

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

1.1. Product identifier

Trade name or designation of the mixture M1000
Registration number -
Synonyms None.
Issue date 02-23-2015
Version number 01

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
CHEMTREC Sweden (Stockholm) +(46)-85203403
CHEMTREC Germany 0800-181-7059
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 Directive 67/548/EEC or 1999/45/EC as amended

This preparation does not meet the criteria for classification according to Directive 1999/45/EC as amended.

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

Physical hazards Not classified for physical hazards.
Health hazards Not classified for health hazards. However, occupational exposure to the mixture or substance(s) may cause adverse health effects.
Environmental hazards Not classified for hazards to the environment.
Specific hazards None known.
Main symptoms Direct contact with eyes may cause temporary irritation.

2.2. Label elements

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

Hazard pictograms None.
Signal word None.

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| 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

CLP: Regulation No. 1272/2008.

DSD: Directive 67/548/EEC.

M: M-factor

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

Composition comments The full text for all R- and H-phrases 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 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

Suitable extinguishing media Alcohol resistant foam. Water spray. Water fog. 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.

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| 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. |
| 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

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| 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. 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

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| 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 level (DNEL) | Not available. |
| Predicted no effect concentrations (PNECs) | Not available. |

8.2. Exposure controls

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| 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. |
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Individual protection measures, such as personal protective equipment

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| 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

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| Physical state | Solid. |
| Form | Film. |
| Color | Colorless to light yellow. Translucent. |
| Odor | May have a slight acetic acid odor |
| Odor 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.

Vapor pressure Not available.

Vapor density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Not available.

Solubility (other) 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.

Oxidizing 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 oxidizing 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 No data available.

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

Skin sensitization 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.

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 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 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

Not regulated as dangerous goods.

RID

Not regulated as dangerous goods.

ADN

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

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

Not listed.

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex II

Not listed.

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

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended

Not listed.

- Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended**
Not listed.
- Regulation (EC) No. 689/2008 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**
Not listed.
- Regulation (EC) No. 1907/2006, REACH Article 59(10) Candidate List as currently published by ECHA**
Not listed.

Authorizations

- 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**
Not listed.
- Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding**
Not listed.

Other EU regulations

- Directive 96/82/EC (Seveso II) on the control of major-accident hazards involving dangerous substances**
Not listed.
- Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work**
Not listed.
- Directive 94/33/EC on the protection of young people at work**
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.

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 statements or R-phrases and H-statements under Sections 2 to 15

None.

Revision information

None.

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.