Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name):	Aluminium chloride
Chemical Group:	inorganic mono constituent substance
EC Number:	231-208-1
CAS Number:	7446-70-0
Submitted by:	France
Published:	26/03/2014

Note

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

Contents

1 IDENTITY OF THE SUBSTANCE

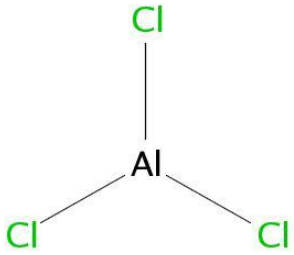
1.1 Other identifiers of the substance

Table 1: Substance identity

EC name:	Aluminium chloride
IUPAC name:	Aluminium trichloride
Index number in Annex VI of the CLP Regulation	013-003-00-7
Molecular formula:	$AlCl_3$
Molecular weight or molecular weight range:	133.3405
Synonyms/Trade names:	Aluminium chloride, anhydrous Aluminiumchlorid Aluminium (III) chloride TK Flock Trichloroaluminium

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

Structural formula:



1.2 Similar substances/grouping possibilities

Aluminium chloride is a soluble aluminium compound and may be grouped with other registered soluble aluminium compounds. A preliminary analysis would be needed to define the scope of such a category.

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

Index No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
	Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
013-003-00-7	Skin Corr. 1B	H314	GHS05, Dgr	H314	-	-	-

2.2 Self classification

- In the registration

Acute Tox 5 – H303[1]
Skin Corr. 1B – H314
STOT RE 1 – H372 (lungs) (inhalation)
STOT RE 2 – H373 (CNS) (oral)

- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:
  - Addition of STOT SE 3 – H335 (respiratory irritation)
  - Addition of Acute Tox 4-H312 and Acute Tox 4 – H 332
  - Skin Irrit 2 and Eye Irrit 2 instead of Skin Corr 1B

2.3 Proposal for Harmonised Classification in Annex VI of the CLP

No current proposal or intention.

3 INFORMATION ON AGGREGATED TONNAGE AND USES

From ECHA 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
-		

[1] Note from the MSCA: Acute Tox 5 is not applicable in the EU

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

The use of aluminium chloride is intended for workers only and consumers are not expected to be exposed according to the registration dossier. Exposure is restricted to closed system with occasional exposure or batch process. The following uses are described:

- Manufacturing and distribution (closed systems with occasional exposure)
- Reactive process agent in inorganic and organic synthesis (Ambient or elevated temperatures)
- Use as intermediate for the production of Aluminium containing substances (use of AlCl3 as vapour) (closed process)
- Use as intermediate for the production of Aluminium containing substances (use of AlCl3 in solutions or slurries) (closed process)
- After hydrolysis: Use as process chemical in process water treatment, sewage water treatment (batch process)
- Use in laboratory (reagent)

Aggregated tonnage however reaches a high amount (10,000-100,000 tpa).

Besides, it is noted that the use in the process for water treatment will lead to a consumer exposure through drinking water that needs to be considered in the cumulative risk assessment.

4 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

4.1 Legal basis for the proposal

☒ Article 44(1) (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

Hazard based concerns		
CMR ☐C ☐M ☐R	Suspected CMR[1] ☐C ☒M ☒R	☐ Potential endocrine disruptor
☐ Sensitiser	☐ Suspected Sensitiser[2]	
☐ 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)

Identification of initial concerns is based on the review of human health aspects only and environmental aspects have not been considered.

For mutagenicity, a positive in vitro test is reported. In absence of any in vivo test it raises a concern on mutagenicity. As no carcinogenicity study or any adequate guideline repeated dose study is available, a potential concern on the carcinogenicity of the substance cannot be excluded.

Developmental findings are reported in the registration dossier (effects on viability and neuromotor maturation) and the registrant concludes that the substance is a candidate for classification in terms of developmental toxicity but that further studies with other Al-compounds are underway and need to be awaited before any decision.
A concern is therefore clearly identified on this endpoint. It is also noted that a report of the Health Council from Netherlands from 2009[3] recommend to classify soluble aluminium compounds (including aluminium chloride) as Repro 2 for developmental toxicity under Directive 67/548/EEC (equivalent to Repr 1B under CLP), confirming a concern on this endpoint.

Besides, results from the repeated dose toxicity studies indicates that the substance disturb acetylcholinesterase activity and inhibition of hexokinase in the brain and its neurotoxic potential constitutes an alert that need to be further investigated and justify that the substance is a candidate for SEv.

No specific warning in relation to endocrine disruption is identified on the basis of the available registration dossier.

RCR of < 0.5 are obtained. It is however noted that several points in the construction of the DNEL need to be checked: no use of oral data by route to route extrapolation, discussion of the LOAEL chosen as a starting point, no use of an interspecies assessment factor. Due to these large uncertainties, RCR of around 0.5 are considered to raise a concern for the identification of potential risk after consideration of these issues.

[2] 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

[3] *Health Council of the Netherlands. Aluminium and aluminium compounds - Evaluation of the effects on reproduction, recommendation for classification. The Hague: Health Council of the Netherlands, 2009; publication no. 2009/02OSH.* ISBN 978-90-5549-756-0.
http://www.gezondheidsraad.nl/en/publications/healthy-working-conditions/aluminium-and-aluminium-compounds-evaluation-effects-reprodu

However considering that aluminium sulphate is in the CoRAP for 2015 and that both the sulphate and the chloride are soluble aluminium compounds, it is relevant that both salts are assessed in parallel.

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

☐ Compliance check, Final decision	☐ 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)	
Aluminium chloride is not evaluated under another regulatory program that may affect suitability for SEv. However, the registrant mentions in the developmental toxicity section that tests are on-going on other Al-compounds. According to the ECHA website, testing proposal for reproductive toxicity studies are on-going for aluminium tris(dialkylphosphinate). The relevance on these results for aluminium chloride needs to be confirmed. Besides, the progress status of the on-going tests is not known and it is not possible to understand its potential impact on the suitability of evaluating aluminium chloride in 2015 together with aluminium sulphate.	

4.5 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 on ED potential	☐ Other (provide further details below)
Main concerns are identified on the toxicological properties but it is not excluded that SEv may raise a need of information on additional issues.	

4.6 Potential follow-up and link to risk management

☒ Harmonised C&L	☐ Restriction	☐ Authorisation	☐ Other (provide further details)
A proposal for classification for developmental toxicity is a potential follow-up of the SEv process. Depending on the outcome of SEv, additional information may be requested or the need for a RMM may be concluded.			