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# USING THE GUIDELINE TO COMPLY WITH THE RESTRICTION

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## Section 1.5 - What are DNELs?

- **DNEL** = Derived no-effect level
- **Level of exposure** to a substance below which **no negative health effects** are expected to occur in humans
- Required under **REACH** for use in **chemical safety assessments**
  - All routes of exposure (inhalation, dermal, oral)
  - All populations (e.g. workers, consumers, general population)
  - Effect specific (e.g. long-term systemic effects, acute local effects)
- Safe use if **Risk Characterization Ratio (RCR) < 1**
  - $RCR = \text{Predicted Exposure} / \text{DNEL}$
  - Predicted Exposure calculated with modelling tools (e.g. ECETOC-TRA)
  - $RCR_{\text{Long term Total Exposure}} = RCR_{\text{Long Term Inhalation}} + RCR_{\text{Long Term Dermal}}$
- DNELs can be found in section 8.1 of Safety Data Sheet



## Section 1.5 - What are OELs?

- **OEL = Occupational Exposure Limit Value**
- **Vapour concentration** for a substance below which workers may be repeatedly exposed, day after day, **without adverse health effects**
- Developed under **OSH legislation** (Chemical Agents Directive - CAD<sup>1)</sup>)
- **Indicative values (IOELV) for NMP** set by EU Commission
- Member states must establish **national OELs** taking into account Community values
  - **National OEL values enforceable by national authorities**
- OELs can be found in section 8.1 of Safety Data Sheet

Note 1) COUNCIL DIRECTIVE 98/24/EC of 7 April 1998 (and subsequent amendments)

# Extended Safety Data Sheet (eSDS) - example NMP

## General Sections

1. Identification of substance/mixture and of company/undertaking
2. Hazards identification
3. Composition / information ingredients
4. First aid measures
5. Firefighting measures
6. Accidental release measures
7. Handling and storage
8. **Exposure controls / personal protection**
9. Physical and chemical parameters
10. Stability and reactivity
11. Toxicological information
12. Ecological information
13. Disposal considerations
14. Transport information
15. Regulatory information
16. Other information

## Extended part

### Exposure Scenarios - Industrial end use

- Manufacture of substance
- Formulation of preparations
- **Charging and discharging**
- Use in industrial chemical processes
- Use in laboratories
- Use in wire coatings
- Use in coatings
- Use in cleaning agents
- Use in functional fluids

### Exposure Scenarios - Professional end use

- Use in laboratories

## Exposure Scenario (ES)

- Describes how exposure of humans and environment to a substance can be controlled to ensure **safe use**
  - refers to **identified use**, or group of similar identified uses, such as formulation, processing or production of an article
  - may include “**contributing scenarios**” (PROC - Process Category / ERC - Environmental Release Category)
    - activity within identified use (e.g. mixing, transferring into small containers, applying a substance by spraying etc.)
  - describes **operational conditions (OCC)** and **risk management measures (RMM)** to ensure safe use for that use and contributing scenario ( $RCR < 1$ )
- Developed by REACH registrants in Chemical Safety Assessment (CSA)
- Attached to **Safety Data Sheet** for communication down Supply Chain





## Section 2.1 - Check if your use is covered by the ES(1)

- Check your use
  - Section 1.2 of SDS - Identified Uses

### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses

: Manufacture of substances; Formulation of preparations;  
Charging and discharging of substances and mixtures; Use in  
industrial chemical processes; Use in laboratories; Uses in  
Coatings; Use in Cleaning Agents; Use in Functional Fluids

## Section 2.1 - Check if your use is covered by the ES(2)

- Check your use
  - Relevant Exposure Scenario - Check titles of Exposure Scenarios attached to SDS

**3. Industrial uses: Uses of substances as such or in preparations at industrial sites;  
Charging and discharging of substances and mixtures**

**3.1. Title section**

<b>Environment</b>	
Formulation of preparations	ERC2
<b>Worker</b>	
Transfer of substance or preparation (charging/ discharging) from/ to vessels/ large containers at dedicated facilities	PROC8b



## Section 2.1 - Check if your use is covered by the ES(3)

- Check your activities (PROC - Process Category)

### 3.1. Title section

Environment	
Formulation of preparations	ERC2
Worker	
Transfer of substance or preparation (charging/ discharging) from/ to vessels/ large containers at dedicated facilities	PROC8b
Transfer of chemicals into small containers (dedicated filling line)	PROC9
Use in laboratories	PROC15
Transfer of substance or preparation (charging/ discharging) from/ to vessels/ large containers at non-dedicated facilities, 1 hour	PROC8a
Transfer of substance or preparation (charging/ discharging) from/ to vessels/ large containers at non-dedicated facilities, 4 hour, EGV	PROC8a
Transfer of substance or preparation (charging/ discharging) from/ to vessels/ large containers at non-dedicated facilities, 61 - 127 °C	PROC8a

## Section 2.1 - Check if your use is covered by the ES(4)

- Check your **Operational Conditions** and **Risk Management Measures**

3.2.2. Control of worker exposure: Transfer of substance or preparation (charging/ discharging) from/ to vessels/ large containers at dedicated facilities (PROC8b)

**Product (article) characteristics**

Liquid  
Fugacity / dustiness: low  
Covers concentrations up to 100.0%

**Amount used (or contained in articles), frequency and duration of use/exposure**

Duration of activity: > 4 hours  
Frequency of use: 5 days/week

**Technical and organizational conditions and measures**

Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour).  
or  
Ensure operation is undertaken outdoors.  
Local exhaust ventilation: no  
Supervision in place to check that the risk management measures in place are being used correctly and operation conditions followed.  
Ensure control measures are regularly inspected and maintained.

**Conditions and measures related to personal protection, hygiene and health evaluation**

Dermal Protection: Wear suitable gloves tested to EN 374. For further specification, refer to section 8 of the SDS.

**Other conditions affecting worker exposure**

Exposed skin surface: 960 cm<sup>2</sup>  
Indoor use  
Ventilation: enhanced (70%)  
Domain: industrial

OC

RMM

OC

## Section 2.2 - Use is covered by Exposure Scenario

- Make sure you **document** your Use Compliance Check and any actions you took to comply

## Section 2.3 - Use is NOT covered by Exposure Scenario received

- Make your use known to your supplier
  - Supplier to make it an “Identified Use” (include in Chemical Safety Assessment) and provide you with updated SDS
- Use included, but conditions of use (OCs and RMMs) differ significantly
  - Implement conditions of use as described in Exposure Scenario
- Substitute NMP with different substance
  - For which Exposure Scenario is available which covers your conditions of use
- Find another supplier
  - Who provides SDS and Exposure Scenario that covers your use
- None of above options available or applicable
  - Prepare downstream user Chemical Safety Report (CSR) and inform ECHA
  - REACH Restriction 71 still applicable

## Section 2.5 - Workplace Risk Assessment

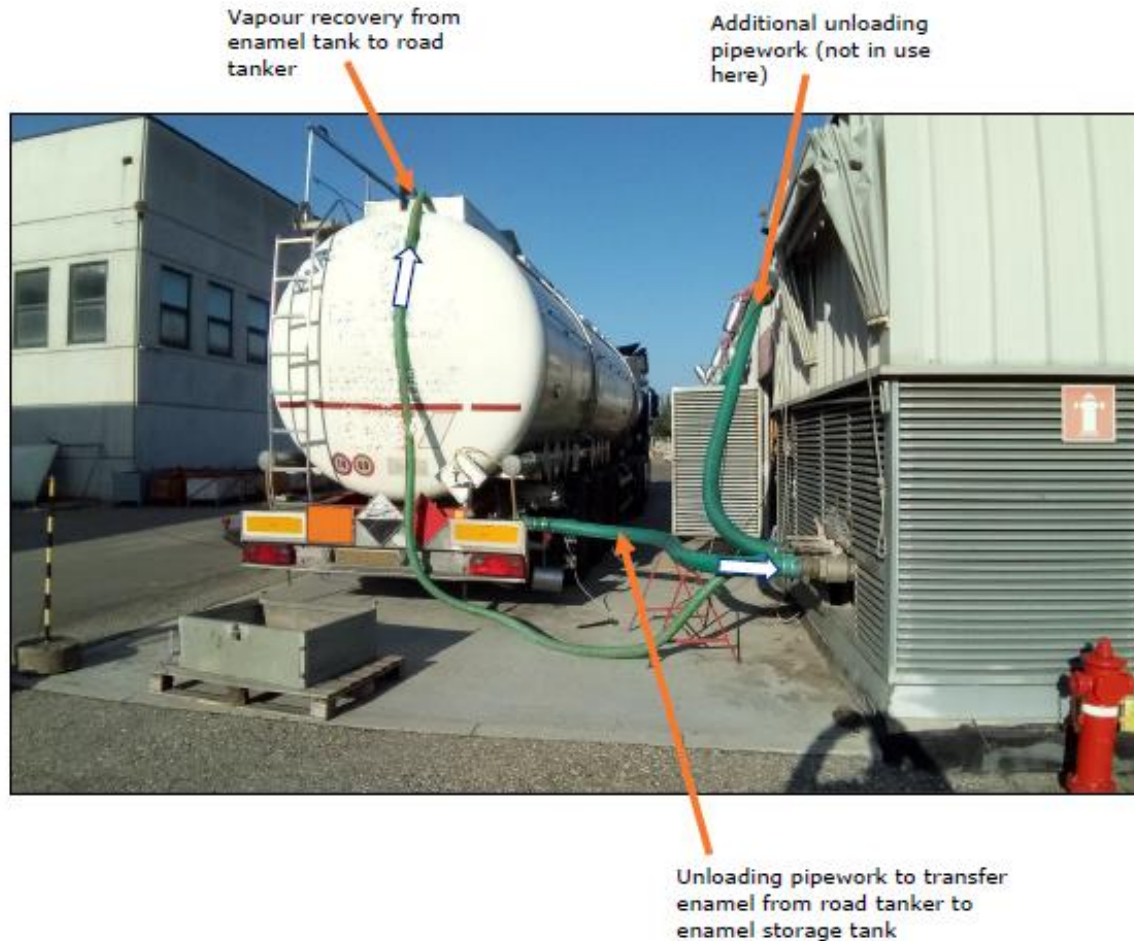
- Required under **EU OSH legislation by Chemical Agents Directive (CAD<sup>1</sup>)** and national legislation
  - Documents **specific preventive measures to reduce risk**
  - Must be performed **before starting any new (or change of) activity**
  - **Pregnant workers** target group given adverse health effects of NMP on unborn child
  
- Hierarchy of control measures (**S.T.O.P.** principle)
  - **S**ubstitute by safer substance or process technology
  - **T**echnical/engineering controls
  - **O**rganizational controls
  - **P**ersonal protective equipment (PPE)
  
- Sources of information for consideration in workplace risk assessments
  - Section 8.2 of Safety Data Sheet (Exposure controls)
  - Section 3 of NMP Guideline (Examples of good practices to control exposure to NMP)

Note 1) COUNCIL DIRECTIVE 98/24/EC of 7 April 1998 (and subsequent amendments) on protection of health and safety of workers from risks related to chemical agents at work.



## Section 3 - Examples of good practices

- 3.1.8: Unloading NMP containing formulation from road tanker



## Section 3 - Examples of good practices

- 3.1.2: Transfer operations (Filling drums)  
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/m<sup>3</sup>. Comparable measurement without LEV resulted in a detectable concentration of 0.11 mg/m<sup>3</sup>.</p>	