

## Justification for the selection of a substance for CoRAP inclusion

### – UPDATE –

<b>Substance Name (Public Name):</b>	Silver
<b>Chemical Group:</b>	
<b>EC Number:</b>	231-131-3
<b>CAS Number:</b>	7440-22-4
<b>Submitted by:</b>	NL-CA
<b>Published:</b>	20/03/2013 Update 26/03/2014

#### **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 1: Substance identity

EC name:	Silver
IUPAC name:	Silver
Index number in Annex VI of the CLP Regulation	Not applicable
Molecular formula:	Ag
Molecular weight or molecular weight range:	107.87
Synonyms/Trade names:	

Type of substance     Mono-constituent     Multi-constituent     UVCB

### 1.2 Similar substances/grouping possibilities

Not applicable

Structural formula:

[Ag]

## 2 CLASSIFICATION AND LABELLING

### 2.1 Harmonised Classification in Annex VI of the CLP

None

### 2.2 Self-classification

- In the registration

The lead Registrant includes the following classifications:

Silver  $\geq 99,9$  % Ag in powder form ( $< 1$  mm) - classified for environment

- Aquatic Acute 1 H400: Very toxic to aquatic life. (M-factor = 1)
- Aquatic Chronic 1 H410: Very toxic to aquatic life with long lasting effects. (M-factor = 10).

Silver  $< 99,9$ % Ag in powder form ( $< 1$  mm) with no classified impurities - classified for environment

- Aquatic Acute 1 H400: Very toxic to aquatic life. (M-factor = 1)
- Aquatic Chronic 1 H410: Very toxic to aquatic life with long lasting effects. (M-factor = 10).

- The following hazard classes are in addition notified among the aggregated self-classifications in the C&L Inventory:
  - Aquatic Acute 1 H400 / Aquatic Chronic 1 H410 (M-factor = 1000).
  - Aquatic Acute 1 H400 / Aquatic Chronic 1 H410 ( $C \geq 0,025\%$ ).
  - Skin Sens. 1; H317: May cause an allergic skin reaction.
  - Skin Irrit. 2; H315: Causes skin irritation.
  - Eye Irrit. 2; H319: Causes serious eye irritation.
  - STOT SE 1; H370: Causes damage to respiratory system (inhalation).
  - STOT SE 3; H335: May cause respiratory irritation.
  - STOT RE 1; H372: Causes damage to eye, respiratory system (inhalation).
  - Acute Tox. 4; H332: Harmful if inhaled.

### 2.3 Proposal for Harmonised Classification in Annex VI of the CLP

Not applicable

### 3 INFORMATION ON AGGREGATED TONNAGE AND USES

From ECHA dissemination site			
<input type="checkbox"/> 1 – 10 tpa	<input type="checkbox"/> 10 – 100 tpa	<input type="checkbox"/> 100 – 1000 tpa	
<input type="checkbox"/> 1000 – 10,000 tpa	<input type="checkbox"/> 10,000 – 100,000 tpa	<input checked="" type="checkbox"/> 100,000 – 1,000,000 tpa	
<input type="checkbox"/> 1,000,000 – 10,000,000 tpa	<input type="checkbox"/> 10,000,000 – 100,000,000 tpa	<input type="checkbox"/> > 100,000,000 tpa	
<input type="checkbox"/> <1 . . . . . >+ tpa (e.g. 10+; 100+; 10,000+ tpa)		<input type="checkbox"/> Confidential	
<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input checked="" type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System

### 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

<b>Hazard based concerns</b>		
CMR <sup>1</sup> <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	Suspected CMR <sup>2</sup> <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	<input type="checkbox"/> Potential endocrine disruptor
<input type="checkbox"/> Sensitizer <sup>1</sup>	<input type="checkbox"/> Suspected Sensitizer <sup>2</sup>	
<input type="checkbox"/> PBT/vPvB	<input type="checkbox"/> Suspected PBT/vPvB <sup>3</sup>	<input checked="" type="checkbox"/> Other (please specify below)
<b>Exposure/risk based concerns</b>		
<input checked="" type="checkbox"/> Wide dispersive use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Exposure of sensitive populations
<input type="checkbox"/> Exposure of environment	<input type="checkbox"/> Exposure of workers	<input type="checkbox"/> Cumulative exposure
<input type="checkbox"/> High RCR	<input checked="" type="checkbox"/> High (aggregated) tonnage	<input checked="" type="checkbox"/> Other (please specify below)
<p>Silver is a widely used material for which more than 50 registrations are received. All registrations for silver are submitted under CAS-nr 7440-22-4. Transformation of the metallic nanoform in ionic form and vice versa may influence the behaviour of silver (including bioavailability and related ecotoxicity). In addition, the size-related environmental behaviour and ecotoxicological effects in the aquatic compartment, including the STP, and the terrestrial compartment pose a concern for the safe use of the nanoform(s) of silver to the environment. Therefore, it is necessary to evaluate the substance characterization, environmental behaviour and ecotoxicity of the nanoforms of silver.</p>		

### 4.4 Other completed/on-going regulatory processes that may affect suitability for substance evaluation

<input type="checkbox"/> Compliance check, Final decision	<input type="checkbox"/> Dangerous substances Directive 67/548/EEC
<input checked="" type="checkbox"/> Testing proposal	<input type="checkbox"/> Existing Substances Regulation 793/93/EEC
<input type="checkbox"/> Annex VI (CLP)	<input type="checkbox"/> Plant Protection Products Regulation 91/414/EEC
<input type="checkbox"/> Annex XV (SVHC)	<input type="checkbox"/> Biocidal Products Directive 98/8/EEC; Biocidal Product Regulation (Regulation (EU) 528/2012)
<input type="checkbox"/> Annex XIV (Authorisation)	<input type="checkbox"/> Other (provide further details below)
<input type="checkbox"/> Annex XVII (Restriction)	
<p>There is a testing proposal for the following end-points;</p> <ul style="list-style-type: none"> <li>- Tox. soil macro-org.</li> <li>- Tox. terrestrial plants.</li> <li>- Tox. soil microorg.</li> </ul>	

<sup>1</sup> CMR/Sensitizer: known carcinogenic and/or mutagenic and/or reprotoxic properties/known sensitizing properties (according to CLP harmonized or registrant self-classification or CLP Inventory)

<sup>2</sup> Suspected CMR/Suspected sensitizer: suspected carcinogenic and/or mutagenic and/or reprotoxic properties/suspected sensitizing properties (not classified according to CLP harmonized or registrant self-classification)

<sup>3</sup> Suspected PBT: Potentially Persistent, Bioaccumulative and Toxic

#### 4.5 Preliminary indication of information that may need to be requested to clarify the concern

<input type="checkbox"/> Information on toxicological properties	<input checked="" type="checkbox"/> Information on physicochemical properties
<input type="checkbox"/> Information on fate and behaviour	<input type="checkbox"/> Information on exposure
<input type="checkbox"/> Information on ecotoxicological properties	<input type="checkbox"/> Information on uses
<input type="checkbox"/> Information ED potential	<input checked="" type="checkbox"/> Other (provide further details below)

A clear indication of the type/form of silver (size, size distribution, agglomeration state, coating, etc.) that is tested in each toxicity test to enable a proper evaluation of the safe use of each nanoform.

#### 4.6 Potential follow-up and link to risk management

<input type="checkbox"/> Harmonised C&L	<input checked="" type="checkbox"/> Restriction	<input type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
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If safe use for the nanoform(s) of silver cannot be demonstrated, it may be anticipated that a restriction is needed as risk management measure.