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

1.1. Product identifier
Trade name or designation of the mixture: L336
Registration number: None.
Synonyms: None.
Issue date: 30-November-2015
Revision date: 20-December-2018
Supersedes date: 17-December-2018

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
Company name: MonoSol AF Ltd.
Address: Oak Drive, Hartlebury Trading Estates
Hartlebury, Worcestershire DY104JB
UK
Division:
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)-85880596
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 available.

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

None known.

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

- DSD: Directive 67/548/EEC.
- vPvB: very persistent and very bioaccumulative substance.
- PBT: persistent, bioaccumulative and toxic substance.
- #: This substance has been assigned Community workplace exposure limit(s).
- *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: Rinse mouth. Get medical attention if symptoms occur.

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

Direct contact with eyes may cause temporary irritation.

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

Treat symptomatically.

SECTION 5: Firefighting measures

General fire hazards

No unusual fire or explosion hazards noted.

5.1. Extinguishing media


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

During fire, gases hazardous to health may be formed. 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.

Use water spray to cool unopened containers.

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 emergency responders: Keep unnecessary personnel away.

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. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water.

6.4. Reference to other sections

Not available.

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 original tightly closed container.

7.3. Specific end use(s)

Not available.
SECTION 8: Exposure controls/personal protection

8.1. Control parameters

<table>
<thead>
<tr>
<th>Occupational exposure limits</th>
<th>No exposure limits noted for ingredient(s).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biological limit values</td>
<td>No biological exposure limits noted for the ingredient(s).</td>
</tr>
<tr>
<td>Recommended monitoring procedures</td>
<td>Follow standard monitoring procedures.</td>
</tr>
<tr>
<td>Derived no effect levels (DNELs)</td>
<td>Not available.</td>
</tr>
<tr>
<td>Predicted no effect concentrations (PNECs)</td>
<td>Not available.</td>
</tr>
</tbody>
</table>

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

Not available.

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

<table>
<thead>
<tr>
<th>Physical state</th>
<th>Solid.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Form</td>
<td>Solid. Film.</td>
</tr>
<tr>
<td>Colour</td>
<td>Colourless to light yellow. Translucent.</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Flammability limit - lower (%)</th>
<th>Not available.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flammability limit - upper (%)</td>
<td>Not available.</td>
</tr>
</tbody>
</table>

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 available.
Oxidising properties Not available.
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 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 this product.
12.3. Bioaccumulative potential No data available.
Partition coefficient n-octanol/water (log Kow) Not available.
Bioconcentration factor (BCF) Not available.
12.4. Mobility in soil  
No data available.

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

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

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.

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.

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

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

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 EC directives or respective national laws. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006.

**National regulations**
Follow national regulation for work with chemical agents.

### 15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out.

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### SECTION 16: Other information

<table>
<thead>
<tr>
<th>List of abbreviations</th>
<th>Not available.</th>
</tr>
</thead>
<tbody>
<tr>
<td>References</td>
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<tr>
<td>Information on evaluation method leading to the classification of mixture</td>
<td>The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.</td>
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<tr>
<td>Full text of any H-statements not written out in full under Sections 2 to 15</td>
<td>None.</td>
</tr>
<tr>
<td>Revision information</td>
<td>None.</td>
</tr>
<tr>
<td>Training information</td>
<td>Follow training instructions when handling this material.</td>
</tr>
<tr>
<td>Disclaimer</td>
<td>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.</td>
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