



## **SAFETY DATA SHEET (1907/2006)**

**R0718465**

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**N-VINYL PYRROLIDONE**

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# 1. OVERVIEW OF EXPOSURE SCENARIOS

**Table 1: Overview on exposure scenarios and coverage of substance life cycle**

Number (ES)	Short description of exposure scenario	Product Category (PC)	Life cycle stage covered by ES					Sector of use (SU)	Process category (PROC)	Article Category (AC)	Environmental release category (ERC)	
			Manufacture	Formulation	End use							Service Life
					Industrial	Professional	Consumer					
1	Manufacture, distribution, and bulk processing of nVP	19	x	x	x			Yes	8 9 10	n/a	1 2	
2	Use of Inks and Coatings Containing nVP	1 9a 18			x			No	7 10 13 17 19	n/a	4	
3	Use of nVP in the manufacturing of contact lenses.	19			x	x		No	14	n/a	4 8b	
4	Use of nVP in laboratory settings.	1 9a 18 21			x	x		No	15	n/a	4 8a	

## 1.1 Assessment of environmental exposures

In the chemical safety assessment performed according to Article 14(3) in connection with Annex I section 3 (Environmental Hazard Assessment) and section 4 (PBT/ vPvB Assessment) no hazard was identified. Therefore, according to REACH Annex I (5.0) an exposure estimation is not necessary. Consequently all identified uses of the substance are assessed as safe for the environment.

## 1.2 Assessment of Worker Exposures

Because nVP is classified as a Category 2 carcinogen, inhalatory and dermal exposures must be prevented and/or minimized to the extent possible.

### 1.2.1 Worker inhalation exposures

These have been estimated using ECETOC TRA worker v2.0 and measured data reported in the EU Risk Assessment Report (Volume 39, 2003) as a starting point with the following considerations and modifications:

- N-Vinyl-2-pyrrolidone (nVP) falls within the low volatility category at processing temperatures below 73°C.
- Where operational conditions (OCs) specify enclosed processing with LEV present, this is taken into account.
- In cases where the concentration of nVP in the product handled is below 100%, this is taken into account.

- In cases where OCs specify exposures of less than 8-hours, the starting point was corrected to an 8-hour time-weighted average.
- Measured data reported in the EU Risk Assessment Report were paired against the most relevant PROC, and served only as a second approximation of the exposures since these data were not reported in this manner. If none of the measured data suitably fit a particular PROC, this is indicated.

### **1.2.2 Worker dermal exposures**

These have been estimated using EUSES/EASE v2 as the starting point with the following considerations and modifications:

- All of the uses considered in this assessment were considered to be non-dispersive and either incidental or intermittent, leading to a starting point of either 0.1 mg/cm<sup>2</sup>/day or 1 mg/cm<sup>2</sup>/day, respectively.
- The following adult exposure factors were applied: skin surface area (hands only) = 840 cm<sup>2</sup>; body-weight = 70kg.
- In no scenario is it foreseen that workers will submerge their entire hands and/or forearms in the substance or in products containing the substance, even when gloves and other protective clothing are worn. As such, contamination of 10% of the hands was assumed.
- Good industrial practice (GIP) for reducing incidental or intermittent exposures to NVP under industrial conditions should include wearing protective gloves over a disposable inner glove coupled with specific training. This specific guidance for dermal protection ensures an efficiency of 98% instead of the standard of 90% at further reducing these incidental or intermittent exposures. From this, the external dermal dose was derived.
- A skin permeability constant ( $K_p$ ) of 0.000769 cm/hr was calculated using U. S. EPA DERMWIN v1.43a and was used in conjunction with ConsExpo v4.1 and the external dermal dose to calculate the internal dose.

### **1.3 Consumer exposures**

There are no consumer exposures associated with this exposure scenario.

### **1.4 Indirect exposure of humans via the environment (oral)**

As a result of the hazard assessment carried out in accordance to article 14.3, the registrant concludes that the substance is readily biodegradable and unlikely to persist in the environment, therefore an assessment of indirect exposures of humans via the environment was not performed.

## 2. MANUFACTURE, DISTRIBUTION, AND BULK PROCESSING OF NVP (ES1)

### 2.1 Description of ES1

Section 1	Characterization of the scenario
Summary of processes, tasks, activities covered	Manufacture of n-Vinylpyrrolidone (nVP) and bulk processing such as in polymer production to manufacture Polyvinyl Pyrrolidone (PVP) or formulating and further processing to produce lacquers, inks, and other coatings. Distribution of nVP to formulators and to polymer production facilities.
Section 2	Contributing scenarios:
ES1CS1	PROC 1 - Use in closed process, no likelihood of exposure. Continuous; daily; >4 hours.
ES1CS2	PROC 2 - Use in closed, continuous process with occasional controlled exposure . Continuous; daily; >4 hours. Sampling would be an example of an occasional controlled exposure.
ES1CS3	PROC 3 - Use in closed batch process (synthesis or formulation). Continuous; daily; >4 hours.
ES1CS4	PROC 4 - Use in batch and other process (synthesis) where opportunity for exposure arises . Continuous; daily; >4 hours, ambient temp. to <73°C when process is open.
ES1CS5	PROC 5 -Mixing or blending in batch processes (multistage and/or significant contact). Continuous; daily; >4 hours, ambient temp. to <73°C when process is open.
ES1CS6	PROC 8a -Transfer of chemicals from/to vessels/ large containers at non dedicated facilities. 1 to 4 hours daily, ambient temp. to <73°C. e.g. drum, railcar, and truck filling.
ES1CS7	PROC 8b -Transfer of chemicals from/to vessels/ large containers at dedicated facilities. 1 to 4 hours daily, ambient temp. to <73°C. e.g. drum, railcar, and truck filling.
ES1CS8	PROC 9 -Transfer of chemicals into small containers (dedicated filling line). 1 to 4 hours daily, ambient temp. to <73°C.
Section 3	Product characteristics
- Physical form of product	Liquid
- Vapour pressure	vapour pressure < 0.5 kPa [OC3]
- Concentration of substance	Covers percentage substance in the product up to 100 % [G13].

### 2.2 Operational conditions and risk management measures

Conditions and measures are applicable to contributing scenarios ES1CS1 to ES1CS8:

Implement the following technical measures when applicable and feasible to reduce exposures:

- Handle substance within a closed system [E47].
- Use dry break couplings for material transfer [E75].
- Use dedicated equipment [E85].
- Transfer materials directly to mixing vessels [E45].
- Clear transfer lines prior to de-coupling [E39].
- Transfer via enclosed lines [E52].
- Provide extract ventilation to points where emissions occur [E54].
- Provide low-point bleeds on pumps and other process equipment.
- Provide closed-loop sampling points.
- Retain drain downs in sealed storage pending disposal or for subsequent recycle [ENV4]

- Assumes a good basic standard of occupational hygiene is implemented [G1].

**Implement the following organisational measures when applicable and feasible:**

- Ensure the ventilation system is regularly maintained and tested [E74].
- Drain down and flush equipment and piping by closed system prior to equipment break-in or maintenance.
- Use walkthrough inspections and preventative maintenance to prevent, identify and correct process leaks.
- Conduct periodic air sampling to verify that breathing zone concentrations are maintained below 0.1 mg/m<sup>3</sup> (0.02 ppm) as an 8-hour time-weighted average and below 0.4 mg/m<sup>3</sup> (0.09 ppm) as a 15-minute short-term exposure limit (STEL) and/or to identify activities where respiratory protective equipment must be prescribed.
- Periodically review operations to ensure the correct exposure minimisation measures (technical, organisational, PPE) are in place.
- Ensure operatives are trained to minimise exposures [E1119].
- Evaluate process changes for opportunities to further minimise exposures.
- Train operatives in the proper use of the prescribed PPE and verify the prescribed PPE is worn and used properly.

**Required PPE:**

- Wear chemically resistant gloves (tested to EN374) over disposable gloves. Includes wearing when surfaces may be contaminated and when process streams or preparations contain >0.1% of the substance.
- Dispose of chemical resistant and inner gloves immediately if outer glove comes into direct contact with substance. Otherwise, dispose of gloves at end of shift.

**Other PPE that will be necessary depending on potential for dermal or inhalation exposure:**

- Wear suitable eye, face and/or disposable chemical resistant coveralls when splashes or contamination of work clothing could occur.
- Wear a half or full mask respirator conforming to EN140 with Type A filter or better when exposures exceed 0.1 mg/m<sup>3</sup>.
- Wear a positive pressure air supplied respirator when exposures could exceed the assigned protection factor for this type of respirator.

## 3. USE OF INKS AND COATINGS CONTAINING NVP (ES2)

### 3.1 Description of ES2

Section 1	Characterization of the scenario
Use Descriptor	Sector of Use: Industrial (SU3, SU8)
	Process Categories: PROC7, PROC10, PROC13, PROC17, PROC 19
	Environmental Release Categories: ERC4
Processes, tasks, activities covered	Use/application of UV curable inks, lacquers and other coatings containing n-vinylpyrrolidone by spraying, roller coating, screen printing, or dipping. Includes manual charging of coating / printing equipment.
Section 2	Contributing scenarios
ES2CS1	PROC 7 -Industrial spraying<25% in a preparation. Daily; >4 hours, ambient temp. to <73°C. Spray coating via automated, enclosed process (including vacuum coating process) with local exhaust ventilation.
ES2CS2	PROC 10 - Roller application or brushing, <25% in a preparation. Daily, >4 hours; ambient temp. to <73°C. e.g. coatings application via semi-automated process.
ES2CS3	PROC 13 -Treatment of articles by dipping and pouring, <25% in a preparation. Daily, >4 hours; ambient temp. to <73°C. e.g. coatings application via semi-automated process.
ES2CS4	PROC 17 - Lubrication at high energy conditions and in partly open process, <25% in a preparation. Daily, >4 hours; ambient temp. to <73°C. e.g. automated and manual UV screen printing. Automated and manual charging of coating equipment, or ink to printer heads and ink application.
ES2CS5	PROC 19 - Hand-mixing with intimate contact, <25% in a preparation. Daily, >4hours; ambient temp. to <73°C. e.g.manual UV screen printing with local exhaust ventilation. Manual charging of coating equipment, or ink to printer heads and ink application.
Section 3	Product characteristics
- Physical form of product	Liquid
- Vapour pressure	vapour pressure < 0.5 kPa [OC3]
- Concentration of substance	Covers percentage substance in the product up to 25 % [G13].

### 3.2 Operational conditions and risk management measures

Conditions and measures are applicable to contributing scenarios ES2CS1 to ES2CS5:

Implement the following technical measures when feasible to reduce exposures:

- Handle substance within a closed system [E47] or a predominantly closed system provided with extract ventilation [E49].
- Fill containers/cans at dedicated fill points supplied with local extract ventilation [E51].
- Provide extract ventilation to points where emissions occur [E54].
- Provide a good standard of general or controlled ventilation (5 to 15 air changes per hour) [E40].
- Carry out in a vented booth or extracted enclosure [E57].
- Use ventilation to extract vapours from freshly coated articles/objects [E56].
- Assumes a good basic standard of occupational hygiene is implemented [G1].

Implement the following organisational measures when feasible:

- Segregate the activity away from other operations [E63].
- Conduct periodic air sampling to verify that breathing zone concentrations are maintained below 0.1 mg/m<sup>3</sup> (0.02 ppm) as an 8-hour time-weighted and below 0.4 mg/m<sup>3</sup> (0.09 ppm) as a 15-minute short-term exposure limit (STEL) and/or to identify activities where respiratory protective equipment must be prescribed.
- Drain down and flush equipment and piping by closed system prior to equipment break-in or maintenance.

- Periodically review operations to ensure the correct exposure minimisation measures (technical, organisational, PPE) are in place.
- Ensure operatives are trained to minimise exposures [E1119].
- Train operatives in the proper use of the prescribed PPE and verify the prescribed PPE is worn and used properly.
- Ensure the ventilation system is regularly maintained and tested [E74].
- Avoid manual contact with wet work pieces [E117].

**Required PPE:**

- Wear chemically resistant gloves (tested to EN374) over disposable gloves. Includes wearing when surfaces may be contaminated and when process streams or preparations contain >0.1% of the substance.
- Dispose of chemical resistant and inner gloves immediately if outer glove comes into direct contact with substance. Otherwise, dispose of gloves at end of shift.

**Other PPE that will be necessary depending on potential for dermal or inhalation exposure:**

- Wear suitable eye, face and/or disposable chemical resistant coveralls when splashes or contamination of work clothing could occur.
- Wear a half or full mask respirator conforming to EN140 with Type A filter or better when exposures exceed 0.1 mg/m<sup>3</sup>.
- Wear a positive pressure air supplied respirator when exposures could exceed the assigned protection factor for this type of respirator.

## 4. USE OF NVP IN THE MANUFACTURING OF CONTACT LENSES (ES3)

### 4.1 Description of ES3

Section 1	Characterization of the scenario
Use Descriptor	Sector of Use: Industrial (SU3, SU10); Professional (SU22)
	Process Categories: PROC14
	Environmental Release Categories: ERC4, ERC8b
Processes, tasks, activities covered	Use of n-vinylpyrrolidone within industrial and professional settings to produce contact lenses. Includes mixing of polymer and moulding process.
Section 2	Contributing scenarios
ES3CS1	PROC 14 - Production of preparations or articles by tableting, compression, extrusion, pelletisation; 100% solution and in unpolymerized polymer preparation. 1-4 hours daily; ambient temp. to <73°Ce.g. contact lens production.
Section 3	Product characteristics
- Physical form of product	Liquid
- Vapour pressure	vapour pressure < 0.5 kPa [OC3]
- Concentration of substance	Covers percentage substance in the product up to 100 % [G13].

### 4.2 Operational conditions and risk management measures

Conditions and measures are applicable to contributing scenarios ES3CS1:

Implement the following technical measures when feasible to reduce exposures:

- Provide extract ventilation to points where emissions occur [E54].

Implement the following organisational measures when feasible:

- Ensure the ventilation system is regularly maintained and tested [E74].
- Conduct periodic air sampling to verify that breathing zone concentrations are maintained below 0.1 mg/m<sup>3</sup> (0.02 ppm) as an 8-hour time-weighted and below 0.4 mg/m<sup>3</sup> (0.09 ppm) as a 15-minute short-term exposure limit (STEL) and/or to identify activities where respiratory protective equipment must be prescribed.
- Evaluate process changes for opportunities to further minimise exposures.
- Ensure operatives are trained to minimise exposures [E119].
- Train operatives in the proper use of the prescribed PPE and verify the prescribed PPE is worn and used properly.
- Assumes a good basic standard of occupational hygiene is implemented [G1].

Required PPE:

- Wear chemically resistant gloves (tested to EN374) over disposable gloves. Includes wearing when surfaces may be contaminated and when process streams or preparations contain >0.1% of the substance.
- Dispose chemical resistant and inner gloves immediately if outer glove comes into direct contact with substance. Otherwise, dispose of gloves at end of shift.

Other PPE that will be necessary depending on potential for dermal or inhalation exposure:

- Wear a half or full mask respirator conforming to EN140 with Type A filter or better exposures when exceed 0.1 mg/m<sup>3</sup>.
- Use suitable eye protection [PPE26].



## 5. USE OF NVP IN LABORATORIES (ES4)

### 5.1 Description of ES4

Section 1	Characterization of the scenario
Use Descriptor	Sector of Use: Industrial (SU3, SU10); Professional (SU22)
	Process Categories: PROC15
	Environmental Release Categories: ERC4, ERC8a
Processes, tasks, activities covered	Use of n-vinylpyrrolidone within industrial and professional laboratory settings.
Section 2	Contributing scenarios
ES4CS1	PROC 15 - Use of laboratory reagents in small scale laboratories. Daily; >4 hours, ambient temp. to <73°C, small quantities. Handling inside laboratory fume hood.
Section 3	Product characteristics
- Physical form of product	Liquid
- Vapour pressure	vapour pressure < 0.5 kPa [OC3]
- Concentration of substance	Covers percentage substance in the product up to 100 % (small quantities) [G13].

### 5.2 Operational conditions and risk management measures

Conditions and measures are applicable to contributing scenarios ES4CS1:

Implement the following technical measures when feasible to reduce exposures:

- Handle in a fume cupboard or under extract ventilation [E83].

Implement the following organisational measures when feasible:

- Ensure the ventilation system is regularly maintained and tested [E74].
- Periodically review operations to ensure the correct exposure minimisation measures (technical, organisational, PPE) are in place.
- Ensure operatives are trained to minimise exposures [E1119].
- Train operatives in the proper use of the prescribed PPE and verify the prescribed PPE is worn and used properly.

Required PPE:

- Wear chemically resistant gloves (tested to EN374) over disposable gloves. Includes wearing when surfaces may be contaminated and when process streams or preparations contain >0.1% of the substance.
- Dispose chemical resistant and inner gloves immediately if outer glove comes into direct contact with substance. Otherwise, dispose of gloves at end of shift.

Other PPE that will be necessary depending on potential for dermal or inhalation exposure:

- Wear a half or full mask respirator conforming to EN140 with Type A filter or better exposures when exceed 0.1 mg/m<sup>3</sup>.
- Use suitable eye protection [PPE26].