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

Date: 17/03/2015

Note

This document has been prepared by the evaluating Member State given in the CoRAP update.
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1 IDENTIFY OF THE SUBSTANCE

1.1 Other identifiers of the substance

Table 1: Substance identity

<p>| | |</p>
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td><strong>EC name:</strong></td>
<td>methacrylamide</td>
</tr>
<tr>
<td><strong>IUPAC name:</strong></td>
<td>methacrylamide</td>
</tr>
<tr>
<td><strong>Index number in Annex VI of the CLP Regulation</strong></td>
<td>NA</td>
</tr>
<tr>
<td><strong>Molecular formula:</strong></td>
<td>C₄H₇NO</td>
</tr>
<tr>
<td><strong>Molecular weight or molecular weight range:</strong></td>
<td>85.1045</td>
</tr>
</tbody>
</table>
| **Synonyms/Trade names:**| 2-methyl-2-propanamide  
                                      2-Propenamide, 2-methyl- |

**Type of substance**  ☑ Mono-constituent  ☐ Multi-constituent  ☐ UVCB

**Structural formula:**

![Structural formula image](image-url)
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

<table>
<thead>
<tr>
<th>From ECHA dissemination site</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ 1 – 10 tpa</td>
<td>☐ 10 – 100 tpa</td>
<td>☐ 100 – 1000 tpa</td>
<td></td>
</tr>
<tr>
<td>☒ 1000 – 10,000 tpa</td>
<td>☐ 10,000 – 100,000 tpa</td>
<td>☐ 100,000 – 1,000,000 tpa</td>
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</tr>
<tr>
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<td>☐ 10,000,000 – 100,000,000 tpa</td>
<td>☐ &gt; 100,000,000 tpa</td>
<td></td>
</tr>
<tr>
<td>☐ &lt;1 . . . . . . . . . . . . .</td>
<td>☐ Confidential</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

☒ Industrial use   ☒ Professional use   ☒ Consumer use   ☐ 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

| ☒ 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 XIV (Authorisation) | ☐ Other (provide further details below) |
| ☐ Annex XVII (Restriction) |

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.

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

<table>
<thead>
<tr>
<th>Hazard based concerns</th>
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</tr>
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<tbody>
<tr>
<td>CMR</td>
<td>Suspected CMR</td>
<td>Potential endocrine disruptor</td>
</tr>
<tr>
<td>☐ C ☐ M ☐ R</td>
<td>☐ C ☐ M ☐ R</td>
<td></td>
</tr>
<tr>
<td>☐ Sensitiser</td>
<td>☐ Suspected Sensitiser</td>
<td></td>
</tr>
<tr>
<td>☐ PBT/vPvB</td>
<td>☐ Suspected PBT/vPvB</td>
<td>☒ Other (please specify below)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Exposure/risk based concerns</th>
<th></th>
<th></th>
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<tbody>
<tr>
<td>☐ Wide dispersive use</td>
<td>☐ Consumer use</td>
<td>☐ Exposure of sensitive populations</td>
</tr>
<tr>
<td>☐ Exposure of environment</td>
<td>☒ Exposure of workers</td>
<td>☐ Cumulative exposure</td>
</tr>
<tr>
<td>☐ High RCR</td>
<td>☐ High (aggregated) tonnage</td>
<td>☐ Other (please specify below)</td>
</tr>
</tbody>
</table>

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).

The exposure assessment seems complex and needs further investigation to clarify if risks are under control in light of its neurotoxicity.

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)

Further information concerning exposure estimation may be needed to clarify the concern.

5.5 Potential follow-up and link to risk management

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

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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.