2 March 2017

Draft background document for 1-methyl-2-pyrrolidone (NMP)

Document developed in the context of ECHA's eighth recommendation for the inclusion of substances in Annex XIV

ECHA is required to regularly prioritise the substances from the Candidate List and to submit to the European Commission recommendations of substances that should be subject to authorisation. This document provides background information on the prioritisation of the substance, as well as on the determination of its draft entry in the Authorisation List (Annex XIV of the REACH Regulation). Information comprising confidential comments submitted during public consultation, or relating to content of registration dossiers which is of such nature that it may potentially harm the commercial interest of companies if it was disclosed, is provided in a confidential annex to this document.

Information relevant for prioritisation and/or for proposing Annex XIV entries provided during the public consultation on the inclusion of 1-methyl-2-pyrrolidone (NMP) on the Authorisation List or in the registration dossiers (as of the last day of the public consultation, i.e. 2 June 2017) will be taken into consideration when finalising the recommendation and will be reflected in an update of the present document.

Contents

1. Identity of the substance

Chemical name:	1-methyl-2-pyrrolidone (NMP)
EC Number:	212-828-1
CAS Number:	872-50-4
IUPAC Name:	1-Methylpyrrolidin-2-one

2. Background information for prioritisation

Priority was assessed by using the General approach for prioritisation of SVHCs for inclusion in the list of substances subject to authorisation[1]. Results of the prioritisation of all substances included in the Candidate List by December 2015 and not yet included or recommended in Annex XIV of the REACH Regulation is available at https://echa.europa.eu/documents/10162/13640/prioritisation_results_CL_substances_march_2017_en.pdf.

2.1. Intrinsic properties

1-methyl-2-pyrrolidone (NMP) was identified as a Substance of Very High Concern (SVHC) according to Article 57 (c) as it is classified in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as Toxic for Reproduction, Category 1B, H360D ("May damage the unborn child"), and was therefore included in the Candidate List for authorisation on 20 June 2011, following ECHA's decision ED/31/2011.

2.2. Volume used in the scope of authorisation

The amount of 1-methyl-2-pyrrolidone (NMP) manufactured and/or imported into the EU is, according to registration data (ECHA, 2016), in the range of 10,000 - 100,000 t/y.

Some uses appear not to be in the scope of authorisation, such as in plant protection products and some of the uses in the manufacturing of pharmaceuticals. Based on an OECD study (2007) on the world market from 2005, the volume corresponding to those uses would be ~30 % of the total volume. The Annex XV report (2011) assumes that a similar use distribution would apply for the European market. ECHA has no further information or indications that the situation regarding the share of uses outside the scope of authorisation on the European market has considerably changed since. Further minor uses in laboratories are also expected not to be in the scope of authorisation.

In the absence of further information, the volume in the scope of authorisation is estimated to be in the range of 10,000 - 100,000 t/y (70 % of total volume).

More detailed information on the main uses and the relative share of the total tonnage is provided in Annex I.

[1] Document can be accessed at http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf

2.3. Wide-dispersiveness of uses

Registered uses of 1-methyl-2-pyrrolidone (NMP) in the scope of authorisation include uses at industrial sites (formulation & (re)packing of substances and mixtures, in coatings, cleaning agents, oil field drilling and production operations, as binders and release agents, as functional fluids, polymer processing, water treatment), and uses by professional workers (in coatings, cleaning agents, oil field drilling and production operations, as binders and release agents, as functional fluids, road and construction applications, polymer processing).

Furthermore, use in plastic articles above 10 t/y has been notified (hoses of PVC). In addition, according to registration the substance may be present in coated articles.

The consumer use in ink is registered. NMP as a reprotoxic substance (Cat 1B) is banned for supply to the general public (entry 30 of Annex XVII to REACH). Hence, NMP should be used in inks supplied to consumers in concentrations below the concentration limit resulting in classification (see below), and therefore outside the scope of authorisation.

2.4. Further considerations for priority setting

There are two other regulatory processes currently ongoing or just recently been concluded.

Harmonised classification and labelling
The Annex VI entry of NMP was revised in the 9th ATP to CLP, removing the Specific Concentration Limit (SCL) of 5% for Repr. 1B (H360D) so that the Generic Concentration Limit (GCL) of 0.3% will apply. The 9th ATP entered into force 8 August 2016 and shall apply from 1 March 2018. This may have an impact on the number of industrial/professional users in the scope of authorisation.

Restriction
In August 2013, the Netherlands submitted a restriction proposal to require users of NMP to meet an exposure limit of 5 mg/m^3 and take appropriate skin protection measures. The opinions of RAC and SEAC were adopted 5 June 2014 and 25 November 2014, respectively, and were submitted to the Commission. RAC and SEAC recommended a harmonised DNEL of 10 mg/m^3 and 4.8 mg/kg/day for workers inhalation and dermal exposure, respectively, for use in registrants' chemical safety assessments. However, a draft amendment to Annex XVII (list of restrictions) has so far not been produced.

The Commission requested ECHA and SCOEL to work together to re-assess the current iOEL established by SCOEL and the DNEL set by RAC. The report of the two Committees was submitted to the Commission on 30 November 2016. However, it was not possible to agree on a joint health based limit value. The suggested restriction if it is implemented may influence the level of control at industrial sites and professional settings. However, any new limit value is not foreseen to have an impact on the volume in the scope of authorisation or the wide-dispersiveness of uses.

It should further be noted that NMP is a polar aprotic solvent that can be used (to some extent) in same applications as DMF and DMAC both of which have been already recommended for inclusion in Annex XIV, therefore also grouping considerations apply.

2.5. Conclusion

Verbal descriptions and scores			Total score (= IP + V + WDU)	Further considerations
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)		
NMP is classified as toxic for reproduction 1B meeting the criterion of Article 57 (c) Score: 1	The amount of NMP used in the scope of authorisation is in the range of 10,000 – 100,000 t/y Score: 15	NMP is used at industrial sites and by professional workers. Initial score: 10 Furthermore, the substance is used in articles in volumes > 10 t/y. Refined score: 12	28	Grouping with other polar aprotic solvents already recommended.

Conclusion
On the basis of the prioritisation criteria further strengthened by grouping considerations, NMP receives priority among the substances in the Candidate List (see link to the prioritisation results above). Therefore, it is proposed to prioritise NMP for inclusion in Annex XIV.

3. Background information for the proposed Annex XIV entry

Draft Annex XIV entries were determined on the basis of the General approach for preparation of draft Annex XIV entries for substances to be included in Annex XIV[2] and as further specified in the practical implementation document[3]. The draft Annex XIV entries for all the substances included in this draft recommendation are available at https://echa.europa.eu/documents/10162/13640/8th_recom_draft_axiv_entries_en.pdf.

3.1. Latest application and sunset dates

ECHA proposes to recommend the following transitional arrangements:

Latest application date (LAD): Date of inclusion in Annex XIV plus **18 months**

Sunset date: 18 months after LAD

The LAD slots are set in 3 months intervals (normally 18, 21 and 24 months after inclusion in Annex XIV).

Allocation of (groups of) substances to LAD slots aims at an even workload for all parties during the opinion forming and decision making on the authorisation applications. All substances can therefore not be set at the same LAD. ECHA proposes to allocate those

[2] General approach can be accessed at http://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf
[3] Practical implementation document can be accessed at https://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries_implementation_en.pdf

substances to the "later" LAD slots (21 months or more) for which the available information indicates a relatively higher complexity of supply chain.

Applying the criteria described in the implementation document[3] the time required for the preparation of application(s) for authorisation for NMP is assumed to be relatively shorter than for other (groups of) substances prioritised for this recommendation.

Therefore the substance is assigned to the 1st slot (LAD 18 months after inclusion in Annex XIV).

More detailed information is provided in Annex I.

3.2. Review period for certain uses

ECHA proposes not to include in Annex XIV any review period for NMP.

3.3. Uses or categories of uses exempted from authorisation requirement

3.3.1 Exemption under Article 58(2)

ECHA proposes not to recommend exemptions for uses of NMP on the basis of Article 58 (1)(e) in combination with Article 58(2) of the REACH Regulation.

3.3.2 Exemption of product and process oriented research and development (PPORD)

ECHA proposes not to recommend to include in Annex XIV any exemption from authorisation for the use of NMP for PPORD.

4. References

Annex XV report (2011): Proposal for identification of a substance as a CMR Cat 1A or 1B, PBT, vPvB or a substance of an equivalent level of concern. 1-methyl-2-pyrrolidone. Submitted by ECHA, February 2011.

https://echa.europa.eu/documents/10162/01e8a6d8-ba7a-474d-a640-49053005ec99

ECHA (2014): Background document by RAC and SEAC to the opinion on the Annex XV dossier proposing restrictions on 1-methyl-2-pyrrolidone (NMP). 25 November 2014.

https://echa.europa.eu/documents/10162/f6cd9c0f-47b0-48d0-abfa-8e4224b3620e

ECHA (2016): 1-methyl-2-pyrrolidone. ECHA's dissemination website on registered substances as of 1 June 2015.

https://echa.europa.eu/search-for-chemicals

OECD (2007): 1-methyl-2-pyrrolidone, SIDS Initial Assessment Report for SIAM 24, 19-20 April 2007, Paris, France.

RCOM (2011): Comments on an Annex XV dossier for identification of a substance as SVHC and responses to these comments. Document compiled by ECHA from the commenting period 21/02/2011-07/04/2011 on the proposal to identify 1-methyl-2-pyrrolidone (NMP) as a Substance of Very High Concern.

https://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807da281

Annex I: Further information on uses

The majority of the volume of NMP seems to be used in coatings, cleaning agents, as solvent in the electronics sector and in petrochemical processing (about 70 % according to OECD, 2007).

For electronics and petrochemical use, the number of sites seems limited (Annex XV report, 2011; RCOM, 2011).

The use in coatings and in cleaning agents seem to cover a wide range of mixtures in a high number of applications and sectors, having both industrial and professional users and including a number of SMEs. Typical concentrations of NMP in applied coating and cleaning products vary from 1 – 10 % and 5 - 15 % (in specific cleaning applications up to 60 %), respectively (Annex XV report, 2011). The supply chains for coating and cleaning products seem to be complex, with hundreds of formulators and thousands of industrial and professional end-users, but the information in the Annex XV report (2011) appears to generally relate to the coating and cleaning sectors, rather than specifically to NMP users.

The final background document to the RAC and SEAC opinion on proposing restrictions on NMP (ECHA, 2014) describes some uses in more detail by giving examples, e.g. non-wire coaters (automotive industry) using NMP in car coatings. The use descriptions given in that document were derived from registrations and the SVHC Annex XV dossier, but supplemented further by other sources, like stakeholder consultation, grey literature and product registries.

It is possible that the supply chains for the use of NMP in coatings and cleaning agents are affected by the change in the specific concentration limit for the harmonised classification as toxic for reproduction (9th ATP to CLP)[4]. According to the Annex XV report (2011), NMP can be used by consumers in coating and cleaning products in concentrations between 1 to 5 %[5]. Furthermore, a consumer use in ink is registered (no information on concentration available). In order to comply with entry 30 in Annex XVII of REACH, supply of such mixtures for the consumer market will not be allowed anymore unless the concentration of NMP in those products is reduced below 0.3 % w/w.

Regarding the use of NMP in the manufacture of pharmaceuticals, there are indications that NMP is used as penetration enhancer for a more rapid transfer of substances through the skin (Annex XV report, 2011). It seems that such kind of uses (i.e. where NMP is included in the final product) would be outside the scope of authorisation. Other information (Annex XV report, 2011; RCOM, 2011) suggests that NMP could also be used as solvent in the extraction, purification and/or crystallisation of drugs. These latter uses are likely to be in the scope of authorisation.

For the purpose of setting LAD[6], the following has been considered:

- Relevant life cycle stages: formulation, use at industrial sites, use by professional workers and service life.
- No specific information available on the number of industrial sites where the substance is used.
- The substance seems to be formulated in diverse products. Product categories considered as relevant: PC18, PC24, PC35, PC9a and PC17.
- The following use descriptors have been considered relevant to characterise the sectors of end uses: SU1, SU8, SU9, SU2a, SU16, SU17.
- The substance ends up in diverse article types. The following use descriptors have been considered as relevant to characterise them: AC1, AC2, AC0, AC13.

[4] That is, removal of SCL of 5% for Repr. 1B (H360D) to GCL of 0.3% (see Section 2.4)
[5] That use not confirmed in registrations
[6] See practical implementation document accessible at https://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries_implementation_en.pdf