Justification for the selection of a substance for CoRAP inclusion

- Update -

Substance Name (Public Name):	3-Methylpyrazole
Chemical Group:	Pyrazole
EC Number:	215-925-7
CAS Number:	1453-58-3
Submitted by:	BE CA
Date:	17/03/2015 21/03/2017 (Updated version)

Note

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

Contents

1 IDENTITY OF THE SUBSTANCE

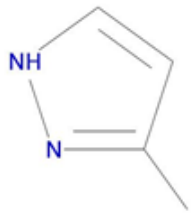
1.1 Other identifiers of the substance

Table 1: Substance identity

EC name:	3-methylpyrazole
IUPAC name:	3-methyl-1H-pyrazole
Index number in Annex VI of the CLP Regulation	NA
Molecular formula:	$C_4H_6N_2$
Molecular weight or molecular weight range:	82.10 g/mol
Synonyms/Trade names:	/

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

Structural formula:



1.2 Similar substances/grouping possibilities

Not known

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

NA

2.2 Self classification

- In the registration

Acute Tox. 4 H302: Harmful if swallowed.

Skin Corr. 1B H314: Causes severe skin burns and eye damage.

Eye Damage 1 H318: Causes serious eye damage

Repr. 2; H361: Suspected of damaging fertility or the unborn child <state specific effect if known> <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.
route of exposure: Oral

- The following hazard classes are in addition notified among the aggregated

Skin Irrit. 2; H315: Causes skin irritation

Eye Irrit. 2; H319: Causes serious eye irritation

STOT SE 3; H335 (Respiratory sys...)(Inhalation): May cause respiratory irritation

Acute Tox. 3; H331: Toxic if inhaled

STOT RE 2; H373(all organs): May cause damage to organs through prolonged or repeated exposure

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
*the total tonnage band has been calculated by excluding the intermediate uses; for details see the Manual for Dissemination and Confidentiality under REACH Regulation (section 2.6.11): https://echa.europa.eu/documents/10162/22308542/manual_dissemination_en.pdf/7e0b87c2-2681-4380-8389-cd655569d9f0		

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

Formulation
Handling of nitrification inhibitors and liquid fertilisers with nitrification inhibitors by retailers.
Handling and application of liquid fertilisers by farmers.

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.	

5 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

5.1 Legal basis for the proposal

☒ Article 44(2) (refined prioritisation criteria for substance evaluation)

☐ Article 45(5) (Member State priority)

5.2 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

5.3 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: self-classification in the registration dossier Repro 2 (but 31 notified C&L do not contain this classification)

There is a need for an assessment of the observed effects on offsprings in relation to the toxic effect of the substance on the maternal organisms.

If the effects on fetuses are not considered to be related to the observed maternal toxicity, the classification could be more severe.

Dose related reprotoxic effects are seen in an OECD Guideline 414 (Prenatal Developmental Toxicity Study). The test substance was administered to the animals orally (by gavage; 15, 45 and 90 mg/kg body weight) once a day during the period of major organogenesis (day 6 to day 15 p.c.).

Embryotoxic / teratogenic effects are:
At dose group 90 mg/kg, embryo-/foetotoxicity and clear indication for teratogenicity:
Besides reduced fetal body weights and delayed ossification, malformations of the urogenital tract, cardiovascular system, thoracic vertebral bodies were observed

At dose group 45 mg/kg, embryo-/foetotoxicity, but no teratogenic effects

At 15 mg/kg bw/day, no signs of developmental toxicity.

Maternal toxic effects are reported (details are not given)
At dose group: 90 mg/kg
-reduced food consumption
-significantly lower body weights

At dose group: 45 mg/kg
-reduced food consumption

Furthermore, there are indications that 3-methylpyrazole crosses the placental barrier.

Potential endocrine disruptor : concern linked to the group family (pyrazole)

[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

Exposure:
The registrant did not take into account the application of the fertilizer on crops and this is most likely the path with the highest environmental exposure. In view of the tonnage of the imported substance and the foreseen use, wide dispersive use is expected.

5.4 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)

An extended-one generation test could be requested to clarify the concern.

5.5 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.