

How to comply with REACH Restriction 71, guideline for users of NMP (1-methyl-2-pyrrolidone)

July 2019

ABC

Disclaimer

This document aims to assist users in complying with their obligations under the REACH Regulation. However, users are reminded that the text of the REACH Regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. In some sections reference is made to the obligations stemming from EU and national Occupational Safety and Health (OSH) legislation. However, the implementation of EU OSH Directives at national level can differ from the examples mentioned in this document. Usage of the information remains under the sole responsibility of the user. The European Chemicals Agency does not accept any liability with regard to the use that may be made of the information contained in this document.

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European Chemicals Agency

Mailing address: P.O. Box 400, FI-00121 Helsinki, Finland

Visiting address: Annankatu 18, Helsinki, Finland

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1. Introduction

1.1 Who is this guideline written for?

This document intends to help those who use 1-Methyl-2-pyrrolidone (NMP) or mixtures containing NMP (C ≥ 0.3%) , to comply with the restriction requirements under the REACH Regulation. Moreover this guidance may help the authorities to understand what is expected and evaluate the compliance at a site.

NMP has a harmonised classification as toxic to / for reproduction (reproductive toxicant category 1B) and is also a respiratory, skin and eye irritant. In Europe, NMP is subject to REACH Annex XVII restriction 71. If you have to use NMP in your workplace, you need to protect anyone that could be exposed to it. This guideline is intended to help you understand what you need to do to comply with the provisions of this restriction in its own right but also against the background of your existing occupational safety and health (OSH) obligations.

The general approach described in this guideline can be applied to other aprotic solvents similar to NMP (such as DMF and DMAC), if similar REACH restrictions are introduced for other aprotic solvents. Some elements of the guideline are NMP specific (e.g. good practice examples, monitoring methods, description of uses etc.) and therefore may not be directly applicable to other substances.

To ensure the scope of the guideline is clear, it is worth clarifying the meaning of some of the terms used in the document.

Use: as defined in the REACH legislation any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation.

User of NMP: in this guideline, the term user is to be understood as "end user" i.e. any actor using NMP or mixture containing NMP in his industrial or professional activities but not supplying it further.

Supplier of NMP: any actor that supplies NMP or mixtures containing NMP to other actors. Suppliers of NMP can be

- NMP registrants (manufacturers or importers)
- Downstream users supplying NMP (e.g. re-fillers)
- Distributors supplying NMP

Suppliers of mixtures containing NMP can be

- Registrants formulating and supplying mixtures containing NMP
- Downstream users formulating and supplying mixtures containing NMP
- Distributors supplying mixtures containing NMP.

Worker: In this guideline, the term worker is to be understood as any person employed by an employer including trainees and apprentices but excluding domestic workers¹ (see ILO C189) as well as professionals (e.g. self-employed working persons).

1.2 The restriction

Due to its hazardous properties, the use of NMP has been restricted by the European

¹ See ILO C189

https://www.ilo.org/dyn/normlex/en/f?p=NORMLEXPUB:12100:0::NO::P12100_INSTRUMENT_ID:2551460

Commission in April 2018. The restriction entry 71 of Annex XVII to REACH applies to the manufacture, placing on the market, and use of NMP and it sets out the following requirements:

1. *Shall not be placed on the market as a substance on its own or in mixtures in a concentration equal to or greater than 0.3% after 9 May 2020 unless manufacturers, importers and downstream users have included in the relevant chemical safety reports and safety data sheets, Derived No-Effect Levels (DNELs) relating to exposure of workers of 14.4 mg/m³ for exposure by inhalation and 4.8 mg/kg/day for dermal exposure.*

In practice paragraph 1 requires suppliers of NMP or of mixtures containing NMP (C ≥ 0.3% w/w) to perform a chemical safety assessment using the mandatory DNELs for workers of 14.4 mg/m³ for exposure by inhalation and 4.8 mg/kg/day for dermal. Suppliers must document this assessment in a report and communicate the results of the assessment (appropriate conditions of use and risk management measures) with the safety datasheet they provide to their customers. The mandatory DNELs need to be communicated in the safety data sheets regardless of tonnage. Suppliers of NMP must be compliant with this paragraph from 9 May 2020 onward.

2. *Shall not be manufactured, or used, as a substance on its own or in mixtures in a concentration equal to or greater than 0.3% after 9 May 2020 unless manufacturers and downstream users take the appropriate risk management measures and provide the appropriate operational conditions to ensure that exposure of workers is below the DNELs specified in paragraph 1.*

In practice paragraph 2 requires manufacturers, suppliers and users of NMP to use NMP or mixtures containing NMP (C ≥ 0.3% w/w) in a way that ensures workers are not exposed to NMP above the DNELs set in the restriction. NMP manufacturers and users must be compliant with this paragraph from 9 May 2020 onward.

3. *By way of derogation from paragraphs 1 and 2, the obligations laid down therein shall apply from 9 May 2024 in relation to placing on the market for use, or use, as a solvent or reactant in the process of coating wires.*

In practice paragraph 3 gives more time to suppliers and users of NMP as a solvent or reactant in the process of wire coatings to comply with the restriction. They must be compliant with paragraph 1 and 2 from 9 May 2024.

The restriction is published in the Official Journal of the European Union² and more information on the restriction dossier is available on the ECHA website³.

This guideline focuses on the compliance with paragraph 2 of the restriction, from the user point of view. The situation of users of NMP is different from the usual situation of users of substances or mixtures under REACH because the NMP DNELs are now mandatory for all actors and the timeline for compliance is set by the restriction.

² Commission Regulation (EU) 2018/588 of 18 April 2018 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards 1-methyl-2-pyrrolidone https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.099.01.0003.01.ENG&toc=OJ:L:2018:099:TOC

³ Restriction dossier on ECHA web site <https://echa.europa.eu/previous-consultations-on-restriction-proposals/-/substance-rev/1899/term?viewsubstances WAR echarevsubstanceportlet SEARCH CRITERIA EC NUMBER=212-828-1&viewsubstances WAR echarevsubstanceportlet DISS=true>

1.3 What is NMP?

NMP is an organic chemical compound identified with European Community number 212-828-1, CAS registry number 872-50-4 and by its molecular formula C_5H_9NO . NMP is imported into and manufactured in large volume (20,000 – 30,000 tonnes per year in 2017-18) in Europe. It is commonly used as a solvent in various industries such as petrochemical, surface treatment or pharmaceutical. For more information on uses, see Appendix 7.3.

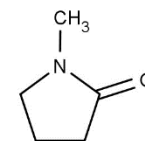


Table 1: 1-Methyl-2-pyrrolidone common names and main properties.

Property	Value
Common names	NMP, N-methyl-2-pyrrolidone, Methyl pyrrolidone, 1-methylpyrrolidone & N-Methylpyrrolidone
Appearance	Liquid at room temperature
Colour	Colourless
Odour	Slight amine (fishy) odour
Melting / freezing point	-24.2 °C at 101 325 Pa
Boiling point	204.1 °C at 101 325 Pa
Density	1.03 g/cm ³ at 25 °C
Vapour pressure	32 Pa at 20 °C
Water solubility	Miscible with water 1 000 g/L at 20 °C
Flash point	91 °C at 101 325 Pa
Biodegradation in water	Readily biodegradable (100%)

1.4 Hazards

NMP is a reproductive toxicant (it may damage the unborn child), causes serious eye irritation, causes skin irritation and may cause respiratory irritation. The European Union has recognised these hazardous properties and provided a harmonised classification (and labelling) under the Classification, Labelling and Packaging (CLP) Regulation. Since 1 March 2018, NMP has the classification presented in Table 2.

In the workplace environment, NMP can enter the body by inhaling vapours (or aerosols) of the substance, or via the skin from splashes or droplets, wearing soiled personal protective equipment and touching soiled surfaces. NMP present as vapour in the atmosphere can also enter the body via the skin.

Table 2: Harmonised classification of NMP.

Mandatory harmonised classification of NMP (CLP00, ATP09), index No 606-021-00-7		
Hazard class and category	Hazard code and statement	
Repr. 1B	H360D***	Reproductive toxicity, may damage the unborn child
Eye Irrit. 2	H319	Serious eye irritation, causes serious eye irritation
Skin Irrit. 2	H315	Skin irritation, causes skin irritation
STOT SE 3	H335	Specific target organ toxicity – single exposure, may cause respiratory irritation

The *** associated with H360D mean that the Repr. 1B classification was transposed from the previous legislation⁴ without any more recent examination under the CLP. However, the Repr. 1B classification was confirmed in the restriction dossier.

Note:

- For the classification Repr. 1B – H360D***, the generic concentration limit of $C \geq 0.3\%$ applies. Below this concentration, the classification Repr. 1B – H360D*** does not apply.
- For the classification STOT SE 3 - H335, there is a specific concentration limit of $C \geq 10\%$. Below this concentration, the classification STOT SE 3 - H335 does not apply.
- For the classification Eye Irrit. 2 – H319, the generic concentration limit of the generic concentration limit of $C \geq 10\%$. Below this concentration, the classification Eye Irrit. 2 – H319 does not apply.
- For the classification Skin Irrit. 2 – H315, the generic concentration limit of $C \geq 10\%$. Below this concentration, the classification Skin Irrit. 2 – H315 does not apply.

The following elements need to be visible on the label which is fixed to the NMP container/packaging:

Danger



Health hazard (GHS08)



Exclamation mark (GHS07)

Signal word

For further information on classification, labelling and packaging requirements, consult the Guidance on labelling and packaging in accordance with Regulation (EC) 1272/2008⁵.

1.5 What are DNELs?

Derived no-effect levels (DNELs) are the levels of exposure to a substance below which no negative health effects are expected to occur in humans. They are calculated from hazard information generated and collated for substance registration under REACH and function as reference values for chemical safety assessment. These no-effect levels are derived by registrants i.e. substance manufacturers and importers, as part of the REACH registration process for hazardous substances. In certain situations under REACH, DNELs may be derived

⁴ The European Directive on Dangerous Substances (DSD) covering dangerous substances was introduced in 1967 to protect public health, in particular the health of workers handling dangerous substances. The directive was replaced by a new law known as the Regulation on the Classification, Labelling and Packaging of Substances and Mixtures (CLP) from 20 January 2009.

⁵ Guidance on labelling and packaging https://echa.europa.eu/documents/10162/23036412/clp_labelling_en.pdf/

by authorities (restriction procedure) or may be recommended by ECHA's Risk Assessment Committee (authorisation procedure).

More than one DNEL can exist for a substance since the DNEL is exposure route- and effect-specific. In such cases, the combined risk also has to be considered where there are multiple routes applicable. Long-term/chronic systemic⁶ DNELs are calculated for a shift-long exposure. Therefore, they are to be used for the risk evaluation due to a daily exposure averaged over 8 hours.

When a chemical safety assessment is carried out for a substance under REACH, the DNELs are used as reference values to establish and identify the operational conditions⁷ and appropriate risk management measures⁸. The DNELs are compared with the exposure of a worker (based on measured or modelled data) for a specific use, or uses, of NMP under appropriate risk management measures. If the exposure level does not exceed the DNEL, the conditions of use are considered sufficient to adequately control the risks. If not, the operational conditions and risk management measures need to be revised until the level of exposure does not exceed the DNEL. If there are multiple routes of exposure (and multiple DNELs as in the case of NMP) then the combined exposure also from all routes has to be accounted for in the risk assessment.

Usually the chemical safety assessment is carried out by the registrant or the supplier. For practical reasons the exposure level is often estimated by the registrant using exposure modelling tools. Information on the conditions of safe use are provided with the extended safety data sheet.

For NMP, the DNELs for inhalation and dermal exposure have been derived by authorities, as part of the REACH restriction process. These specific, mandatory DNELs relating to inhalation and dermal exposure of workers must be applied in the chemical safety assessment by any manufacturer, importer, and (downstream) user if required, using the substance according to the conditions of the restriction.

In the case of NMP, the DNEL for inhalation is lower than the current European indicative occupational exposure limit (14.4 mg/m³ versus 40 mg/m³). These two values arise from separate but critical adverse health effects of reproductive (developmental) toxicity and respiratory irritation, respectively. So in practical terms, complying with the DNELs by applying the risk management measures described in the exposure scenario annexed to the safety data sheet should ensure that the applicable exposure limit is not exceeded. In addition to the inhalation DNEL, the dermal DNEL of 4.8 mg/kg bw/day is an important element in evaluation of the combined (systemic) effects from inhaled and dermally absorbed NMP. If you comply with the exposure scenario(s), the level of exposure should be below all relevant DNELs.

For NMP and some other substances, DNELs co-exist with occupational exposure limit values (OELs). DNELs and OELs do apply simultaneously to the same work activities. This may be confusing at first glance if the values are different. However, DNEL and OEL values are derived under different EU legislation. Both values are found in Section 8.1 of the safety data sheet.

⁶ *Systemic effect* means an adverse health effect when the substance is absorbed into the body, becomes distributed and acts on organs remote from the point of contact.

⁷ *Operational conditions* are the activities of workers related to the processes involved, and the duration and frequency of their exposure to the substance.

⁸ *Risk management measures* are measures to reduce or avoid direct or indirect exposure to workers.

Remember!

→ Derived no-effect levels (DNELs) and occupational exposure limits (OELs) contribute to protect workers against adverse health effects from chemical exposure at work.

→ By law, for NMP, you must take steps to comply with both the DNELs under REACH and European Union OELs adopted in implementation of Directive 98/24/EC on risks related to chemical agents as well as with the national limit values.

→ DNEL and OEL values are both found in Section 8.1 of the safety data sheet.

→ Adequate controls (operational conditions and risk management measures) must be in place to ensure that exposure of workers is below the value(s).

→ For NMP, recommended operational conditions and risk management measures are found in the exposure scenarios annexed to the safety data sheet.

→ Downstream users - as employers - are under the obligation to assess all the risks to which workers are exposed and to put in place the resulting preventive and protective measures. The safety data sheet provides very useful information to support this activity.

→ For NMP, controlling exposure below the DNEL should also ensure compliance with most national occupational exposure limit values.

More on occupational exposure limit values

Occupational exposure limit values (OELs) in parallel to DNELs, define the limit of the time-weighted average of the concentration of a chemical agent in the air within the breathing zone of a worker in relation to a specified reference period (typical 8-hours per day). Short term limit values define the level below which adverse health effects are unlikely to occur over 15 minutes exposure time as long as the 8-hour average is not exceeded. For NMP, both 8 hours and short-term indicative occupational exposure limit values exist (see Appendix 7.2, Table 6).

OELs are national, directly enforceable, limit values that must be set by Member States taking into account the occupational exposure limit values derived within the framework of European Directives, such as Directive 98/24/EC on risks related to chemical agents.

A worker must not be exposed above the occupational exposure limit. Employers are responsible for ensuring compliance with occupational exposure limits and must therefore have risk management measures in place to ensure that exposure to NMP is prevented or reduced to a minimum, at least controlled to a level below the occupational exposure limit.

As dermal uptake is a relevant route of exposure for NMP the indicative OEL is complemented with a skin notation, to limit overall exposure to the substance. Biological limit values for metabolites of NMP have been derived as a guideline for the control of potential health risks.⁹

⁹ Scientific Committee on Occupational Exposure Limits (SCOEL) List of recommended health-based biological limit values, June 2014

<https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=2ahUKewiyi8SdquHgAhWyposKHVRTBZIQfjAAegQIABAC&url=https%3A%2F%2Fec.europa.eu%2Fsocial%2FBlobServlet%3FdocId%3D12629%26langId%3Deu&usq=AOvVaw2URakCQKGLBgDWEJYWKR>

2. What you need to do to adequately control risk

When you purchase NMP, your supplier must provide you with an (extended) safety data sheet.¹⁰ Information about REACH restriction 71 can be found in the safety data sheet in Section 15. When exposure scenarios are attached, the operational conditions and appropriate risk management measures to adequately control the risk for each relevant use are described there. Downstream users are required by law to apply those risk management measures or take other appropriate action (see Section 2.3) to ensure that the level of exposure predicted in the exposure scenario is not exceeded. If you comply with the exposure scenario(s), you should be below all relevant DNELs.

There may be situations where you do not receive an updated safety data sheet e.g. because your last supply was more than 12 months before the restriction. Alternatively you may have received an updated safety data sheet but without any attached exposure scenarios e.g. because your supplier has registered <10 tonnes/year. The first thing to do in these situations is to contact your supplier and check (see Section 5). Remember the conditions imposed by REACH restriction 71 are still applicable, and must be complied with. Ultimately this means that you have to be able to demonstrate compliance according to your national requirements (mainly through monitoring the exposure; some Member States may accept modelling).

The next four subsections describe what you have to do according to the requirements of REACH. You should keep in mind that you also have to comply with your occupational safety and health (OSH) obligations (some aspects of this are covered in Section 2.5).

Your first step is to check whether your use of NMP is described in the extended safety data sheet that you have received with your substance.

2.1 How to check if your use is covered by the exposure scenarios received

You can do this by:

1. Checking your use(s): look at (i) the safety data sheet Section 1.2 on Identified uses, and (ii) in the title section of the attached exposure scenarios. Verify that your use(s) is/are described there (bear in mind that you may have multiple uses).

As a good practice, your supplier should provide a Table of Contents to the annex of exposure scenarios, so that you can easily identify the scenarios most relevant to your use(s).

¹⁰ *Extended* means that a registrant in your supply chain has registered the substance as being manufactured or imported into Europe in a quantity greater than 10 tonnes per year, and that the safety data sheet has exposure scenarios (ES) annexed to it. The registration number can be found in Section 1 of the safety data sheet.

Annex: Exposure Scenarios

- Index**
1. Use as a Process chemical
SU3; SU3; ERC4; PROC1, PROC2, PROC3
 2. Charging and discharging of substances and mixtures
SU3; SU3; ERC1, ERC2, ERC4; PROC8a, PROC8b, PROC9
 3. Formulation
SU3; SU3; ERC2; PROC1, PROC2, PROC3, PROC5, PROC14
 4. Use in laboratories
SU3; SU3; ERC4; PROC15
 5. Use in laboratories
SU22; SU22; ERC8a; PROC15
 6. Use in construction chemicals
SU3; SU3; ERC4; PROC10, PROC13, PROC14
 7. Use in Coatings
SU3; SU3; ERC4; PROC7, PROC10, PROC13
 8. Use in Coatings
SU3; SU3; ERC8a, ERC8c, ERC8d, ERC8f; PROC13
 9. Use in Cleaning Agents
SU3; SU3; ERC4; PROC3, PROC4, PROC5, PROC7, PROC10, PROC13
 10. Use in Functional Fluids
SU3; SU3; ERC4, ERC7; PROC17, PROC18

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ES Title indicating use(s) covered

If a Table of Contents is not provided then you have to check the title section of every exposure scenario to identify the ones that match your uses.

2. **Short title of exposure scenario**
Charging and discharging of substances and mixtures
SU3; SU3; ERC1, ERC2, ERC4; PROC8a, PROC8b, PROC9

Exposure scenario: Title section showing use(s) covered.

2. Checking your activities: In the exposure scenario(s) which corresponds to your use(s), (or contributing scenario(s) which corresponds with your tasks/activities), check the title sections to make sure that all your process types / tasks are described by the process categories listed there (normally written as PROC / ERC with a number e.g. PROC2 / ERC3).¹¹

Contributing exposure scenario	PROC8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities Use domain: industrial
Use descriptors covered	

Contributing scenario showing tasks/activities covered.

3. Checking your conditions of use: Compare the information given in the exposure scenario (often called the "contributing scenario for workers" or similar) with the operational conditions and the risk management measures that you apply in your workplace.

¹¹ PROC is an abbreviation of Process Category, which is a way of coding tasks, application techniques or process types from the occupational perspective. When estimating exposure with modelling tools some PROCs are associated with exposure reduction factors. ERC is an abbreviation of Environmental Release Category, and is a way of characterising a use and its potential for release or emission to the environment. Sector of use category (SU) describes in which sector of the economy the substance is used e.g. rubber manufacturing sector, agriculture, forestry, fishery etc. PROC, ERC, SU are elements of the use descriptor system.

Contributing exposure scenario	
Use descriptors covered	PROC8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities Use domain: industrial
Operational conditions	
Concentration of the substance	N-methyl-2-pyrrolidone Content: >= 0 % - <= 100 %
Physical state	liquid
Vapour pressure of the substance during use	32 Pa
Process temperature	20 °C
Duration and Frequency of activity	480 min 5 days per week
Indoor/Outdoor	Indoor
Risk Management Measures	
Provide a good standard of general or controlled ventilation (5 to 10 air changes per hour)	Effectiveness: 70 %
Wear chemically resistant gloves in combination with 'basic' employee training.	Effectiveness: 90 %
Provide a good standard of general ventilation (not less than 3 - 5 air changes per hour)	
Alternatively:, Ensure operation is undertaken outdoors.	
Use suitable eye protection.	

Contributing scenario showing operational conditions and risk management measures covered.

Applicable to this contributing scenario

NOT applicable to this contributing scenario

Applicable to this contributing scenario

If the conditions of use in your workplace differ from the exposure scenario of your supplier, you may still be able to demonstrate that, under your conditions of use, the exposure levels (for humans and the environment) are equivalent to or lower than under the conditions described by the supplier. When assessing the exposure level (using a modelling tool), modification of one factor can be compensated by modification of another factor. If applicable, your supplier should provide information (e.g. the scaling tool/method, the parameters that can be modified and their boundaries) in the exposure scenario to help you.

2.2 Use is covered by the exposure scenarios received

If the conclusion of your check is that your use is covered by one of the exposure scenarios received and that you have the appropriate risk management measures in place in the workplace, no further action under REACH is needed at this point. You should document your check and any action you have taken to guarantee the compliance with the conditions of use in the exposure scenario. Under worker protection legislation you may be required to monitor worker exposure (i.e. due to the existence of an OEL), and this can be used to confirm compliance. If the monitoring indicates otherwise then there are duties under REACH to inform your supplier that the risk management measures being communicated are inappropriate (see Section 5).

Taken together, applying the operational conditions and risk management measures described in the exposure scenario should ensure that exposure of workers is below the DNELs for both inhalation and dermal adverse effects. If you are unsure, then get advice from a competent person, for example an occupational hygienist.

2.3 Use is NOT covered by the exposure scenarios received

If the conclusion of your check is that your use is not covered by any of the exposure scenarios received (your use does not match any exposure scenario, or it deviates significantly from

them), then you have a number of choices.¹² Bear in mind the timeline for compliance with restriction 71 (May 2020), when considering the following options:

- Make your use known to your supplier with the aim of making it an “identified use” and included in the supplier’s chemical safety assessment under the REACH Regulation. Your supplier will then provide you with an updated extended safety data sheet / exposure scenario.
- If your use is included, but the conditions of use (operational conditions and risk management measures) differ significantly, implement the conditions of use described in the exposure scenario you have received. You may need to change your process or your existing control equipment in some way to match the conditions described in the exposure scenario.
- Substitute NMP with a different substance, for which an exposure scenario is available which covers your conditions of use.
- Find another supplier who provides NMP with a safety data sheet and exposure scenario that covers your use.
- If none of the above options are available or applicable, prepare a downstream user chemical safety report, and inform ECHA. Remember the conditions imposed by REACH restriction 71 are still applicable, and must be complied with. Check if any exemptions apply to you with regards to the downstream user chemical safety report i.e. if you use NMP in quantities less than 1 tonne per year, or for the purposes of product and process oriented research and development (PPORD). ECHA’s Practical Guide 17¹³ supports the preparation of a downstream user chemical safety report, and includes an example of how to use measured data to demonstrate that the risk is adequately controlled.

2.4 Checking your use: Mixture safety data sheet

If you purchase and use NMP in a mixture with the associated mixture safety data sheet, the same obligations apply to you as for a substance. However, it may be more difficult to identify your use and conditions of use (operational conditions and risk management measures), as the information may be incorporated into the safety data sheet itself rather than attached to it in an annex. You still have to do the checks described earlier but this time you may have to look in the main body of the safety data sheet to identify the relevant information. In this case, you should check the identified uses in Section 1.2 and see if there are any attachments / annexes to the safety data sheet where the conditions of use are described. If there are no attachments, then you need to look at the different sections in the main body of the safety data sheet for the information on the operational conditions and risk management measures; for instance, the most likely being Sections 7.3 and 8.2. If you conclude that your use is not covered, then the bullet points in Section 2.3 above will apply to you. Remember the conditions imposed by REACH Restriction 71 are still applicable, and must be complied with.

¹² For more details, consult ECHA’s Guidance for downstream users, Chapter 4.4.

https://echa.europa.eu/documents/10162/23036412/du_en.pdf/

¹³ ECHA’s Practical Guide 17 https://echa.europa.eu/documents/10162/13655/pg17_du_csr_final_en.pdf

2.5 How does the (extended) safety data sheet support your workplace risk assessment?

If you use NMP in your workplace, you should determine what measures and equipment need to be put in place to manage the risks, while being in line with the conditions of use described in the (extended) safety data sheet, at the same time complying with the provisions of the restriction. National legislation for the protection of the health and safety of workers from the risks related to chemical agents (like NMP) at work also requires you to carry out a workplace risk assessment. This risk assessment should document what specific preventive measures are required to reduce the risk. Pregnant workers are a particular target population / group given the adverse health effects that NMP has on the unborn child, and measures to avoid exposure should be taken to satisfy national requirements for the protection of pregnant workers.¹⁴ Information contained in the safety data sheet from your supplier must be taken into account in your risk assessment and you should determine if you can satisfy the conditions described in it. The assessment and the implementation of the preventive measures should be done before any new activity with NMP commences, and if there is any change in existing working conditions. If you consider that the information in the safety data sheet is not sufficient to enable you to assess any risk to health and safety of workers arising from the use of NMP, in particular the safety data sheet Section 8.2.1 on appropriate engineering controls, please contact your supplier (as described in Section 5).

Under the REACH Regulation, a supplier must update a safety data sheet without delay once a restriction has been introduced, identify it as "Revision: (date)", and provide the new version to all former recipients supplied by them in the preceding 12 months. The receipt of a new safety data sheet from your supplier should trigger a review of your workplace arrangements for the control of exposure of your workers to NMP. You should identify what changes in the operational conditions and risk management measures are now described for your use(s) in the exposure scenarios, and what changes are necessary to your existing workplace exposure control equipment and supporting management systems.

According to worker protection legislation, the hierarchy of control measures means that you should focus on preventing exposure of your workers (by all routes, e.g. inhalation, skin contact, oral) as a priority i.e. substitute by a safer substance or process technology. Where exposure may still occur, technical or engineering controls will need to be applied to minimise risk and exposure for inhalation and dermal (direct or vapour skin contact) at source, for example by enclosing the process or tasks, e.g. with suitably designed containment and associated local exhaust ventilation¹⁵, complemented by the provision of organisational arrangements e.g. reducing the number of workers exposed (or avoiding particular target populations/groups) or duration of their exposure. Only when these approaches have been exhausted and if a residual risk remains, should personal protective equipment be considered. If, based on the workplace risk assessment, you have doubts about the appropriateness of the risk management measures communicated to you in the (extended) safety data sheet, you should communicate with your supplier (see Section 5).

Please remember that personal protective equipment is specific to the wearer and so more than one type / style of personal protective equipment (respiratory protective equipment,¹⁶

¹⁴ Council Directive 1992/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding.

¹⁵ Correct installation and operation of an LEV system is essential to ensure exposure is controlled; for guidance see <http://www.hse.gov.uk/lev/employers.htm>

¹⁶ For good practice on respiratory protective equipment, see <http://www.hse.gov.uk/respiratory-protective-equipment/how-to-choose.htm>

gloves¹⁷ or protective clothing) may be required across your workforce. For all exposure controls introduced, their selection, installation, worker training, operation / use, and maintenance must be properly managed by you. More details on the S.T.O.P. principle - Substitution, Technical measures, Organisational measures, Personal protection - can be found on the EU OSHA web site^{18, 19}. There is a tendency to adopt strategies which rely heavily on personal protective equipment when controlling dermal exposure. This is incorrect. The risk management strategy for dermal exposure should follow the same philosophy as that for inhalation exposure. The hierarchy of control applies equally to all exposure routes. For dermal, technical measures such as automation, barriers, design of tools must be considered before personal protection. If the risk cannot be sufficiently controlled by technical/ organisational measures, then the only remaining strategy may be to rely on personal protective equipment.

Your existing exposure controls, as determined by your existing workplace chemical risk assessment, will have been based upon previous exposure scenarios provided by your supplier(s) and considering existing national limit values (i.e. occupational exposure limit values, and in some cases, national biological limit values). The NMP restriction introduces a new harmonised no adverse health effect value at European level, which is lower than existing national occupational limit values, which will still need to be complied with. Following the conditions described in the exposure scenario(s) for your use(s) of NMP, should help you to achieve exposure lower than the national limit values. In applying these conditions, you should follow the hierarchy of control measures (see above). For NMP, both 8 hours and short-term indicative occupational exposure limit (OEL) values exist in parallel to DNELs (see Appendix 7.2, Table 6). Adequate controls must be in place to ensure that exposure of workers is below these values.

Appendix 7.1 provides a flowchart to illustrate the steps, decisions and action you need to take. Further advice can be obtained from your national authority.

Remember!

- NMP is a reproductive toxicant and its use is restricted in Europe.
- The restriction for NMP will have triggered a revision to the safety data sheet for the substance (and of mixtures containing it) provided by your supplier(s). More specifically, the operational conditions and risk management measures recommended to be put in place as exposure controls may have changed. In case you have been supplied in the last 12 months but you have not received an updated safety data sheet, and think that you should have, please contact your supplier.
- Review your own use(s) of NMP against the revised (extended) safety data sheet from your supplier, modify your process and/or control equipment where necessary, record your decisions and instruct your workforce.
- Comply with the hierarchy of control measures (S.T.O.P. principle) at your workplace(es).

¹⁷ For good practice on glove selection and glove management, see <http://www.hse.gov.uk/skin/employ/gloves.htm>

¹⁸ EU OSHA https://osha.europa.eu/sites/default/files/publications/documents/WEB-info-sheet-legislation-HWC-2018-19_0.pdf

¹⁹ Refer to ECHA's Guidance for downstream users https://echa.europa.eu/documents/10162/23036412/du_en.pdf/

3. Examples of good practices to control exposure to NMP

Controlling exposure during industrial processes where NMP is used will require that risk management measures are designed and implemented at each step (or task) where the substance is used and there is a potential for exposure. Although NMP is used in a wide number of sectors and settings, many activities or tasks are common across industry sectors. Table 3 below gives an overview of some generic tasks and examples of good practices for the control of inhalation and dermal exposure. It is important to note that this is not a comprehensive list and that other risk management measures may be suitable to control exposure as well.

The examples and handling recommendations provided in this section are not meant to exempt every employer from their responsibility to assess and manage the risks at their own site in accordance with applicable national requirements and guidance.

Table 3: Some examples of good practices to control exposure.

Task	Possible PROCs	Good practices to control exposure	Example of use
Loading, unloading	8B, 9	Vapour recovery system Permanent and (semi-)closed systems such as piping and dedicated hoses (or arms) for loading and unloading of NMP trucks/containers	Formulation, chemical processes, coatings. When substance or mixture is delivered in large quantities (truck).
Storage	0 - other	Dedicated area Closed containers Integrated retention designed to retain any spillage	Most uses will include storage
Transfer	8B, 9	Permanent and (semi-)closed systems such as piping for regular transfers where possible Fume cabinet Local exhaust ventilation	Most uses will contain some transfer operations
Mixing	5, 19	Closed systems where possible Local exhaust ventilation	Formulation, chemical processes, cleaning, coatings
Sampling	1, 2, 3, 4, 9*	Closed sampling valves where possible Local exhaust ventilation	Formulation, chemical processes, coatings
Spraying	7, 11	Automation Full enclosure	Cleaning, coatings
Wiping (roller application or brushing)	10	Fume cabinet Local exhaust ventilation	Cleaning, coatings
Dipping / pouring	13	Automation Closed systems where possible Full enclosure Covered dipping tanks Local exhaust ventilation	Cleaning, coatings
Laboratory activities	15	Fume cabinet	Laboratory use, quality control of samples

Task	Possible PROCs	Good practices to control exposure	Example of use
Maintenance	28	Clean and purge any system/equipment before maintenance	Most uses will contain some maintenance operations
* Sampling activity may be included in a more general activity such as closed transfers (PROC 1 – 4) or transfer into small containers (PROC 9).			


Technical measures such as engineering controls aim at enclosing (fully or partially) and removing fumes or vapours from the tasks where NMP is used and will help to control both inhalation and dermal exposure. Organisational measures such as special working methods (standard operating procedures, written working instructions, permits to work etc.) aim to separate the worker from harm (restrict access), reduce the exposure time (by design, ergonomic organisation, provision of appropriate personal protective equipment), and ensure workers are aware of the risk and properly trained to apply the technical measures correctly, to handle emergency measures and to use the personal protective equipment when it is required (fitting, wearing, removing and maintenance).

Where open tasks are involved, best possible and well maintained exhaust ventilation, good housekeeping and occupational hygiene practices as well as correct use of appropriate personal protection equipment become increasingly important to control exposure. Special attention should be given to prevent surface contamination and spillage.

3.1 Illustrated examples

Concrete and illustrated examples of some of the risk management measures listed in Table 3 are shown below. These examples are not exhaustive but illustrate the type of equipment that some companies have in place to control exposure for different tasks. It should be recognised that certain exposure control equipment may be specific to a few industry sectors. The examples included below have been kindly provided by some of the stakeholders mentioned in the acknowledgments.




 Elements for consideration from the assessment/modelling of exposure to workers under REACH.

 Additional safety measures (not necessarily for exposure control to hazardous substances).

3.1.1 Charging and discharging

Bulk: Road tanker / truck or other tank container

Charging and discharging at tank farm or from a buffer tank in case of a continuous production process (PROC 8b).

		<p>Filling pipe</p> <p>Safety rope and harness (work is 4m above ground level)</p> <p>LEV pipe</p> <p>Chemical resistant gloves and goggles (not visible)</p> <p>Cone ensures fitting, and effectiveness of LEV</p> <p>Safety shoes, working clothes</p>
	<p>Above: Tank container at filling station (outdoor)</p> <p>Below: Opening of dome</p> <p>Picture is showing inserting of the filling pipe & risk minimization measures.</p> <p>Manual task: coupling and decoupling</p>	
<p>Personal sampling representing exposure during a normal shift at a tank farm/filling station operations (example from a company) measured concentrations of 0.003 – 0.12 mg/m³. Moreover, five out of twelve results were below the LoD or LoQ.</p> <p>Standard personal protection equipment for the worker: gloves, goggles for manual handling with potential exposure (e.g. sampling), working clothing, safety shoes, helmet.</p> <p>There are special tasks requiring additional measures e.g. loading and unloading from railcars (precautionary splash protection), maintenance etc. Requirements for additional safety measures are defined in the workplace risk assessment by the local occupational safety advisor knowing the exact working environment.</p>		

3.1.2 Transfer operations

Standard IBC – container (intermediate bulk container, IBC)

Semi-automatic filling of IBC (PROC 8b)



	<p>Product supply and off-gas pipes</p> <p>LEV with capturing hood</p> <p>Filling pipe</p> <p>Electrical grounding</p>
<p>The task is conducted indoor with enhanced ventilation. A fork lifter is used to place the IBC under the filling station. The filling pipe is inserted automatically and the filling is done automatically. Manual tasks with potential exposure: closing of the IBC with the cap.</p>	
<p>Standard personal protection equipment for the worker (not shown): gloves, goggles, working clothing, safety shoes.</p>	
<p>Personal sampling representing exposure during a normal shift showed NMP concentrations of 0.023 - 0.046 mg/m³.</p>	

Standard Drum


Semi-automatic filling unit for drums (PROC 8b)

	<p>Product supply</p> <p>LEV</p> <p>Filling pipe</p>
<p>The details of the unit are more or less identical with details of the filling unit of an automated filling line.</p>	
<p>Standard personal protection equipment for the worker (not shown): gloves, goggles, working clothing, safety shoes.</p>	
<p>Personal sampling representing exposure during a normal shift showed NMP concentrations of 0.003 - 0.064 mg/m³. Comparable measurement without LEV resulted in a detectable concentration of 0.11 mg/m³.</p>	

Automatic filling unit for drums

	
<p>Loading of empty drums for automated filling</p>	<p>Outside control of automated filling in a closed chamber</p>
<p>The filling task and capping the drum with the lid is performed automatically in the closed chamber.</p>	
<p>Standard personal protection equipment for the worker: gloves, goggles, working clothing, safety shoes, helmet.</p>	
<p>Due to the full containment of the NMP filling inside a closed chamber, a potential of exposure towards the worker does not exist.</p>	

3.1.3 Transfer into small container

<p>Perform volume transfer in a fume cupboard</p>	
<p>Use moveable sashes (horizontal and vertical) to shield unused areas to optimize air-flow around into the fume cupboard -> minimized working area </p>	
<p>Prefer small storage canisters (here 10 litres) -> one person can handle it safely and ergonomically without space consuming equipment and place storage canister upright again after usage -> no leakage possible</p>	
<p>Prefer the use of drain taps with pressure compensation (liquid flow out of and air flow into the canister happen at the same time in a controlled manner -> even liquid flow)</p>	
<p>Wear protection clothing according to the SDS: shoes, Lab coat, gloves, eye/face protection</p>	
<p>Use plastic bottles that are suitable for your application</p>	
<p>Place drip catcher below and clean after usage -> clean and dry floor</p>	
<p>No monitoring data available however, exposure modelling with Stoffenmanager estimates levels clearly below the limits.</p>	



Task: filling small containers for further analysis in a laboratory setting. The labels are attached to the bottles once the transfer is completed.

The task is performed in a fume cupboard specified in accordance with DIN EN 14175, with the vertical shash only partially opened during the task.

Standard personal protection equipment for the worker: gloves, goggles, working clothing, safety shoes.

Personal sampling representing exposure during a normal shift showed NMP concentrations of 0.022 - 0.27 mg/m³.

3.1.4 Storage

	<p>Dedicated area</p> <p>Integrated retention</p> <p>Container under permanent ventilation and air conditioning, equipped with flame and temperature detection</p> <p>No specific PPE for workers (only handling of the closed IBCs)</p>
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3.1.5 Sampling


Semi-closed sampling

	<p>Product containing line</p> <p>Fixed connector</p> <p>Off-gas line</p> <p>Sampling bottle</p>
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Standard operations like manual sampling require personal protection equipment: gloves, goggles for manual handling with potential exposure, working clothing, safety shoes, helmet (when outside the building).

Personal sampling representing exposure during a normal shift showed NMP concentrations of 0.004 - 0.083 mg/m³.

Sampling point

	<p>Double block valve (1: gate valve, 2: needle valve)</p>
	<p>Drain to slop system</p>
	<p>Pressure: 14 bars, Temperature: 36 °C</p>
<p>Sample taken 3 times per day (once per shift). Task takes about 5 minutes. PPE: normal PPE (incl. goggles) and additionally NMP resistant gloves</p>	

3.1.6 Preparation for maintenance


High level description of the preparations that equipment such as filters, pumps or short piping undergo before being sent for maintenance. The first step is to obtain permit-to-work.

1. Block out up- and downstream pipework, if possible with double-block-and-bleed valve arrangement.
2. Drain equipment of NMP to slop vessel/container, preferably connected to flare for lighter hydrocarbon fraction components. Slop is recovered and returned to the process or disposed of with certified waste disposal handler. If no flare connection is available, vent vessel/container to safe location to prevent worker exposure.
3. Preferably flush equipment with water to slop vessel/container, bio treatment plant or disposal container. Flushing is done while the equipment is still closed. Flush water is fed into the equipment via dedicated nozzles.
4. Purge with nitrogen to slop vessel/container or disposal container with vent to safe location or disposal to bio treatment plant
5. Set spectacle blinds up- and downstream at the interfaces with equipment that is still under pressure (to avoid spillage in case of leaking valves).
6. Dismantle / open equipment for final cleaning.
7. Jet wash the piece of equipment with high pressure water in the plant or at dedicated area.
8. Hand over to maintenance or workshop personnel to carry out maintenance task(s).

PPE:

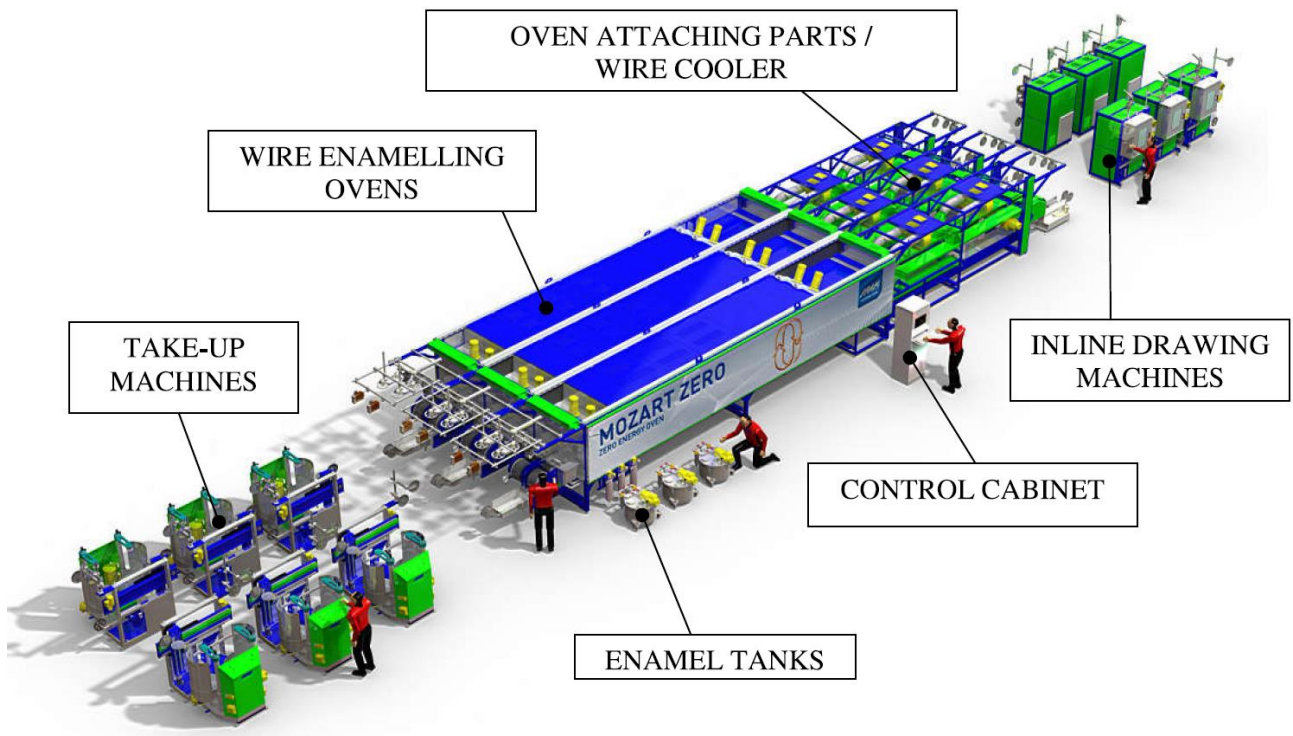
- For open system (such as jet washing): NMP resistant gloves, chemical resistant overall and face shield.
- RPE is used during blinding (step 5).
- For closed system: high shoes, flame retarding suit, gloves helmet and goggles.

3.1.7 Cleaning equipment using NMP

	<p>Gloves, face shield, full chemical resistant overall to be protected against potential NMP projections during manual cleaning</p>
	<p>PROC28</p>
<p>Task: Cleaning of large industrial mixers with recycled NMP. The task takes about 2-3 hours and is conducted a maximum of 15 to 20 times per week.</p>	

3.1.8 Wire winding, sector example

For illustration, here is an example of a new type of enamelling machine for serial production of wire winding (Source: MAG Maschinen- und Apparatebau AG). Wire winding operations with this type of machine can be associated with PROC 2. Occupational airborne measurement (personal sampling) have shown typical inhalation values <math><1 \text{ mg/m}^3</math> in the vicinity of the machine.



A. Enamel supply

Enamel is a mixture containing typically 20-50% NMP. The mixture can be supplied in large quantities by road tanker or in IBCs (intermediate bulk container).

Example of unloading enamel from a road tanker to storage tanks in the enamelling department. At this installation, this operation is conducted weekly and takes a maximum of one hour.

⇒ Indication of direction of flow.

Vapour recovery from
enamel tank to road
tanker

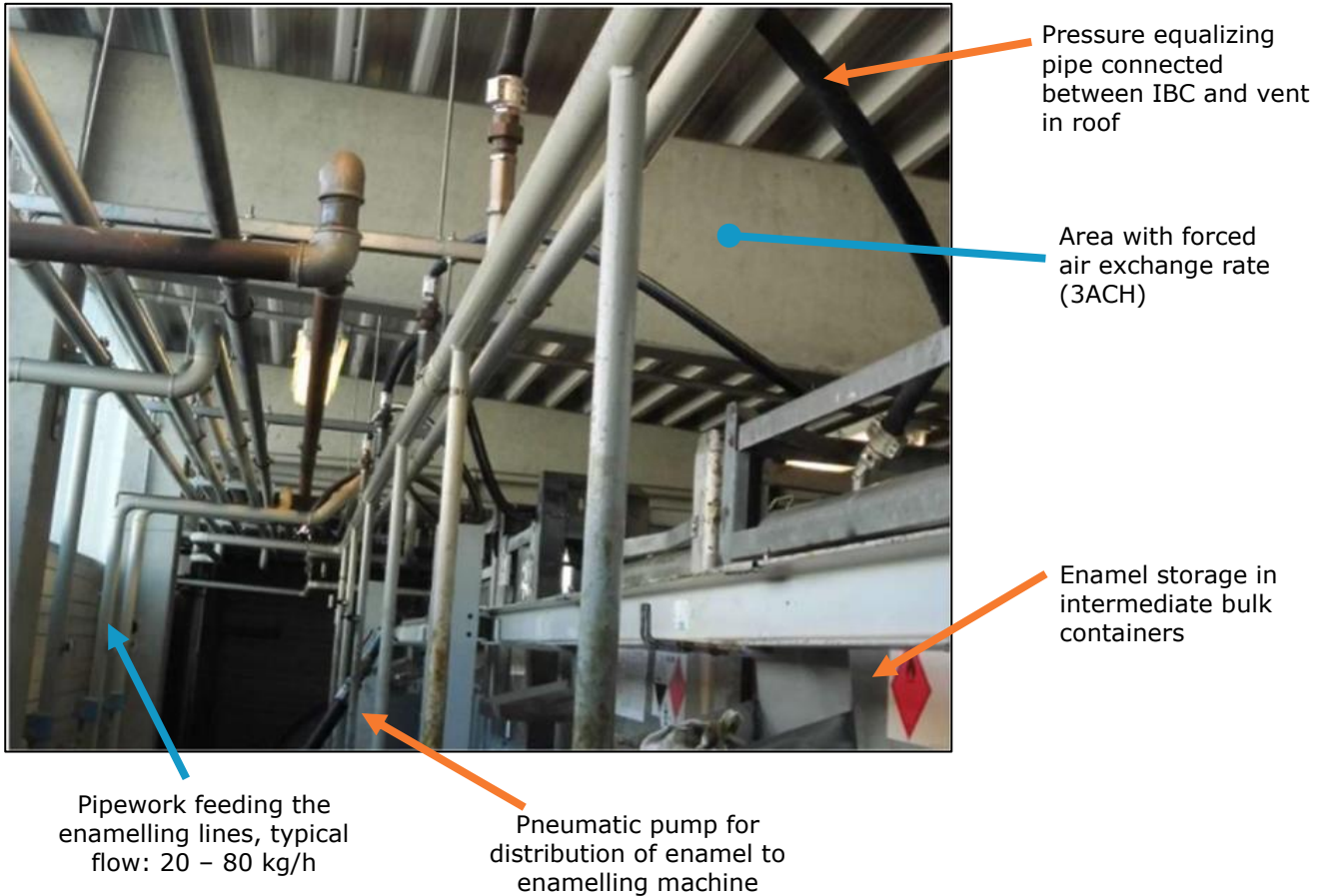
Additional unloading
pipework (not in use
here)



Unloading pipework to transfer
enamel from road tanker to
enamel storage tank

B. Central enamel storage

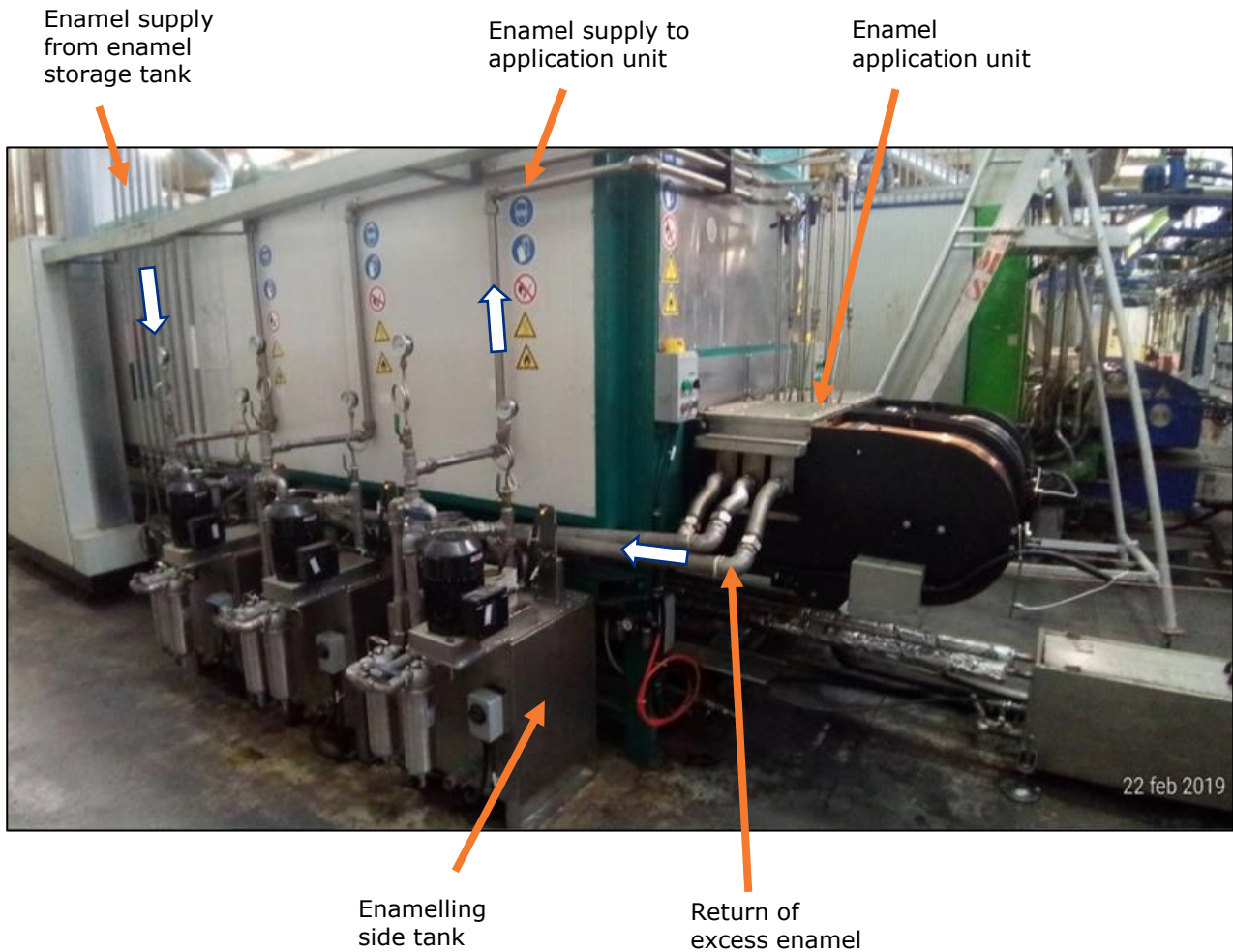
The NMP containing enamel, as all other enamels, are stored in a dedicated area with control access. Here is an example of a facility where the enamel is delivered and stored in intermediate bulk containers (IBC).



The containers are connected to a closed central pipework system and enamel is pumped automatically to the enamel coating machinery. During normal production, no manual operation with enamels at the machinery is necessary.

C. Enamel supply at enamelling machine

⇒ Indication of direction of flow.

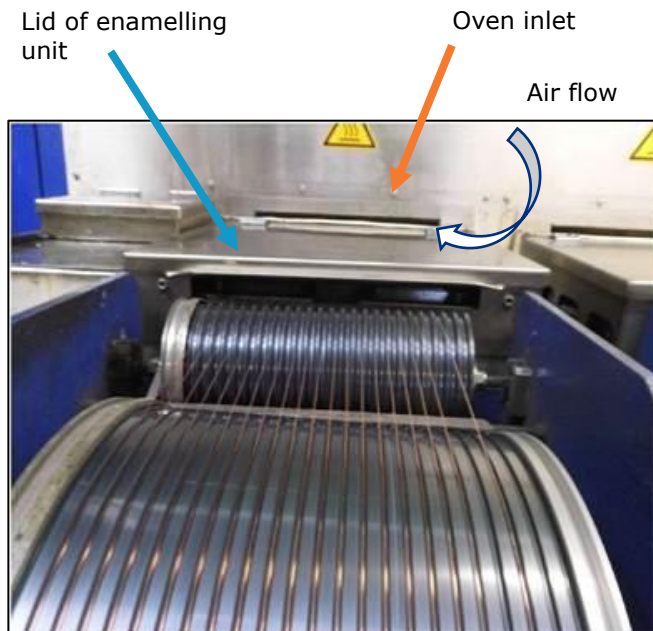


D. Enamel application unit

One wire runs several times through the enamelling oven (in the picture below, the same wire can be seen coiled several times). At each passage through the application unit, a thin coat of enamel is applied on the wire. The enamel is slowly and constantly extruded through a small tube, the wire is pulled through the enamel at the tip of the tube. It is then passed through a die that scrapes superfluous enamel off the wire. The wire then enters the oven for curing. The excess enamel is recovered and recirculated in a closed system (see Enamel supply at enamelling machine above).

The lids of the application units are always closed during the process. The enamelling chamber at the inlet of the oven is maintained under negative pressure to capture emissions from the enamel supply system, and to contain any degradation products or products of combustion from entering the workplace air. The ventilation is part of the regulation system of the enamelling machine and is monitored.

The combination of the die arrangement and the negative pressure from the oven extracts vapours generated during the process into the oven where they are burned off with the help of a catalyst.



E. Cleaning Process

Cleaning of enamelling side tank

Manual cleaning of side tank using NMP is conducted on rare occasions only in a closed room with air extraction. The work takes place on a designated table.

The operator is protected with safety glasses, chemical resistant gloves and other equipment like an apron and forearm protection. Additionally the operator wears respiratory protection.



3.1.9 Additional good practice material

German Federal Institute for Occupational Safety and Health (BAuA) material on the safe filling of organic liquids (English content): <https://www.baua.de/EN/Topics/Work-design/Hazardous-substances/Working-with-hazardous-substances/Organic-liquids.html?pos=1>

European Solvent Industry Group (ESIG) material to encourage responsible and safe handling of solvents at work: <https://www.esig.org/product-stewardship/solventwork/>

4. Monitoring and checking compliance

Under the REACH restriction, the primary duty for the NMP user in ensuring the exposure of workers is below the DNELs is to comply with risk management measures described in the exposure scenarios attached to or incorporated into the body of the safety data sheet. Under the worker protection legislation, the S.T.O.P. (see Section 2.5) and minimisation principles need to be followed when complying with the OEL set for NMP to keep the exposure not only below the limit value but also as low as possible in line with the ALARA²⁰ principle that applies for substances that are not carcinogenic or mutagenic. However companies should check that the Member States in which they operate have not implemented stricter legislation for substances that are toxic to reproduction. An important aspect of the good control practice in complying both with the NMP DNELs and OEL is to ensure that workers are properly trained, the process integrity is maintained and associated technical or engineering controls and personal protective equipment are appropriately used and maintained.

Under the worker protection legislation, the employer must assess the risk and take the necessary preventive measures to ensure the exposure to hazardous chemicals is appropriately managed. This may include some form of measurements or exposure modelling in line with national requirements. Exposure measurements are generally preferred over modelling. In some Member States, monitoring of exposure is a legal requirement when a substance has an exposure limit value. This may involve air sampling and/or biological monitoring of the worker as part of health surveillance. The workplace risk assessment may detail what kind of monitoring is necessary and how it should be performed. An equation in Section 7.2 in Appendix 2 provides a method for exposure calculation with a work shift longer than eight hours.

NMP users commonly verify exposure levels by workplace air monitoring according to a recognised standard. Air sampling is an established practice to verify that the exposure by inhalation remains below the national occupational exposure limit value. For substances readily absorbed through the skin, like NMP, the evaluation of exposure by the inhalation route may underestimate the body's uptake. In such a case there may be a role for biological monitoring with a validated method that provides information on the total exposure to NMP (inhalation and skin absorption) if required by national legislation. An example of a biological monitoring method that uses urine analysis is available in Section 7.2 in Appendix 2.

Even if the aim of exposure monitoring is normally to verify compliance with an OEL, manufacturers and users of NMP may also use the monitoring data to demonstrate that the risk management measures communicated in the exposure scenario deliver compliance with the NMP restriction in their site-specific operational conditions. Available surveillance methodologies include the EN-689²¹ or national equivalent, which provides a methodological framework for monitoring exposure by inhalation. Others include the BOHS / NVvA guidance²², the French (INRS NMP M-15²³) and German (TRGS 402²⁴) methodologies. Chapter R.14 of the ECHA Guidance on IR&CSA²⁵ also provides advice on exposure estimation (including use of measurements) in Section R.14.6. A few examples of analytical techniques with the potential to fulfil the requirements for workplace exposure can be found in Appendix 2. Occupational safety and health authorities or service providers may have information available about local

²⁰ As Low As Reasonably Achievable

²¹ Abstract of EN 689 https://oem.bmj.com/content/75/Suppl_2/A199.3

²² NVvA guidance <https://www.arbeidshygiene.nl/-uploads/files/insite/2011-12-bohs-nvva-sampling-strategy-guidance.pdf>

²³ French INRS NMP M-15 http://www.inrs.fr/publications/bdd/metropol/fiche.html?refINRS=METROPOL_15

²⁴ German TRGS 402 <https://www.baua.de/EN/Service/Legislative-texts-and-technical-rules/Rules/TRGS/TRGS-402.html>

²⁵ ECHA Guidance R.14 Occupational exposure assessment
https://echa.europa.eu/documents/10162/13632/information_requirements_r14_en.pdf/

requirements and available methodologies.

Enforcement of the compliance with the NMP restriction may be carried out by national labour inspectors and/or REACH enforcement authorities depending on the Member State. Users of NMP should contact their national authorities for advice on local requirements.

5. Why and when to communicate with your supplier

According to the restriction, the new DNEL values have to be communicated to users of NMP in the safety data sheet and the users of NMP need to implement the appropriate risk management measures and provide the appropriate operational conditions to ensure that exposure of workers is below these DNELs. The deadline set to comply with these requirements is 9 May 2020 (9 May 2024 for use as a solvent or reactant in the process of coating wires).

Every downstream user has an important role to play in the way this transition happens. By being in active contact with your suppliers of NMP, you can make sure they are aware of your uses and can provide you with the necessary information in time.

There are specific situations where it is important that you contact your supply chain. For instance:

- Once a restriction has been imposed, suppliers need to add the restriction information into their safety data sheet without undue delay. They also need to send the updated document to customers they have supplied to during the last 12 months preceding the update. If you have not yet received an updated document, contact your supplier and clarify when you can expect an updated safety data sheet.
- There may be situations where you have received an updated safety data sheet but without any attached exposure scenarios e.g. because your supplier has registered <10 tonnes/year. If in doubt, contact your supplier to clarify this point.
- If you have information showing that the conditions of use described in the safety data sheet you have received from your supplier are inappropriate, you need to inform your supplier.
For example, if you have air sampling (static or personal) results for NMP showing that the exposure levels at the workplace are above the DNEL for inhalation although the operational conditions and risk management measures in place correspond to those described in the extended safety data sheet for the use. This is an important information to share with your suppliers, so that they can review the recommendation given in the extended safety data sheet.
- You may source NMP from several suppliers. If you notice that the operational conditions and risk management measures described in the extended safety data sheets for the same use differ from one supplier to another, it is recommended to contact your suppliers. In this way, the suppliers can explain the reason for the difference or even come to an agreed set of operational conditions and risk management measures for the use.

Is the information in the safety data sheet applicable to your own use? If the way you use NMP is not described, or is different from what is described in the extended safety data sheet you have received from your supplier, it is important to clarify the situation with your supplier.

- If your use or conditions of use are not covered by any of the exposure scenarios received from your suppliers, one of your options is to ask your supplier to include your use / conditions of use in their chemical safety report and to provide you with an exposure scenario for it (see Section 2.4). You need to make sufficient information available to your supplier to enable them to make such an assessment. Your sector

organisation may have developed a sector use map²⁶ as a convenient means of supplying an overview of the relevant uses and associated conditions of use specifically for your sector.

- If the risk management measures described contradict the hierarchy of control measures or it is difficult to know if you have implemented all RMMs with the right efficiency required for safe use (for example, efficiency for the ventilation or the gloves), contact your supplier to clarify the situation.
- If you use a mixture containing NMP, it is likely that no exposure scenario is attached to the safety data sheet you receive from your supplier. It may be difficult to recognise if exposure scenario information has been integrated into the main body of the document. If in doubt, contact your supplier to clarify this point.

Last but not least, suppliers of NMP may be aware of alternative substances or technologies for some use of NMP that could be relevant for your process and may enable you to substitute NMP.

²⁶ The use map is a concept developed to improve the quality of the information on use and conditions of use communicated from downstream users to suppliers and the efficiency of this communication process. See <https://echa.europa.eu/csr-es-roadmap/use-maps/concept>

6. References and further reading

Interim Guidance for National Labour Inspectors on how to use Occupational Exposure Limits (OELs), Derived No Effect Levels (DNELs) and Derived Minimal Effect Levels (DMELs) when assessing effective control of exposure to Chemicals in the workplace; SLIC WG Chemex, 2015 <http://ec.europa.eu/social/BlobServlet?docId=15614&langId=en>

Guidance for National Labour Inspectors on the interaction of the Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (REACH) (Regulation (EC) No. 1907/2006), the Chemical Agents Directive (CAD) and the Carcinogens and Mutagens Directive (CMD); SLIC, 2013 <http://ec.europa.eu/social/BlobServlet?docId=11812&langId=en>

Restriction entry in the European Commission's Official Journal https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.099.01.0003.01.ENG&toc=OJ:L:2018:099:TOC

Restriction dossier on the ECHA website https://echa.europa.eu/previous-consultations-on-restriction-proposals/-/substance-rev/1899/term?viewsubstances_WAR_echarevsubstanceportlet_SEARCH_CRITERIA_EC_NUMBER=212-828-1&viewsubstances_WAR_echarevsubstanceportlet DISS=true

Guidance for downstream users, ECHA, October 2014 https://echa.europa.eu/documents/10162/23036412/du_en.pdf/9ac65ab5-e86c-405f-a44a-190ff4c36489

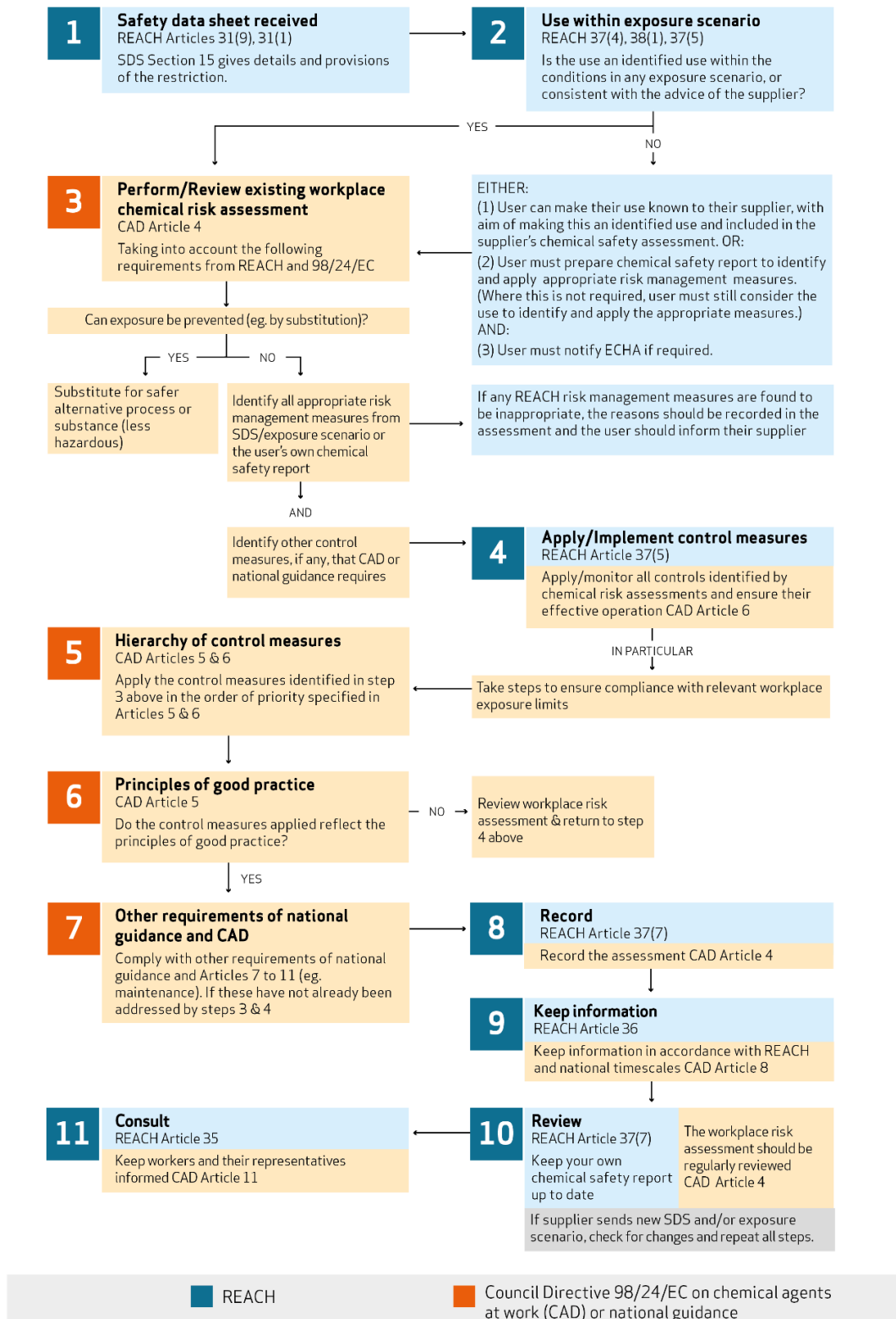
How to prepare a downstream user chemical safety report, Practical guide 17, ECHA, September 2015 https://echa.europa.eu/documents/10162/13655/pg17_du_csr_final_en.pdf/03aeab25-405a-45a4-9a66-5fa5c2dbfcb2

How downstream users can handle exposure scenarios, Practical guide 13, ECHA, July 2016 https://echa.europa.eu/documents/10162/13655/du_practical_guide_13_en.pdf

Regulatory management option analysis (RMOA) for three aprotic solvents: DMF (EC 200-679-5), DMAC (EC 204-826-4) and NMP (EC 212-828-1) <https://echa.europa.eu/documents/10162/>

7. Appendixes

7.1 Appendix 1. Flowchart to illustrate REACH and Chemical Agents Directive interaction



Flowchart adapted from the Senior Labour Inspectors' Committee's Guidance for National Labour Inspectors on the interaction of REACH and the Chemical Agents Directive..., November 2013 (see link in Section 6).

7.2 Appendix 2. Potential analytical methods

The sampling and analysis methods used to compare exposure concentrations with a limit value should fulfil certain requirements in terms of uncertainty and measuring range among other parameters.

The standard EN 482 "Workplace exposure. General requirements for the performance of procedures for the measurement of chemical agents" provides requirements for methods for sampling and analysis used to compare exposure concentrations with a limit value. In terms of measuring ranges the method should be able to measure 0.1-2 times the occupational exposure limit for an 8-hour time-weighted average (TWA).

The methods included in Table 4 below have validation data that show compliance with the requirements of the standard EN 482 or potential to meet these requirements for the DNEL value. The list of methods by which NMP can be monitored in the air at the workplace is non-exhaustive and only aims to illustrate that it is possible to measure concentrations to show compliance with the DNEL.

Validation data can be consulted in the "methods sheets" provided by the Gestis – Analytical methods database²⁷ or in the actual analytical method.

Table 4: Potential analytical methods for workplace exposure (air) monitoring

Method/type of sampling	Analytical technique	Limit of quantification LOQ and (sampling volume and/or time)
NIOSH Method 1302 (Activated charcoal tube)	GC/NPD ⁽¹⁾ GC/ FID ⁽²⁾	0.16 mg/m ³ (120 l) 2.4 mg/m ³ (120 l)
OSHA PV2043 (Activated charcoal tube)	GC/FID	0.2 mg/m ³ (10 l, 50 minutes)
MAK method 1 (Rosenberger et al., 2014)	GC/MS	0.15 mg/m ³ (40 l, 2 hours)
MAK method 2 (Breuer et al. 2015) ²⁸	MS/N-FID	0.42 mg/m ³ (40 l, 2 hours)

(1) Gas Chromatography – Nitrogen Phosphorus Detector

(2) Gas Chromatography – Flame Ionisation Detector

Exposure calculation with a work shift longer than 8h

It is not uncommon that a worker has a work-shift longer than 8 hours in a day. Calculation methods exist whereby the exposure of a worker in any 24-hour period can be treated as equivalent to a single uniform exposure for 8-hours, the 8-hour time-weighted average (TWA) exposure. The general formula to calculate the daily exposure is given by:

$$\frac{C_1T_1+C_2T_2+\dots+C_nT_n}{8}$$

²⁷ Gestis – Analytical methods database <http://www.dguv.de/ifa/gestis/gestis-analysenverfahren-fuer-chemische-stoffe/index-2.jsp>

²⁸ Rosenberger, W., Bader, M. (2011). Method 3. N-Methyl-2-pyrrolidon. In: Parlar, H., Brock, TH., Hartwig, A., eds. The MAK Collection Part III: Air monitoring methods, Vol. 12; pp. 133-144; Wiley-VCH, Weinheim

where C_1 is the occupational exposure and T_1 is the associated exposure time in hours in any 24-hour period. This approach can also be applied to give the same protection to extended work shift workers that is given to usual work shift ones. The European standard EN:689 Annex G *Workplace exposure - Measurement of exposure by inhalation to chemical agents - Strategy for testing compliance with occupational exposure limit values* provides some examples of applications of the calculation method²⁹; other methods exist at national level³⁰.

Biological monitoring

NMP is readily absorbed through the skin and dermal exposure thus is considered to contribute significantly to the internal NMP dose. There is no legal requirement in the REACH restriction on NMP to perform biological monitoring. However, biological monitoring can be a very useful complementary technique to air monitoring. Biological monitoring is the measurement and assessment of hazardous substances or their metabolites in tissues, secretions, excreta or expired air, or any combination of these, in exposed workers. Measurements reflect absorption of a substance by all routes (inhalation, dermal and oral). This approach has been summarised by SCOEL in its recommendations on NMP (SCOEL, 2016)³¹. Any biological monitoring undertaken in association with a guidance value needs to be conducted on a voluntary basis i.e. with the fully informed consent of all concerned. Guidance values are intended to be used as tools to ensure adequate control on exposure is being achieved. Where a value is exceeded, it does not necessarily mean that any corresponding airborne standard has been exceeded or that ill health will occur. It gives an indication that investigation into current control measures and work practices is necessary.

The SCOEL recommendation (SCOEL, 2016) provides biological limit values (BLV) for metabolites of NMP based upon the indicative occupational exposure limit value of 40 mg/m³, which can be used as general quantitative biomarker for NMP exposure. Where industry carries out biological monitoring, the data can be compared with the biological limit values but can as well be used to determine the overall NMP exposure of the worker using NMP.

Given that the REACH restriction on NMP introduces the DNEL for workers of 14.4 mg/m³ for exposure by inhalation, a biomarker for NMP that corresponds to the DNEL is described in the next section. Where industry carries out biological monitoring, the data can be compared with the biomarker to be sure the risk management measures are sufficient.

Suggested biomonitoring approach for NMP³²

5-hydroxy-N-methyl-2-pyrrolidone (5-HNMP) and 2-hydroxy-N-methylsuccinimide (2-HMSI) are the major urinary metabolites and the preferred biomarkers of exposure. Biological half-lives of 5-HNMP and 2-HMSI after inhalation exposure are 6-8 h and 16-28 h, respectively (SCOEL, 2016). Currently 5-HNMP is the one which is most often used in commercial laboratories in Europe. If significant dermal exposure is anticipated, 2-HMSI might be a better biomarker than 5-HNMP because of its longer half-life.

The optimum sampling time for 5-HNMP is 2-4 h after the work-shift, and for the longer half-life metabolite 2-HMSI, the sampling time is 16 h after the exposure (on the morning after an

²⁹ EN689:2018, CEN

³⁰ Health and Safety Executive, EH40/2005, 2018 Calculation methods, p.33

³¹ SCOEL/REC/119 N-Methyl-2-Pyrrolidone. Recommendation from the Scientific Committee on Occupational Exposure Limits, European Union, 2016. <https://publications.europa.eu/en/publication-detail/-/publication/c0dbb7a4-0c3a-11e6-ba9a-01aa75ed71a1/language-en>

³² Reproduced with permission from Simo Porras and Tiina Santonen, Finnish Institute of Occupational Health (FIOH). For full explanatory text see https://echa.europa.eu/documents/10162/13641/entry_71_exp_note_biomonitoring_en.pdf.

8 h work-shift). It should be noted that because of the longer half-time of 2-HMSI, some accumulation during the work week may occur. This may result in higher levels in the end of the work week when compared to the samples taken in the second morning of the work week.

Based on the data of Bader et al. (2007)³³, the urinary metabolite concentrations corresponding to the present inhalation DNEL of 14.4 mg/m³ can be derived. Since 10 mg/m³ air level was the lowest level tested in Bader's study, no extrapolation to lower concentrations, which could create some uncertainties, is needed.

The following biomarkers **for NMP** are suggested:

5-HNMP: 25 mg/g creatinine (post-shift sample)

2-HMSI: 8 mg/g creatinine (next morning sample).

Analytical measurement systems exist to determine the biomarkers for NMP with an appropriate level of precision and accuracy (see Table 5). The limit of quantification (LOQ) of the analytical method should be less than reference level.

Table 5: Potential analytical methods for biological monitoring

Method/type of sampling	Analytical technique	Limit of quantification LOQ
Urine sample (Ulrich et al., 2018) ³⁴	GC/MS ⁽¹⁾	2.5 µg/L for 5-HNMP 2 µg/L for 2-HMSI
Urine sample (Meier et al., 2013) ³⁵	GC/MS	69 µg/L for 5-HNMP* 45 µg/L for 2-HMSI*

(1) Gas Chromatography – Mass Spectrometry

* Limit of quantification (LOQ) converted from limit of detection (LOD) based on LOQ ~ 3 x LOD.

Table 6 beneath summarises the current European values / recommendations for exposure control for 1-methyl-2-pyrrolidone.

Table 6: Current European values for exposure control

Inhalation exposure	14,4 mg/m ³ (DNEL) REACH	40 mg/m ³ (iOELV, 8-hour TWA)* Chemical Agents Directive	80 mg/m ³ (iOELV, 15-minute STEL)* Chemical Agents Directive
Dermal exposure	4,8 mg/kg/day (DNEL) REACH	"Skin" notation Chemical Agents Directive	
Critical adverse health	Reproductive toxicity	Respiratory irritation / chemosensory	

³³ Bader, M., Wrbitzky, R., Blaszkewicz, M., van Thriel, C. (2007). Human experimental exposure study on the uptake and urinary elimination of N -methyl-2-pyrrolidone (NMP) during simulated workplace conditions. Arch.Toxicol. 81(5), 335-346. <http://doi.org/10.1007/s00204-006-0161-6>

³⁴ Ulrich, N., Bury, D., Koch, H.M., R  ther, M., Weber, T., K  fferlein, H.-U., Weiss, T., Br  ning, T., Kolossa-Gehring, M. (2018). Metabolites of the alkyl pyrrolidone solvents NMP and NEP in 24-h urine samples of the German Environmental Specimen Bank from 1991 to 2014. Int. Arch. Occup. Environ. Health 91, 1073-1082. <https://doi.org/10.1007/s00420-018-1347-y>

³⁵ Meier, S., Schindler, B.K., Koslitz, S., Koch, H.M., Weiss, T., K  fferlein, H.-U., Br  ning, T. (2013). Biomonitoring of Exposure to N-Methyl-2-Pyrrolidone in Workers of the Automobile Industry. Ann. Occup. Hygiene, 57(6), 766-773. <https://dx.doi.org/10.1093/annhyg/mes111>

effect	effects
* indicative Occupational Exposure Limit Value (iOELV) recommended by SCOEL. National values set by Member States may vary from country to country above or below this iOELV (see the RMOA document in Section 6)	

7.3 Appendix 3. Where NMP is used: sectors & typical uses

NMP is used predominantly as a solvent in the industrial production of other chemicals and in the industrial production of articles. In most uses, NMP is not part of the final product because it is removed during the production process or recycled or disposed of as waste.

In the production of chemicals, NMP has a very high solvency power for high performance polymers such as polyurethane (PU), polyaniline (PANI), polyamideimide (PAI), polyimide (PI), polyvinylidene fluoride (PVDF), polysulfone (PFS) and poly ethersulfone (PES), but also in the preparation of poly paraphenyleneterephthalamide (PPTA), polyphenylene sulfide (PPS) and other high performance thermoplastics (HPTP). In the production of articles NMP is used to deposit a thin film of the polymer on a surface (coating), to remove a polymer from a surface (cleaning), or to give the polymer a special shape like in the production of membranes or fibers.

Table 7: Overview of industrial sectors using NMP³⁶

Short description of the use <i>Value chain information</i> → Typical processes
Process solvent in the industrial manufacture of other chemicals
High volume chemicals - Extraction processes for the production of chemicals of importance like Butadiene, Acetylene, and Aromatics. <i>Butadiene is the raw material for synthetic rubber required for the production of tires and other rubber products of daily life.</i> → Industrial setting. Extraction.
Oil and gas products - Extraction processes for the cleaning of oil and gas products and emissions from their production. Examples for processes requiring NMP are desulfuration, removal of CO ₂ , COS (carbonyl sulphide) and H ₂ S → Industrial setting. Extraction.
Other chemicals – Solvent for chemical synthesis in the manufacture of other chemicals. This includes for example the production of bulk and fine chemicals, pharmaceuticals, and agrochemicals. <i>Value chains include many high-performance plastics/polymers and fibres as well as vitamins and other specialty products.</i> → Industrial setting. Mainly closed systems. Elevated process temperatures possible.
Process solvent in the industrial production of articles
Batteries - NMP is used both in lithium ion batteries as in other hybrid batteries using nickel, manganese, or cobalt lithiated oxides. In lithium ion batteries it is used in the production of the cathode. In addition, NMP is used as a cleaning agent for process equipment. → Industrial setting.
Microprocessors & semiconductor - Solvent in the electronics industry and for the production of printed circuit boards. In semiconductors, NMP is used as a carrier solvent in dedicated formulations and coating formulations, and as a manufacturing process aid for wafer cleaning and stripping. → Industrial setting. Clean room environment. High level of containment and automation.

³⁶ From: Background document to the restriction dossier and industry sources

Short description of the use**Value chain information**→ **Typical processes**

Membranes - Process solvent in the production of drinking water filtration, or dialysis *used e.g. for civil protection and military medical equipment*

→ Industrial setting, chemical industry standard

Protective fibres - Process solvent in the production of polymer-based clothing/fibres e.g. for helmets, bullet proofed jackets etc. *used e.g. for civil protection and military medical equipment*

→ Industrial setting, chemical industry standard

Winding wire - Solvent in special enamels in the production of coated/insulated wire for coils e.g. used in *motors, electric engine and generators*

Important for e-mobility

→ Industrial setting, metalworking industry

Other coated articles - Solvent in a wide range of different coatings and as a cleaning agent. *Includes e.g. automotive, textile, aeronautics and space industry as well as production of laboratory equipment (capillary tubes for gas chromatography).*

→ Industrial setting. Type of processes and tasks vary.

EUROPEAN CHEMICALS AGENCY
ANNANKATU 18, P.O. BOX 400,
FI-00121 HELSINKI, FINLAND
ECHA.EUROPA.EU