Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name):	Ammonium thiocyanate
Chemical Group:	Thiocyanates
EC Number:	217-175-6
CAS Number:	1762-95-4
Submitted by:	Czech Republic
Published:	20/03/2013

NOTE

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

Contents

1 IDENTITY OF THE SUBSTANCE

1.1 Name and other identifiers of the substance

Table 1: Substance identity

Public Name:	Ammonium thiocyanate
EC number:	217-175-6
EC name:	Ammonium thiocyanate
CAS number (in the EC inventory):	1762-95-4
CAS number:	1762-95-4
CAS name:	
IUPAC name:	Ammonium thiocyanate
Index number in Annex VI of the CLP Regulation	615-004-00-3
Molecular formula:	CHNS.H3N
Molecular weight or molecular weight range:	76.1209
Synonyms:	Trade name: Ammoniumrhodanid

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

Structural formula:

2 CLASSIFICATION AND LABELLING

*Comment: It seems to be a confusing which harmonized C&L entry to use for this substance. The names of the group entries for thiocyanic acid salts were changed in the 1st ATP to CLP to better specify the groups and EUH032 was removed from 615-030-00-5 (*alkali salts and alkali earth salts of thiocyanic acid, with the exception of those specified elsewhere in this Annex*), but not from entry 615-004-00-3 (*salts of thiocyanic acid, with the exception of those specified elsewhere in this Annex*). Ammonium salts is neither alkali nor alkali earth salts, so entry 615-004-00-3 should be used for this substance.*

2.1 Harmonised Classification in Annex VI of the CLP

Group entry in Annex VI CLP, Table 3.1

615-004-00-3: salts of thiocyanic acid, with the exception of those specified elsewhere in this Annex

Acute Tox. 4; H332: Harmful if inhaled.

Acute Tox. 4; H312: Harmful in contact with skin.

Acute Tox. 4; H302: Harmful if swallowed.

Aquatic Chronic 3; H412: Harmful to aquatic life with long lasting effects.

Suppl. Hazard Statement: EUH032: Contact with acids liberates very toxic gas.

DSD, Annex VI CLP, Table 3.2; 615-004-00-3:

Xn; R20/21/22: Harmful by inhalation, in contact with skin and if swallowed.

R32: Contact with acids liberates very toxic gas.

R52/53: Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

2.2 Proposal for Harmonised Classification in Annex VI of the CLP

None

2.3 Self classification

In the registration data:

It is referred to the C&L entry 615-030-00-5, but with the old name of the entry (alkali salts, alkali earth salts and other salts of thiocyanic acid not mentioned elsewhere in this Annex). "other salts" was removed from the name in the 1st ATP to CLP. The following changes to this entry are given in the registration data:

According to CLP Criteria:

Adding, based on test results: Eye damage 1; H318: Causes serious eye damage.
Also the signal word is changed to "Warning" and pictogram GHS05 (corrosion) is added on the label.

Remove Aquatic chronic 3; H412 (propose to change to no C&L for env.)

Propose to return the additional labeling requirement EUH032. (But this is included for the entry 615-004-00-3.)

According to DSD Criteria:

As for CLP criteria, they self classify regarding hazard to eyes and remove classification as hazardous to the aquatic environment and self classify as follows:

Xn; R20/21/22: Harmful by inhalation, in contact with skin and if swallowed.

Xi; R41: Risk of serious damage to eyes.

R32: Contact with acids liberates very toxic gas .

C&L inventory for EC-no. 217-175-6:

In addition to the four hazard classes given in 2.1, the following are notified to the inventory:

Eye Dam. 1; H318: Causes serious eye damage.

Aquatic Acute 1; H400: Very toxic to aquatic life.

Aquatic Chronic 1; H410: Very toxic to aquatic life with long lasting effects.

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

☒ (Suspected) CMR	☒ Wide dispersive use	☐ Cumulative exposure
☐ (Suspected) Sensitiser	☐ Consumer use	☒ High RCR
☐ (Suspected) PBT	☐ Exposure of sensitive populations	☒ Aggregated tonnage
☒ Suspected endocrine disruptor	☐ Other (provide further details below)	

The substance is of concern because of high occupational exposure in industrial and professional settings and suspected reproductive toxicity and (neuro) developmental toxicity.

From registration data it follows:

Category "thiocyanates": ammonium thiocyanate, sodium thiocyanate and potassium thiocyanate. The provided justification is incomplete (Appendix missing)

Read-across to neg. LLNA study with sodium thiocyanate

Waiver 2-generation study

Several non-standard developmental studies available. Unclarity regarding potential effect on brain microtubuli formation and thyroid function in conjunction with maternal effects. MoA? (endocrine?)

NOAEL 20mg/kg bw/d from a 90d oral repeat dose study in rats, based on effects on clinical chemistry, hematology and histopathology of liver, bone marrow and thymus, and squamous hyperplasia of the forestomach at 100 and 500 mg/kg (In this study the thyroid has not been examined functionally (no detection of parameters TSH, T4 and/or T3 levels in blood). Testes: Seminiferous epithelium degeneration is reported at 500mg/kg bw/d

Several exposure scenarios with RCRs in the range 0,5<RCR<1.

3.3 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 tpa	
☐ Confidential		

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

Widespread dispersive use i.a. as processing aid, in building and construction (concrete)

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

☐ Compliance check	☐ 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)	
Please provide further details	

3.5 Information to 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
☐ Other (provide further details below)	
Clarification of reproductive toxicity concern (incl. MoA aspects (endocrine?) and CLH) and uses/exposure	

3.6 Potential follow-up and link to risk management

☐ Restriction	☒ Harmonised C&L	☐ Authorisation	☐ Other (provide further details)
CLH modification concerning reproductive toxicity			