO • TITANIO BIOSSIDO ANATASIO SCR • TITANIO BIOSSIDO RUTILO • TITANIO BIOSSIDO RUTILO 501 • TITANIO BIOSSIDO RUTILO 502 • TITANIO BIOSSIDO RUTILO 602 • TITANIO BIOSSIDO RUTILO 688 • TITANIO BIOSSIDO RUTILO 699 • TITANIO BIOSSIDO RUTILO LOMON R-996 • TITANIO BIOSSIDO RUTILO R-202 • TITANIO BIOSSIDO RUTILO R-203 • TITANIO BIOSSIDO RUTILO R-206 • TITANIO BIOSSIDO RUTILO R-248 • TITANIO BIOSSIDO RUTILO R-258 • TITANIO BIOSSIDO RUTILO R-298 • TITANIO BIOSSIDO RUTILO R02 • Titanium bioxide enamel grade GZ • Titanium bioxide enamel grade LNB • Titanium Dioxide • TITANIUM DIOXIDE 3328 USP • Titanium dioxide anatase • Titanium Dioxide Cotiox KA 100 • TITANIUM DIOXIDE ST-705SA • TITANIUM DIOXIDE ST-705WD • TITANIUM DIOXIDE ST-710EC • TITANIUM DIOXIDE ST-710WD • TITANIUM DIOXIDE ST-750EC • titanium white • TITANIX • TITONE • Tronox • TYTANPOL • ULTRA FINE TITANIUM DIOXIDE ST-101T • ULTRA FINE TITANIUM DIOXIDE ST-4 • ULTRA FINE TITANIUM DIOXIDE ST-410WB • ULTRA FINE TITANIUM DIOXIDE ST-450 • ULTRA FINE TITANIUM DIOXIDE ST-450EC • ULTRA FINE TITANIUM DIOXIDE ST-450SA • ULTRA FINE TITANIUM DIOXIDE ST-450WD • ULTRA FINE TITANIUM DIOXIDE ST-455 • ULTRA FINE TITANIUM DIOXIDE ST-455WB • ULTRA FINE TITANIUM DIOXIDE ST-455WS • ULTRA FINE TITANIUM DIOXIDE ST-457SA • ULTRA FINE TITANIUM DIOXIDE ST-457WD • ULTRA FINE TITANIUM DIOXIDE ST-

	485SA15 • ULTRA FINE TITANIUM DIOXIDE ST-486EFS • ULTRA FINE TITANIUM DIOXIDE ST-495MC • ULTRA FINE TITANIUM DIOXIDE ST-500 • ULTRA FINE TITANIUM DIOXIDE ST-550 • ULTRA FINE TITANIUM DIOXIDE ST-550R • ULTRA FINE TITANIUM DIOXIDE ST-570 • ULTRA FINE TITANIUM DIOXIDE ST-6 • ULTRA FINE TITANIUM DIOXIDE STT-100H • ULTRA FINE TITANIUM DIOXIDE STT-300 • ULTRA FINE TITANIUM DIOXIDE STT-30A-I • ULTRA FINE TITANIUM DIOXIDE STT-30A-I-FS10 • ULTRA FINE TITANIUM DIOXIDE STT-30A-I-FS5 • ULTRA FINE TITANIUM DIOXIDE STT-30S • ULTRA FINE TITANIUM DIOXIDE STV-455 • UV TITAN

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

Structural formula:



1.2 Similar substances/grouping possibilities

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 In 2014, ECHA performed a compliance check of the registration for titanium dioxide and concluded on the need of further information regarding substance identity information including name of the substance, composition and description of the analytical method. In 2017, the board appeal annulled this decision (case number: A-011-2014).
		☐ 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) In September 2017, the RAC concluded that titanium dioxide should be classified as Carc. 2 – H351 (inhalation).	
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)	
Montreal convention (PO	☐ Assessment	

[1] Please specify the relevant entry.

	☐ In relevant Annex
Other processes / EU legislation	☐ Other (provide further details below)
Further details	Titanium dioxide is included in many European project related to nanotechnology.

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

None

3.1.2 Self classification

- In the registration:

The registration data did not include any classification.

- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:
  - Acute Tox. 4 – H332
  - Acute Tox. 4 – H302
  - Acute Tox. 4 – H312
  - Skin Irrit. 2 – H315
  - Eye Irrit. 2 – H319
  - Resp. Sens. 1B – H334
  - STOT SE 2 – H371
  - STOT SE 3 – H335
  - STOT RE 1 – H372
  - Muta. 2 – H341
  - Carc. 1B – H350
  - Carc. 2 – H351
  - Aquatic Chronic 4 – H413

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

In 2015, a proposal for EU harmonized classification was submitted by France for titanium dioxide as Carc. Cat 1B – H350i. This proposal covered "particles of titanium dioxide in all phases, phase combinations and morphologies". In September 2017, the RAC concluded that titanium dioxide should be classified as Carc. 2 – H351 (inhalation).

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

4.2 Overview of uses

The following information is issued from the CLH report submitted by France in 2015.

Titanium dioxide is a pigment and an opacifying agent. Its other important properties are resistance to chemical attack, thermal stability, resistance to UV degradation (UV blocker) and photocatalysis potential.

Titanium dioxide is very widely used in industrial/professional settings and is included in numerous products and articles used by industrials, professionals and consumers. All existing process categories (PROC), environmental release categories (ERC), product categories (PC) and articles categories (AC) are claimed in the Reach registration dossier. Products/articles in which titanium dioxide is incorporated are numerous and include paints, varnishes, inks, coatings, plastics, rubbers, papers, plasters, adhesives, coated fabrics and textiles, glassware, ceramics, electroceramics, electronic components, catalysts,

[2] T*he dissemination site was accessed January 2018.*

welding fluxes, welding rods, floor coverings, roofing granules, food additives (E 171), pharmaceuticals, cosmetics, dental impressions, etc. Due to its photocatalytic properties, when the size of the particle is reduced to the nanoscale in one or more dimensions, nano titanium dioxide is also used for water and surfaces treatment.

The uses of TiO_2 depend on its properties that are determined by the crystallinity, the size, the shape and surface chemistry of the TiO_2 particle.

No uses are reported as advised against in the Reach registration dossier.

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)

[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

Although it was initially foreseen by France to propose an EU harmonized classification for mutagenicity in addition to carcinogenicity, this endpoint was judged as inconclusive. The FR-MSCA was not able to identify specific physicochemical parameter justifying the discrepancies along the mutagenic results and whether the differences reported in the results could be due to different study protocols having been employed. Therefore, further data can be needed to clarify this point.

Several grades of titanium dioxide exist for titanium dioxide (characterized by size, shape, surface treatment etc). Moreover, titanium dioxide is used in several products that can be used by consumers (including sensitive population).

TiO2 is widely used and lead to significant exposure. However, how to deal with this issue depending on the grades, forms… is still under debate. The strategy on how to tackle this difficult issue with a registration dossier as the one currently available is still unclear and will required ENORMOUS work from France.

In this context, we will reflect on how to guaranty appropriate safe conditions for all populations that can be exposed to titanium dioxide in the light of the possible impact of these intrinsic variations of parameters on (eco)toxicology properties.

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)
Previous work conducted by France in the scope of CLP regulation allowed to identify inconsistent genotoxic profile obtained from *in vitro* studies. In the absence of reliable *in vivo* assays, there is an essential need of further *in vitro* and *in vivo* investigations of the genotoxicity potential of TiO_2-NPs. Further details are available in the CLH report (see https://echa.europa.eu/documents/10162/594bf0e6-8789-4499-b9ba-59752f4eafab) and will be soon published in a scientific journal. What is missing and will be required after SEv needs to be determined while having deeply evaluated the dossier and additional litterature. Another concerns might arise while working on the dossier.	

5.5. Potential follow-up and link to risk management

☒ Harmonised C&L	☐ Restriction	☐ Authorisation	☐ Other (provide further details)
Depending on results of the required data, update of the current harmonized classification could be needed for germ cell mutagenicity.			