SUBSTANCE EVALUATION CONCLUSION

as required by REACH Article 48

and

EVALUATION REPORT

for

2,4,6-trichloro-1,3,5-triazine

EC No 203-614-9

CAS No 108-77-0

Evaluating Member State(s): Poland

Dated: 17 October 2018

Evaluating Member State Competent Authority

MSCA name: Bureau for Chemical Substances
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Year of evaluation in CoRAP: 2017

Member State concluded the evaluation without any further need to ask more information from the registrants under Article 46(1) decision.

Further information on registered substances here:

http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

DISCLAIMER

Foreword

Substance evaluation is an evaluation process under REACH Regulation (EC) No. 1907/2006. Under this process the Member States perform the evaluation and ECHA secretariat coordinates the work. The Community rolling action plan (CoRAP) of substances subject to evaluation, is updated and published annually on the ECHA web site[1].

Substance evaluation is a risk driven process, which aims to clarify whether a substance constitutes an unacceptable risk to human health or the environment. Member States evaluate assigned substances in the CoRAP with the objective to clarify the potential concern and, if necessary, to request further information from the registrant(s) regarding the substance. If the evaluating Member State concludes that no further information needs to be requested, the substance evaluation is completed. If additional information is required, this is sought by the evaluating Member State. The evaluating Member State then draws conclusions on how to use the existing and obtained information for the safe use of the substance.

This Conclusion document, as required by Article 48 of the REACH Regulation, provides the final outcome of the Substance Evaluation carried out by the evaluating Member State. The document consists of two parts i.e. A) the conclusion and B) the evaluation report. In the conclusion part A, the evaluating Member State considers how the information on the substance can be used for the purposes of regulatory risk management such as identification of substances of very high concern (SVHC), restriction and/or classification and labelling. In the evaluation report part B the document provides explanation how the evaluating Member State assessed and drew the conclusions from the information available.

With this Conclusion document the substance evaluation process is finished and the Commission, the Registrant(s) of the substance and the Competent Authorities of the other Member States are informed of the considerations of the evaluating Member State. In case the evaluating Member State proposes further regulatory risk management measures, this document shall not be considered initiating those other measures or processes. Further analyses may need to be performed which may change the proposed regulatory measures in this document. Since this document only reflects the views of the evaluating Member State, it does not preclude other Member States or the European Commission from initiating regulatory risk management measures which they deem appropriate.

[1] http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan

Contents

Part A. Conclusion

1. CONCERN(S) SUBJECT TO EVALUATION

2,4,6-trichloro-1,3,5-triazine was originally selected for substance evaluation in order to clarify concerns about:

- suspected PBT/vPvB,
- exposure concern (wide dispersive use, exposure of environment)

No additional concerns were identified during the substance evaluation.

2. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

A Compliance check was performed by ECHA on the registration dossier for EC 203-614-9 in 2015.

A compliance check decision was issued on 30 March 2017.

3. CONCLUSION OF SUBSTANCE EVALUATION

The evaluation of the available information on the substance has led the evaluating Member State to the conclusion that there is no need for regulatory follow-up action at EU level. Summary of conlusion is presented in the table below:

Table 1

CONCLUSION OF SUBSTANCE EVALUATION	
Conclusions	**Tick box**
Need for follow-up regulatory action at EU level *[if a specific regulatory action is already identified then, please, select one or more of the specific follow-up actions mentioned below]*	
Harmonised Classification and Labelling	
Identification as SVHC (authorisation)	
Restrictions	
Other EU-wide measures	
No need for regulatory follow-up action at EU level	x

4. FOLLOW-UP AT EU LEVEL

4.1. Need for follow-up regulatory action at EU level

No need for follow-up regulatory action at EU-level.

5. CURRENTLY NO FOLLOW-UP FORESEEN AT EU LEVEL

5.1. No need for regulatory follow-up at EU level

Table 2

REASON FOR REMOVED CONCERN	
The concern could be removed because	**Tick box**
Clarification of hazard properties/exposure	x
Actions by the registrants to ensure safety, as reflected in the registration dossiers(e.g. change in supported uses, applied risk management measures, etc.)	

After finalising the substance evaluation, the Polish Competent Authority (eMSCA) concluded that 2,4,6-trichloro-1,3,5-triazine is not persistent, not bioaccumulative and not toxic.

The degradation product cyanuric acid is potentially persistent but not bioaccumulative. Consequently, the evaluating MSCA overall concludes that 2,4,6-trichloro-1,3,5-triazine is not PBT/vPvB.

The exposure concern can be clarified with the conclusion that due to the use information provided in the registration dossier the exposure data did not suggest any indications for a high risk for the environment. These conclusions were based on the originally available and updated registration dossiers.

The available information is sufficient and reliable to clarify the initial concerns. There is no need for new studies and information under this substance evaluation.

6. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS (IF NECESSARY)

Not applicable.

Part B. Substance evaluation

7. EVALUATION REPORT

7.1. Overview of the substance evaluation performed

2,4,6-trichloro-1,3,5-triazine was originally selected for substance evaluation in order to clarify concerns about:

- suspected PBT/vPvB

- exposure concern (wide dispersive use, exposure of environment)

Table 3

EVALUATED ENDPOINTS	
Endpoint evaluated	**Outcome/conclusion**
Endpoint 1 - Degradation	- Not P/vP - Metabolite cyanuric acid is potentially P/vP
Endpoint 2 - Bioaccumulation	- Not B/vB - Metabolite cyanuric acid is not B/vB
Endpoint 3 – Environmental toxicity	- Not T - Metabolite cyanuric acid is not T
Endpoint 4 – PBT Assessment	- Concern not substantiated - Not PBT - Metabolite cyanuric acid is not PBT
Endpoint 5 – Exposure	Concern not substantiated

7.2. Procedure

On 30 March 2017 the registrant of 2,4,6-trichloro-1,3,5-triazine with tonnage band of 1000 tonnes or more per year was addressed in a compliance check decision by ECHA (decision number: CCH-D-2114355438-42-01/F) requesting the following information:

- Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3. test method: EU B.56./OECD TG 443) in rats, oral route;
- Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test method: EU B.31./OECD TG 414) in a second species (rabbits), oral route;
- Classification and labelling (Annex VI, Section 4.)

The deadline for submitting the information requested in the above mentioned ECHA decision is 7 October 2019. As the information requested by ECHA concerns human health part of the registration dossier, eMSCA focuses only on environmental conerns.

The substance evaluation was performed based on the registration dossier (updated on 20/08/2015) and Chemical Safety Report (CSR) as well as on the the basis of additional information available in scientific databases and publications.

All the information was assessed regarding the reliability for evaluation of the main grounds of concern. The particular emphasis was placed on the possible PBT/vPvB properties of 2,4,6-trichloro-1,3,5-triazine. Other aspects as physical and chemical properties have been checked and described in general in this report.

The results of the evaluation are documented in this report. Available information is enough to clarify the initial concerns. Thus, no further information was requested under this substance evaluation.

7.3. Identity of the substance

Table 4

SUBSTANCE IDENTITY	
Public name:	2,4,6-trichloro-1,3,5-triazine
EC number:	203-614-9
CAS number:	108-77-0
Index number in Annex VI of the CLP Regulation:	613-009-00-5
Molecular formula:	C3Cl3N3
Molecular weight range:	184.4112
Synonyms:	cyanuric chloride 2,4,6-Trichloro-1,3,5-triazin 2,4,6-Trichloro-1,3,5-triazine trichloro-1,3,5-triazine

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

Structural formula:

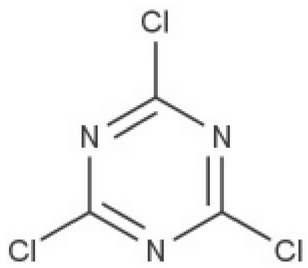


Table 5

Constituent			
Constituents	**Typical concentration**	**Concentration range**	**Remarks**
2,4,6-trichloro-1,3,5-triazine *EC no.: 203-614-9*	Confidential information	Confidential information	-

Table 6

Impurity			
Constituents	**Typical concentration**	**Concentration range**	**Remarks**
Cyanuric acid *EC no.: 203-618-0*	Confidential information	Confidential information	-
6-chloro-1,3,5-triazine-2,4(1H,3H)-dione *EC no.: 273-888-2*	Confidential information	Confidential information	-

Table 7: Degradation (transformation) product/metabolite

EC number:	203-618-0
EC name:	Cyanuric acid
SMILES:	-
CAS number (in the EC inventory):	108-80-5
CAS number:	-
CAS name:	-
IUPAC name:	1,3,5-Triazin-2,4,6-triol 1,3,5-Triazinane-2,4,6-trione 1,3,5-Triazine-2,4,6(1H,3H,5H)-trione 1,3,5-triazine-2,4,6-triol 2,4,6-Trichloro-1,3,5-triazin 4-amino-1,2,5-oxadiazole-3-carboxylic acid Cyanuric Acid
Index number in Annex VI of the CLP Regulation	-
Molecular formula:	C3H3N3O3
Molecular weight range:	129.075 g/mol
Synonyms:	Cyanuric Acid Isocyanuric acid / ICA Tricarbimide tricyanic acid Trihydroxycyanidine

Structural formula:

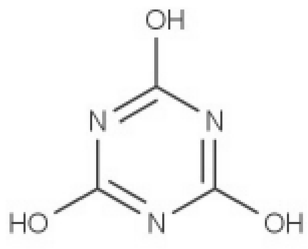
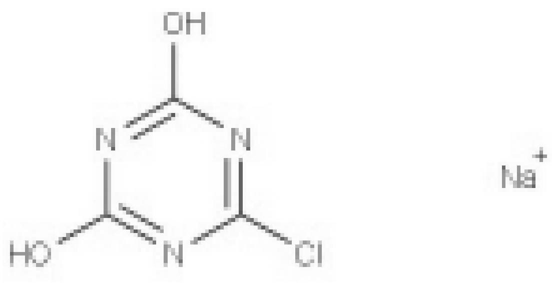


Table 8: Degradation (transformation) product/metabolite

EC number:	251-327-2
EC name:	6-chloro-1,3,5-triazine-2,4(1H,3H)-dione, sodium salt
SMILES:	-
CAS number (in the EC inventory):	32998-00-8
CAS number:	-
CAS name:	-
IUPAC name:	-
Index number in Annex VI of the CLP Regulation	-
Molecular formula:	C3HClN3NaO2
Molecular weight range:	169.50200
Synonyms:	6-chloro-1,3,5-triazine-2,4(1H,3H)-dione, sodium salt

Structural formula:



Indication of the process, organism and/or organ in which the formation takes place:

The intermediate and final degradation products of cyanuric chloride were identified in the hydrolysis study as 2,4-dichlor-6-hydroxy-1,3,5-triazine (first intermediate, DT50(pH 7.0, T=298.15 K) = 0.52 h = 31.5 min), 2-chlor-4,6-dihydroxy-1,3,5-triazine (also named 6-chloro-1,3,5-triazine-2,4(1H,3H) -dione, sodium salt) (second intermediate, CAS no.: 32998-00-8, DT50 (pH 7.0, T=298.15 K) = 3.98 h =239.0 min) and cyanuric acid (final degradation product, CAS no: 108 -80-5), respectively. The increasing amount of acid compounds formed during hydrolysis is most likely responsible for the irritating and caustic effects of cyanuric chloride.

7.4. Physico-chemical properties

Table 9

OVERVIEW OF PHYSICOCHEMICAL PROPERTIES		
Property	**Value**	**Remarks**
Physical state at 20°C and 101.3 kPa	*White powder*	*ECHA dissemination site, 2017*
Melting/freezing point	*>= 146.5 - <= 147.5 °C*	*ECHA dissemination site, 2017*
Boiling point	*192 - 195 °C @ 101.3 - 101.858 kPa*	*ECHA dissemination site, 2017*
Vapour pressure	*1.2 Pa* *60 Pa* *2.5 Pa (200C)* *267 Pa (700C)*	*OECD SIDS, 2001* *ECHA dissemination site, 2017*
Surface tension	*195 °C at 101.3 kPa*	
Water solubility	*440 mg/L at 20 0C* *338 mg/L @ 25 °C*	*OECD SIDS, 2001* *ECHA dissemination site, 2017*
Partition coefficient n-octanol/water (log value) *log Kow*	*0.51>* *1.7* *1.73* *2.14* *Log Kow = 1.73*	*OECD SIDS, 2001* *ECHA dissemination site, 2017* *KOWWIN v1.68 estimate*
Partition coefficient n-octanol/air (log value) *Log KOA*	*6.43*	*KOAWIN v.1.10 estimate*
Dissociation constant	*Not applicable*	

7.5. Manufacture and uses

7.5.1. Quantities

This substance has 12 active registrations under REACH, 1 Joint Submission and 3 Individual Submissions.

Table 10

AGGREGATED TONNAGE (PER YEAR)				
☐ 1 – 10 t	☐ 10 – 100 t	☐ 100 – 1000 t	☐ 1000- 10,000 t	☒ 10,000-50,000 t
☐ 50,000 – 100,000 t	☐ 100,000 – 500,000 t	☐ 500,000 – 1000,000 t	☐ > 1000,000 t	☐ Confidential

7.5.2. Overview of uses

This substance is used by professional workers (widespread uses), in formulation or re-packing, at industrial sites and in manufacturing.

Release to the environment of this substance can occur from industrial use: as an intermediate step in further manufacturing of another substance (use of intermediates) and during manufacturing of the substance.

Table 11

USES	
	Use(s)
Uses as intermediate	Use as intermediate, use as a monomer
Formulation	Formulation into mixture
Uses at industrial sites	Use as intermediate, use as a monomer
Uses by professional workers	Products such as ph-regulators, flocculants, precipitants, neutralisation agents Laboratory chemicals
Consumer Uses	-
Article service life	-

7.6. Classification and Labelling

7.6.1. Harmonised Classification (Annex VI of CLP)

Table 12

HARMONISED CLASSIFICATION ACCORDING TO ANNEX VI OF CLP REGULATION (REGULATION (EC) 1272/2008)							
Index No	**International Chemical Identification**	**EC No**	**CAS No**	**Classification**		**Spec. Conc. Limits, M-factors**	**Notes**
				Hazard Class and Category Code(s)	**Hazard statement code(s)**		
613-009-00-5	2,4,6-trichloro-1,3,5-triazine; cyanuric chloride	203-614-9	108-77-0	Acute Tox. 2 Acute Tox. 4 Skin Corr. 1B Skin Sens. 1	H330 H302 H314 H317 EUH014	STOT SE 3 H335: C≥5%	-

7.6.2. Self-classification

Table 12: In the registration dossier

Classification		
Hazard Class and Category Codes	**Hazard Statement Codes**	**Spec. Conc. Limits**
STOT SE 3 Eye Dam. 1	H335 H318	C ≥ 5%

Self-classification notifications for cyanuric chloride (EC 203-614-9) are available in the C&L Inventory (https://echa.europa.eu/pl/information-on-chemicals/cl-inventory-database/-/discli/details/113877).

In the following table the additional notified classification for cyanuric chloride listed in C&L Inventory is given (dating of September 2017).

Table 13

Classification	
Hazard Class and Category Codes	**Hazard Statement Codes**
Resp. Sens. 1 Eye Dam. 1 Met. Corr. 1	H334 H318 H290

7.7. Environmental fate properties

7.7.1. Degradation

7.7.1.1. Abiotic degradation

7.7.1.1.1. Hydrolysis

In accordance with the key study (Unnamed, 1985) available in the registration dossier, a fast and stepwise hydrolysis of cyanuric chloride takes palce. In the study the half-times for the first hydrolysis step of cyanuric chloride (decay of cyanuric chloride to first intermediate) in different pH and temperature were determined. The half time for the hydrolysis in pH 7.0 and T= 25°C was dermined to be 3.47 min (DT50 (pH 2.0, T=25°C) = 1.2 min and DT50 (pH 7.0, T= 25°C) = 3.47 min) and was used as value for the key parameter.
The study showed that rates of hydrolysis rise significantly at acidic medium and are slower at basic pH (for T = constant).

The intermediate and final degradation products of cyanuric chloride were identified as

1) 2,4-dichlor-6-hydroxy-1,3,5-triazine, DT_{50} of 0.52 h = 31.5 min (first intermediate, pH 7.0, T=25°C),
2) 2-chlor-4,6-dihydroxy-1,3,5-triazine, DT_{50} of 3.98 h =239.0 min (second intermediate, pH 7.0, T=25°C)
3) cyanuric acid (final degradation product, CAS no: 108 -80-5).

The results of available studies show that in water cyanuric chloride hydrolyses quickly to cyanuric acid via the intermediates 2,4-dichloro-6-hydoxy-s-triazine and 2-chloro-4,6-dihydroxy-s-triazine (DT_{50}<5h). The DT_{50} for the disappearance of cyanuric chloride in aqueous medium is <5 minutes (first step of hydrolysis).

In one of the supporting studies available in the registration dossier, the hydrolysis of cyanuric chloride in acid in neutral and alkaline solution (Horrobin, S., 1963) was tested. Due to the stepwise process of the hydrolysis of cyanuric chloride, different (intermediate) degradation products were identified and the rate constants (DT50) of the hydrolysis steps in the temperature range 0-25 °C were determined to be in the range 4-50 minutes.

According to the results of the study:

- DT50 for hydrolysis of 2,4-dichlor-6-hydroxy-1,3,5-triazine to 2-chlor-4,6-dihydroxy-1,3,5-triazine at 25°C in alkaline solution (pH 9.2-11.2) was 1.6-90 days; in acid solutions (pH 1.1-1.6) DT50 was 5-15 min.

- DT50 for hydrolysis of 2-chlor-4,6-dihydroxy-1,3,5-triazine to cyanuric acid at 25°C in alkaline solution (pH 11-13) was 29-76 days; in acid solutions (pH 1-2) DT50 was 10 min.-5h. At pH 7 no degradation was seen after one month.

Reliability of above study is reported as 'acceptable, well documented publication which meets basic scientific principles - no guideline followed - influence of buffer ions at higher pH values is unclear'.

In another supporting study investigating the hydrolysis of cyanuric chloride it was found that the substance completely hydrolysed (1 g/L at 20 ± 2 °C) within 2 hours (Unnamed, 1979). No information about pH was given.

In additional sources of information, studied by eMSCA, the measured DT50-values for cyanuric chloride (based on hydrolysis to cyanuric acid) range from 1 hour (Fierz-David H.E.,1937) to 1-2 days (Unnamed, 1978) in different studies, without specification of the pH.

The hydrolysis of sodium salt solutions of cyanuric acid was also analysed by eMSCA. In a test available on ECHA dissemination site, hydrolysis of cyanuric acid was studied at three concentrations and in three pH buffers (pH 5, 7 and 9) using three sources of water (distilled, tap and well water). The hydrolysis half life was determined to be >30 days at pH 5,7 and 9 (Unnamed 1981, key study, non guideline). The result of study shows cyanuric acid to be stable to hydrolysis at pH 5,7 and 9.

After analyzing available data originated from registration dossier and additional sources of information eMSCA notes the evidences that demonstrate the rapid stepwise hydrolysis of the cyanuric chloride. Hydrolysis to the final product cyanuric acid proceeds rapidly at all pHs with the exception of pH12 where the intermediate and final hydrolysis steps are signifiantly slower (DT 50 = 3465 min ~2 days). The available information is deemed sufficient to demonstrate the rapid hydrolysis in the environmentally relevant pH range.

7.7.1.1.2. Oxidation

No data.

7.7.1.1.3. Phototransformation/photolysis

7.7.1.1.3.1. Phototransformation in air

As is stated in the registration dossier the atmospheric oxidation potential (AOP) predicted from the Epiwin vs. 1.9 program indicates that cyanuric chloride is not photolytically reactive (degradation half-life of > 15 year) (Karlaganis G., 2001a).

Additionally, SAR computer software calculations of the half time of cyanuric chloride in the troposphere during the reaction with hydroxyl radicals estimated the half time to be approximately 12 years (4417 days) (Jäckel H., 1993).

The results of calculations show that cyanuric chloride is not photolytically reactive in air (degradation half-life of > 15 year).

According to information on cyanuric acid, available on ECHA dissemination site, the atmospheric oxidation potential (AOP) predicted from the Epiwin v. 1.9 program indicates that cyanuric acid is slowly reactive chemicals (degradation half-life of 3.5 days).

7.7.1.1.3.2. Phototransformation in water

In the registration dossier one study on phototransformation of cyanuric chloride in water is available. The study was performed with cyanuric acid, the final degradation product of cyanuric chloride.
Cyanuric acid (concentration: ca. 275 mg/L) was treated both with UV radiation and with UV-irradiated H_2O_2. After 30 minutes treatment the concentration of the test item was determined to be ca. 225 mg/L and ca. 275 mg/L, respectively. Since these concentrations do not differ strongly from the initial test item concentration, photodegradation of the test item is not considered (Götzelmann, G., 1991; Unnamed, 1989).

Information on cyanuric acid available on ECHA dissemination site, confirms that phototransformation of the substance in water does not take place (study with aqueous sodium salt solutions of cyanuric acid carried out in pH 7.5 phosphate buffers under simulated sunlight irradiation (Light source: GE 20 watt F20T12.BL Blacklight fluorescent lamp) to determin an extent of photodegradation of the substance). No phototransformation products were detected.

7.7.1.1.3.3. Phototransformation in soil

No relevant information available for cyanuric chloride and its degradation products.

7.7.1.2. Biodegradation

Probability of rapid biodegradation of cyanuric chloride and its final degradation product was calculated by eMSCA using BIOWIN v4.10. Based on the calculations no probability of rapid biodegradation for both substances is concluded.

7.7.1.2.1. Biodegradation in water

7.7.1.2.1.1. Screening tests

Due to the fast hydrolysis of the cyanuric chloride a read across approach with a supporting, analogous substances (i. e. intermediate and final degradation products of the hydrolysis of cyanuric chloride) was applied.

In the key study (Unnamed, 1990), conducted in accordance with modified OECD guideline 301 E and EU-method C.4-B, the aerobic biodegradation behaviour of the supporting substance (2-chlor-4, 6-dihydroxy-1,3,5-triazin, mono sodium salt) was assessed. The test revealed that after an exposure period of 28 days a low level of biodegradation occurred (8% measured with DOC removal). Therefore, the test item was considered to be not ready biodegradable.

In another test the biodegradation of the monosodium salt of cyanuric acid was investigated in seawater according to OECD TG 306 and 4% biodegradation (by DOC removal) was attained in 60 days (Unnamed, 2008).

In the supporting study (Unnamed, 1989) the biological oxygen demand of the read across substance (2-chlor-4, 6-dihydroxy-1,3,5-triazin, mono sodium salt – intermediate degradation product was measured in accordance with EU-method C.5. After an exposure period of 5 days the test revealed that the BOD was 5% at a concentration of 2 mg/L test item and 0% at a concentration of 10 mg/L.

Another test (Unnamed, 1989), performed according to method similar to OECD guideline 302 B, revealed that the read across substances (cyanuric acid - final degradation product of the hydrolysis of cyanuric chloride) is not inherently biodegradable. There was no degradation of test substance (0%) after 14 d (TOC removal).

In additional sources of information there are available results of study, carried out according to OECD 301C method, that shows cyanuric acid not to be readily biodegradable in water (MITI, Japan).

The available biodegradation studies show no significant biodegradation of the hydrolysis products (2-chlor-4, 6-dihydroxy-1,3,5-triazin, mono sodium salt and cyanuric acid) in ready and inherent tests.

7.7.1.2.1.2. Simulation tests

No data.

7.7.1.2.2. Biodegradation in sediments

No data.

7.7.1.2.3. Biodegradation in soil

In registration dossier there are not available data on biodegradation of cyanuric chloride in soil. However, data on the biodegradation of the cyanuric acid are available on ECHA dissemination site as well as in additional sources of information.

In a series of studies performed in different anaerobic soils (Saldick J 1974) it was observed that cyanuric acid biodegrades readily in anaerobic soils. In highly aerobic media cyanuric acid resists biodegradation.

7.7.1.3. Summary and discussion on degradation

Cyanuric chloride is not photolytically reactive in air (degradation half-life of > 15 year).

Final product of hydrolysis of cyanuric chloride - cyanuric acid is not photolytically reactive in water.

Cyanuric chloride hydrolyses quickly to cyanuric acid via the intermediates 2,4-dichloro-6-hydoxy-s-triazine and 2-chloro-4,6-dihydroxy-s-triazine (DT50<5h). The DT50 for the disappearance of cyanuric chloride in aqueous medium is <5 minutes (first step of hydrolysis), while cyanuric acid is stable to hydrolysis at pH 5,7 and 9 (Unnamed 1981).

The results of the study determining the hydrolysis of cyanuric chloride in acid, neutral and alkaline solution was studied (Horrobin, S., 1963) show that hydrolysis is much slower in neutral and alkaline solutions.

QSAR based screening criterion for identifying substances for persistence (P/vP) for cyanuric chloride is met (Biowin 2<0.05 / Biowin 6<0.6 and Biowin<2.25).

No studies on biodegradability of cyanuric chloride were available. Due to the low solubility and its hydrolysis properties, the actual concentration of cyanuric chloride in water is very low. For the biodegradation process of cyanuric chloride the hydrolysis products are much more relevant than cyanuric chloride itself. Therefore a read across approach with a supporting, analogous substances was applied.

Studies on hydrolysis products showed very limited biodegradability of these compounds under standard test conditions (Unnamed, 1990, Unnamed, 1989).

Th following studies, performed according to OECD guidelines/ EU-method or similar, were used to support a read across approach to assess potency of cyanuric chloride to biodegradability:

Biodegradation in water Screening tests				
Method /Guideline	**Tested analogous substance**	**Result**	**Conclusion**	**Referece**
modified OECD guideline 301 E /EU-method C.4-B Reliability: 1 (reliable without restriction)	6-chloro-1,3,5-triazine-2,4(1H,3H)-dione, sodium salt (CAS: 32998-00-8)	8% after 28 d - a low level of biodegradation occurred (measured with DOC removal)	not ready biodegradable **potentially P or vP**	Unnamed, 1990
EU-method C.5 Reliability: 1 (reliable without restriction)	6-chloro-1,3,5-triazine-2,4(1H,3H)-dione, sodium salt (CAS: 32998-00-8)	After 5 d BOD was 5% at a concentration of 2 mg/L test item and 0% at a concentration of 10 mg/L	no bio-degradation observed **potentially P or vP**	Unnamed, 1989
similar to OECD guideline 302 B Reliability: 4 (not assignable)	cyanuric acid	no degradation of test substance (0%) after 14 d (TOC removal)	not inherently biodegradable **potentially P or vP**	Unnamed, 1989
OECD 301C Reliability: not reported	cyanuric acid	0% by BOD after 14d; 7.8% by TOC after 14d; 5.3% by HPLC after 14d	not ready biodegradable **potentially P or vP**	OECD SIDS - 1999 - Cyanuric acid (Japan)
OECD GD 306 (Biodegradability in seawater – aerobic conditions) Reliability: 1 (reliable without restriction)	monosodium salt of cyanuric acid	4% biodegradation (by DOC removal) after 60d	not ready biodegradable **potentially P or vP**	Unnamed , 2008

BOD - biochemical oxygen demand
DOC - dissolved organic carbon
TOC - total organic carbon

In view of the limited toxicity of cyanuric chloride and cyanuric acid to aquatic organisms and the low bioaccumulating potential of cyanuric acid, it is not necessary to perform a biodegradation study.

Based on results of standard biodegradability tests carried on cyanuric chloride hydrolysis products and when read across approach is applied, cyanuric chloride should be considered as potentially persistent or very persistent (vP/P).

7.7.2. Environmental distribution

7.7.2.1. Adsorption/desorption

In the registration dossier the Registrant provided a data waiver indicating that the study is scientifically unjustified because, in accordance with column 2 section 1 of Annex VIII (section 9.3.1) and Annex |IX (section 9.3.3). It was concluded that studies on adsorption/desorption can be omitted as the log Kow value (ACD/Log D Suit 2.14 and KOWWIN v1.68 - 1.73) for the test substance is <3.0 and the test substance has low potential for adsorption.
However, there were presented four supporting studies on adsorption/desorption in the dossier. All of them report values of log Koc estimated by calculation using QSAR methods (log Koc=0.74 to 5.4).

In the registration dossier
The log Koc was calculated using the EPIWEB KOCWIN v2.00 software by eMS to be 1.902 (or 2.898 MCI Method).

In additional source of information (OECD SIDS - 2001 - Cyanuric chloride) there is reported Koc value of 124 (log Koc = 2.09) estimated with PCKOC Program and it is noted that Koc may be sensitive to pH and may vary significantly depending on pH. Furthermore, there is reported soil Koc 22, calculated by the level III Fugacity model.
In the same document the information on distribution of cyanuric chloride during chemical production is available. It was assessed with several models, i.e. USES and EQC. Both models indicated that the substance would predominantly end up in the aquatic compartment either directly or via passage of a biological waste treatment plant and hydrolyse rapidly (5 min). The detectable hydrolyse product that would end up in the surface water are 2-chloro-4,4-dihydroxy-s-triazine or cyanuric acid. As from EQC and USES can be deducted that around 98% of cyanuric chloride would end up in the surface water, it was considered not necessary to conduct an adsorption-desorption study in soil.

According to another source of information (HSDB Database) cyanuric chloride's production and use may result in its release to the environment through various waste streams including soil. As stated in the same source, if released to soil, cyanuric chloride is expected to have high mobility based upon an estimated Koc of 120.

Taking into account information presented above and emphasizing that cyanuric chloride hydrolyses rapidly in water, it can be considered unlikely to have potential for adsorption/desorption. However, possible high mobility of the degradation product cyanuric acid should be further analysed.

In the registration dossier for cyanuric acid the study (Unnamed, 1982) that characterizes the adsorption of cyanuric acid on soils is reported. The soil/water partition coefficient, Kd, was determined to be less than 1 for all soils tested, indicating that cyanuric acid is weakly absorbed and highly mobile in soil and sediments. The mobility of cyanuric acid in soil appeared to decrease with decreasing organic matter concentration.

Consequently, cyanuric acid should be considered highly mobile in soils and not strongly adsorbed.

7.7.2.2. Volatilisation

Volatilization of cyanuric chloride from moist soil surfaces is not expected based upon an estimated Henry's Law constant of 4.9x10-7 atm-cu m/mole (HSDB Database). Volatilization from dry soil surfaces is not expected to be an important fate process given the estimated vapor pressure 60 Pa (Unnamed, 1987) of cyanuric chloride. If released to water, cyanuric chloride is not expected to adsorb to suspended solids or sediment in the water column based upon the estimated Koc value. Volatilization from water surfaces is not expected to be an important environmental fate process given the estimated Henry's Law constant.

Estimation of cyanuric acid volatilisation from aqueous solution performed by eMSCA via calculation of the Henry’s Law Constant based on vapour pressure < 5.0 x 10-3 Pa at 25 °C (OECD SIDS), water solubility 2700 mg/l (MITI, Japan) resulted in value of 0.000239 Pa·m3·mol^{-1} at 25°C, providing that volatilization of cyanuric acid from water surfaces is not expected to be an important fate process based upon the compound's estimated Henry's Law constant.

7.7.2.3. Distribution modelling

Potential environmental distributions of cyanuric chloride are reported in OECD SIDS – 2001 (cyanuric chloride) using level III fugacity model. According to the results, 99.5% of the substance ends up in water, 0,187% in soil, 0.032% in air and 0.288% in sediment.

The potential environmental distributions of cyanuric acid was considered as well and obtained from a generic Mackay level III fugacity model. The results show that, if cyanuric acid is released into water, it is unlikely to be distributed into other compartments (99.8% of the substance ends up in water). If it is released into air and soil, it is likely to be distributed in other compartments.

7.7.3. Potential for long range transport

The eMSCA used multi-media OECD Long Range Transport model for calculation of the potential for long range environmental transport - mainly air transport. However, it was not possible to perform the calculation due to the fact that not all required input data for cyanuric chloride were available.

In the literature relevant publications were found regarding LRT potential of cyanuric chloride. In one of them (Zarfl and Matthies, 2013) it was concluded that no biodegradation was observed in case of cyanuric chloride and the substance is very persistent (vP). Moreover the authors assumed that cyanuric chloride shows LRT potential based on:

- the half-life criterion t1/2(air) > 2 days (according to Stockholm Convention)
- simulations with the multimedia model ELPOS
- the chemical structure of known Arctic contaminants as given by Brown and Wania (2008)
- combination of the half-life criterion with the log K_{AW} condition defined by Muir and Howard (2006) (log KAW ≥ 5 and ≤1)

In another publication of Zarfl at al. (2012) 2,4,6-trichloro-1,3,5-triazine is one of the substances fulfilling all of the three screening criteria indicating LRTP: half-life, multimedia model and chemical profile of known Arctic contaminant.

In Greenpeace China Chemicals Calling for Priority Action an Analysis of the Inventory of Existing Chemical Substances in China 2009 (Ma and Zhang, 2010) 2,4,6-trichloro-1,3,5-

triazine is considered as one of hazardous chemicals for priority action based on Brown and Wania's List of 120 Arctic Contaminants.

According to the last publication, of Brown and Wania (2008), cyanuric chloride has been included in List of High Production Volume Chemicals Predicted to Become Arctic Contaminants or Which Match the Structural Profile of Known Arctic Contaminants based on conclusion that this substance is persistent and matches the structural profile of known Arctic contaminants.

Potential for LRT of 2-chlor-4, 6-dihydroxy-1,3,5-triazin, mono sodium salt was also analized. According to data included in registration dossier on cyanuric chloride, intermediate hydrolysis product (2-chlor-4, 6-dihydroxy-1,3,5-triazin, mono sodium salt) was considered to be not ready biodegradable after 28 days (OECD guideline 301 E). No further relevant information on LRT potential of this substance is available, including additional literature sources.

For defining potential for LRT of cyanuric acid eMSCA analysed data available in the registration dossier and additional literature.

The eMSCA used multi-media OECD Long Range Transport model for calculation of the potential for long range environmental transport - mainly air transport. However, it was not possible to perform the calculation due to the fact that not all required input data for cyanuric acid were available.

No further relevant information on LRT potential of this substance is available in any source accessible to eMSCA, including databases developed as a results of national monitoring programmes of Member States (e.g. Swedish national monitoring data collection), European monitoring programmes (e.g. NORMAN Network) and internationally acknowledged organisations (such as OSPAR or the Danube Convention).

7.7.4. Bioaccumulation

7.7.4.1. Bioaccumulation in aquatic organisms (pelagic and sediment organisms)

In the registration dossier a read across justification regarding bioaccumulation of cyanuric chloride is provided because of the rapid hydrolysis of the substance confirmed with numerous hydrolysis studies presented in the registration dossier and literature. Due to the rapid hydrolysis of cyanuric chloride to cyanuric acid the PBT assessment should focus on the hydrolysis product, *i.e.* cyanuric acid.

Cyanuric chloride has a logKow of 1.73 and bioaccumulation estimated by eMSCA by BCFBAF v3.01: Log BCF from regression-based method = 0.955 (BCF = 9.021 L/kg wet-wt).

The same approach regarding the bioaccumulation of cyanuric chloride is presented in the report of OECD related to that substance (OECD SIDS Initial Assessment Report, Cyanuric chloride, 25 September 2001). The report summarises that "released cyanuric chloride will end up in surface water for 99% (EQC-model). In water cyanuric chloride hydrolyses quickly to cyanuric acid via the intermediates 2,4-dichloro-6-hydroxy-s-triazine and 2-chloro-4,6-dihydroxy-s-triazine (DT50 < 5 hours). The DT50 for disappearance of cyanuric chloride in aqueous medium is < 5 minutes.

Cyanuric chloride has a low vapour pressure and log Kow of 1.73. Due to its low solubility (440 mg/L) and its hydrolysis properties, the actual concentration of cyanuric chloride in water is low. For the biodegradation process of cyanuric chloride the hydrolysis products are much more relevant than cyanuric chloride itself. Studies on these hydrolysis products showed very limited biodegradability of these compounds under standard test conditions.

Information on bioacumulation of **cyanuric acid** were also analysed by eMSCA.

On the ECHA dissemination site the experimental study performed to determine residue depletion of melamine and cyanuric acid in catfish and rainbow trout following oral administration is available. In that GLP study catfish and trout filets were harvested at 1, 3, 7, 14, 28 and 42 days after a single oral dose of 20 mg/kg body weight. The highest concentration of cyanuric acid, occurred on day 1 following administration, 0.68 mg/ kg in catfish (highest individual) or 0.46 mg/kg (mean of 6), 2.59 mg/ kg in trout (highest individual) or 0.86 mg/kg (mean of 6) with mean cyanuric acid concentrations declining rapidly during the first week. Other than one trout on day 1, no fish had cyanuric acid muscle residues greater than 2.5 mg/ kg at any time point.

Cyanuric acid residues in all dosage groups on day 3 had decreased to a level similar to that of controls. The t1/2 for fish receiving only cyanuric acid was less than 1 day for either catfish or trout. Only 2 of 30 catfish receiving only cyanuric acid developed renal crystals (days 14 and 28).

In the additional source of information related to cyanuric acid the experimental bioaccumulation study was presented. The study was performed with carp (Cyprinus carpio), according to OECD TG 305C under flow-through conditions.

Based on the results of this study the BCF was established: BCF < 0.1 (10 mg/L); < 0.5 (1 mg/L). However, there were several deviations from the guideline in conducting the study. Additionally, there was only limited information on the study design and its performing, also reaching of equilibration phase at calculation of the BCF was not reported. Therefore, the reliability of this study was 4.

In another study (by Karbiwnyk, C.M. et al,2010) the results of cyanuric acid bioaccumulation in edible tissues of shrimp following experimental feeding were presented and the biomagnification factor (BMF) esdtablished. Based on the results of the test the biomagnification factor (BMF) to shrimp is 0.014 (for average dose level at 55 mg/kg) and 0.003 (for average dose level at 124 mg/kg).

This study was well documented (with analytical part) and its results can serve as supporting information. The study is considered to be reliable with restriction.

Both BCF (< 0.5, in carp) and BMF (0.014, in shrimp) are based on measured data.

7.7.4.2. Bioaccumulation in terrestrial organisms (soil dwelling organisms, vertebrates)

There are no relevant data available in the registration dossier and literature regarding bioaccumulation of 2,4,6-trichloro-1,3,5-triazine and its hydrolysis products in terrestrial organisms.

For cyanuric chloride and cyanuric acid estimated log Koc, log Kow and BCF values are available. Additionally the experimental data for cyanuric acid are available.

On the basis of the available information, the eMSCA considers that the cyanuric chloride and its degradation product cyanuric acid are not potentially bioaccumulative.

Overall, neither cyanuric chloride nor its hydrolysis product cyanuric acid is a B/vB substance according to the criteria of REACH Annex XIII.

7.8. Environmental hazard assessment

7.8.1. Aquatic compartment (including sediment)

In the registration dossier a read across justification regarding bioaccumulation of cyanuric chloride is provided because of the rapid hydrolysis of the substance.

Due to the rapid hydrolysis of cyanuric chloride the P criterion is not fulfilled and any PBT assessment for the registered substance should focus on the hydrolysis products, mainly cyanuric acid.

Measure LogKow (OECD 107 and GLP) for the degradation product cyanuric acid is given in the dossier (Unnamed,2007) as -1.31 so bioaccumulation potential seems low.

According to OECD SIDS (Isocyanuric acid, 1999) the water solubility of cyanuric acid is at 2,7 g/L (corresponding to 2700 mg/L). The solubility in water is high.

7.8.1.1. Fish

7.8.1.1.1. Short-term toxicity to fish

The key study presented in the dossier was performed with 2-chlor-4, 6-dihydroxy-1,3,5-triazine sodium salt (CAS no. 32998-00-8), based on OECD 203 method. It showed no effects up to the maximum concentration value of 1000 mg/l. The 96 hr LC50 was set at 1000 mg/L.

Three supporting studies are presented in the registration dossier. Two of them are with registered substance, but the registrant assigned them a low reliabaility scores of 3 and 4 due to a lack of guideline and shorter exposure duration respectively. In the first supporting study with Goldorfe (*Leuciscus idus melanotus*), no effects were seen in the 48 h study (reliability 4) up to the maximum concentration value of 525 mg/L. The 48 h NOEC was detrmined to be 525 mg/L.

In the second supporting study the effects were seen in the 24 h (1957 study lacking guideline, reliability 3) at the concentration 5 ppm = 5 mg/L.

The third supporting study was performed with with final hydrolysis product of cyanuric chloride (OECD 203). It showed no effects up to the maxiumum concentration of 100 mg/L (96h LC50).

According to additional source of information (OECD SIDS report for cyanuric chloride) the aquatic toxicity of cyanuric chloride is not directly determinable due to its poor solubility and its hydrolytic properties. The QSAR calculations on acute toxicity towards fish, daphnia and algae were performed resulting in low toxicity values.

In view of the rapid hydrolysis of this compound it is expected that these organisms will be exposed to the reaction products found after hydrolysis, particularly 2-chloro-4,6-dihydroxy-s-triazine and cyanuric acid, rather than to the parent compound.

In relation to cyanuric acid and short-term toxicity to fish, eMSCA analysed data available on ECHA dissemination site and information in additional sources.

On ECHA dissemination there is presented study of acute toxicity of cyanuric acid to bluegill sunfish. The study was not performed according to GLP or current guideline but was well reported (2, reliable with restrictions). The LC50 > 1000 mg/L was established.

In additional source of information (OECD SIDS report for cyanuric acid) results of both 96-h LC50 and 14-day LC50 are available and are more than 100 mg/l.

7.8.1.1.2. Long-term toxicity to fish

In the registration dossier the results of test (Unnamed, 1997) performed according to OECD TG 204 (Fish, Prolonged Toxicity Test: 14-day Study) on the read across substance cyanuric acid are provided. The 14-day maximum no-observable effect concentration (NOEC), 7-day median lethal concentration (LC50) and the 14-day median lethal concentration (LC50) were determined to be > 100.0 mg/L (nominal concentration).

OECD SIDS report presents prolonged toxicity study, with the morality endpoind 14d LC50 > 100 mg/L but information on NOEC was not provided. This test was performed according to OECD TG 203 with effects observed after 14 days and adhering to principles of GLP.

On ECHA dissemination site, there is available the fish, juvenile growth test with Oncorhynchus mykiss for cyanuric acid. This test was performed according to OECD TG 215 and to GLP (1, reliable without restriction). The NOEC was equivalent to 756 mg of cyanuric acid/L and the LOEC was equivalent to > 756 mg of cyanuric acid/L. There were no sublethal effects of exposure observed in the test.

7.8.1.2. Aquatic invertebrates

7.8.1.2.1. Short-term toxicity to aquatic invertebrates

The key study (Unnamed, 1997) presented in the registration dossier was performed based on the OECD TG 202 and adhering to principles of GLP with the read across substance cyanuric acid (final hydrolysis product of the hydrolysis of cyanuric chloride).The 48h EC50 and 24h EC50 was assessed to be 1000 mg/L and > 1000 mg/L. The maximum no-observable effect level concentration (NOEC) of Daphnia exposed to cyanuric acid for a period of 24 and 48 hours was determined to be >1000mg/L and 580 mg/L, respectively.

In the supporting study (Unnamed, 1997) a read across approach was applied with the supporting substance 2-chlor-4, 6-dihydroxy-1,3,5-triazin, mono sodium salt (CAS no.: 32998-00-8), that is a hydrolysis product of the hydrolysis of cyanuric chloride. The influence of test item on invertebrates (Daphnia magna) was investigated according to EU-method C.2 and OECD TG 202. Daphnids were exposed to the test item for 24 hours under static conditions. A limit concentration of 1000 mg/L was tested. The 24 h EC50 value was determined to be > 1000 mg/L.

On the ECHA dissemination site there is available value of 48 h LC50 > 1000 mg/L for cyanuric acid. That result was obtained based on “Methods for acute toxicity tests with fish, macroinvertebrates and amphibians” (US EPA 1975) (2, reliable with restrictions).

7.8.1.2.2. Long-term toxicity to aquatic invertebrates

In the registration dossier the reproduction test (OECD TG 202 (Unnamed, 1984)) on aquatic invertebrates was provided. This study was performed with cyanuric acid, hydrolysis product of cyanuric chloride. The maximum non-observable effect concentration (NOEC reproduction) was determined to be 32.00 mg/L and the lowest concentration (LOEC reproduction) at which a significant difference with the control group can be observed was determined to be 100.00 mg/L.

For cyanuric acid there is available Daphnia magna Reproduction Test (ECHA dissemination site). The study was performed according to OECD TG 211 and to GLP (1, reliable without restriction). Exposure of Daphnia magna to monosodium salt of cyanuric acid resulted in significant mortalities at the test concentrations of 500, 1600 and 5000 mg/l resulting in 30%, 50% and 70% mortalities by day 21 respectively, compared to an observed mortality of 20% in the control by day 21.

The NOEC was considered to be 160 mg/L (equivalent to 121 mg/L CYA) on the basis that at this concentration there were no significant mortalities (immobilisation) observed in the parental generation (P1) and that there were no significant differences between the control and the 160 mg/L test group in terms of numbers of live young per adult by day 21.

The 21 day EC50 (immobilisation) values, based on nominal test concentrations, for the parental Daphnia (P1) was calculated to be 2600 mg/l. The 21-day EC50 (reproduction) based on nominal test concentrations was 2800 mg/l.

7.8.1.2.3. Algae and aquatic plants

In the key study (Unnamed, 1997) presented in the registration dossier, cyanuric acid, hydrolysis product of cyanuric chloride, was tested for toxicity to algae in a 72 h-static test according to OECD TG 201 and adhering to principles of GLP. The 72h, 24h and 48h EC50 based on the area under the growth curve and based on the growth rate was determined to be 620.0 mg/L, 780.0 mg/L and 800.0 mg/L, respectively. The 72h NOEC was determined to be 62.5 mg/L, 24h NOEC at 250 mg/L and 48h NOEC at 125 mg/L.

In additional source of ionformation on cyanuric chloride (OECD SIDS report) is stated that the toxicity of 2-chloro-4,6-dihydroxy-1,3,5-s-triazine can be reliably approximated with QSAR methods. The calculated value of EC50(algae) was reported as 909 mg/L.

Regarding cyanuric acid, the results of Algae Growth Inhibition Test performer with Navicula pelliculos and according to OECD TG 201 and to GLP (1, reliable without restriction) are available.

The 72 h EbC50 value = 2700 mg/L and the 72 h ErC50 value > 5000 mg/L were obtained. The NOEC based on area under the curve was 625 mg/L; in terms of the 0-72 hour growth rate the NOEC was 1250 mg/L. After 96 hours exposure EC50 values of greater than 5000 mg/L were obtained. The NOEC based on area under the curve was 1250 mg/L; in terms of the 0-96 hour growth rate the NOEC was 5000 mg/L.

7.8.1.2.4. Sediment organisms

In the registration dossier for cyanuric chloride is stated that the chemical safety assessment does not indicate the need to investigate further the effects of the substance on sediment organisms. Moreover, exposure to sediments is unlikely as the substance hydrolyses rapidly. Studies on the long-term and the short-term aquatic toxicity show that the hydrolysis products of cyanuric chloride do not have severe adverse effects. As cyanuric chloride (as well as its hydrolysis products) has a low Koc (~80) it is not likely to adsorb to sediment. For these reasons testing on soil dwelling organisms is not triggered.

However, on the ECHA dissemination site there is available for cyanuric acid Sediment-Water Chironomid Toxicity Test Using Spiked Sediment with Chironomus riparius. The study was performer according to OECD TG 218 and to GLP (1, reliable without restriction). The toxicity of monosodium salt of cyanuric acid to the sediment dwelling larvae of Chironomus riparius has been investigated and gave a 28-Day EC50 (emergence) of greater than 1000 mg test material/kg dry weight of sediment (equivalent to 756 mg cyanuric acid/kg dry weight of sediment). The No Observed Effect Concentration was 1000 mg test material/kg dry weight of sediment (equivalent to 756 mg cyanuric acid/kg dry weight of sediment). The EC50 (development rate) based on nominal test concentrations was greater than 1000 mg test material/kg dry weight of sediment (equivalent to 756 mg cyanuric acid).

7.8.1.2.5. Other aquatic organisms

No relevant information available.

7.8.2. Terrestrial compartment

7.8.2.1. Toxicity data

In the registration dossier no relevant information on cyanuric chloride and 6-chloro-1,3,5-triazine-2,4(1H,3H)-dione, sodium salt is available on terrestrial toxicity.

However, we identified other sources of information where data on toxicity related to the terrestrial compartment for cyanuric acid are available. According to EFSA Journal 2010; 8(4):1573 no adverse effects were seen in sheep at 600 mg/kg b.w. per day for 77 days, or at 400 mg/kg b.w. per day in pigs. The estimated exposures to melamine and cyanuric acid at the scenarios of 0.5, 2.5 and 10 mg/kg in feed are well below these doses and are not expected to pose a risk to the animals.

7.8.2.1.1. Toxicity to soil macro organisms

In the registration dossier no relevant information on cyanuric chloride and 6-chloro-1,3,5-triazine-2,4(1H,3H)-dione, sodium salt are available.

However, on the ECHA dissemination site there are available results of a study performed to assess the acute toxicity of the monosodium salt of cyanuric acid, which is the main product of hydrolysis of cyanuric chloride, to earthworms (Eisenia foetida) in an artificial soil (Unnamed, 2007). 60 earthworms (six replicates of 10 worms were exposed to a single concentration of 1000 mg test material/kg of dry soil for a period of 14 days. The number of mortalities was determined after 7 and 14 days exposure. The 14 day LC50 for the test material based on nominal test concentrations was > 1000 mg test material/kg dry soil (equivalent to 756 mg cyanuric acid/kg dry soil). The NOEC was 1000 mg test material/kg dry soil (equivalent to 756 mg cyanuric acid/kg dry soil).

7.8.2.1.2. Toxicity to terrestrial plants

In the registration dossier no relevant information on cyanuric chloride and 6-chloro-1,3,5-triazine-2,4(1H,3H)-dione, sodium (= monosodium salt of cyanuric acid) is available.

However, data on cyanuric acid are available in different literature sources including ECHA dissemination site. According to those data cyanuric acid, the final product of cyanuric chloride hydrolysis, naturally occurs in soils at concentrations of 0.9 to 6.5 ppm (Wise L E and Walters E H, 1917). It presents results also from commercial manufacture and use of products which breakdown to cyanuric acid. That substance is also present in soil as a result of using of plant protection products such as the S-triazines, atrazine and simazine which have been commercially used for over 40 years (Müller PW and Payot PH, 1966).

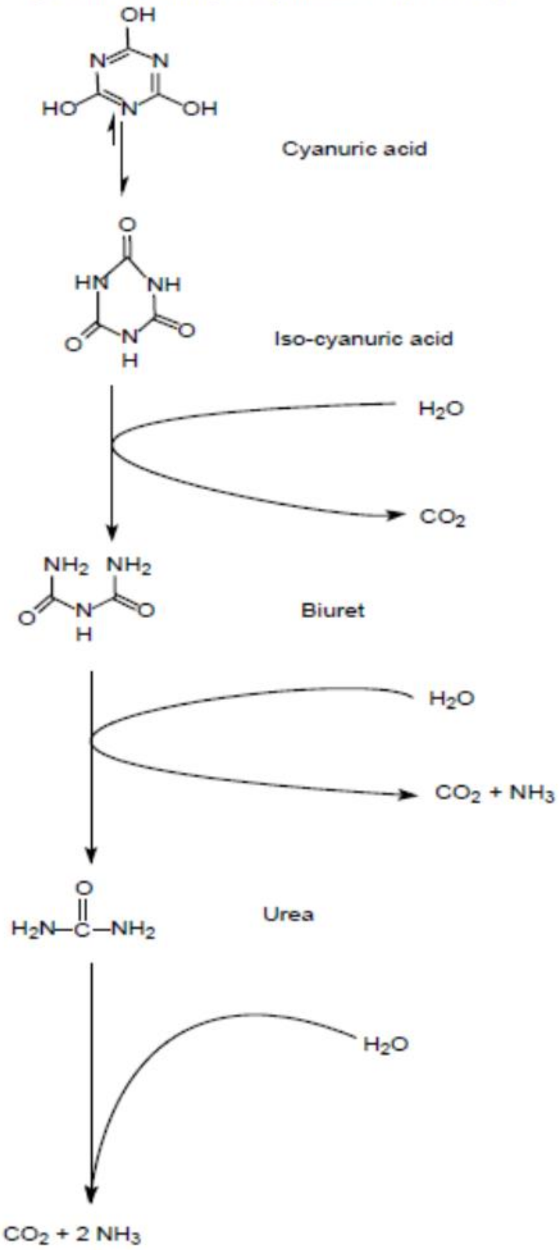
Cyanuric acid in soil is rapidly degraded (to carbon dioxide) by microorganisms under anaerobic conditions (Saldick, 1974). The mineralization of cyanuric acid in soil has also been found to occur from investigation of the nitrification of triazine nitrogen (Müller PW and Payot PH, 1966). Furthermore, is was found that certain plant species are capable of metabolizing cyanuric acid, inter alia corn that it is capable of metabolizing 80% of cyanuric acid (Müller PW and Payot PH, 1966).
According to the study of Bremner JM & Krogmeier MJ, 1989, cyanuric acid at test concentrations up to 2.5 mg/g soil (equivalent to 0.8 mg of N/g of soil) did not have an adverse effect on the germination of seeds under the conditions of the study.

7.8.2.1.3. Toxicity to soil micro-organisms

The data information requirements on soil micro-organisms has been waived by the registrant. For that reason additional sources of information were analysed by the eMSCA.

According to OECD SIDS report for cyanuric chloride the discussion on toxicity to soil micro-organisms is based on data related to cyanuric acid. As is stated in the report "cyanuric acid was reported not to affect nitrifying micro-organisms at 25°C over a 90 day period. However, at 20°C a transient effect was observed and at 10°C nitrification was inhibited during the whole observation period up to levels of 25%. In a poorly reported nitrification test cyanuric acid did not affect the CO_2 production by micro-organism. In fact several bacteria and fungi can use cyanuric acid as nitrogen source. The course of the degradation pathway (in bacteria) is via cleavage of the triazine-ring. For two strains of pseudomonas and one strain of Klebsiella pneumonia the degradation pathway of cyanuric acid was analysed. An enzymatic transformation to urea was identified. However, the report was limited and the analytical methods used were insufficiently specified.

Fig. 2 degradation pathway of cyanuric acid (bacteria)



No information on toxicity to soil micro-organisms is available in the registration dossier for cyanuric chloride, but on the ECHA dissemination website, information on a Respiration Inhibition Test with cyanuric acid is provided. The study was performed according to OECD Guideline 209 and to GLP (1, reliable without restriction).

The effect of the test material on the respiration of activated sewage sludge micro-organisms gave a 3-hour EC50 of greater than 4500 mg/l, equiavlent to 3402 mg cyanuric acid/l. The No Observed Effect Concentration (NOEC) after 3 hours exposure was 2700 mg/l, equivalent to 2041 mg cyanuric acid.

7.8.2.2. Toxicity to other terrestrial organisms

7.8.2.2.1. Toxicity to birds

In the study presented in the registration dossier the value 14 d-LD50 = 192 mg/kg bw (japanese quail, single oral application via gavage in PEG 400) based on the lowest observed value in a study is given (Unnamed, 1981).

In a supporting study, presented in the registration dossier (Unnamed, 1981), cyanuric chloride (2,4,6-trichloro-1,3,5-triazine) was tested (Peking ducklings, single oral application via gavage in PEG 400) according to guideline EPA OPPTS 850.2100 (Avian Acute Oral Toxicity Test) with minor deviations (10 ml/Kg bw application volume). Under the present conditions a LD50 of > 20 mg/kg bw was determined for the Peking duckling.

Additional information on toxicity of cyanuric chloride to birds is present on ECHA dissemination site. There are available two eight day dietary studies in mallard duck and bobwhite quail. They are performed with the monosodium salt of cyanuric acid. The results of the first study did not show any symptoms of toxicity or behavioural abnormalities at the dosage levels tested. There was no mortality at any dosage level.

In the second study with bobwhite quail none symptoms of the toxicity or behavioural abnormalities at the dosage levels tested were caused and there was no mortality at any dosage level.

7.8.2.2.2. Toxicity to mammals

In the registration dossier no relevant information available for cyanuric chloride and 6-chloro-1,3,5-triazine-2,4(1H,3H)-dione, sodium salt are available.

In the relevant literature there is available study on No Observable Adverse Effects Level (NOAEL) for pigs fed melamine and cyanuric acid (Stine CB1 at al., 2011). Test for 7 and 28 days were performed to_assess the potential risk of developing crystal nephropathy following co-ingestion of MEL and cyanuric acid by weanling pigs. On the basis of the results the no-observed-adverse-effect level (NOAEL) for pigs fed MEL and cyanuric acid for 28 days was concluded to be 1.0 mg/kg bw/day corresponding to 25 mg/kg (ppm) MEL and 25 mg/kg (ppm) cyanuric acid in dry feed.

7.8.2.3. Microbiological activity in sewage treatment systems

In the registration dossier as a key study the result of activated sludge test with registered substance is presented. In this study (Unnamed, 1979) the dehydrogenase activity of activated sludge from a sewage was assayed after incubation with different concentrations of cyanuric chloride (following the guideline Deutsches Einheitsverfahren (DEV) zur Wasser-, Abwasser- und Schlammuntersuchung, 7. Lieferung, 1975, DEV3). No effect of cyanuric chloride or its hydrolysis products on bacteria in sludge (dehydrogenase activity) was reported. As concentrations of cyanuric chloride up to to 576 mg/L dissolved in water did not show any negative effects on the activated sludge, the NOEC of cyanuric chloride is 576 mg/L.

7.8.2.4. PNEC derivation and other hazard conclusions

PNEC values derived in the registration dossier(s) are acceptable.

7.8.3. Conclusions for classification and labelling

The existing Annex VI entry for 2,4,6-trichloro-1,3,5-triazine is considered appropriate. On the basis of the collected data on environmental hazard, there is no basis for changing Annex VI for 2,4,6-trichloro-1,3,5-triazine.

7.9. Human Health hazard assessment

Not evaluated. eMSCA notes that studies on reproduction toxicity are on going and subject to follow up assessment by ECHA under compliance check.

7.10. Assessment of endocrine disrupting (ED) properties

Not assessed.

7.11. PBT and vPvB assessment

1) Persistence

Due to the fast hydrolysis of cyanuric chloride to cyanuric acid the substance itself is not persistent. However, the hydrolysis leads to the degradation product cyanuric acid which is regarded as potentially persistent/very persistent ("P or vP") based on available data.

2) Bioaccumulation

Based on the available screening data (log Kow 1.73), cyanuric chloride is not B. No experimental BCF data is available for cyanuric chloride. However, as cyanuric chloride degrades rapidly to cyanuric acid, the bioaccumulation potential of this degradation product is evaluated.

The measured log Kow of cyanuric acid is -1.31. Both experimental values of BCF (< 0.5, in Carp) and BMF (0.014, in shrimp) are low.

Taking all information into account all information both cyanuric chloride and it degradation products are considered not bioaccumulative.

3) Toxicity

Neither cyanuric chloride nor cyanuric acid fulfil currently the toxicity criterion. The lowest aquatic toxicity endpoint for cyanuric acid is more than 0,01 mg/l. Furthermore, this substance is not classified as a CMR (on the basis of available data) or for chronic toxicity. However, studies are on the way to address reproductive toxicity. Therefore the assessment of the toxicity criterion and the conclusion "not T" is only preliminary.

4) Overall conclusion on the PBT/vPvB assessment

The eMSCA considers cyanuric chloride as persistent, but not bioaccumulative and – preliminary - not toxic. Cyanuric acid, the hydrolysis product of cyanuric chloride is potentially persistent/very persistent, but not bioaccumulative.

The evaluating MSCA overall concludes that cyanuric chloride is therefore not PBT/vPvB.

7.12. Exposure assessment

Not assessed.

7.13. Risk characterisation

Not assessed.

7.14. References

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7.15. Abbreviations

C&L - Classification and labelling

CLP – Classification, Labelling and Packaging

CoRAP – Community Rolling Action Plan

CSR – Chemical Safety Report

DMEL - Derived Minimal Effect Level

DNEL – Derived No Effect Level

ECETOC - European Centre for Ecotoxicology and Toxicology of Chemicals

ECHA – European Chemical Agency

EC3 - the concentration of test chemical required to induce a 3-fold increase in lymph node cell proliferation

EFSA – European Food Safety Agency

ES – Exposure Scenario

EU – European Union

eMSCA – Evaluating Member State

EPA – Environmental Protection Agency

GPL – Good Laboratory Practice

INRS – Reference body for occupational risk prevention in France

JECFA - The Joint FAO/WHO Expert Committee on Food Additives

LD – Lethal Dose

LC – Lethal Concentration

LLNA - Local lymph node assay

LOAEL – Lowest Adverse Observed Effect Level

LOAEC - Lowest Adverse Observed Effect Concentration

MSCA – Member State Competent Authority

NIOSH - The National Institute for Occupational Safety and Health

NOAEC - No Observed Adverse Effect Concentration

NOAEL – No Observed Adverse Effect Level

NTP - National Toxicology Program

OC – Operational Conditions

PBT – Persistent, Bioaccumulative, Toxic

(Q)SAR - Quantitative structure–activity relationship

RAR – Risk Assessment Report

RCR – Risk Characterisation Ratio

RMM - Risk Management Measures

SVHC – Substance of Very High Concern

TG – Technical Guidance

TWA -Time-weighted average

WCS – Working contributing scenario

vPvB – very Persistent, very Bioaccumulative