SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier
Trade name or designation of the mixture: L339

1.2. Relevant identified uses of the substance or mixture and uses advised against
Identified uses: Polyvinyl alcohol-based film used as a water-soluble unit-dose delivery system.
Uses advised against: None known.

1.3. Details of the supplier of the safety data sheet
Supplier: MonoSol AF Ltd.
Company name: MonoSol AF Ltd.
Address: Oak Drive, Hartlebury Trading Estates, Hartlebury, Worcestershire DY104JB, UK
Telephone: General Assistance 44 1299 25 1335
e-mail: reach@monosol.com
Contact person: Not available.

1.4. Emergency telephone number
CHEMTREC (London) +(44)-870-8200418 & 1 703-527-3887
CHEMTREC Sweden +(46)-85203403
CHEMTREC Germany +(44)-870-8200418
CHEMTREC Hungary +(36)-18088425
CHEMTREC France + (33)-975181407
CHEMTREC Poland (Warsaw) +(48)-223988029
CHEMTREC Netherlands +(31)-858880596
CHEMTREC Spain 900-868538
CHEMTREC Italy 800-789-767

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture
The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Classification according to Regulation (EC) No 1272/2008 as amended
This mixture does not meet the criteria for classification according to Regulation (EC) 1272/2008 as amended.

Hazard summary
Not classified for health hazards. However, occupational exposure to the mixture or substance(s) may cause adverse health effects.

2.2. Label elements
Label according to Regulation (EC) No. 1272/2008 as amended

Hazard pictograms: None.
Signal word: None.
Hazard statements: The mixture does not meet the criteria for classification.

Precautionary statements
Prevention: Observe good industrial hygiene practices.
Response: Wash hands after handling.
Storage: Store away from incompatible materials.
Disposal: Dispose of waste and residues in accordance with local authority requirements.
Supplemental label information  None.

2.3. Other hazards  Not a PBT or vPvB substance or mixture.

SECTION 3: Composition/information on ingredients

3.2. Mixtures
The components are not hazardous or are below required disclosure limits.

List of abbreviations and symbols that may be used above
- #: This substance has been assigned Union workplace exposure limit(s).
- M: M-factor
- PBT: persistent, bioaccumulative and toxic substance.
- vPvB: very persistent and very bioaccumulative substance.

All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume. *Product is a non-hazardous mixture of which the composition is a trade secret

SECTION 4: First aid measures

General information  Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

4.1. Description of first aid measures

- **Inhalation**  Move to fresh air. Call a physician if symptoms develop or persist.
- **Skin contact**  Wash off with soap and water. Get medical attention if irritation develops and persists.
- **Eye contact**  Rinse with water. Get medical attention if irritation develops and persists.
- **Ingestion**  Exposure may cause temporary irritation, redness, or discomfort.

4.2. Most important symptoms and effects, both acute and delayed

- Treat symptomatically.

4.3. Indication of any immediate medical attention and special treatment needed

SECTION 5: Firefighting measures

General fire hazards  No unusual fire or explosion hazards noted.

5.1. Extinguishing media

- **Suitable extinguishing media**  Water spray. Alcohol resistant foam. Dry powder. Carbon dioxide (CO2).
- **Unsuitable extinguishing media**  Do not use water jet as an extinguisher, as this will spread the fire.

5.2. Special hazards arising from the substance or mixture

- Upon decomposition, this product emits carbon monoxide, carbon dioxide and/or low molecular weight hydrocarbons.

5.3. Advice for firefighters

- **Self-contained breathing apparatus and full protective clothing** must be worn in case of fire.
- **Special fire fighting procedures**  Use water spray to cool unopened containers.

5.4. Specific methods

- Use standard firefighting procedures and consider the hazards of other involved materials.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- **For non-emergency personnel**  Keep unnecessary personnel away. In case of spills, beware of slippery floors and surfaces. For personal protection, see section 8 of the SDS.
- **For emergency responders**  Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.

6.2. Environmental precautions

- Avoid discharge into drains, water courses or onto the ground.

6.3. Methods and material for containment and cleaning up

- Stop the flow of material, if this is without risk. Following product recovery, flush area with water. For waste disposal, see section 13 of the SDS.

6.4. Reference to other sections

- For personal protection, see section 8 of the SDS. For waste disposal, see section 13 of the SDS.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Avoid prolonged exposure. Observe good industrial hygiene practices.

7.2. Conditions for safe storage, including any incompatibilities

- Store in tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).
Section 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits
No exposure limits noted for ingredient(s).

Biological limit values
No biological exposure limits noted for the ingredient(s).

Recommended monitoring procedures
Follow standard monitoring procedures.

Derived no effect levels (DNELs)
Not available.

Predicted no effect concentrations (PNECs)
Not available.

8.2. Exposure controls

Appropriate engineering controls
Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Individual protection measures, such as personal protective equipment

General information
Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.

Eye/face protection
Wear safety glasses with side shields (or goggles).

Skin protection
- Hand protection
Wear appropriate chemical resistant gloves.
- Other
Wear suitable protective clothing.

Respiratory protection
In case of insufficient ventilation, wear suitable respiratory equipment.

Thermal hazards
Wear appropriate thermal protective clothing, when necessary.

Hygiene measures
Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

Environmental exposure controls
Environmental manager must be informed of all major releases.

Section 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance
- Physical state
Solid.
- Form
Solid. Film.
- Colour
Colourless to light yellow. Translucent.
- Odour
May have a slight acetic acid odor
- Odour threshold
Not available.
- pH
Not available.
- Melting point/freezing point
Not available.
- Initial boiling point and boiling range
Not available.
- Flash point
Not available.
- Evaporation rate
Not available.
- Flammability (solid, gas)
Not available.
- Upper/lower flammability or explosive limits
- Flammability limit - lower (%)
Not available.
- Flammability limit - upper (%)
Not available.
- Vapour pressure
Not available.
- Vapour density
Not available.
- Relative density
Not available.
- Solubility(ies)
Solubility (water)
Not available.
Partition coefficient (n-octanol/water) Not available.
Auto-ignition temperature Not available.
Decomposition temperature Not available.
Viscosity Not available.
Explosive properties Not explosive.
Oxidising properties Not oxidising.

9.2. Other information
No relevant additional information available.

SECTION 10: Stability and reactivity
10.1. Reactivity The product is stable and non-reactive under normal conditions of use, storage and transport.
10.2. Chemical stability Material is stable under normal conditions.
10.3. Possibility of hazardous reactions No dangerous reaction known under conditions of normal use.
10.4. Conditions to avoid Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. Contact with incompatible materials.
10.5. Incompatible materials Strong oxidising agents.
10.6. Hazardous decomposition products No hazardous decomposition products are known.

SECTION 11: Toxicological information
General information Occupational exposure to the substance or mixture may cause adverse effects.
Information on likely routes of exposure
Inhalation Prolonged inhalation may be harmful.
Skin contact No adverse effects due to skin contact are expected.
Eye contact Direct contact with eyes may cause temporary irritation.
Ingestion May cause discomfort if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.
Symptoms Exposure may cause temporary irritation, redness, or discomfort.
11.1. Information on toxicological effects
Acute toxicity Not known.
Skin corrosion/irritation Due to partial or complete lack of data the classification is not possible.
Serious eye damage/eye irritation Due to partial or complete lack of data the classification is not possible.
Respiratory sensitisation Due to partial or complete lack of data the classification is not possible.
Skin sensitisation Due to partial or complete lack of data the classification is not possible.
Germ cell mutagenicity Due to partial or complete lack of data the classification is not possible.
Carcinogenicity Hungary. 26/2000 EüM Ordinance on protection against and preventing risk relating to exposure to carcinogens at work (as amended) Not listed.
Reproductive toxicity Due to partial or complete lack of data the classification is not possible.
Specific target organ toxicity - single exposure Due to partial or complete lack of data the classification is not possible.
Specific target organ toxicity - repeated exposure Due to partial or complete lack of data the classification is not possible.
Aspiration hazard Due to partial or complete lack of data the classification is not possible.
Mixture versus substance information No information available.
Other information Not available.

SECTION 12: Ecological information
12.1. Toxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
12.2. Persistence and degradability No data is available on the degradability of any ingredients in the mixture.
12.3. Bioaccumulative potential
12.4. Mobility in soil
Not available.

12.5. Results of PBT and vPvB assessment
Not a PBT or vPvB substance or mixture. Not available.

12.6. Other adverse effects
No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

SECTION 13: Disposal considerations

13.1. Waste treatment methods
Residual waste
Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging
Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

EU waste code
The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Disposal methods/information
Collect and reclaim or dispose in sealed containers at licensed waste disposal site.

13.1. Special precautions
Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR
14.1. - 14.6.: Not regulated as dangerous goods.

RID
14.1. - 14.6.: Not regulated as dangerous goods.

ADN
14.1. - 14.6.: Not regulated as dangerous goods.

IATA
14.1. - 14.6.: Not regulated as dangerous goods.

IMDG
14.1. - 14.6.: Not regulated as dangerous goods.

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulations
Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I and II, as amended
Not listed.

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 1 as amended
Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 2 as amended
Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 3 as amended
Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex V as amended
Not listed.

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(10) Candidate List as currently published by ECHA
Not listed.

Authorisations
Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended
Not listed.

Restrictions on use
Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended
Not listed.

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work, as amended.
Not listed.

Other EU regulations

Directive 2012/18/EU on major accident hazards involving dangerous substances, as amended
Not listed.

Other regulations
The product is classified and labelled in accordance with Regulation (EC) 1272/2008 (CLP Regulation) as amended. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006, as amended.

National regulations
Follow national regulation on the protection of workers from the risks of exposure to carcinogens and mutagens at work, in accordance with Directive 2004/37/EC.

15.2. Chemical safety assessment
No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations
Not available.

References
Not available.

Information on evaluation method leading to the classification of mixture
The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.

Full text of any H-statements not written out in full under Sections 2 to 15
None.

Revision information
This document has undergone significant changes and should be reviewed in its entirety.

Training information
Follow training instructions when handling this material.

Disclaimer
The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.