

Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name): Methacrylamide

Chemical Group:

EC Number: 201-202-3

CAS Number: 79-39-0

Submitted by: Swedish Chemicals Agency

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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 Other identifiers of the substance

Table 1: Substance identity

EC name:	methacrylamide
IUPAC name:	methacrylamide
Index number in Annex VI of the CLP Regulation	NA
Molecular formula:	C ₄ H ₇ NO
Molecular weight or molecular weight range:	85.1045
Synonyms/Trade names:	2-methyl-2-propenamide 2-Propenamide, 2-methyl-

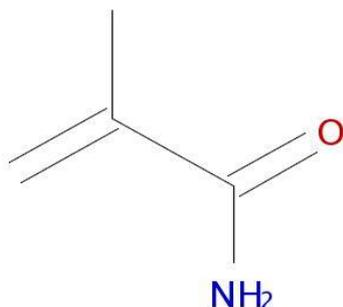
Type of substance

Mono-constituent

Multi-constituent

UVCB

Structural formula:



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

Eye Irrit. 2;H319: Causes serious eye irritation

STOT SE 3;H335: May cause respiratory irritation

STOT SE 2;H371: May cause damage to nervous system

STOT RE 2;H373: May cause damage to nervous system through prolonged or repeated exposure

- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory (including the number of notifiers):

Skin Irrit. 2 ;H315: Causes skin irritation (23)

Acute Tox. 4;H332: Harmful if inhaled (21)

Carc. 1B;H350: May cause cancer (1)

2.3 Proposal for Harmonised Classification in Annex VI of the CLP

None

3 INFORMATION ON AGGREGATED TONNAGE AND USES

From ECHA dissemination site			
<input type="checkbox"/> 1 - 10 tpa	<input type="checkbox"/> 10 - 100 tpa	<input type="checkbox"/> 100 - 1000 tpa	
<input checked="" type="checkbox"/> 1000 - 10,000 tpa	<input type="checkbox"/> 10,000 - 100,000 tpa	<input type="checkbox"/> 100,000 - 1,000,000 tpa	
<input type="checkbox"/> 1,000,000 - 10,000,000 tpa	<input type="checkbox"/> 10,000,000 - 100,000,000 tpa	<input type="checkbox"/> > 100,000,000 tpa	
<input type="checkbox"/> <1 >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		<input type="checkbox"/> Confidential	
<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input checked="" type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System
Methacrylamide is primarily used as a raw material in the production of chemicals with different applications such as in textiles, leather, fur, building and construction work etc.			

4 OTHER COMPLETED/ONGOING REGULATORY PROCESSES THAT MAY AFFECT SUITABILITY FOR SUBSTANCE EVALUATION

<input checked="" type="checkbox"/> Compliance check, Final decision	<input type="checkbox"/> Dangerous substances Directive 67/548/EEC
<input type="checkbox"/> Testing proposal	<input type="checkbox"/> Existing Substances Regulation 793/93/EEC
<input type="checkbox"/> Annex VI (CLP)	<input type="checkbox"/> Plant Protection Products Regulation 91/414/EEC
<input type="checkbox"/> Annex XV (SVHC)	<input type="checkbox"/> Biocidal Products Directive 98/8/EEC ; Biocidal Product Regulation (Regulation (EU) 528/2012)
<input type="checkbox"/> Annex XIV (Authorisation)	<input type="checkbox"/> Other (provide further details below)
<input type="checkbox"/> Annex XVII (Restriction)	
<p>In 2010, a compliance check decision was sent to the Registrant requesting information related to exposure assessment and a couple of physico-chemical properties. The Registrant submitted an updated dossier as response to the decision.</p>	

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 <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	Suspected CMR ¹ <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	<input type="checkbox"/> Potential endocrine disruptor
<input type="checkbox"/> Sensitiser	<input type="checkbox"/> Suspected Sensitiser ¹	
<input type="checkbox"/> PBT/vPvB	<input type="checkbox"/> Suspected PBT/vPvB ¹	<input checked="" type="checkbox"/> Other (please specify below)
Exposure/risk based concerns		
<input type="checkbox"/> Wide dispersive use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Exposure of sensitive populations
<input type="checkbox"/> Exposure of environment	<input checked="" type="checkbox"/> Exposure of workers	<input type="checkbox"/> Cumulative exposure
<input type="checkbox"/> High RCR	<input type="checkbox"/> High (aggregated) tonnage	<input type="checkbox"/> Other (please specify below)
<p>Methacrylamide has neurotoxic potential and it is self-classified for this hazard under Specific Target Organ Toxicity category 2 through both single and repeated exposure. Effects observed in acute or sub-acute studies include neuronal cell death in cerebellum, degeneration of sciatic nerve fibers, ataxia, decrease in muscle tone and grip strength. In a long term repeated dose toxicity study at a LOAEL of ca. 19.5 mg/kg bw/d effects on clinical signs, rotarod performance and histopathological changes of the nervous system were observed (SIAM 15, 22-25 October 2002, http://webnet.oecd.org/HPV/UI/handler.axd?id=b2742cf1-483a-4df6-80eb-b11a2da5ba27, last accessed 15-12-2014).</p> <p>The exposure assessment seems complex and needs further investigation to clarify if risks are under control in light of its neurotoxicity.</p>		

5.4 Preliminary indication of information that may need to be requested to clarify the concern

<input type="checkbox"/> Information on toxicological properties	<input type="checkbox"/> Information on physico-chemical properties
<input type="checkbox"/> Information on fate and behaviour	<input checked="" type="checkbox"/> Information on exposure
<input type="checkbox"/> Information on ecotoxicological properties	<input type="checkbox"/> Information on uses
<input type="checkbox"/> Information ED potential	<input type="checkbox"/> Other (provide further details below)
Further information concerning exposure estimation may be needed to clarify the concern.	

5.5 Potential follow-up and link to risk management

<input type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Restriction	<input type="checkbox"/> Authorisation	<input checked="" type="checkbox"/> Other (provide further details)
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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

Depending on the outcome of the evaluation, a risk management option analysis may need to be performed.