5 February 2018

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) was taken into consideration when finalising the recommendation and is reflected in the present document. The extensive background documentation stemming from the recent restriction process (ECHA, 2014) was used in addition to the commonly used information sources referred to in the general prioritisation approach[1].

The background document also describes how ECHA has taken into account the MSC opinion.

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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.

The prioritisation results of the substances included in the draft 8th recommendation have been updated as necessary after the public consultation. The updated results are available at https://echa.europa.eu/documents/10162/13640/prioritisation_results_draft8threc_substances_february2018_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, 2017), in the range of 10,000 - 100,000 t/y.

Some uses appear not to be in the scope of authorisation, such as some minor uses in laboratories and the uses in plant protection products and in medicinal products (pharmaceuticals).

An OECD study (2007) on the world market estimated the volume of NMP used in the pharmaceutical and agrochemical industry to be ~30 % of the total volume (in 2005). The Annex XV SVHC report (2011) assumed a similar use distribution for the European market. Some information on future market shares was made available during the restriction process (ECHA, 2014, confidential Annex), however it did not allow to refine the exact share used in the pharmaceutical and agricultural sector at present. Therefore the same ~30 % given above are assumed for the priority assessment.

NMP can have different functions when used in the pharmaceutical and agricultural sector. Information provided within the SVHC identification process (Annex XV report and RCOM,

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

2011) and in the restriction background document (ECHA, 2014) indicates that NMP can be used both as process agent/solvent in e.g. the manufacture of active ingredients or of pharmaceuticals, and as component of the final products (e.g. use as penetration enhancer). Whereas the first use type (as process agent) is likely to be in the scope of authorisation, the latter (in which NMP ends up in the final medicinal or plant protection product) seem to be outside the scope of authorisation[2]. ECHA has no information on how much of the assumed combined market share of 30 % in these two sectors is used outside the scope of authorisation. However, even if it was assumed that the 30 % are used completely outside the scope of authorisation, the remaining volume of NMP in the scope of authorisation is still very high, i.e. in the highest volume range used for priority assessment.

In conclusion, the volume in the scope of authorisation is estimated to be in the range of 10,000 - 100,000 t/y. This corresponds to 70 % of the total volume which represents the estimated minimum amount used in the scope of authorisation.

Additional information on the main uses is provided in Annex I of this background document as well as in ECHA (2014).

2.3. Wide-dispersiveness of uses

Registered uses of 1-methyl-2-pyrrolidone (NMP) in the scope of authorisation include uses at industrial sites (e.g. formulation and (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 (e.g. in coatings, as functional fluids).

There is somewhat contradicting information regarding the use of NMP in articles. The use in plastic articles above 10 t/y has been notified (hoses of PVC). In addition, according to registrations the substance may be present in coated articles (NMP used in coatings). On the other hand, no article service life has been registered for NMP. Furthermore, a number of comment submitters, representing a significant share of the sectors where NMP can be used in the production of articles, pointed out that the substance is not, or only in amounts <0.1%, present in the final articles (ComRef, 2018). ECHA cannot further clarify the presence/non-presence of NMP in articles and its potential release from these. This uncertainty is expressed by the assignment of a range of 0-2 in the WDU assessment for the article service life (see Section 2.5).

The consumer use in ink is registered. However, it is not considered in the priority assessment. NMP as a reprotoxic substance (Cat 1B) is banned for supply to the general public (entry 30 of Annex XVII to REACH) for all its uses above the concentration limit resulting in classification (see also Section 2.4). Potential remaining uses, if any[3], should be limited to uses below the concentration limits. Those are outside the scope of authorisation and therefore not considered in the priority assessment.

More detailed information on uses is provided in Annex I.

[2] According to REACH Art. 2(5)(a) and Art. 56(4)(a). See also Q&A 1027 on ECHA's website.
[3] Some comments received in the public consultation claim that the consumer use in inks is outdated (ComRef, 2018).

2.4. Further considerations for priority setting

2.4.1. Impact of other regulatory process on the priority of the substance

In parallel to the recommendation process NMP has undergone two other regulatory processes further described below. ECHA has considered the impact of the future entry into force of these now concluded regulatory actions on the priority of the substance.

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% applies. The 9th ATP entered into force 8 August 2016 and shall apply from 1 March 2018.

It is difficult to predict what impact this will have on the uses of NMP. On the one hand it may be possible that the number of industrial and/or professional uses that fall under the authorisation requirement is higher when compared to the situation when the higher concentration limit was still in place. On the other hand obligations might exist from certain legislations (e.g. 94/33/EC on the protection of young people at work) that could lead to a reduction in professional uses, for example because the use of certain mixtures previously allowed is now prohibited.

Restriction

In August 2013, the Netherlands submitted a proposal to restrict the manufacture and use of NMP unless specified exposure limit values are met. In the REACH Committee in October 2017 the Member States voted positively on the draft Annex XVII amendment prepared by the Commission. After scrutiny by the European Parliament and Council, the restriction is foreseen to be adopted in the first half of 2018.

The suggested restriction sets exposure limit values for workers. Therefore, it may influence the level of control at industrial sites and professional settings. It remains to be seen, however, whether and to which extend the new limit values would have an impact on the volume in the scope of authorisation or the wide-dispersiveness of uses – factors which are taken into account in prioritisation.

2.4.2. Grouping consideration

NMP is a polar aprotic solvent that can be used (to some extent) in the same applications as DMF (N,N-Dimethylformamide, EC 200-679-5) and DMAC (N,N-Dimethylacetamide, EC 204-826-4) 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 Uncertainty about presence of the substance in articles in volumes > 10 t/y. [score 0-2] Refined score: 10-12	[26-28] 27	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, **NMP is recommended 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[4] and as further specified in the practical implementation document[5]. The draft Annex XIV entries for all the substances that underwent public consultation are available at https://echa.europa.eu/documents/10162/13640/8th_recom_draft_axiv_entries_en.pdf.

The final draft Annex XIV entries that ECHA recommends are available at https://echa.europa.eu/documents/10162/13640/8th_axiv_recommendation_february2018_en.pdf.

3.1. Latest application and sunset dates

ECHA recommends the following transitional arrangements:

Latest application date (LAD): Date of inclusion in Annex XIV plus **24 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).

[4] General approach can be accessed at http://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf
[5] Practical implementation document can be accessed at https://www.echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries_draft_implementation_en.pdf

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

In its draft recommendation, having applied the criteria described in the implementation document[5], ECHA had assumed the time required for the preparation of application(s) for authorisation for NMP to be relatively shorter than for other (groups of) substances prioritised for this recommendation.

During the public consultation comments from many different sectors were received. These comments indicated a higher complexity of the supply chain as well as a high number (> 100) of industrial use sites (ComRef, 2018).

In its opinion[6] the MSC proposes the consideration of a latest application date of 24 months for NMP. This proposal is based on the comments and information received through the public consultation.

ECHA has carefully assessed the comments submitted in the public consultation as well as the MSC opinion. Considering the additional information provided in the comments the LAD setting for NMP was re-assessed according to the criteria described in the implementation document[5]. Thus, NMP seems to have the most complex supply chain among the (groups of) substances in this recommendation.

Therefore the substance is assigned to the 3rd slot (LAD 24 months after inclusion in Annex XIV).

More detailed information is provided in Annex I.

3.2. Review period for certain uses

In its draft recommendation ECHA had seen no ground to include in Annex XIV any review period for NMP.

During the public consultation, comments on the need to have long review periods were received, but there were no specific requests for upfront review periods for certain uses (ComRef, 2018).

ECHA therefore **does not recommend to include in Annex XIV any review periods** for uses of NMP.

3.3. Uses or categories of uses exempted from authorisation requirement

3.3.1 Exemption under Article 58(2)

In its draft recommendation ECHA had not proposed any exemptions for (categories of) uses of NMP on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

[6] MSC opinion on ECHA's 8th draft recommendation available at https://echa.europa.eu/documents/10162/13576/msc_opinion_draft_8th_axiv_recommendation_en.pdf

During the public consultation ECHA received some requests for exemptions. Those were referring to other existing Community legislation but also to the upcoming restriction on NMP.

In its opinion MSC expresses the view that no information was submitted that would warrant the inclusion of a specific exemption for a use or a category of uses.

ECHA has carefully assessed all the requests made (see detailed assessment in Section C, in particular C.2, of the response document (RCOM, 2018)). ECHA concluded that there is currently no sufficient basis to propose Article 58(2) exemptions for a use or a category of uses of NMP.

ECHA therefore **does not 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)

In its draft recommendation ECHA had not proposed to include in Annex XIV any exemption from authorisation for the use of NMP for PPORD.

During the public consultation ECHA did not receive any specific requests for exemptions from the authorisation requirement for PPORD. One comment claimed that generally the use in PPORD should be exempt, giving as example the case of identification of an active ingredient in pharmaceutical research and development. However, no specific process details were provided nor a specific PPORD request made (ComRef, 2018; RCOM, 2018).

No PPORD notifications had been submitted by the end of public consultation.

ECHA therefore **does not recommend exempting any use of NMP for PPORD** from authorisation.

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

ComRef (2018): "Comments and references to responses" document. Document compiling comments and references to respective answers from commenting period 02/03/2017 – 02/06/2017 on ECHA's proposal to include NMP in its 8th recommendation of priority substances for inclusion in the list of substances subject to authorisation (Annex XIV).

https://echa.europa.eu/documents/10162/13640/8th_recom_comref_methylpyrrolidone_en.rtf

ECHA (2014): Background document by RAC and SEAC to the opinion on the Annex XV dossier proposing restrictions on 1-methyl-2-pyrrolidone (NMP)[7]. 25 November 2014.

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

ECHA (2017): 1-methyl-2-pyrrolidone. ECHA's dissemination website on registered substances as of 2 June 2017.

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

RCOM (2018): "Responses to comments" document. Document compiling the responses to comments by ECHA from the commenting period 02/03/2017 – 02/06/2017 on ECHA's proposal to include NMP in its 8th recommendation of priority substances for inclusion in the list of substances subject to authorisation (Annex XIV).

https://echa.europa.eu/documents/10162/13640/8th_recom_respdoc_methylpyrrolidone_en.pdf

[7] The background document is based on the restriction report submitted by The Netherlands (2013) but updated with relevant information received during the opinion forming process.

Annex I: Further information on uses

NMP is mainly used as solvent in various processes in a wide variety of applications.

During the restriction process, extensive work has been performed to collect and summarise information on uses. The final background document to the RAC and SEAC opinion on the proposed restriction on NMP (ECHA, 2014) presents the outcome of that work and will not be reproduced here. The underlying information stems from registrations but was supplemented by information from the SVHC Annex XV dossier, stakeholder consultations, grey literature and product registries (ECHA, 2014).

In ECHA (2014) the users of NMP were categorised in sector types. Exemplary major sectors given there:

- Petrochemical industries
- Formulators
- Non-wire coaters
- Wire coaters
- Cleaners
- Electronic and semi-conductor industries
- Battery industries
- Membrane manufacturers
- High performance polymer producers
- Agricultural chemical industry (formulation, synthesis)
- Pharmaceutical industry
- Laboratories
- Functional fluids
- Construction industry

In ECHA (2014), professional uses are described to take place in the following sectors: formulators, non-wire coaters, agricultural chemical industry, laboratories, functional fluids. It is stated that professional uses in some other sectors – although still in registrations – might be outdated or will be phased out over time e.g. in the cleaner sector. More information can be found in ECHA (2014) and references given therein.

In registrations (ECHA, 2017), there are professional uses registered to date, e.g. cleaning agent, oil field drilling and production operations, binders and release agents, road and construction applications, polymer processing. ECHA is not in a position to assess which (part) of this information may potentially be outdated.

Taking all available information into account, professional uses have therefore been considered in the priority assessment for NMP.

NMP is used in a wide range of processes leading to the production of articles. Based on the information available, it is unclear whether some of these processes lead to the incorporation of the substance in articles.

In the restriction background document (ECHA, 2014) uses of NMP in the production of articles are described and structured according to the most relevant sectors. NMP is used as solvent, cleaner or processing aid in the production of polymer articles and for polymer based coatings and binders used for article production. It has a high solvating power for plastics and resins.

Relevant sectors using NMP for the production of articles are:

- Polymer manufacturers (various types of polymers for wide range of applications)
- Wire coaters (coatings made from various polymers)

- Non-wire coaters (polymer based coatings and binders for many sectors, e.g. automotive industry)
- Electronics and (semi)conductor industry (electronic equipment, printed circuit boards and microelectronic and semiconductor elements)
- Battery industry (e.g. electrode production, coatings)
- Membrane manufacturers (membranes made from various polymers)
- High performance polymer producers (poly-aromatic polymers like para-aramid for the production of high-tensile yarns)
- Construction industry (may be used as primer or finish for production of articles)

In comments received during the public consultation on the Annex XIV recommendation the following uses of NMP for the production of articles are mentioned (ComRef, 2018):

- Use as solvent, reactant and catalyst in the production of high performance polymers (polyamide-imide, PAI; PAI enamels) for the electrical industry (e.g. manufacture of electric motors, generators and transformers)
- Use as solvent for PAI enamels for wire production
- Creation of electronic circuits on a substrate made of semiconductor materials (solvent in polymer coatings for silicon wafers and for wafer stripping used e.g. in IR detectors and optoelectronic devices)
- Use as process solvent in the production of positive electrodes of Li ion batteries
- Use as process solvent in the production of polymer based membranes (like polyether sulfones, PES) used in filtration applications for e.g. drinking water and blood dialysis.
- Use as processing aid in the production of a polymer (para-aramid) that is converted into high performance fibre products (e.g. anti-ballistic, stab resistant, heat and cut resistant textiles)
- Use as adhesive for layers of multilayer PVC hoses used as food contact materials
- Coated films

From a significant number of the sectors involved, comments were received in the public consultation stating that NMP is not contained in final articles or only in residual amounts <0.1% at which NMP has no function in the articles.

According to eight substance in article notifications[8], NMP is contained in several articles including flexible PVC hoses which may be used by consumers.

In registrations, there are indications that the substance may potentially end up in articles. A number of uses are reported using environmental release categories indicating inclusion of the substance into/onto articles/materials[9]. This includes the industrial uses in dip coating, as binders and release agents, for marking as well as the professional uses in road and construction applications, polymer processing, coating, marking. Besides, the use marking is flagged explicitly as having subsequent service life.

Structure and complexity of supply chain

For the purpose of setting LAD[5], the following had been considered for the draft recommendation based mainly on information in the registrations:

- Relevant life cycle stages: formulation, use at industrial sites, use by professional workers and service life.
- Product categories considered as relevant: PC18, PC24, PC35, PC9a and PC17.
- Sectors of end uses relevant: SU1, SU8, SU9, SU2a, SU16, SU17.
- Articles categories relevant: AC1, AC2, AC0, AC13.

[8] Number of SiA notifications as of 2 June 2017

[9] Relevant environmental release categories mentioned are: ERC5 - use at industrial site leading to inclusion into/onto article, ERC8c/f - widespread use leading to inclusion into/onto article indoor/outdoor

- No specific information available on the number of industrial sites where the substance is used.

During the public consultation further information on the complexity of supply chain was received (ComRef, 2018). Based on this information a further life cycle stage for service life and additional use descriptors relevant were acknowledged. Furthermore, it was recognised that there is a high number (> 100) of industrial use sites.

Consequently, the complexity of supply chain (vertical, horizontal, number of industrial use sites) were re-assessed to be the relatively highest of all the substances in this recommendation round.