



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 M8534
Registration number -
Synonyms None.
Issue date 25-November-2015
Version number 04
Revision date 05-June-2020
Supersedes date 02-June-2020

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

Health hazards
Reproductive toxicity Category 2 H361 - Suspected of damaging fertility or the unborn child.

Hazard summary Possible reproductive hazard. Occupational exposure to the substance or mixture may cause adverse health effects.

2.2. Label elements

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

Contains: Propylidyntrimethanol

Hazard pictograms



Signal word

Warning

Hazard statements

H361

Not applicable.
Suspected of damaging fertility or the unborn child.

Precautionary statements

Prevention

P201

P202

P280

Observe good industrial hygiene practices.
Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Wear protective gloves/protective clothing/eye protection/face protection.

Response

P308 + P313

Wash hands after handling.
IF exposed or concerned: Get medical advice/attention.

Storage

P405

Store locked up.

Disposal

Dispose of waste and residues in accordance with local authority requirements.

Supplemental label information

81,33 % of the mixture consists of component(s) of unknown acute oral toxicity. 90,52 % 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

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	Index No.	Notes
Propylidynetrimethanol	3 - < 5	77-99-6 201-074-9	-	-	
Classification:	Repr. 2;H361, Repr. 2;H361fd				
Other components below reportable levels	90 - 100				

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. *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

IF exposed or concerned: Get medical advice/attention. If you feel unwell, seek medical advice (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance.

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

Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.

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 (CO ₂).
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	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid prolonged exposure. Pregnant or breastfeeding women must not handle this product. Should be handled in closed systems, if possible. Use personal protective equipment as required. Observe good industrial hygiene practices.
7.2. Conditions for safe storage, including any incompatibilities	Store locked up. 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

Bulgaria. OELs. Regulation No 13 on protection of workers against risks of exposure to chemical agents at work

Components	Type	Value
Propylidyntrimethanol (CAS 77-99-6)	TWA	50 mg/m ³

Lithuania. OELs. Limit Values for Chemical Substances, General Requirements

Components	Type	Value
Propylidyntrimethanol (CAS 77-99-6)	Ceiling	5 ppm

Sweden. OELs. Work Environment Authority (AV), Occupational Exposure Limit Values (AFS 2015:7)

Components	Type	Value
Propylidyntrimethanol (CAS 77-99-6)	TWA	5 mg/m ³

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 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 If contact is likely, safety glasses with side shields are recommended.

Skin protection

- **Hand protection** Wear appropriate chemical resistant gloves.

- **Other** Use of an impervious apron is recommended.

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

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

Hygiene measures Observe any medical surveillance requirements. 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 dangerous reaction known under conditions of normal use.

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	Suspected of damaging fertility or the unborn child.
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.		
Components	Species	Test Results	
Propylidynetrimethanol (CAS 77-99-6)			
Aquatic			
Crustacea	EC50	Water flea (Daphnia magna)	10330 - 16360 mg/l, 48 hours
Fish	LC50	Bleak (Alburnus alburnus)	> 10000 mg/l, 96 hours
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. Dispose of contents/container in accordance with local/regional/national/international regulations.

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. According to Directive 92/85/EEC as amended, pregnant women should not work with the product, if there is the least risk of exposure.

National regulations

Young people under 18 years old are not allowed to work with this product according to EU Directive 94/33/EC on the protection of young people at work, as amended.

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

H361 Suspected of damaging fertility or the unborn child.

H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.

Revision information

SECTION 3: Composition/information on ingredients: Component 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.