Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name):	1,2,4-triazole
Chemical Group:	triazole
EC Number:	206-022-9
CAS Number:	288-88-0
Submitted by:	Belgium
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

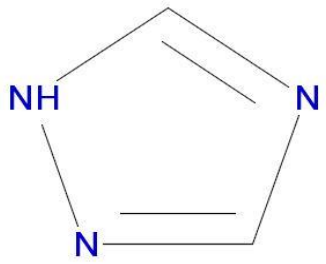
1.1 Other identifiers of the substance

Table 1: Substance identity

EC name:	1,2,4-triazole
IUPAC name:	1H-1,2,4-triazole
Index number in Annex VI of the CLP Regulation	613-111-00-X
Molecular formula:	$C_2H_3N_3$
Molecular weight or molecular weight range:	69.0653
Synonyms/Trade names:	1,2,4-Triazol 1,2,4-triazool 1,2,4-triazole 1H-1,2,4-Triazole

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

Structural formula:



1.2 Similar substances/grouping possibilities

NA

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

Index number 613-111-00-X

Repr. 2; H361d: Suspected of damaging the unborn child.

Acute Tox. 4; H302: Harmful if swallowed.

Eye Irrit. 2; H319: Causes serious eye irritation.

Signal word: Warning Pictograms: GHS07, GHS08

2.2 Self classification

- In the registration

Same as in Annex VI

- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:

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

2.3 Proposal for Harmonised Classification in Annex VI of the CLP

NA

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

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

Industrial uses:

Use as intermediate, laboratory chemicals, pharmaceuticals, fertilizers, washing and cleaning products, semiconductors.

Professional uses:

Handling and application by farmers as solid and liquid fertilizers.

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

Hazard based concerns		
CMR ☐C ☐M ☒R	Suspected CMR[1] ☐C ☐M ☐R	☐ Potential endocrine disruptor
☐ Sensitiser	Suspected Sensitiser[1]	
☐ 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)
Reprotoxicity: The substance is classified as Repr.2 (CLP). This classification has been discussed in 1996. It has been included by the 24th ATP (Directive 98/73/EC) in annex I of Directive 67/548. The available information in the registration dossier (although not enough details are provided) could suggest the need for a more severe classification.		

[1] 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

Other concerns:

Neurotoxicity:

In the two-generation study, neurotoxicity in the P-generation (at ~200 mg/kg/day) has been observed.

Carcinogenicity and endocrine disruption:

In the registration dossier of 1,2,4-triazole, 5 in vitro and 1 in vivo genotoxicity tests are negative. No carcinogenicity test is available.

However, based on data from aminotriazole (which belongs to the same family) carcinogenicity and endocrine disruption cannot be excluded.

Indeed, 3-amino-triazole induced inconsistent genotoxic effects in vitro, but no genotoxic effects in vivo. Thyroid tumors have been observed in rats and mice. Mechanism of these tumours is not genotoxic. An endocrine mode of action is presumed. Even if the relevance for the humans of this tumour induced mechanism is still under debate (INRS, toxicological fiche of Aminotriazole, edition 2008).

Changes of thyroid hormones levels have also been observed in fish following 3-amino-1,2,4-triazole exposure (Changes of thyroid hormone levels and related gene expression in Chinese rare minnow (Gobiocypris rarus) during 3-amino-1,2,4-triazole exposure and recovery, Li et al., 2009).

Therefore, some further assessment to clarify these indications might be initiated if warranted.

Consumers exposure:

1,2,4-triazole is a common metabolite of the triazole pesticides family, that can be absorbed by plants. This substance meets the definition as residue (regulation 1107/2009). The substance has also been found in farm animals, potentially exposed via their diet to residues of triazole.

Use of the substance as fertilizer can increase the consumer exposure. (ANSES "2011-SA-0207")

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 ; Biocidal Product Regulation (Regulation (EU) 528/2012)
☐ Annex XIV (Authorisation)	☐ Other (provide further details below)
☐ Annex XVII (Restriction)	
Information on other completed/ongoing regulatory processes was not found.	

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 ED potential	☐ Other (provide further details below)

The possible information to be requested will be linked to the initial grounds for concern as explained under section 4.3.

4.6 Potential follow-up and link to risk management

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

Depending on the outcome of the evaluation any of the above mentioned risk management measures could be initiated if warranted.

Regarding reprotoxicity, the available data could suggest a more severe classification, but more detailed information is needed in order to conclude.

Regarding the other potential concerns (endocrine disruption, neurotoxicity, carcinogenicity), it is too premature to consider risk management measures.