acc. to OSHA HCS

1 Identification

- · Product identifier
- · Trade name: UniSpend Anhydrous Unsweet
- · Article number: 103728
- · Application of the substance / the mixture Pharma excipient
- · Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

Fagron Inc 2400 Pilot Knob Road

St. Paul, MN 55120 www.fagron.us QA@fagron.us

· Information department:

Tel.: 800-423-6967 Fax: 800-339-1596

· Emergency telephone number:

Emergency Telephone: US: 1-800-535-5053

International: 1-352-323-3500

2 Hazard(s) identification

· Classification of the substance or mixture The product is not classified, according to the Globally Harmonized System (GHS).

- · Label elements
- · GHS label elements Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · Classification system:
- · NFPA ratings (scale 0 4)



Health = 0Fire = 1Reactivity = 0

· HMIS-ratings (scale 0 - 4)



Health = 0Fire = 1

· Other hazards

· Results of PBT and vPvB assessment

· **PBT:** Not applicable. · **vPvB**: Not applicable.

3 Composition/information on ingredients

- · Chemical characterization: Mixtures
- · **Description:** Mixture of the substances listed below with nonhazardous additions.

(Contd. on page 2)



acc. to OSHA HCS

Trade name: UniSpend Anhydrous Unsweet

(Contd. of page 1)

Dangerous components: Void

4 First-aid measures

- · Description of first aid measures
- · General information: No special measures required.
- · After inhalation: Supply fresh air; consult doctor in case of complaints.
- After skin contact:

Immediately wash with water and soap and rinse thoroughly.

If skin irritation continues, consult a doctor.

· After eve contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

- After swallowing: If symptoms persist consult doctor.
- Information for doctor:
- · Most important symptoms and effects, both acute and delayed

No further relevant information available.

· Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Fire-fighting measures

- · Extinguishing media
- · Suitable extinguishing agents: Use fire fighting measures that suit the environment.
- · Special hazards arising from the substance or mixture

No further relevant information available.

- Advice for firefighters
- · Protective equipment: No special measures required.

6 Accidental release measures

- · Personal precautions, protective equipment and emergency procedures Not required.
- · Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- · Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

Protective Action Criteria for Chemicals

PAC-1:

None of the ingredients is listed.

PAC-2:

None of the ingredients is listed.

· PAC-3:

None of the ingredients is listed.

7 Handling and storage

- · Handling:
- · Precautions for safe handling No special measures required.
- Information about protection against explosions and fires: No special measures required



acc. to OSHA HCS

Trade name: UniSpend Anhydrous Unsweet

(Contd. of page 2)

- · Conditions for safe storage, including any incompatibilities
- · Storage:
- Requirements to be met by storerooms and receptacles: No special requirements.
- Information about storage in one common storage facility: Not required.
- Further information about storage conditions:
 Store in cool, dry conditions in well sealed receptacles.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- · Additional information about design of technical systems: No further data; see item 7.
- · Control parameters
- · Components with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

- · Additional information: The lists that were valid during the creation were used as basis.
- · Exposure controls
- Personal protective equipment:
- · General protective and hygienic measures:

The usual precautionary measures for handling chemicals should be followed.

- · Breathing equipment: Suitable respiratory protective device recommended.
- · Protection of hands:



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

- Eye protection: Goggles recommended during refilling.
- · Body protection: Protective work clothing

9 Physical and chemical properties

- · Information on basic physical and chemical properties
- · General Information
- · Appearance:

Form: Viscous
Color: Colorless
Odor: Odorless

· Odor threshold: Not determined.



acc. to OSHA HCS

Trade name: UniSpend Anhydrous Unsweet

	(Contd. of pag	
· pH-value:	Not determined.	
 Change in condition Melting point/Melting range: Boiling point/Boiling range: 	-5°C (23°F) >300°C (>572°F)	
· Flash point:	250°C (482°F)	
· Flammability (solid, gaseous):	Not applicable.	
Decomposition temperature:	Not determined.	
· Auto igniting:	Product is not selfigniting.	
· Danger of explosion:	Product does not present an explosion hazard.	
· Explosion limits: Lower: Upper:	Not determined. Not determined.	
· Vapor pressure:	Not determined.	
 Density at 20°C (68°F): Relative density Vapor density Evaporation rate 	0.945–0.949 g/cm³ (7.88603–7.91941 lbs/gal) Not determined. Not determined. Not determined.	
· Solubility in / Miscibility with Water at 20°C (68°F):	0.0038 g/l	
· Partition coefficient (n-octanol/wa	ater): 0.91381–1.03743	
· Viscosity: Dynamic at 20°C (68°F): Kinematic at 40°C (104°F):	27–33 mPas 13–15.6 mm²/s	
Solvent content: VOC content:	0.00 % 0.0 g/l / 0.00 lb/gal	
Solids content:	3.8 %	
· Other information	No further relevant information available.	

10 Stability and reactivity

- · Reactivity No further relevant information available.
- Chemical stability
- Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

- Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: No dangerous decomposition products known.

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(Contd. on page 5)



acc. to OSHA HCS

Trade name: UniSpend Anhydrous Unsweet

(Contd. of page 4)

11 Toxicological information

- · Information on toxicological effects
- · Additional toxicological information:

The product is not subject to classification according to internally approved calculation methods for preparations:

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

- · Carcinogenic categories
- · IARC (International Agency for Research on Cancer)

None of the ingredients is listed.

NTP (National Toxicology Program)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

12 Ecological information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behavior in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- Additional ecological information:
- General notes:

Water hazard class 1 (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · **vPvB**: Not applicable.
- · Other adverse effects No further relevant information available.

13 Disposal considerations

- · Waste treatment methods
- · **Recommendation:** Must be specially treated adhering to official regulations.
- Uncleaned packagings:
- · Recommendation: Disposal must be made according to official regulations.

14 Transport information

- · UN-Number
- · DOT, IMDG, IATA not regulated
- · UN proper shipping name
- · DOT, IMDG, IATA not regulated



acc. to OSHA HCS

Trade name: UniSpend Anhydrous Unsweet

		(Contd. of page §
· Transport hazard class(es)		
· DOT, ADN, IMDG, IATA		
· Class	not regulated	
Packing group		
· DOT, IMDG, IATA	not regulated	
· Environmental hazards:	Not applicable.	
Special precautions for user	Not applicable.	
Transport in bulk according to Annex	t II of	
MARPOL73/78 and the IBC Code	Not applicable.	
· UN "Model Regulation":	not regulated	

15 Regulatory information

· Safety, health and environmental regulations/legislation specific for the substance or mixture

No further relevant information available.

· Sara

· Section 355 (extremely hazardous substances):

None of the ingredients is listed.

· Section 313 (Specific toxic chemical listings):

None of the ingredients is listed.

· TSCA (Toxic Substances Control Act):

All components have the value ACTIVE.

· Hazardous Air Pollutants

None of the ingredients is listed.

Proposition 65

Chemicals known to cause cancer:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

· Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

· Carcinogenic categories

· EPA (Environmental Protection Agency)

None of the ingredients is listed.

· TLV (Threshold Limit Value)

None of the ingredients is listed.

· NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.



acc. to OSHA HCS

Printing date 06/26/2023 Reviewed on 06/26/2023

Trade name: UniSpend Anhydrous Unsweet

(Contd. of page 6)

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Department issuing SDS:

Fagron US

Quality Assurance

· Contact: QA@fagron.us

· Date of preparation / last revision 06/26/2023

Abbreviations and acronyms:

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA) HMIS: Hazardous Materials Identification System (USA) VOC: Volatile Organic Compounds (USA, EU)

PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health TLV: Threshold Limit Value PEL: Permissible Exposure Limit REL: Recommended Exposure Limit

USA

