



SAFETY DATA SHEET

DRAFT VERSION

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

1.1. Product identifier

Trade name or designation of the mixture M8312
Registration number -
Synonyms None.
Issue date None.
Version number 04

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. This product is an article. Water Soluble Film
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. According to REACH Regulation (EC) No 1907/2006, the product is considered as an article. The creation of a safety data sheet in accordance with Article 31 of the Regulation (EC) No 1907/2006 is not legally required for articles. This product is an article in accordance with CLP Regulation (EC) 1272/2008. This safety data sheet (SDS) is provided on a voluntary basis for informational purposes only.

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	77,1 % of the mixture consists of component(s) of unknown acute oral toxicity. 82,7 % of the mixture consists of component(s) of unknown acute dermal toxicity.
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 article of which the composition is a trade secret. *The remaining composition is non-hazardous and 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 Upon decomposition, this product emits carbon monoxide, carbon dioxide and/or low molecular weight hydrocarbons.

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 At thermal decomposition temperatures, carbon monoxide and carbon dioxide.

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. This product is an article and is not expected to release hazardous chemicals under normal conditions of use.
12.2. Persistence and degradability	No data is available on the degradability of any ingredients in the mixture.
12.3. Bioaccumulative potential	
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. 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	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.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

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. 166/2006 Annex II Pollutant Release and Transfer Registry, as amended

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. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006, as amended. According to REACH Regulation 1907/2006 EC, the product is considered as an article. The preparation of a safety data sheet in accordance with Article 31 of the Regulation (EC) No.1907/2006 is not legally required for articles.

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

Product and Company Identification: Material Attributes
SECTION 2: Hazards identification: Classification of the substance or mixture
SECTION 2: Hazards identification: Supplemental label information
Composition / Information on Ingredients: Ingredients
SECTION 3: Composition/information on ingredients: Component information
Physical & Chemical Properties: Multiple Properties
Regulatory Information: Regulatory Information

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.