SAFETY DATA SHEET

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

1.1. Product identifier
Trade name or designation of the mixture: M8310
Registration number: -
Synonyms: None.
Issue date: 09-September-2014
Version number: 07
Revision date: 19-December-2018
Supersedes date: 11-May-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
Company name: MonoSol LLC
Address: 707 East 80th Place, Suite 301
Merrillville, IN 46410
Country: United States
General Assistance Phone: +1 219-762-3165
Fax: +1 219-763-4477
E-mail: reach@monosol.com
Website: www.MonoSol.com

1.4. Emergency Phone Numbers
CHEMTREC (London): +(44)-870-8200418 & 1 703-527-3887
CHEMTREC Sweden (Stockholm): +(46)-85203403
CHEMTREC Germany: +(44)-870-8200418
CHEMTREC Hungary (Budapest): +(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

Composition comments
The full text for all H-statements is displayed in section 16.

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
Exposure may cause temporary irritation, redness, or discomfort.

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
Suitable extinguishing media
Water fog. Foam. Dry chemical 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
During fire, gases hazardous to health may be formed.

5.3. Advice for firefighters
Special protective equipment 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.

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).

7.3. Specific end use(s)  
Not available.

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  
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
Due to partial or complete lack of data the classification is not possible.

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
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. 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.

Special precautions

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
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.

Not listed.

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.