

Justification for the selection of a candidate CoRAP substance

– Update –

Substance Name (Public Name):	Titanium dioxide
Chemical Group:	
EC Number:	236-675-5
CAS Number:	13463-67-7
Submitted by:	FRANCE
Published:	20/03/2013 Update 22/03/2016

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 Name and other identifiers of the substance

Table 1: Substance identity

Public Name:	titanium dioxide
EC number:	236-675-5
EC name:	titanium dioxide
CAS number (in the EC inventory):	13463-67-7
CAS number:	13463-67-7
CAS name:	-
IUPAC name:	dioxotitanium
Index number in Annex VI of the CLP Regulation	-
Molecular formula:	O ₂ Ti
Molecular weight or molecular weight range:	79.8658
Synonyms:	

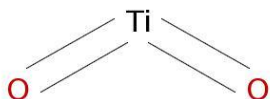
Type of substance:

Mono-constituent

Multi-constituent

UVCB

Structural formula:



2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

None

2.2 Proposal for Harmonised Classification in Annex VI of the CLP

2.3 Self classification

The registration data did not include any classification.

In addition are the following classification(s) included in the Classification and Labelling Inventory:

Acute Tox. 4	H332: Harmful if inhaled.
Carc. 2	H351: suspected of causing cancer.
Eye Irrit. 2	H319: Causes serious eye irritation.
STOT SE 3	H335: may cause respiratory irritation.
STOT RE 1	H372; causes damage to organs.
Skin Irrit. 2	H315; causes skin irritation.
STOT SE 2	H371; may cause damage to organs.
Carc. 1B	H350; may cause cancer.
Aquatic Chronic 4	H413; may cause long lasting effects to aquatic life.

3 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

3.1 Legal basis for the proposal

- Article 44(1) (refined prioritisation criteria for substance evaluation)
- Article 45(5) (Member State priority)

3.2 Grounds for concern

<input checked="" type="checkbox"/> (Suspected) CMR	<input checked="" type="checkbox"/> Wide dispersive use	<input type="checkbox"/> Cumulative exposure
<input checked="" type="checkbox"/> (Suspected) Sensitiser	<input checked="" type="checkbox"/> Consumer use	<input type="checkbox"/> High RCR
<input type="checkbox"/> (Suspected) PBT/vPvB	<input checked="" type="checkbox"/> Exposure of sensitive populations	<input checked="" type="checkbox"/> Aggregated tonnage
<input type="checkbox"/> Suspected endocrine disruptor	<input checked="" type="checkbox"/> Other (provide further details below)	

Titanium dioxide is classified Carc. Cat. 2B by IARC. See also the work published by Afsset (Evaluation des risques liés aux nanomatériaux pour la population générale et pour l'environnement, Mars 2010, France. See website of Anses: www.anses.fr).

Given the state of knowledge in the field of nanomaterials and in particular to the titanium dioxide nanomaterials, it is recommended to include titanium dioxide in the CoRAP for 2014 in order to get a better understanding of the properties of the titanium dioxide nanomaterials.

3.3 Information on aggregated tonnage and uses

<input type="checkbox"/> 1 - 10 t	<input type="checkbox"/> 10 - 100 t	<input type="checkbox"/> 100 - 1000 t	<input type="checkbox"/> 1000 - 10,000 t	
<input type="checkbox"/> 10,000 - 100,000 t	<input type="checkbox"/> 100,000 - 1000,000 t	<input type="checkbox"/> > 1000,000 t	<input checked="" type="checkbox"/> 1,000,000 - 10,000,000 t	<input type="checkbox"/> Confidential
1,000,000 - 10,000,000 tonnes per annum				
<input type="checkbox"/> Industrial Use	<input type="checkbox"/> Professional Use	<input type="checkbox"/> Consumer Use	<input type="checkbox"/> Closed System	

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

<input type="checkbox"/> Compliance Check	<input type="checkbox"/> Annex VI (CLP)
<input type="checkbox"/> Testing Proposal(s)	<input type="checkbox"/> Annex XIV (Authorisation)
<input type="checkbox"/> Substance Identification Issues	<input type="checkbox"/> Annex XVII (Restriction)
<input type="checkbox"/> ESR Programme	<input checked="" type="checkbox"/> Other (provide further details below)
<p>Working Party on Manufactured Nanomaterials of the OECD where France is co-sponsored with Germany on the assessment of health and environmental risks of titanium dioxide (Subgroup of WPMN 3).</p> <p>Joint Action NANOGENOTOX, which began in March 2010 and is coordinated by FR. This action is dedicated on four titanium dioxide nanomaterials referenced by the OECD. The complete results of this work will therefore should be available in March 2013.</p>	

3.5 Information to be requested to clarify the suspected risk

<input checked="" type="checkbox"/> Information on toxicological properties	<input checked="" type="checkbox"/> Information on exposure
<input checked="" type="checkbox"/> Information on fate and behaviour	<input checked="" type="checkbox"/> Information on uses
<input type="checkbox"/> Information on ecotoxicological properties	<input type="checkbox"/> Other (provide further details below)
<input type="checkbox"/> Information on physico-chemical properties	
Exact information required to be determined during the substance evaluation	

3.6 Potential follow-up and link to risk management

<input type="checkbox"/> Restriction	<input type="checkbox"/> Harmonised C&L
<input type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details below)
Depends on the outcome of substance evaluation	