Safety Data Sheet

acc. to OSHA HCS

1 Identification

- · Product identifier
- Trade name: Versatile anhydrous
- Article number: 615242, 107427
- · Application of the substance / the mixture Additive for cosmetic or pharmaceutic preparations
- · 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

Distributor: Bella Corp Trading Pty Ltd 6/34 Dominions Rd, Ashmore QLD 4214

Australia | T: 07 5597 4169 E: bellacorp@bellacorp.com.au

IN CASE OF EMERGENCY: Chemtrec

Outside USA and Canada:

+1 703-527-3887

NSW Poisons Information Centre: 131 126 (24 hours)

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 = 2Reactivity = 0

HMIS-ratings (scale 0 - 4)



Health = 0Fire = 2

- 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.
- Dangerous components:

Transcutol P CAS: 111-90-0

Ethoxy Diglycol

2-(2-ethoxyethoxy)ethanol



medicingsA

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 CAS: 5949-29-1
 Citric Acid Monohydrate
 (Contd. of page 1)

 0.1-≤1%
 0.1-≤1%

4 First-aid measures

- Description of first aid measures
- · After inhalation: Supply fresh air; consult doctor in case of complaints.
- After skin contact: Generally the product does not irritate the skin.
- After eye contact: Rinse opened eye for several minutes under running water.
- 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:

CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam

· Special hazards arising from the substance or mixture

No further relevant information available.

- Advice for firefighters
- · Protective equipment: Wear self-contained respiratory protective device.

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: Pick up mechanically.
- 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:		
CAS: 111-90-0	Transcutol P Ethoxy Diglycol 2-(2-ethoxyethoxy)ethanol	75 ppm
CAS: 36653-82-4	Cetylalcohol Alcohol cetylicus	1.6 mg/m ³
CAS: 68439-49-6	Macrogolcetylstearylether Macrogoli aether cetostearylicus	3.8 mg/m ³
PAC-2:		
CAS: 111-90-0	Transcutol P Ethoxy Diglycol 2-(2-ethoxyethoxy)ethanol	100 ppm
CAS: 36653-82-4	Cetylalcohol Alcohol cetylicus	18 mg/m ³
CAS: 68439-49-6	Macrogolcetylstearylether Macrogoli aether cetostearylicus	Fac ⁴² mg/m³ (Control impressed 3)

personalizing medicine

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· PAC-3:		(Contd. of page 2
CAS: 111-90-0	Transcutol P Ethoxy Diglycol 2-(2-ethoxyethoxy)ethanol	450 ppm
CAS: 36653-82-4	Cetylalcohol Alcohol cetylicus	110 mg/m ³
CAS: 68439-49-6	Macrogolcetylstearylether Macrogoli aether cetostearylicus	250 mg/m ³

7 Handling and storage

- Handling:
- · Precautions for safe handling No special precautions are necessary if used correctly.
- · Information about protection against explosions and fires: No special measures required.
- · 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: None.
- · 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 section 7.
- **Control parameters**
- Components with limit values that require monitoring at the workplace:

The following constituent is the only constituent of the product which has a PEL, TLV or other recommended exposure limit.

At this time, the remaining constituent has no known exposure limits.

CAS: 111-90-0 Transcutol P
Ethoxy Diglycol
2-(2-ethoxyethoxy)ethanol

WEEL Long-term value: 25 ppm

- · Additional information: The lists that were valid during the creation were used as basis.
- **Exposure controls**
- Personal protective equipment:
- General protective and hygienic measures: Wash hands before breaks and at the end of work.
- Breathing equipment: Not required.
- Protection of hands:

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.

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• 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: Not required.

Body protection: Protective work clothing

9 Physical and chemical properties

Information on basic physical and	chemical properties
General Information Appearance:	
Form: Color:	Pasty
Odor:	According to product specification Light
Odor threshold:	Not determined.
pH-value:	Not applicable.
Change in condition	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	175°C (347°F)
Flash point:	91°C (195.8°F)
Flammability (solid, gaseous):	Not determined.
Auto igniting:	205°C (401°F)
Decomposition temperature:	Not determined.
Ignition temperature:	Product is not selfigniting.
Danger of explosion:	Product does not present an explosion hazard.
Explosion limits:	
Lower:	1.2 Vol %
Upper:	23.5 Vol %
Vapor pressure at 20°C (68°F):	0.1 hPa
Density:	Not determined.
Relative density	Not determined.
Vapor density	Not applicable.
Evaporation rate	Not applicable.
Solubility in / Miscibility with	
Water:	Soluble.
Partition coefficient (n-octanol/wat	ter): Not determined.
Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
Solvent content:	
Organic solvents:	12.3 %
VOC content:	12.30 %
Other information	No further relevant information available.



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(Contd. of page 4)

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.

11 Toxicological information

- · Information on toxicological effects
- Acute toxicity:

· LD/LC5	0 valu	es that are relevant for classification:
CAS: 11	11-90-0	Transcutol P Ethoxy Diglycol 2-(2-ethoxyethoxy)ethanol
Oral	LD50	6031 mg/kg (mouse)
		>5001 mg/kg (rat)
Dermal	LD50	5900 mg/kg (guinea pig)
		6000 mg/kg (rat)
		9143 mg/kg (rabbit)
CAS: 59	949-29	-1 Citric Acid Monohydrate
Oral	LD50	5400 mg/kg (mouse)
		11700 mg/kg (rat)
Dermal	LD50	>2000 mg/kg (rat)

- Primary irritant effect:
- on the skin: No irritant effect.
- Sensitization: No sensitizing effects known.
- Additional toxicological information:
- · Carcinogenic categories
- IARC (International Agency for Research on Cancer)

CAS: 128-37-0 Butylated hydroxytoluene

3

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:

CAS: 111-90-0 Transcutol P

Ethoxy Diglycol

2-(2-ethoxyethoxy)ethanol

LC50 (96h) 6010 mg/l (fish)

Persistence and degradability No further relevant information available.



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- 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 not be disposed of together with household garbage. Do not allow product to reach sewage system.

- · Uncleaned packagings:
- · Recommendation: Disposal must be made according to official regulations.
- Recommended cleansing agent: Water, if necessary with cleansing agents.

14 Transport information

· UN-Number · DOT, IMDG, IATA	not regulated
 UN proper shipping name DOT, IMDG, IATA 	not regulated
· 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 MARPOL73/78 and the IBC Code	II of 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.





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. Section 313 (Sp.	ecific toxic chemical listings):	(Contd. of page
CAS: 111-90-0 T	• <i>,</i>	
	thoxy Diglycol	
2	-(2-ethoxyethoxy)ethanol	
· TSCA (Toxic Su	ostances Control Act):	
CAS: 73398-61-5	Glycerides, mixed decanoyl and octanoyl	ACTIV
CAS: 85251-77-0	Glycerol monostearate 40-55 (type II) Glycerides, C16-18 mono- and di-	ACTIV
CAS: 111-90-0	Transcutol P Ethoxy Diglycol 2-(2-ethoxyethoxy)ethanol	ACTIV
CAS: 6309-51-9	Isopentyl laurate	ACTIV
CAS: 68956-68-3	Cremerlin® Pura Oils, vegetable	ACTIV
CAS: 24271-12-3	Octadecyl docosanoate	ACTIV
CAS: 8012-89-3	Beeswax white - Cera alba Beeswax,yellow - Cera flava	ACTIV
CAS: 36653-82-4	Alcohol cetylicus	ACTIVI
CAS: 77538-19-3	Compritol® 888 Docosanoic acid, ester with 1,2,3-propanetriol	ACTIVI
CAS: 68439-49-6	Macrogolicetylstearylether Macrogoli aether cetostearylicus	ACTIV
CAS: 128-37-0	Butylated hydroxytoluene	ACTIV
· Hazardous Air P	ollutants	
None of the ingre	dients is listed.	
Proposition 65		
· Chemicals know	n to cause cancer:	
None of the ingre	dients is listed.	
	n to cause reproductive toxicity for females:	
None of the ingre		
	n to cause reproductive toxicity for males:	
None of the ingre		
	n to cause developmental toxicity:	
None of the ingre		
· Carcinogenic ca		
	ntal Protection Agency)	
None of the ingre		
TLV (Threshold	,	A
	utylated hydroxytoluene	A
-	nal Institute for Occupational Safety and Health)	
None of the ingre	dients is listed. assessment: A Chemical Safety Assessment has not be	

16 Other information

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

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Department issuing SDS:

Fagron US

Quality Assurance

- Contact: QA@fagron.us
- Date of preparation / last revision 09/09/2024 / 1.0
- Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

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, ÉU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

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

* Data compared to the previous version altered.

USA

