Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name):	1, 3, 5-tris(oxiranylmethyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione
EC Number:	219-514-3
CAS Number:	2451-62-9
Submitted by:	Bureau for Chemical Substances, Poland
Published:	20/03/2013

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

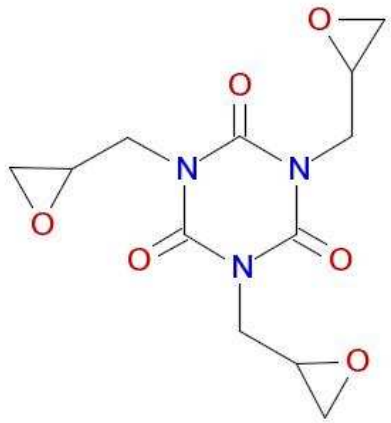
1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	219-514-3
EC name:	1,3,5-tris(oxiranylmethyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione
CAS number (in the EC inventory):	2451-62-9
CAS number:	2451-62-9
CAS name:	1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-
IUPAC name:	1,3,5-tris(oxiran-2-ylmethyl)-1,3,5-triazinane-2,4,6-trione
Index number in Annex VI of the CLP Regulation	615-021-00-6
Molecular formula:	C12H15N3O6
Molecular weight or molecular weight range:	297,26 g/mol
Synonyms:	TGIC; Teroxirone; TEPIC; Tris(2,3-epoxypropyl) isocyanurate; Tris(2,3-epoxypropyl)-s-triazine-2,4,6(1H,3H,5H)-trione; Isocyanuric Acid Triglycidyl Ester; 1,3,5-Triglycidylisocyanuric acid; Isocyanurate de triglycidyle (French); 1,3,5-tris(oxiranylmethyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione; Tris(epoxypropyl) isocyanurate; 1,3,5-tris(2,3-epoxypropyl)-s-triazine-2,4,6(1H,3H,5H)-trione; N,N',N''-Triglycidyl isocyanurate;

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

Structural formula:



2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

Classification according to part 3 of Annex VI, Table 3.1 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008:

Classification		Labelling		Specific Conc. Limits, M-factors	Notes
Hazard Class and Category Code(s)	**Hazard statement Code(s)**	**Pictogram, Signal Word Code(s)**	**Hazard statement Code(s)**		
Muta. 1B	H340	GHS06	H340		
Acute Tox. 3 *	H331	GHS08	H331		
Acute Tox. 3 *	H301	GHS05	H301		
STOT RE 2 *	H373 **	Dgr	H373 **		
Eye Dam. 1	H318		H318		
Skin Sens. 1	H317		H317		
Aquatic Chronic 3	H412		H412		

H301: Toxic if swallowed.

H317: May cause an allergic skin reaction.

H318: Causes serious eye damage.

H331: Toxic if inhaled.

H340: May cause genetic defects.

H373: May cause damage to organs.

H412: Harmful to aquatic life with long lasting effects.

Classification according to part 3 of Annex VI, Table 3.2 (list of harmonized classification and labelling of hazardous substances from Annex I of Council Directive 67/548/EEC) of Regulation (EC) No 1272/2008:

Classification	Labelling	Concentration Limits	Notes
Muta. Cat. 2; R46 T; R23/25 Xn; R48/22 Xi; R41 R43 R52-53	T R: 46-23/25-41-43-48/22-52/53 S: 53-45-61		E

R46: May cause heritable genetic damage.

R23/25: Toxic by inhalation and if swallowed.

R41: Risk of serious damage to eyes.

R43: May cause sensitization by skin contact.

R48/22: Harmful: danger of serious damage to health by prolonged exposure if swallowed.

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 proposed.

2.3 Self-classification

The registrants follow the harmonised classification except for the acute toxicity for which they give the following information:

"Recent data show that the classification for acute inhalation and acute oral toxicity is not appropriate. The classification below is based on the most recent hazard data".

Acute Tox. 4 H302: Harmful if swallowed.

Acute Tox. 4 H332: Harmful if inhaled.

All notifications other than the one from the registrants to the Classification and Labelling Inventory follow the harmonised classification given in 2.1.

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 toxic by oral and inhalation routes and classified as Muta. 1B. Recent animal toxicity studies indicated a potential for TGIC to cause genetic damage. There is concern that the substance could be a human carcinogen and could have adverse reproductive effects. [http://www.nicnas.gov.au/Publications/CAR/PEC/PEC1/PEC_1_Full_Report_PDF.pdf].

The substance is potentially persistent and toxic to environment.

The substance has wide dispersive use, high release for environment, high exposure for workers and presence in consumer goods.

3.3 Information on aggregated tonnage and uses

☐ 1 – 10 tpa	☐ 10 – 100 tpa	☒ 100 – 1,000 tpa
☐ 1,000 – 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	
☐ <1 . . . . . >+ tpa	☐ Confidential	

Please provide further details if appropriate

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

TGIC is used in various polyester powder coatings in the metal finishing industry, manufacture of plastics products According to the registration the substance is used by workers in industrial settings and by professional workers.

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)	

The substance was in 2012 (ED/87/2012) included in the Candidate List because it is mutagenic. From the SVHC support document:
"*The Industry has recognized that the available worker exposure data is outdated, and acknowledged the necessity to obtain occupational exposure monitoring data relating to the applications of TGIC in the European Union. Therefore the Industry will collect monitoring data and report this to support the planned Substance Evaluation for 2013*."
The substance evaluation has in the CoRAP update been postponed to 2015.

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)	

Detailed evaluation of the available data may lead to further information requirements.

3.6 Potential follow-up and link to risk management

☐ Restriction	☐ Harmonised C&L	☐ Authorisation	☐ Other (provide further details)

Depending on outcome of the substance evaluation.