

POLYVINYL PYRROLIDONE K90

GHS Safety Data Sheet

Version No:5

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Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME

POLYVINYL PYRROLIDONE K90

OTHER NAMES

(C₆H₉NO)_n, poly(vinylpyrrolidone), "polyvinyl pyrrolidone", polyvinylpyrrolidone, "1-ethenyl-2-pyrrolidinone polymer", "1-ethenyl-2-pyrrolidinone polymer", "1-ethenyl-2-pyrrolidinone homopolymer", "1-ethenyl-2-pyrrolidinone homopolymer", "2-pyrrolidinone, 1-ethenyl polymer", "2-pyrrolidinone, 1-ethenyl polymer", "2-pyrrolidinone, 1-ethenyl homopolymer", "2-pyrrolidinone, 1-ethenyl homopolymer",

PRODUCT USE

Blood plasma extender; in pharmacy for tabletting; detoxification of chemicals and drugs; in laundry detergents to prevent dye transfer, cosmetics, hair setting compositions, textile finishes, protective colloids, detergents, adhesives, beer & wine clarification.

NOTE: Polyvinylpyrrolidone [CAS RN: 25249-54-1] is the highly cross-linked form of polyvinylpyrrolidone.

SUPPLIER

Company: S D FINE - CHEM LIMITED

Address:

315- 317, T.V.IND.ESTATE,
248 WORLI ROAD,
MUMBAI- 400 030, INDIA

technical@sdfine.com

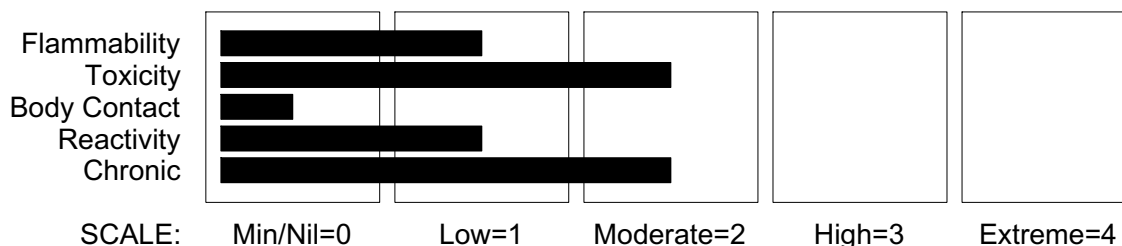
Telephone: 91- 22 24959898

Telephone: 91- 22 24959899

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Section 2 - HAZARDS IDENTIFICATION

HAZARD RATINGS



GHS Classification

Acute Toxicity (Oral) Category 4

continued...

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Section 2 - HAZARDS IDENTIFICATION



EMERGENCY OVERVIEW

HAZARD

WARNING

Determined by using GHS criteria:

H302

Harmful if swallowed

PRECAUTIONARY STATEMENTS

Prevention

Wash thoroughly after handling.

Do not eat, drink or smoke when using this product.

Response

IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

Rinse mouth.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME	CAS RN	%
vinylpyrrolidone homopolymer	9003-39-8	>90
residual as 2- pyrrolidinone	616-45-5	>0.5-<1.5

Section 4 - FIRST AID MEASURES

SWALLOWED

- If swallowed do NOT induce vomiting.
- If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.
- Observe the patient carefully.
- Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious.
- Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink.
- Seek medical advice.

EYE

- If this product comes in contact with the eyes:
- Wash out immediately with fresh running water.
- Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.
- Seek medical attention without delay; if pain persists or recurs seek medical attention.
- Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

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Section 4 - FIRST AID MEASURES

SKIN

- If skin or hair contact occurs:
- Flush skin and hair with running water (and soap if available).
- Seek medical attention in event of irritation.

INHALED

- If fumes or combustion products are inhaled remove from contaminated area.
- Other measures are usually unnecessary.

NOTES TO PHYSICIAN

- Treat symptomatically.

Section 5 - FIRE FIGHTING MEASURES

EXTINGUISHING MEDIA

- Foam.
- Dry chemical powder.
- BCF (where regulations permit).
- Carbon dioxide.
- Water spray or fog - Large fires only.

FIRE FIGHTING

- Alert Fire Brigade and tell them location and nature of hazard.
- Wear breathing apparatus plus protective gloves.
- Prevent, by any means available, spillage from entering drains or water courses.
- Use water delivered as a fine spray to control fire and cool adjacent area.
- DO NOT approach containers suspected to be hot.
- Cool fire exposed containers with water spray from a protected location.
- If safe to do so, remove containers from path of fire.
- Equipment should be thoroughly decontaminated after use.

FIRE/EXPLOSION HAZARD

- Combustible solid which burns but propagates flame with difficulty; it is estimated that most organic dusts are combustible (circa 70%) - according to the circumstances under which the combustion process occurs, such materials may cause fires and / or dust explosions.
- Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust (420 micron or less) may burn rapidly and fiercely if ignited - particles exceeding this limit will generally not form flammable dust clouds.; once initiated, however, larger particles up to 1400 microns diameter will contribute to the propagation of an explosion.
- In the same way as gases and vapours, dusts in the form of a cloud are only ignitable over a range of concentrations; in principle, the concepts of lower explosive limit (LEL) and upper explosive limit (UEL).are applicable to dust clouds but only the LEL is of practical use; - this is because of the inherent difficulty of achieving homogeneous dust clouds at high temperatures (for dusts the LEL is often called the "Minimum Explosible Concentration", MEC)
- A dust explosion may release of large quantities of gaseous products; this in turn creates a subsequent pressure rise of explosive force capable of damaging plant and buildings and injuring people.
- Usually the initial or primary explosion takes place in a confined space such as plant or machinery, and can be of sufficient force to damage or rupture the plant. If the shock wave from the primary explosion enters the surrounding area, it will disturb any settled dust layers, forming a second dust cloud, and often initiate a much larger secondary explosion. All large scale explosions have resulted from chain reactions of this type.
- Dry dust can be charged electrostatically by turbulence, pneumatic transport, pouring, in exhaust ducts and during transport.
- Build-up of electrostatic charge may be prevented by bonding and grounding.
- Powder handling equipment such as dust collectors, dryers and mills may require additional protection

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Section 5 - FIRE FIGHTING MEASURES

- measures such as explosion venting.
- All movable parts coming in contact with this material should have a speed of less than 1-meter/sec
 - A sudden release of statically charged materials from storage or process equipment, particularly at elevated temperatures and/ or pressure, may result in ignition especially in the absence of an apparent ignition source
 - One important effect of the particulate nature of powders is that the surface area and surface structure (and often moisture content) can vary widely from sample to sample, depending of how the powder was manufactured and handled; this means that it is virtually impossible to use flammability data published in the literature for dusts (in contrast to that published for gases and vapours).
 - Autoignition temperatures are often quoted for dust clouds (minimum ignition temperature (MIT)) and dust layers (layer ignition temperature (LIT)); LIT generally falls as the thickness of the layer increases.
- Combustion products include: carbon monoxide (CO), carbon dioxide (CO₂), nitrogen oxides (NO_x), other pyrolysis products typical of burning organic material.

May emit poisonous fumes.

Dusts with Minimum Ignition Energies (MIEs) ranging between 10 and 20 mJ

are highly sensitive to ignition

They require that:

- plant is grounded
- personal might also need to be grounded
- the use of high resistivity materials (such as plastics) should be restricted or avoided during handling or in packaging
- electrostatic hazards from bulk powders of high resistivity are considered.

FIRE INCOMPATIBILITY

- Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result.

PERSONAL PROTECTION

Glasses:

Chemical goggles.

Respirator:

Type A- P Filter of sufficient capacity

Section 6 - ACCIDENTAL RELEASE MEASURES

MINOR SPILLS

- Remove all ignition sources.
- Clean up all spills immediately.
- Avoid contact with skin and eyes.
- Control personal contact by using protective equipment.
- Use dry clean up procedures and avoid generating dust.
- Place in a suitable, labelled container for waste disposal.

MAJOR SPILLS

- Moderate hazard.
- CAUTION: Advise personnel in area.
- Alert Emergency Services and tell them location and nature of hazard.
- Control personal contact by wearing protective clothing.
- Prevent, by any means available, spillage from entering drains or water courses.
- Recover product wherever possible.
- IF DRY: Use dry clean up procedures and avoid generating dust. Collect residues and place in sealed plastic bags or other containers for disposal. IF WET: Vacuum/shovel up and place in labelled containers for disposal.
- ALWAYS: Wash area down with large amounts of water and prevent runoff into drains.
- If contamination of drains or waterways occurs, advise Emergency Services.

Personal Protective Equipment advice is contained in Section 8 of the MSDS.

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Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59].

HANDS/FEET

■ Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include: such as:

- frequency and duration of contact,
- chemical resistance of glove material,
- glove thickness and
- dexterity

Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739).

- When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374) is recommended.
- When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374) is recommended.
- Contaminated gloves should be replaced.

Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly.

Application of a non-perfumed moisturiser is recommended.

Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present.

- polychloroprene
- nitrile rubber
- butyl rubber
- fluorocautchouc
- polyvinyl chloride

Gloves should be examined for wear and/ or degradation constantly.

OTHER

- Overalls.
- P.V.C. apron.
- Barrier cream.
- Skin cleansing cream.
- Eye wash unit.

- Respirators may be necessary when engineering and administrative controls do not adequately prevent exposures.
- The decision to use respiratory protection should be based on professional judgment that takes into account toxicity information, exposure measurement data, and frequency and likelihood of the worker's exposure - ensure users are not subject to high thermal loads which may result in heat stress or distress due to personal protective equipment (powered, positive flow, full face apparatus may be an option).
- Published occupational exposure limits, where they exist, will assist in determining the adequacy of the selected respiratory . These may be government mandated or vendor recommended.
- Certified respirators will be useful for protecting workers from inhalation of particulates when properly selected and fit tested as part of a complete respiratory protection program.
- Use approved positive flow mask if significant quantities of dust becomes airborne.
- Try to avoid creating dust conditions.

RESPIRATOR

■ Selection of the Class and Type of respirator will depend upon the level of breathing zone contaminant and the chemical nature of the contaminant. Protection Factors (defined as the ratio of contaminant outside and inside the mask) may also be important.

Breathing Zone Level
ppm (volume)

Maximum Protection
Factor

Half- face Respirator

Full- Face Respirator

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Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

The following materials had no OELs on our records

- vinylpyrrolidone homopolymer:
- 2- pyrrolidinone:

CAS:9003- 39- 8 CAS:25249- 54- 1
CAS:616- 45- 5

MATERIAL DATA

VINYLPYRROLIDONE HOMOPOLYMER:

■ It is the goal of the ACGIH (and other Agencies) to recommend TLVs (or their equivalent) for all substances for which there is evidence of health effects at airborne concentrations encountered in the workplace.

At this time no TLV has been established, even though this material may produce adverse health effects (as evidenced in animal experiments or clinical experience). Airborne concentrations must be maintained as low as is practically possible and occupational exposure must be kept to a minimum.

NOTE: The ACGIH occupational exposure standard for Particles Not Otherwise Specified (P.N.O.S) does NOT apply.

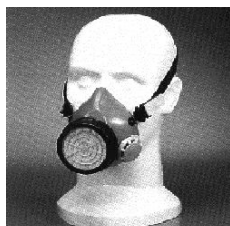
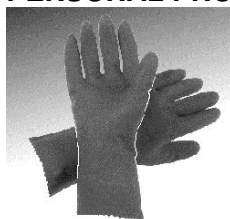
2-PYRROLIDINONE:

■ Sensory irritants are chemicals that produce temporary and undesirable side-effects on the eyes, nose or throat. Historically occupational exposure standards for these irritants have been based on observation of workers' responses to various airborne concentrations. Present day expectations require that nearly every individual should be protected against even minor sensory irritation and exposure standards are established using uncertainty factors or safety factors of 5 to 10 or more. On occasion animal no-observable-effect-levels (NOEL) are used to determine these limits where human results are unavailable. An additional approach, typically used by the TLV committee (USA) in determining respiratory standards for this group of chemicals, has been to assign ceiling values (TLV C) to rapidly acting irritants and to assign short-term exposure limits (TLV STELs) when the weight of evidence from irritation, bioaccumulation and other endpoints combine to warrant such a limit. In contrast the MAK Commission (Germany) uses a five-category system based on intensive odour, local irritation, and elimination half-life. However this system is being replaced to be consistent with the European Union (EU) Scientific Committee for Occupational Exposure Limits (SCOEL); this is more closely allied to that of the USA.

OSHA (USA) concluded that exposure to sensory irritants can:

- cause inflammation
- cause increased susceptibility to other irritants and infectious agents
- lead to permanent injury or dysfunction
- permit greater absorption of hazardous substances and
- acclimate the worker to the irritant warning properties of these substances thus increasing the risk of overexposure.

PERSONAL PROTECTION



EYE

- Safety glasses with side shields
- Chemical goggles.
- Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lens or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of

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Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

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ppm (volume)

Maximum Protection
Factor

Half- face Respirator

Full- Face Respirator

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Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

1000	10	A- AUS P	-
1000	50	-	A- AUS P
5000	50	Airline *	-
5000	100	-	A- 2 P
10000	100	-	A- 3 P
	100+		Airline**

* - Continuous Flow ** - Continuous-flow or positive pressure demand.

The local concentration of material, quantity and conditions of use determine the type of personal protective equipment required. For further information consult your Occupational Health and Safety Advisor.

ENGINEERING CONTROLS

- Local exhaust ventilation is required where solids are handled as powders or crystals; even when particulates are relatively large, a certain proportion will be powdered by mutual friction.
- Exhaust ventilation should be designed to prevent accumulation and recirculation of particulates in the workplace.
- If in spite of local exhaust an adverse concentration of the substance in air could occur, respiratory protection should be considered. Such protection might consist of:
 - (a): particle dust respirators, if necessary, combined with an absorption cartridge;
 - (b): filter respirators with absorption cartridge or canister of the right type;
 - (c): fresh-air hoods or masks
- Build-up of electrostatic charge on the dust particle, may be prevented by bonding and grounding.
- Powder handling equipment such as dust collectors, dryers and mills may require additional protection measures such as explosion venting.

Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to efficiently remove the contaminant.

Type of Contaminant:	Air Speed:
direct spray, spray painting in shallow booths, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)	1- 2.5 m/s (200- 500 f/min.)
grinding, abrasive blasting, tumbling, high speed wheel generated dusts (released at high initial velocity into zone of very high rapid air motion).	2.5- 10 m/s (500- 2000 f/min.)

Within each range the appropriate value depends on:

Lower end of the range	Upper end of the range
1: Room air currents minimal or favourable to capture	1: Disturbing room air currents
2: Contaminants of low toxicity or of nuisance value only	2: Contaminants of high toxicity
3: Intermittent, low production.	3: High production, heavy use
4: Large hood or large air mass in motion	4: Small hood- local control only

Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example,

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should be a minimum of 4-10 m/s (800-2000 f/min) for extraction of crusher dusts generated from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE

■ Family of products which vary in their physical properties as a result of variations in production. Data presented here is for typical family member.

White powder, very soluble in water. No odour. Hygroscopic and soluble in organic solvents. Compatible with hydrophilic and hydrophobic resins. Aqueous solutions are stable and may be sterilized by autoclaving. Molecular Weights 10,000; 40,000; 160,000; 360,000.

PHYSICAL PROPERTIES

Solid.

State	Divided solid	Molecular Weight	10, 000 upwards.
Melting Range (°C)	>130 (decomposes)	Viscosity	Not Applicable
Boiling Range (°C)	Not available.	Solubility in water (g/L)	Varies by MW
Flash Point (°C)	>215 (DIN 51755)	pH (1% solution)	4.5- 7.0
Decomposition Temp (°C)	Not available.	pH (as supplied)	Not applicable
Autoignition Temp (°C)	425 (DIN 51794)	Vapour Pressure (kPa)	Negligible
Upper Explosive Limit (%)	Not available.	Specific Gravity (water=1)	1.23- 1.29
Lower Explosive Limit (%)	Not available.	Relative Vapour Density (air=1)	Not Applicable
Volatile Component (%vol)	Negligible	Evaporation Rate	Not Applicable

Section 10 - CHEMICAL STABILITY AND REACTIVITY INFORMATION

CONDITIONS CONTRIBUTING TO INSTABILITY

- Presence of incompatible materials.
- Product is considered stable.
- Hazardous polymerisation will not occur.

For incompatible materials - refer to Section 7 - Handling and Storage.

Section 11 - TOXICOLOGICAL INFORMATION

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

- Accidental ingestion of the material may be damaging to the health of the individual.
- High molecular weight material; on single acute exposure would be expected to pass through gastrointestinal tract with little change / absorption. Occasionally accumulation of the solid material within the alimentary tract may result in formation of a bezoar (concretion), producing discomfort.

EYE

- Although the material is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may cause transient discomfort characterised by tearing or conjunctival redness (as with windburn). Slight abrasive damage may also result. The material may produce foreign body irritation in certain individuals.

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Section 11 - TOXICOLOGICAL INFORMATION

SKIN

- The material is not thought to produce adverse health effects or skin irritation following contact (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting.
- Open cuts, abraded or irritated skin should not be exposed to this material.
- Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

INHALED

- The material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation (as classified by EC Directives using animal models). Nevertheless, adverse systemic effects have been produced following exposure of animals by at least one other route and good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.
- Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled. If prior damage to the circulatory or nervous systems has occurred or if kidney damage has been sustained, proper screenings should be conducted on individuals who may be exposed to further risk if handling and use of the material result in excessive exposures.

CHRONIC HEALTH EFFECTS

- There has been some concern that this material can cause cancer or mutations but there is not enough data to make an assessment. Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure. Long term exposure to high dust concentrations may cause changes in lung function i.e. pneumoconiosis; caused by particles less than 0.5 micron penetrating and remaining in the lung. Prime symptom is breathlessness; lung shadows show on X-ray. This material contains a substantial amount of polymer considered to be of low concern. These are classified under having MWs of between 1000 to 10000 with less than 25% of molecules with MWs under 1000 and less than 10% under 500; or having a molecular weight average of over 10000. Functional groups contained on the polymer are then classified into risk categories. Being classified as a polymer of "low concern" does not mean that there are no hazards associated with the chemical. Polyvinylpyrrolidone (syn: vinylpyrrolidone polymer; PVP) is non-antigenic and generally well tolerated. PVP has been shown to cause sarcomas in rats but there is not confirmation that it is carcinogenic in human patients. [Martindale] The material may cause irritation or dermatitis in some individuals upon prolonged contact.

TOXICITY AND IRRITATION

- unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.

TOXICITY

Oral (rat) LD50: 3000 mg/kg
Oral (rat) LD50: >100, 000 mg/kg *
Oral (Rabbit) LD50: 1040 mg/kg
Inhalation (Rat) LC50: >5200 mg/m³/4h **

- The substance is classified by IARC as Group 3:

NOT classifiable as to its carcinogenicity to humans.

Evidence of carcinogenicity may be inadequate or limited in animal testing.

Chronic toxicity **

Genetic toxicity:

No mutagenic effect was found in various tests with microorganisms and mammalian cell culture.

The substance was not mutagenic in studies with mammals.

Carcinogenicity:

In long-term animal studies in which the substance was given in high doses by feed, a carcinogenic effect was not observed.

IRRITATION

Skin (rabbit):non- irritating(Draize)**
Eye (rabbit):non- irritating (Draize)*

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Section 11 - TOXICOLOGICAL INFORMATION

Developmental toxicity/teratogenicity:

No indications of a developmental toxic / teratogenic effect were seen in animal studies

* ISP MSDS

2-PYRROLIDINONE:

■ unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.

TOXICITY

Oral (rat) LD50: 328 mg/kg

Intraperitoneal (rat) LD50: 160 mg/kg

Intraperitoneal (rat) LD50: 3700 mg/kg

Oral (g.pig) LD50: 6500 mg/kg

■ Asthma-like symptoms may continue for months or even years after exposure to the material ceases. This may be due to a non-allergenic condition known as reactive airways dysfunction syndrome (RADS) which can occur following exposure to high levels of highly irritating compound. Key criteria for the diagnosis of RADS include the absence of preceding respiratory disease, in a non-atopic individual, with abrupt onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. A reversible airflow pattern, on spirometry, with the presence of moderate to severe bronchial hyperreactivity on methacholine challenge testing and the lack of minimal lymphocytic inflammation, without eosinophilia, have also been included in the criteria for diagnosis of RADS. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance. Industrial bronchitis, on the other hand, is a disorder that occurs as result of exposure due to high concentrations of irritating substance (often particulate in nature) and is completely reversible after exposure ceases. The disorder is characterised by dyspnea, cough and mucus production.

For 2-pyrrolidone (syn: 2-pyrrolidinone; 2-P)

The oral LD50 of 2-P is very high with values of 8000 and greater than 5000 mg/kg being reported Exposure of rats to saturated vapor for 8 hours did not produce any adverse effects and the dermal LD50 in rabbits is greater than 2000 mg/kg.

A subchronic drinking water study of 2-P showed low repeated-dose toxicity with a 90-day NOAEL of 2400 ppm and a LOAEL of 7200 ppm in drinking water. The kidneys many have been affected but no target organs were identified by histopathological examination.

Genetic toxicity: Adequate in vitro tests of genetic toxicity for 2-P are available. A Salmonella typhimurium reverse mutation assay shows lack of mutagenic activity in the presence or absence of metabolic activation and a guideline cytogenetics study using human lymphocytes displayed a lack of genotoxicity activity in the presence or absence of metabolic activation.

Developmental toxicity has been investigated using an OECD 414 Guideline study. The results of this investigation conducted in rats by oral gavage at 0, 190, 600 or 1900 mg/kg-day indicate that 2-P affects the conceptus only at doses that exceed the maternally toxic level. The developmental NOAEL was found to be 600 mg/kg-day while the maternal NOAEL was 190 mg/kg-day.

The combination of the negative developmental toxicity study with a robust subchronic study in which specific damage to reproductive organs was not observed fulfills the current requirement for reproductive toxicity information.

Coma, dyspnea recorded.

IRRITATION

CARCINOGEN

Polyvinyl pyrrolidone

International Agency
for Research on Cancer
(IARC) - Agents
Reviewed by the IARC
Monographs

Group

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POLYVINYL PYRROLIDONE K90

Section 12 - ECOLOGICAL INFORMATION

Refer to data for ingredients, which follows:

2-PYRROLIDINONE:

VINYLPYRROLIDONE HOMOPOLYMER:

■ DO NOT discharge into sewer or waterways.

VINYLPYRROLIDONE HOMOPOLYMER:

Environmental fate and transport

Biodegradation:

Test method: OECD Guideline 302 B (aerobic), activated sludge, industrial

Method of analysis: DOC reduction

Degree of elimination: < 10 % (15 d)

Evaluation: Poorly eliminated from water.

Bioaccumulation:

Based on its structural properties, the polymer is not biologically available. Accumulation in organisms is not to be expected.

Environmental toxicity

Acute and prolonged toxicity to fish: DIN 38412 Part 15 static

Fish LC50 (96 h): golden orfe: > 10,000 mg/l

Toxicity to microorganisms: OECD Guideline 209 aerobic

Activated sludge, industrial EC20 (0.5 h): > 1,995 mg/l

MSDS for Kollidon 90F

2-PYRROLIDINONE:

■ Fish LC50 (96hr.) (mg/l):	100
■ Daphnia magna EC50 (48hr.) (mg/l):	3.4
■ BOD5:	1.16

■ For 2-Pyrrolidone (syn: 2-pyrrolidinone; 2-P)

Environmental fate:

2-P is slightly volatile liquid with high water solubility. 2-P will not bioaccumulate (log Kow -0.71) and will distribute primarily to water where it will be subject to limited volatilization and rapid biodegradation. It is expected to react rapidly with atmospheric hydroxyl radicals with a half-life of about 11 hours.

Biodegradation: Biodegradation potential has been determined using a Zahn Wellens test. In this DOC removal test, DOC was 80% eliminated after 5 days of incubation. Although this only definitively shows "inherent biodegradability" the speed of removal and completeness (99% at 9 days) suggest that this material is easily biodegraded by non-adapted bacteria. It can be estimated that 2-P is readily biodegradable with quantitative estimates suggesting a high likelihood that it should be considered "readily biodegradable". Furthermore, the analog and surrogate compound, N-methyl-2-pyrrolidone (NMP) has been demonstrated to be readily biodegradable in the MITI test.

Photodegradation: APOWIN software has been used to estimate the rate constant for the atmospheric, gas-phase reaction between photochemically produced hydroxyl radicals and organic chemicals. The estimated rate constant is used to calculate atmospheric half-lives for organic compounds based upon average atmospheric concentrations of hydroxyl radical. The program produced a estimated rate constant of 11.9 E-12 cm³/molecule-sec. Using the default atmospheric hydroxyl radical concentration in APOWIN and the estimated rate constant for reaction of 2-P with hydroxyl radical, the estimated half-life of 2-P vapor in air is approximately 10.75 hours.

Hydrolysis: There is no evidence available that 2-P is unstable in water, although it has a potentially hydrolysable amide group, amides are considered resistant to hydrolysis at environmental pH values and require strong base or acid to accomplish hydrolysis. Vollhardt states: "Amides are the least reactive of the carboxylic derivatives, mainly because of the extra resonance capacity of the nitrogen lone electron pair". As a consequence, their nucleophilic addition-eliminations require relatively harsh conditions. For example, hydrolysis occurs only on prolonged heating in strongly acidic or basic water.

In addition, 2-P is a cyclic amide in a 5-membered ring, which is generally the ring size showing the least

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Section 12 - ECOLOGICAL INFORMATION

strain and, hence making ring opening a less favored occurrence increasing resistance to hydrolysis.

Ecotoxicity:

A recent GLP guideline (OECD 203) study of acute fish toxicity using measured concentrations of 2-P is available demonstrating low hazard to zebra fish after 96 hours of exposure. The test material stability in the dilution water with fish was very good over the 96-hour period. Daphnia studies indicate an EC₅₀, greater than 1000 mg/L in one test, greater than 500 mg/L in another guideline-like study and a report of an EC₅₀ values less than 20 mg/L. Although experimental data give differing results, the weight of evidence indicates a low aquatic hazard. Other invertebrates, specifically, flatworms and snails, showed no effects in limit tests at 112 mg/L. Algae growth inhibition, according to a guideline study, has an EC₅₀ of about 84 mg/L after 96-hours.

Unvalidated but multiple study results indicate that the analogue 1-methyl-2-pyrrolidone has low acute toxicity to fish, invertebrates and algae (short-term LC₅₀ or EC₅₀ values >500 mg/L). This lends support to the higher values for the LC₅₀ and EC₅₀ values of 2-P that have been reported. The reason some investigations have found higher degrees of toxicity is unknown but a reasonable speculation would be that the samples tested were contaminated with more toxic agents. For example, it is known that gamma-butyrolactone which is one of the primary starting materials for 2-Pyrrolidone is more toxic to fish and daphnids. Likewise, aliphatic amines, which are potential side products from 2-Pyrrolidone manufacture, typically have LC and EC₅₀ values in a range where contamination of a sample might result in a low EC₅₀.

Ecotoxicity

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
vinylpyrrolidone homopolymer	HIGH		LOW	HIGH
2- pyrrolidinone	LOW		LOW	HIGH

Section 13 - DISPOSAL CONSIDERATIONS

■ Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.

A Hierarchy of Controls seems to be common - the user should investigate:

- Reduction
- Reuse
- Recycling
- Disposal (if all else fails)

This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate.

- DO NOT allow wash water from cleaning or process equipment to enter drains.
- It may be necessary to collect all wash water for treatment before disposal.
- In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first.
- Where in doubt contact the responsible authority.
- Recycle wherever possible.
- Consult manufacturer for recycling options or consult local or regional waste management authority for disposal if no suitable treatment or disposal facility can be identified.
- Dispose of by: burial in a land-fill specifically licenced to accept chemical and / or pharmaceutical wastes or Incineration in a licenced apparatus (after admixture with suitable combustible material)
- Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.

Section 14 - TRANSPORTATION INFORMATION

HAZCHEM:

☐ None

continued...

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Section 14 - TRANSPORTATION INFORMATION

NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS: UN, IATA, IMDG

Section 15 - REGULATORY INFORMATION

REGULATIONS

vinylpyrrolidone homopolymer (CAS: 9003-39-8,25249-54-1) is found on the following regulatory lists;

"Australia Inventory of Chemical Substances (AICS)", "CODEX General Standard for Food Additives (GSFA) - Additives Permitted for Use in Food in General, Unless Otherwise Specified, in Accordance with GMP", "International Agency for Research on Cancer (IARC) - Agents Reviewed by the IARC Monographs" Regulations for ingredients

2-pyrrolidinone (CAS: 616-45-5) is found on the following regulatory lists;

"Australia Illicit Drug Precursors/Reagents - Category I", "Australia Inventory of Chemical Substances (AICS)", "International Council of Chemical Associations (ICCA) - High Production Volume List", "OECD Representative List of High Production Volume (HPV) Chemicals"

Section 16 - OTHER INFORMATION

Denmark Advisory list for selfclassification of dangerous substances

Substance	CAS	Suggested codes
2- pyrrolidinone	616- 45- 5	

INGREDIENTS WITH MULTIPLE CAS NUMBERS

Ingredient Name	CAS
vinylpyrrolidone homopolymer	9003- 39- 8, 25249- 54- 1

MSDS SECTION CHANGES

The following table displays the version number of and date on which each section was last changed.

Section Name	Version	Date	Section Name	Version	Date	Section Name	Version	Date
First Aid (eye)	4	27- Mar- 2007	Storage (storage requirement)	4	27- Mar- 2007	Acute Health (eye)	4	27- Mar- 2007
First Aid (swallowed)	4	27- Mar- 2007	Storage (suitable container)	4	27- Mar- 2007	Acute Health (inhaled)	4	27- Mar- 2007
Fire Fighter (extinguishing media)	4	27- Mar- 2007	Engineering Control	4	27- Mar- 2007	Acute Health (skin)	4	27- Mar- 2007
Fire Fighter (fire fighting)	4	27- Mar- 2007	Exposure Standard	4	27- Mar- 2007	Acute Health (swallowed)	4	27- Mar- 2007
Fire Fighter (fire/explosion hazard)	4	27- Mar- 2007	Personal Protection (eye)	4	27- Mar- 2007	Chronic Health	4	27- Mar- 2007
Spills (major)	4	27- Mar- 2007	Personal Protection (hands/feet)	4	27- Mar- 2007	Toxicity and Irritation (Toxicity Figure)	4	27- Mar- 2007
Spills (minor)	4	27- Mar- 2007	Personal Protection (other)	4	27- Mar- 2007	Environmental	4	27- Mar- 2007
Handling Procedure	4	27- Mar- 2007	Appearance	4	27- Mar- 2007	Disposal	4	27- Mar- 2007
Storage (storage incompatibility)	4	27- Mar- 2007	Physical Properties	4	27- Mar- 2007			

■ The (M)SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

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Section 16 - OTHER INFORMATION

The above information is believed to be accurate and represent the best information currently available to us, but does not represent any warranty expressed or implied of the properties of the product. User should make their own investigation to determine the suitability of the information for their particular purpose.

Issue Date: 5-Apr-2018